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Contents

I *Legislative acts*

## DIRECTIVES

- ★ **Directive 2012/26/EU of the European Parliament and of the Council of 25 October 2012 amending Directive 2001/83/EC as regards pharmacovigilance <sup>(1)</sup> .....** 1
- ★ **Directive 2012/28/EU of the European Parliament and of the Council of 25 October 2012 on certain permitted uses of orphan works <sup>(1)</sup> .....** 5

## DECISIONS

- ★ **Decision No 994/2012/EU of the European Parliament and of the Council of 25 October 2012 establishing an information exchange mechanism with regard to intergovernmental agreements between Member States and third countries in the field of energy <sup>(1)</sup> .....** 13

Price: EUR 4

(Continued overleaf)

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<sup>(1)</sup> Text with EEA relevance

EN

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

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

II *Non-legislative acts*

REGULATIONS

★ <b>Commission Implementing Regulation (EU) No 995/2012 of 26 October 2012 laying down detailed rules for the implementation of Decision No 1608/2003/EC of the European Parliament and of the Council concerning the production and development of Community statistics on science and technology <sup>(1)</sup></b> .....	18
★ <b>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 <sup>(1)</sup></b> .....	31
Commission Implementing Regulation (EU) No 997/2012 of 26 October 2012 establishing the standard import values for determining the entry price of certain fruit and vegetables .....	42

DECISIONS

2012/664/EU:

★ <b>Council Decision of 25 October 2012 on the launch of automated data exchange with regard to Vehicle Registration Data (VRD) in Sweden</b> .....	44
★ <b>Council Decision 2012/665/CFSP of 26 October 2012 amending Decision 2010/638/CFSP concerning restrictive measures against the Republic of Guinea</b> .....	45

2012/666/EU:

★ <b>Commission Implementing Decision of 25 October 2012 amending Decision 2008/855/EC as regards animal health control measures relating to classical swine fever in Hungary (notified under document C(2012) 7433) <sup>(1)</sup></b> .....	46
---	----

2012/667/EU:

★ <b>Commission Implementing Decision of 25 October 2012 establishing the financial contribution by the Union to the expenditure incurred in the context of the emergency measures taken to combat avian influenza in the Netherlands in 2011 (notified under document C(2012) 7440)</b> .....	47
--	----

2012/668/EU:

★ <b>Commission Implementing Decision of 25 October 2012 establishing the financial contribution by the Union to the expenditure incurred in the context of the emergency measures taken to combat foot-and-mouth disease in Bulgaria in 2011 (notified under document C(2012) 7454)</b> .....	49
--	----



<sup>(1)</sup> Text with EEA relevance

## I

(Legislative acts)

## DIRECTIVES

## DIRECTIVE 2012/26/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 25 October 2012

amending Directive 2001/83/EC as regards pharmacovigilance

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 and Article 168(4)(c) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee <sup>(1)</sup>,

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure <sup>(2)</sup>,

Whereas:

(1) Recent pharmacovigilance incidents in the Union have shown the need for an automatic procedure at Union level in cases of specific safety issues to ensure that a matter is assessed and addressed in all Member States where the medicinal product is authorised. The scope of different Union procedures concerning products authorised at national level, as laid down in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use <sup>(3)</sup>, should be clarified.

(2) In addition, voluntary action by the marketing authorisation holder should not lead to a situation where concerns relating to the risks or benefits of a medicinal product authorised in the Union are not properly addressed in all Member States. Therefore, the marketing authorisation holder should be obliged to inform the relevant competent authorities and the European Medicines Agency of the reasons for withdrawing or interrupting the placing on the market of a medicinal product, for requesting that a marketing authorisation be revoked, or for not renewing a marketing authorisation.

(3) It is appropriate to further clarify and strengthen the Normal Procedure and the Urgent Union Procedure in order to ensure coordination, swift assessment in case of urgency and the possibility to take immediate action, where necessary to protect public health, before a decision is taken at Union level. The Normal Procedure should be initiated for matters concerning quality, safety or efficacy of medicinal products where the interests of the Union are involved. The Urgent Union Procedure should be initiated when there is a need to swiftly assess concerns resulting from the evaluation of data from pharmacovigilance activities. Regardless of whether the Urgent Union Procedure or the Normal Procedure is applied, and regardless of the procedure by means of which the medicinal product was authorised, be it centralised or otherwise, the Pharmacovigilance Risk Assessment Committee should always give its recommendation when the reason for taking action is based on pharmacovigilance data. It is appropriate that the coordination group and the Committee for Medicinal Products for Human Use rely on that recommendation when carrying out the assessment of the issue.

(4) It is appropriate that Member States bring cases concerning new contraindications, reductions in the recommended dose or restrictions to the indication for medicinal products authorised in accordance with the decentralised procedure and the mutual recognition procedure to the attention of the coordination group when the Urgent Union Procedure is not initiated. In

<sup>(1)</sup> OJ C 181, 21.6.2012, p. 201.

<sup>(2)</sup> Position of the European Parliament of 11 September 2012 (not yet published in the Official Journal) and decision of the Council of 4 October 2012.

<sup>(3)</sup> OJ L 311, 28.11.2001, p. 67.

order to ensure harmonisation for those products, the coordination group may discuss whether any action is necessary in the event that no Member State has triggered the Normal Procedure.

- (5) Since the objective of this Directive, namely to harmonise the rules on pharmacovigilance across the Union, cannot be sufficiently achieved by the Member States and can therefore be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve that objective.
- (6) Directive 2001/83/EC should therefore be amended accordingly,

HAVE ADOPTED THIS DIRECTIVE:

*Article 1*

Directive 2001/83/EC is hereby amended as follows:

- (1) in Article 23a, the second paragraph is replaced by the following:

'If the product ceases to be placed on the market of a Member State, either temporarily or permanently, the marketing authorisation holder shall notify the competent authority of that Member State. Such notification shall, other than in exceptional circumstances, be made no less than two months before the interruption in the placing on the market of the product. The marketing authorisation holder shall inform the competent authority of the reasons for such action in accordance with Article 123(2).';

- (2) Article 31 is amended as follows:

- (a) in paragraph 1, the third subparagraph is replaced by the following:

'However, where one of the criteria listed in Article 107i(1) is met, the procedure laid down in Articles 107i to 107k shall apply.';

- (b) paragraph 2 is replaced by the following:

'2. Where the referral to the Committee concerns a range of medicinal products or a therapeutic class, the Agency may limit the procedure to certain specific parts of the authorisation.

In that event, Article 35 shall apply to those medicinal products only if they were covered by the authorisation procedures referred to in this Chapter.

Where the scope of the procedure initiated under this Article concerns a range of medicinal products or a therapeutic class, medicinal products authorised in

accordance with Regulation (EC) No 726/2004 which belong to that range or class shall also be included in the procedure.

3. Without prejudice to paragraph 1, a Member State may, where urgent action is necessary to protect public health at any stage of the procedure, suspend the marketing authorisation and prohibit the use of the medicinal product concerned on its territory until a definitive decision is adopted. It shall inform the Commission, the Agency and the other Member States, no later than the following working day, of the reasons for its action.

4. Where the scope of the procedure initiated under this Article, as determined in accordance with paragraph 2, includes medicinal products authorised in accordance with Regulation (EC) No 726/2004, the Commission may, where urgent action is necessary to protect public health, at any stage of the procedure, suspend the marketing authorisations and prohibit the use of the medicinal products concerned until a definitive decision is adopted. The Commission shall inform the Agency and the Member States no later than the following working day of the reasons for its action.';

- (3) in Article 34(3), the following subparagraph is added:

'Where the scope of the procedure initiated under Article 31 includes medicinal products authorised in accordance with Regulation (EC) No 726/2004 pursuant to the third subparagraph of Article 31(2) of this Directive, the Commission shall, where necessary, adopt decisions to vary, suspend or revoke the marketing authorisations or to refuse the renewal of the marketing authorisations concerned.';

- (4) in Article 37, the words 'Articles 35 and 36 shall apply' are replaced by the words 'Article 35 shall apply';

- (5) Article 63 is amended as follows:

- (a) in paragraph 1, the first subparagraph is replaced by the following:

'1. The particulars for labelling listed in Articles 54, 59 and 62 shall appear in an official language or official languages of the Member State where the medicinal product is placed on the market, as specified, for the purposes of this Directive, by that Member State.';

- (b) in paragraph 2, the first subparagraph is replaced by the following:

'2. The package leaflet must be written and designed in such a way as to be clear and understandable, enabling users to act appropriately, when necessary with the help of health professionals. The

package leaflet must be clearly legible in an official language or official languages of the Member State where the medicinal product is placed on the market, as specified, for the purposes of this Directive, by that Member State.;

(c) paragraph 3 is replaced by the following:

‘3. Where the medicinal product is not intended to be delivered directly to the patient, or where there are severe problems in respect of the availability of the medicinal product, the competent authorities may, subject to measures they consider necessary to safeguard human health, grant an exemption to the obligation that certain particulars should appear on the labelling and in the package leaflet. They may also grant a full or partial exemption to the obligation that the labelling and the package leaflet must be in an official language or official languages of the Member State where the medicinal product is placed on the market, as specified, for the purposes of this Directive, by that Member State.;

(6) Article 85a is replaced by the following:

*Article 85a*

In the case of wholesale distribution of medicinal products to third countries, Article 76 and point (c) of the first paragraph of Article 80 shall not apply. Moreover, points (b) and (ca) of the first paragraph of Article 80 shall not apply where a product is directly received from a third country but not imported. However, in that case wholesale distributors shall ensure that the medicinal products are obtained only from persons who are authorised or entitled to supply medicinal products in accordance with the applicable legal and administrative provisions of the third country concerned. Where wholesale distributors supply medicinal products to persons in third countries, they shall ensure that such supplies are only made to persons who are authorised or entitled to receive medicinal products for wholesale distribution or supply to the public in accordance with the applicable legal and administrative provisions of the third country concerned. The requirements set out in Article 82 shall apply to the supply of medicinal products to persons in third countries authorised or entitled to supply medicinal products to the public.;

(7) in Article 107i, paragraph 1 is replaced by the following:

‘1. A Member State or the Commission, as appropriate, shall, on the basis of concerns resulting from the evaluation of data from pharmacovigilance activities, initiate the procedure provided for in this section by informing the other Member States, the Agency and the Commission where:

- (a) it considers suspending or revoking a marketing authorisation;
- (b) it considers prohibiting the supply of a medicinal product;

(c) it considers refusing the renewal of a marketing authorisation; or

(d) it is informed by the marketing authorisation holder that, on the basis of safety concerns, the holder has interrupted the placing on the market of a medicinal product or has taken action to have a marketing authorisation withdrawn, or intends to take such action or has not applied for the renewal of a marketing authorisation.

1a. A Member State or the Commission, as appropriate, shall, on the basis of concerns resulting from the evaluation of data from pharmacovigilance activities, inform the other Member States, the Agency and the Commission where it considers that a new contraindication, a reduction in the recommended dose or a restriction to the indications of a medicinal product is necessary. The information shall outline the action considered and the reasons therefor.

Any Member State or the Commission, as appropriate, shall, when urgent action is considered necessary, initiate the procedure provided for in this section in any of the cases referred to in this paragraph.

Where the procedure provided for in this section is not initiated, for medicinal products authorised in accordance with the procedures laid down in Chapter 4 of Title III, the case shall be brought to the attention of the coordination group.

Article 31 shall be applicable where the interests of the Union are involved.

1b. Where the procedure provided for in this section is initiated, the Agency shall verify whether the safety concern relates to medicinal products other than the one covered by the information, or whether it is common to all products belonging to the same range or therapeutic class.

Where the medicinal product involved is authorised in more than one Member State, the Agency shall without undue delay inform the initiator of the procedure of the outcome of this verification, and the procedures laid down in Articles 107j and 107k shall apply. Otherwise, the safety concern shall be addressed by the Member State concerned. The Agency or the Member State, as applicable, shall make the information that the procedure has been initiated available to marketing authorisation holders.;

(8) in Article 107i(2) the words ‘paragraph 1 of this Article’ are replaced by the words ‘paragraphs 1 and 1a of this Article’;

(9) in the second subparagraph of Article 107i(3) the words ‘in accordance with paragraph 1’ are replaced by the words ‘in accordance with paragraphs 1 and 1a’;

- (10) in Article 107i(5) the words 'in paragraph 1' are replaced by the words 'in paragraphs 1 and 1a';
- (11) in the first subparagraph of Article 107j(1) the words 'in Article 107i(1)' are replaced by the words 'in paragraphs 1 and 1a of Article 107i';
- (12) Article 123 is amended as follows:

- (a) paragraph 2 is replaced by the following:

'2. The marketing authorisation holder shall be obliged to notify the Member States concerned forthwith of any action taken by the holder to suspend the marketing of a medicinal product, to withdraw a medicinal product from the market, to request the withdrawal of a marketing authorisation or not to apply for the renewal of a marketing authorisation, together with the reasons for such action. The marketing authorisation holder shall in particular declare if such action is based on any of the grounds set out in Article 116 or Article 117(1).

2a. The marketing authorisation holder shall also make the notification pursuant to paragraph 2 of this Article in cases where the action is taken in a third country and where such action is based on any of the grounds set out in Article 116 or Article 117(1).

2b. The marketing authorisation holder shall furthermore notify the Agency where the action referred to in paragraph 2 or 2a of this Article is based on any of the grounds referred to in Article 116 or Article 117(1).

2c. The Agency shall forward notifications received in accordance with paragraph 2b to all Member States without undue delay.;

- (b) paragraph 4 is replaced by the following:

'4. Each year, the Agency shall make public a list of the medicinal products for which marketing authorisations have been refused, revoked or suspended in the Union, whose supply has been prohibited or which have been withdrawn from the market, including the reasons for such action.'

#### Article 2

1. Member States shall adopt and publish the laws, regulations and administrative provisions necessary to comply with this Directive by 28 October 2013 at the latest. They shall forthwith communicate to the Commission the text of those provisions.

They shall apply those provisions from 28 October 2013.

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

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

#### Article 3

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

#### Article 4

This Directive is addressed to the Member States.

Done at Strasbourg, 25 October 2012.

*For the European Parliament*  
*The President*  
M. SCHULZ

*For the Council*  
*The President*  
A. D. MAVROYIANNIS

**DIRECTIVE 2012/28/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**of 25 October 2012**

**on certain permitted uses of orphan works**

**(Text with EEA relevance)**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 53(1), 62 and 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee <sup>(1)</sup>,

Acting in accordance with the ordinary legislative procedure <sup>(2)</sup>,

Whereas:

- (1) Publicly accessible libraries, educational establishments and museums, as well as archives, film or audio heritage institutions and public-service broadcasting organisations, established in the Member States, are engaged in large-scale digitisation of their collections or archives in order to create European Digital Libraries. They contribute to the preservation and dissemination of European cultural heritage, which is also important for the creation of European Digital Libraries, such as Europeana. Technologies for mass digitisation of print materials and for search and indexing enhance the research value of the libraries' collections. Creating large online libraries facilitates electronic search and discovery tools which open up new sources of discovery for researchers and academics who would otherwise have to content themselves with more traditional and analogue search methods.
- (2) The need to promote free movement of knowledge and innovation in the internal market is an important component of the Europe 2020 Strategy, as set out in the Communication from the Commission entitled 'Europe 2020: A strategy for smart, sustainable and inclusive growth', which includes as one of its flagship initiatives the development of a Digital Agenda for Europe.
- (3) Creating a legal framework to facilitate the digitisation and dissemination of works and other subject-matter which are protected by copyright or related rights and for which no rightholder is identified or for which the rightholder, even if identified, is not located — so-called orphan works — is a key action of the Digital Agenda for Europe, as set out in the Communication from the

Commission entitled 'A Digital Agenda for Europe'. This Directive targets the specific problem of the legal determination of orphan work status and its consequences in terms of the permitted users and permitted uses of works or phonograms considered to be orphan works.

- (4) This Directive is without prejudice to specific solutions being developed in the Member States to address larger mass digitisation issues, such as in the case of so-called 'out-of-commerce' works. Such solutions take into account the specificities of different types of content and different users and build upon the consensus of the relevant stakeholders. This approach has also been followed in the Memorandum of Understanding on key principles on the digitisation and making available of out-of-commerce works, signed on 20 September 2011 by representatives of European libraries, authors, publishers and collecting societies and witnessed by the Commission. This Directive is without prejudice to that Memorandum of Understanding, which calls on Member States and the Commission to ensure that voluntary agreements concluded between users, rightholders and collective rights management organisations to licence the use of out-of-commerce works on the basis of the principles contained therein benefit from the requisite legal certainty in a national and cross-border context.
- (5) Copyright is the economic foundation for the creative industry, since it stimulates innovation, creation, investment and production. Mass digitisation and dissemination of works is therefore a means of protecting Europe's cultural heritage. Copyright is an important tool for ensuring that the creative sector is rewarded for its work.
- (6) The rightholders' exclusive rights of reproduction of their works and other protected subject-matter and of making them available to the public, as harmonised under Directive 2001/29/EC of the European Parliament and of the Council of 22 May 2001 on the harmonisation of certain aspects of copyright and related rights in the information society <sup>(3)</sup>, necessitate the prior consent of rightholders to the digitisation and the making available to the public of a work or other protected subject-matter.
- (7) In the case of orphan works, it is not possible to obtain such prior consent to the carrying-out of acts of reproduction or of making available to the public.
- (8) Different approaches in the Member States to the recognition of orphan work status can present obstacles to the functioning of the internal market and the use of, and cross-border access to, orphan works. Such different approaches can also result in restrictions on the free

<sup>(1)</sup> OJ C 376, 22.12.2011, p. 66.

<sup>(2)</sup> Position of the European Parliament of 13 September 2012 (not yet published in the Official Journal) and decision of the Council of 4 October 2012.

<sup>(3)</sup> OJ L 167, 22.6.2001, p. 10.

movement of goods and services which incorporate cultural content. Therefore, ensuring the mutual recognition of such status is appropriate, since it will allow access to orphan works in all Member States.

- (9) In particular, a common approach to determining the orphan work status and the permitted uses of orphan works is necessary in order to ensure legal certainty in the internal market with respect to the use of orphan works by publicly accessible libraries, educational establishments and museums, as well as by archives, film or audio heritage institutions and public-service broadcasting organisations.
- (10) Cinematographic or audiovisual works and phonograms in the archives of public-service broadcasting organisations and produced by them include orphan works. Taking into account the special position of broadcasters as producers of phonograms and audiovisual material and the need to adopt measures to limit the phenomenon of orphan works in the future, it is appropriate to set a cut-off date for the application of this Directive to works and phonograms in the archives of broadcasting organisations.
- (11) Cinematographic and audiovisual works and phonograms contained in the archives of public-service broadcasting organisations and produced by them, should for the purposes of this Directive be regarded as including cinematographic and audiovisual works and phonograms which are commissioned by such organisations for the exclusive exploitation by them or other co-producing public-service broadcasting organisations. Cinematographic and audiovisual works and phonograms contained in the archives of public-service broadcasting organisations which have not been produced or commissioned by such organisations, but which those organisations have been authorised to use under a licensing agreement, should not fall within the scope of this Directive.
- (12) For reasons of international comity, this Directive should apply only to works and phonograms that are first published in the territory of a Member State or, in the absence of publication, first broadcast in the territory of a Member State or, in the absence of publication or broadcast, made publicly accessible by the beneficiaries of this Directive with the consent of the rightholders. In the latter case, this Directive should only apply provided that it is reasonable to assume that the rightholders would not oppose the use allowed by this Directive.
- (13) Before a work or phonogram can be considered an orphan work, a diligent search for the rightholders in the work or phonogram, including rightholders in works and other protected subject-matter that are embedded or incorporated in the work or phonogram, should be carried out in good faith. Member States should be permitted to provide that such diligent search may be carried out by the organisations referred to in this Directive or by other organisations. Such other organisations may charge for the service of carrying out a diligent search.
- (14) It is appropriate to provide for a harmonised approach concerning such diligent search in order to ensure a high level of protection of copyright and related rights in the Union. A diligent search should involve the consultation of sources that supply information on the works and other protected subject-matter as determined, in accordance with this Directive, by the Member State where the diligent search has to be carried out. In so doing, Member States could refer to the diligent search guidelines agreed in the context of the High Level Working Group on Digital Libraries established as part of the i2010 digital library initiative.
- (15) In order to avoid duplication of search efforts, a diligent search should be carried out in the Member State where the work or phonogram was first published or, in cases where no publication has taken place, where it was first broadcast. The diligent search in respect of cinematographic or audiovisual works the producer of which has his headquarters or habitual residence in a Member State should be carried out in that Member State. In the case of cinematographic or audiovisual works which are co-produced by producers established in different Member States, the diligent search should be carried out in each of those Member States. With regard to works and phonograms which have neither been published nor broadcast but which have been made publicly accessible by the beneficiaries of this Directive with the consent of the rightholders, the diligent search should be carried out in the Member State where the organisation that made the work or phonogram publicly accessible with the consent of the rightholder is established. Diligent searches for the rightholders in works and other protected subject-matter that are embedded or incorporated in a work or phonogram should be carried out in the Member State where the diligent search for the work or phonogram containing the embedded or incorporated work or other protected subject-matter is carried out. Sources of information available in other countries should also be consulted if there is evidence to suggest that relevant information on rightholders is to be found in those other countries. The carrying-out of diligent searches may generate various kinds of information, such as a search record and the result of the search. The search record should be kept on file in order for the relevant organisation to be able to substantiate that the search was diligent.
- (16) Member States should ensure that the organisations concerned keep records of their diligent searches and that the results of such searches, consisting in particular of any finding that a work or phonogram is to be considered an orphan work within the meaning of this Directive, as well as information on the change of status and on the use which those organisations make of orphan works, are collected and made available to the public at large, in particular through the recording of the

relevant information in an online database. Considering in particular the pan-European dimension, and in order to avoid duplication of efforts, it is appropriate to make provision for the creation of a single online database for the Union containing such information and for making it available to the public at large in a transparent manner. This can enable both the organisations which are carrying out diligent searches and the rightholders easily to access such information. The database could also play an important role in preventing and bringing to an end possible copyright infringements, particularly in the case of changes to the orphan work status of the works and phonograms. Under Regulation (EU) No 386/2012<sup>(1)</sup>, the Office for Harmonization in the Internal Market ('the Office') is entrusted with certain tasks and activities, financed by making use of its own budgetary means, aimed at facilitating and supporting the activities of national authorities, the private sector and the Union institutions in the fight against, including the prevention of, infringement of intellectual property rights.

In particular, pursuant to point (g) of Article 2(1) of that Regulation, those tasks include providing mechanisms which help to improve the online exchange of relevant information between the Member States' authorities concerned and fostering cooperation between those authorities. It is therefore appropriate to rely on the Office to establish and manage the European database containing information related to orphan works referred to in this Directive.

(17) There can be several rightholders in respect of a particular work or phonogram, and works and phonograms can themselves include other works or protected subject-matter. This Directive should not affect the rights of identified and located rightholders. If at least one rightholder has been identified and located, a work or phonogram should not be considered an orphan work. The beneficiaries of this Directive should only be permitted to use a work or phonogram one or more of the rightholders in which are not identified or not located, if they are authorised to carry out the acts of reproduction and of making available to the public covered by Articles 2 and 3 respectively of Directive 2001/29/EC by those rightholders that have been identified and located, including the rightholders of works and other protected subject-matter which are embedded or incorporated in the works or phonograms. Rightholders that have been identified and located can give this authorisation only in relation to the rights that they themselves hold, either because the rights are their own rights or because the rights were transferred to them, and should not be able to authorise under this Directive any use on behalf of rightholders that have not been identified and located. Correspondingly, when

previously non-identified or non-located rightholders come forward in order to claim their rights in the work or phonogram, the lawful use of the work or phonogram by the beneficiaries can continue only if those rightholders give their authorisation to do so under Directive 2001/29/EC in relation to the rights that they hold.

(18) Rightholders should be entitled to put an end to the orphan work status in the event that they come forward to claim their rights in the work or other protected subject-matter. Rightholders that put an end to the orphan work status of a work or other protected subject-matter should receive fair compensation for the use that has been made of their works or other protected subject-matter under this Directive, to be determined by the Member State where the organisation that uses an orphan work is established. Member States should be free to determine the circumstances under which the payment of such compensation may be organised, including the point in time at which the payment is due. For the purposes of determining the possible level of fair compensation, due account should be taken, inter alia, of Member States' cultural promotion objectives, of the non-commercial nature of the use made by the organisations in question in order to achieve aims related to their public-interest missions, such as promoting learning and disseminating culture, and of the possible harm to rightholders.

(19) If a work or phonogram has been wrongly found to be an orphan work, following a search which was not diligent, the remedies for copyright infringement in Member States' legislation, provided for in accordance with the relevant national provisions and Union law, remain available.

(20) In order to promote learning and the dissemination of culture, Member States should provide for an exception or limitation in addition to those provided for in Article 5 of Directive 2001/29/EC. That exception or limitation should permit certain organisations, as referred to in point (c) of Article 5(2) of Directive 2001/29/EC and film or audio heritage institutions which operate on a non-profit making basis, as well as public-service broadcasting organisations, to reproduce and make available to the public, within the meaning of that Directive, orphan works, provided that such use fulfils their public interest missions, in particular the preservation of, the restoration of, and the provision of cultural and educational access to, their collections, including their digital collections. Film or audio heritage institutions should, for the purposes of this Directive, cover organisations designated by Member States to collect, catalogue, preserve and restore films and other audiovisual works or phonograms forming part of their cultural heritage. Public-service broadcasters should, for the purposes of this Directive, cover broadcasters with a public-service remit as conferred, defined and organised

<sup>(1)</sup> Regulation (EU) No 386/2012 of the European Parliament and of the Council of 19 April 2012 on entrusting the Office for Harmonization in the Internal Market (Trade Marks and Designs) with tasks related to the enforcement of intellectual property rights, including the assembling of public and private-sector representatives as a European Observatory on Infringements of Intellectual Property Rights (OJ L 129, 16.5.2012, p. 1).

by each Member State. The exception or limitation established by this Directive to permit the use of orphan works is without prejudice to the exceptions and limitations provided for in Article 5 of Directive 2001/29/EC. It can be applied only in certain special cases which do not conflict with the normal exploitation of the work or other protected subject-matter and do not unreasonably prejudice the legitimate interests of the rightholder.

- (21) In order to incentivise digitisation, the beneficiaries of this Directive should be allowed to generate revenues in relation to their use of orphan works under this Directive in order to achieve aims related to their public-interest missions, including in the context of public-private partnership agreements.
- (22) Contractual arrangements may play a role in fostering the digitisation of European cultural heritage, it being understood that publicly accessible libraries, educational establishments and museums, as well as archives, film or audio heritage institutions and public-service broadcasting organisations, should be allowed, with a view to undertaking the uses permitted under this Directive, to conclude agreements with commercial partners for the digitisation and making available to the public of orphan works. Those agreements may include financial contributions by such partners. Such agreements should not impose any restrictions on the beneficiaries of this Directive as to their use of orphan works and should not grant the commercial partner any rights to use, or control the use of, the orphan works.
- (23) In order to foster access by the Union's citizens to Europe's cultural heritage, it is also necessary to ensure that orphan works which have been digitised and made available to the public in one Member State may also be made available to the public in other Member States. Publicly accessible libraries, educational establishments and museums, as well as archives, film or audio heritage institutions and public-service broadcasting organisations that use an orphan work in order to achieve their public-interest missions should be able to make the orphan work available to the public in other Member States.
- (24) This Directive is without prejudice to the arrangements in the Member States concerning the management of rights such as extended collective licences, legal presumptions of representation or transfer, collective management or similar arrangements or a combination of them, including for mass digitisation.
- (25) Since the objective of this Directive, namely ensuring legal certainty with respect to the use of orphan works, cannot be sufficiently achieved by the Member States and can therefore, by reason of the need for uniformity of the rules governing the use of orphan works, be better achieved at Union level, the Union may adopt

measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve that objective,

HAVE ADOPTED THIS DIRECTIVE:

#### Article 1

##### Subject-matter and scope

1. This Directive concerns certain uses made of orphan works by publicly accessible libraries, educational establishments and museums, as well as by archives, film or audio heritage institutions and public-service broadcasting organisations, established in the Member States, in order to achieve aims related to their public-interest missions.

2. This Directive applies to:

- (a) works published in the form of books, journals, newspapers, magazines or other writings contained in the collections of publicly accessible libraries, educational establishments or museums as well as in the collections of archives or of film or audio heritage institutions;
- (b) cinematographic or audiovisual works and phonograms contained in the collections of publicly accessible libraries, educational establishments or museums as well as in the collections of archives or of film or audio heritage institutions; and
- (c) cinematographic or audiovisual works and phonograms produced by public-service broadcasting organisations up to and including 31 December 2002 and contained in their archives;

which are protected by copyright or related rights and which are first published in a Member State or, in the absence of publication, first broadcast in a Member State.

3. This Directive also applies to works and phonograms referred to in paragraph 2 which have never been published or broadcast but which have been made publicly accessible by the organisations referred to in paragraph 1 with the consent of the rightholders, provided that it is reasonable to assume that the rightholders would not oppose the uses referred to in Article 6. Member States may limit the application of this paragraph to works and phonograms which have been deposited with those organisations before 29 October 2014.

4. This Directive shall also apply to works and other protected subject-matter that are embedded or incorporated in, or constitute an integral part of, the works or phonograms referred to in paragraphs 2 and 3.

5. This Directive does not interfere with any arrangements concerning the management of rights at national level.

## Article 2

### Orphan works

1. A work or a phonogram shall be considered an orphan work if none of the rightholders in that work or phonogram is identified or, even if one or more of them is identified, none is located despite a diligent search for the rightholders having been carried out and recorded in accordance with Article 3.

2. Where there is more than one rightholder in a work or phonogram, and not all of them have been identified or, even if identified, located after a diligent search has been carried out and recorded in accordance with Article 3, the work or phonogram may be used in accordance with this Directive provided that the rightholders that have been identified and located have, in relation to the rights they hold, authorised the organisations referred to in Article 1(1) to carry out the acts of reproduction and making available to the public covered respectively by Articles 2 and 3 of Directive 2001/29/EC.

3. Paragraph 2 shall be without prejudice to the rights in the work or phonogram of rightholders that have been identified and located.

4. Article 5 shall apply *mutatis mutandis* to the rightholders that have not been identified and located in the works referred to in paragraph 2.

5. This Directive shall be without prejudice to national provisions on anonymous or pseudonymous works.

## Article 3

### Diligent search

1. For the purposes of establishing whether a work or phonogram is an orphan work, the organisations referred to in Article 1(1) shall ensure that a diligent search is carried out in good faith in respect of each work or other protected subject-matter, by consulting the appropriate sources for the category of works and other protected subject-matter in question. The diligent search shall be carried out prior to the use of the work or phonogram.

2. The sources that are appropriate for each category of works or phonogram in question shall be determined by each Member State, in consultation with rightholders and users, and shall include at least the relevant sources listed in the Annex.

3. A diligent search shall be carried out in the Member State of first publication or, in the absence of publication, first broadcast, except in the case of cinematographic or audiovisual works the producer of which has his headquarters or habitual residence in a Member State, in which case the diligent search shall be carried out in the Member State of his headquarters or habitual residence.

In the case referred to in Article 1(3), the diligent search shall be carried out in the Member State where the organisation that made the work or phonogram publicly accessible with the consent of the rightholder is established.

4. If there is evidence to suggest that relevant information on rightholders is to be found in other countries, sources of information available in those other countries shall also be consulted.

5. Member States shall ensure that the organisations referred to in Article 1(1) maintain records of their diligent searches and that those organisations provide the following information to the competent national authorities:

- (a) the results of the diligent searches that the organisations have carried out and which have led to the conclusion that a work or a phonogram is considered an orphan work;
- (b) the use that the organisations make of orphan works in accordance with this Directive;
- (c) any change, pursuant to Article 5, of the orphan work status of works and phonograms that the organisations use;
- (d) the relevant contact information of the organisation concerned.

6. Member States shall take the necessary measures to ensure that the information referred to in paragraph 5 is recorded in a single publicly accessible online database established and managed by the Office for Harmonization in the Internal Market ('the Office') in accordance with Regulation (EU) No 386/2012. To that end, they shall forward that information to the Office without delay upon receiving it from the organisations referred to in Article 1(1).

## Article 4

### Mutual recognition of orphan work status

A work or phonogram which is considered an orphan work according to Article 2 in a Member State shall be considered an orphan work in all Member States. That work or phonogram may be used and accessed in accordance with this Directive in all Member States. This also applies to works and phonograms referred to in Article 2(2) in so far as the rights of the non-identified or non-located rightholders are concerned.

## Article 5

### End of orphan work status

Member States shall ensure that a rightholder in a work or phonogram considered to be an orphan work has, at any time, the possibility of putting an end to the orphan work status in so far as his rights are concerned.

## Article 6

### Permitted uses of orphan works

1. Member States shall provide for an exception or limitation to the right of reproduction and the right of making available to the public provided for respectively in Articles 2 and 3 of Directive 2001/29/EC to ensure that the organisations referred to in Article 1(1) are permitted to use orphan works contained in their collections in the following ways:

- (a) by making the orphan work available to the public, within the meaning of Article 3 of Directive 2001/29/EC;
- (b) by acts of reproduction, within the meaning of Article 2 of Directive 2001/29/EC, for the purposes of digitisation, making available, indexing, cataloguing, preservation or restoration.

2. The organisations referred to in Article 1(1) shall use an orphan work in accordance with paragraph 1 of this Article only in order to achieve aims related to their public-interest missions, in particular the preservation of, the restoration of, and the provision of cultural and educational access to, works and phonograms contained in their collection. The organisations may generate revenues in the course of such uses, for the exclusive purpose of covering their costs of digitising orphan works and making them available to the public.

3. Member States shall ensure that the organisations referred to in Article 1(1) indicate the name of identified authors and other rightholders in any use of an orphan work.

4. This Directive is without prejudice to the freedom of contract of such organisations in the pursuit of their public-interest missions, particularly in respect of public-private partnership agreements.

5. Member States shall provide that a fair compensation is due to rightholders that put an end to the orphan work status of their works or other protected subject-matter for the use that has been made by the organisations referred to in Article 1(1) of such works and other protected subject-matter in accordance with paragraph 1 of this Article. Member States shall be free to determine the circumstances under which the payment of such compensation may be organised. The level of the compensation shall be determined, within the limits imposed by Union law, by the law of the Member State in which the organisation which uses the orphan work in question is established.

#### Article 7

##### Continued application of other legal provisions

This Directive shall be without prejudice to provisions concerning, in particular, patent rights, trade marks, design rights, utility models, the topographies of semi-conductor products, type faces, conditional access, access to cable of broadcasting services, the protection of national treasures, legal deposit requirements, laws on restrictive practices and unfair competition, trade secrets, security, confidentiality, data protection and privacy, access to public documents, the law of contract, and rules on the freedom of the press and freedom of expression in the media.

#### Article 8

##### Application in time

1. This Directive shall apply in respect of all works and phonograms referred to in Article 1 which are protected by

the Member States' legislation in the field of copyright on or after 29 October 2014.

2. This Directive shall apply without prejudice to any acts concluded and rights acquired before 29 October 2014.

#### Article 9

##### Transposition

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 29 October 2014. They shall forthwith communicate to the Commission the text of those provisions.

When Member States adopt those provisions, they shall contain a reference to this Directive or shall be accompanied by such a reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

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 10

##### Review clause

The Commission shall keep under constant review the development of rights information sources and shall by 29 October 2015, and at annual intervals thereafter, submit a report concerning the possible inclusion in the scope of application of this Directive of publishers and of works or other protected subject-matter not currently included in its scope, and in particular stand-alone photographs and other images.

By 29 October 2015, the Commission shall submit to the European Parliament, the Council and the European Economic and Social Committee a report on the application of this Directive, in the light of the development of digital libraries.

When necessary, in particular to ensure the functioning of the internal market, the Commission shall submit proposals for amendment of this Directive.

A Member State that has valid reasons to consider that the implementation of this Directive hinders one of the national arrangements concerning the management of rights referred to in Article 1(5) may bring the matter to the attention of the Commission together with all relevant evidence. The Commission shall take such evidence into account when drawing up the report referred to in the second paragraph of this Article and when assessing whether it is necessary to submit proposals for amendment of this Directive.

#### Article 11

##### Entry into force

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

*Article 12***Addressees**

This Directive is addressed to the Member States.

Done at Strasbourg, 25 October 2012.

*For the European Parliament*  
*The President*  
M. SCHULZ

*For the Council*  
*The President*  
A. D. MAVROYIANNIS

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## ANNEX

The sources referred to in Article 3(2) include the following:

- (1) for published books:
    - (a) legal deposit, library catalogues and authority files maintained by libraries and other institutions;
    - (b) the publishers' and authors' associations in the respective country;
    - (c) existing databases and registries, WATCH (Writers, Artists and their Copyright Holders), the ISBN (International Standard Book Number) and databases listing books in print;
    - (d) the databases of the relevant collecting societies, in particular reproduction rights organisations;
    - (e) sources that integrate multiple databases and registries, including VIAF (Virtual International Authority Files) and ARROW (Accessible Registries of Rights Information and Orphan Works);
  - (2) for newspapers, magazines, journals and periodicals:
    - (a) the ISSN (International Standard Serial Number) for periodical publications;
    - (b) indexes and catalogues from library holdings and collections;
    - (c) legal deposit;
    - (d) the publishers' associations and the authors' and journalists' associations in the respective country;
    - (e) the databases of relevant collecting societies including reproduction rights organisations;
  - (3) for visual works, including fine art, photography, illustration, design, architecture, sketches of the latter works and other such works that are contained in books, journals, newspapers and magazines or other works:
    - (a) the sources referred to in points (1) and (2);
    - (b) the databases of the relevant collecting societies, in particular for visual arts, and including reproduction rights organisations;
    - (c) the databases of picture agencies, where applicable;
  - (4) for audiovisual works and phonograms:
    - (a) legal deposit;
    - (b) the producers' associations in the respective country;
    - (c) databases of film or audio heritage institutions and national libraries;
    - (d) databases with relevant standards and identifiers such as ISAN (International Standard Audiovisual Number) for audiovisual material, ISWC (International Standard Music Work Code) for musical works and ISRC (International Standard Recording Code) for phonograms;
    - (e) the databases of the relevant collecting societies, in particular for authors, performers, phonogram producers and audiovisual producers;
    - (f) credits and other information appearing on the work's packaging;
    - (g) databases of other relevant associations representing a specific category of rightholders.
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## DECISIONS

## DECISION No 994/2012/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 25 October 2012

**establishing an information exchange mechanism with regard to intergovernmental agreements between Member States and third countries in the field of energy**

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 194 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee <sup>(1)</sup>,

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure <sup>(2)</sup>,

Whereas:

- (1) The European Council has asked Member States to inform the Commission as of 1 January 2012 of all their new and existing bilateral agreements with third countries in the field of energy. The Commission should make this information available to all other Member States in an appropriate form, having regard to the need for protection of commercially sensitive information.
- (2) Article 4 of the Treaty on European Union (TEU) requires Member States to take all appropriate measures to ensure fulfilment of the obligations arising out of the Treaties or resulting from the acts of the Union institutions. Member States should therefore avoid or eliminate any incompatibility between Union law and international agreements concluded between Member States and third countries.
- (3) The proper functioning of the internal energy market requires that the energy imported into the Union be fully governed by the rules establishing the internal energy market. An internal energy market that does not function properly puts the Union in a vulnerable and disadvantageous position with regard to security of

energy supply, and undermines its potential benefits to European consumers and industry. A high degree of transparency with regard to agreements between Member States and third countries in the field of energy would allow the Union to take coordinated action, in the spirit of solidarity, in order to ensure that such agreements comply with Union law and effectively secure energy supply. Such transparency would also be of benefit in achieving both closer intra-Union cooperation in the field of external energy relations and the Union's long-term policy objectives relating to energy, climate and security of energy supply.

- (4) A new information exchange mechanism should therefore be established. It should cover only intergovernmental agreements having an impact on the internal energy market or on the security of energy supply in the Union as the two issues are intrinsically linked. The initial assessment as to whether an intergovernmental agreement, or another text to which an intergovernmental agreement refers explicitly, has an impact on the internal energy market or the security of energy supply in the Union, should be the responsibility of Member States; in case of doubt, Member States should consult the Commission. In principle, agreements that are no longer in force or are no longer applied do not have an impact on the internal energy market or on the security of energy supply in the Union and should therefore not be covered by this information exchange mechanism. The information exchange mechanism should comprise in particular all intergovernmental agreements which have an impact on the supply of gas, oil or electricity through fixed infrastructure or which have an impact on the amount of energy imported into the Union.
- (5) Intergovernmental agreements which must be notified in their entirety to the Commission on the basis of other Union acts should be excluded from the information exchange mechanism. However, that exemption should not apply to intergovernmental agreements with third countries which have an impact on the development and use of gas infrastructure and gas supplies and which must be communicated to the Commission in accordance with point (a) of Article 13(6) of Regulation (EU) No 994/2010 of the European Parliament and of the Council of 20 October 2010 concerning measures to safeguard security of gas supply <sup>(3)</sup>. Such agreements

<sup>(1)</sup> OJ C 68, 6.3.2012, p. 65.

<sup>(2)</sup> Position of the European Parliament of 13 September 2012 (not yet published in the Official Journal) and decision of the Council of 4 October 2012.

<sup>(3)</sup> OJ L 295, 12.11.2010, p. 1.

should be notified according to the rules laid down in this Decision. To avoid duplication, a notification submitted in accordance with this Decision should be considered to fulfil the obligation set out in point (a) of Article 13(6) of Regulation (EU) No 994/2010.

- (6) Intergovernmental agreements concerning matters within the purview of the Treaty establishing the European Atomic Energy Community should not be covered by this Decision.
- (7) This Decision does not create obligations as regards agreements between commercial entities. However, it does not prevent Member States from communicating to the Commission, on a voluntary basis, commercial agreements that are referred to explicitly in intergovernmental agreements. Furthermore, as it is possible that commercial agreements contain regulatory provisions, commercial operators negotiating commercial agreements with operators from third countries should have the possibility to seek guidance from the Commission in order to avoid potential conflicts with Union law.
- (8) Member States should submit to the Commission all existing intergovernmental agreements, whether they have entered into force or are being applied provisionally within the meaning of Article 25 of the Vienna Convention on the Law of Treaties, and all new intergovernmental agreements.
- (9) More transparency with regard to future intergovernmental agreements that will be negotiated or that are being negotiated between Member States and third countries in the field of energy could contribute to consistency in Member States' approaches to such agreements, to compliance with Union law, and to the security of energy supply in the Union. Therefore, Member States should have the option of informing the Commission of negotiations with regard to new intergovernmental agreements or amendments to existing intergovernmental agreements. Where Member States choose that option, the Commission should be kept informed regularly of the progress of the negotiations. Member States should have the possibility to invite the Commission to participate in the negotiations as an observer.

The Commission should also have the possibility to participate as an observer at its own request, subject to the approval of the Member State concerned. Member States should also have the possibility to request the Commission to assist them during their negotiations with third countries. In that case, the Commission should have the possibility to provide advice on how to avoid incompatibility with Union law, and to draw attention to the Union's energy policy objectives and the principle of solidarity between Member States.

- (10) The Commission should assess the compatibility of existing intergovernmental agreements with Union law. In the event of incompatibility, Member States should take all necessary steps to find a suitable solution to eliminate the incompatibility identified.

- (11) In order to ensure more transparency and to avoid potential conflicts with Union law, Member States should have the option of informing the Commission of a new intergovernmental agreement with a third country before or during the negotiations thereof. Where a Member State, which has negotiated an intergovernmental agreement, has informed the Commission before the closure of negotiations accordingly and has submitted the draft intergovernmental agreement to it, the Commission should have the possibility to inform that Member State of its opinion on the compatibility of the negotiated agreement with Union law. The Commission has the right to launch infringement proceedings in accordance with Article 258 of the Treaty on the Functioning of the European Union (TFEU), where it considers that a Member State has failed to fulfil its obligations under the TFEU.
- (12) All final, ratified intergovernmental agreements covered by this Decision should be transmitted to the Commission in order to enable all other Member States to be informed.
- (13) The Commission should make all information it receives available to all other Member States in secure electronic form. The Commission should respect requests from Member States to treat information submitted to it as confidential. Requests for confidentiality should, however, not restrict access of the Commission itself to confidential information, as the Commission needs to have comprehensive information for its own assessments. The Commission should be responsible for guaranteeing the application of the confidentiality clause. Requests for confidentiality should be without prejudice to the right of access to documents as provided for in Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents <sup>(1)</sup>.
- (14) If a Member State considers an intergovernmental agreement to be confidential, it should provide the Commission with a summary of it for the purposes of sharing that summary with the other Member States.
- (15) A permanent exchange of information on intergovernmental agreements at Union level should enable best practices to be developed. On the basis of those best practices, the Commission, where appropriate in cooperation with the European External Action Service (EEAS) as regards the Union's external policies, should develop optional model clauses to be used in intergovernmental agreements between Member States and third countries. The use of such model clauses should aim to avoid conflicts of intergovernmental agreements with Union law, in particular competition law and internal energy market rules, and conflicts with international agreements concluded by the Union. Their use should be optional, and it should be possible to adapt their content to any particular circumstance.

<sup>(1)</sup> OJ L 145, 31.5.2001, p. 43.

- (16) Given the existence of the internal energy market and the objectives of Union energy policy, Member States should take due account of those objectives when negotiating intergovernmental agreements in the field of energy that have an impact on Union energy policy.
- (17) The improved mutual knowledge of existing and new intergovernmental agreements should allow for better coordination in energy matters between Member States and between Member States and the Commission. Such improved coordination should enable Member States to benefit fully from the political and economic weight of the Union and enable the Commission to propose solutions for problems identified in the area of intergovernmental agreements.
- (18) The Commission should facilitate and encourage coordination between Member States with a view to enhancing the overall strategic role of the Union through a strong and effective coordinated approach to producer, transit, and consumer countries.
- (19) The information exchange mechanism, including assessments to be made by Member States in implementing it, is without prejudice to the application of the Union rules on infringements, State aid and competition.
- (20) The Commission should assess whether this Decision is sufficient and effective in ensuring compliance of intergovernmental agreements with Union law and a high level of coordination between Member States with regard to intergovernmental agreements in the field of energy.
- (21) Since the objective of this Decision, namely the exchange of information between Member States and the Commission with regard to intergovernmental agreements in the field of energy, cannot be sufficiently achieved by the Member States but can rather, by reason of the effects of this Decision, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 TEU. In accordance with the principle of proportionality as set out in that Article, this Decision does not go beyond what is necessary in order to achieve this objective,

HAVE ADOPTED THIS DECISION:

#### *Article 1*

##### **Subject matter and scope**

1. This Decision establishes a mechanism for the exchange of information between Member States and the Commission with regard to intergovernmental agreements in the field of energy as defined in Article 2, in order to optimise the functioning of the internal energy market.
2. This Decision shall not apply to intergovernmental agreements which are already, in their entirety, subject to other specific notification procedures under Union law.

Notwithstanding the first subparagraph, this Decision shall apply to intergovernmental agreements which are to be

communicated to the Commission pursuant to point (a) of Article 13(6) of Regulation (EU) No 994/ 2010.

#### *Article 2*

##### **Definitions**

For the purposes of this Decision the following definitions apply:

- (1) 'intergovernmental agreement' means any legally binding agreement between one or more Member States and one or more third countries having an impact on the operation or the functioning of the internal energy market or on the security of energy supply in the Union; however, where such a legally binding agreement also covers other issues, only those provisions that relate to energy, including general provisions applicable to those energy-related provisions, shall constitute an 'intergovernmental agreement';
- (2) 'existing intergovernmental agreement' means an intergovernmental agreement which entered into force or is applied provisionally prior to the entry into force of this Decision.

#### *Article 3*

##### **Exchange of information between Member States and the Commission**

1. By 17 February 2013 Member States shall submit to the Commission all existing intergovernmental agreements, including annexes and amendments to those agreements. Where those existing intergovernmental agreements refer explicitly to other texts, Member States shall also submit to the Commission those other texts, in so far as they contain elements which have an impact on the functioning of the internal energy market or on the security of energy supply in the Union. However, that obligation shall not apply in respect of agreements between commercial entities.

Existing intergovernmental agreements which have already been communicated to the Commission in accordance with point (a) of Article 13(6) of Regulation (EU) No 994/2010 at the date of entry into force of this Decision shall be considered as having been submitted for the purposes of this paragraph, provided that that communication meets the requirements of the first subparagraph of this paragraph. By 17 February 2013 Member States shall inform the Commission whether any part of such intergovernmental agreements is to be regarded as confidential and whether the information provided may be shared with other Member States.

Where, pursuant to this paragraph, a Member State submits existing intergovernmental agreements also falling within the scope of point (a) of Article 13(6) of Regulation (EU) No 994/2010 to the Commission, it shall be considered to have complied with the communication obligation set out in that Article.

2. Where following its first assessment, the Commission has doubts as to the compatibility with Union law of agreements submitted to it under paragraph 1, in particular with Union competition law and internal energy market legislation, the Commission shall inform the Member States concerned accordingly within nine months of the submission of those agreements.

3. Before or during negotiations with a third country on an intergovernmental agreement or on the amendment of an existing intergovernmental agreement, a Member State may inform the Commission in writing of the objectives of, and the provisions to be addressed in, the negotiations and may communicate any other relevant information to the Commission. Where the Member State gives the Commission such notice of negotiations, the Member State concerned shall keep the Commission regularly informed of the progress of the negotiations.

The Member State concerned shall indicate to the Commission whether information submitted under the first subparagraph may be shared with all other Member States. Where the Member State concerned has indicated that the information may be shared, the Commission shall make the information received accessible to all Member States in secure electronic form, with the exception of any confidential parts identified in accordance with Article 4.

4. Where a Member State gives the Commission notice of negotiations pursuant to paragraph 3, the Commission may provide it with advice on how to avoid incompatibility of the intergovernmental agreement or of the amendment to an existing intergovernmental agreement under negotiation with Union law.

5. Upon ratification of an intergovernmental agreement or of an amendment to an intergovernmental agreement, the Member State concerned shall submit the intergovernmental agreement or the amendment, including any annexes to the agreement or the amendment, to the Commission.

Where the intergovernmental agreement or the amendment to the intergovernmental agreement refers explicitly to other texts, Member States shall also submit those other texts in so far as they contain elements which have an impact on the functioning of the internal energy market or on the security of energy supply in the Union. However, that obligation does not apply in respect of agreements between commercial entities.

6. Without prejudice to paragraph 7 of this Article and Article 4, the Commission shall make the documents which it has received under paragraphs 1 and 5 accessible in secure electronic form to all other Member States.

7. Where a Member State instructs the Commission, in accordance with Article 4, not to make an existing intergovernmental agreement, an amendment to an existing intergovernmental agreement or a new intergovernmental agreement accessible to other Member States, it shall make available a summary of the information submitted. That summary shall contain at least the following information regarding the agreement or amendment in question:

- (a) the subject matter;
- (b) the aim and the scope;
- (c) the duration;
- (d) the contracting parties;
- (e) information on the main elements.

The Commission shall make the summaries accessible in electronic form to all other Member States.

#### Article 4

##### Confidentiality

1. When providing information to the Commission in accordance with Article 3(1) to (6), a Member State may indicate whether any part of the information, be it commercial or other information the disclosure of which could harm the activities of the parties involved, is to be regarded as confidential and whether the information provided can be shared with other Member States. The Commission shall respect those indications.

2. Requests for confidentiality under this Article shall not restrict access of the Commission itself to confidential information. The Commission shall ensure that access to the confidential information is strictly limited to the Commission services for which it is absolutely necessary to have the information available.

#### Article 5

##### Assistance from the Commission

Where a Member State gives the Commission notice of negotiations pursuant to Article 3(3), that Member State may request the assistance of the Commission in those negotiations.

At the request of the Member State concerned, or at the request of the Commission and with the written approval of the Member State concerned, the Commission may participate in the negotiations as an observer.

Where the Commission participates in the negotiations as an observer, it may provide the Member State concerned with advice on how to avoid incompatibility of the intergovernmental agreement or amendment under negotiation with Union law.

#### Article 6

##### Compatibility assessment

1. Where a Member State is negotiating an intergovernmental agreement or an amendment to an existing intergovernmental agreement and it has been unable, on the basis of its own assessment, to reach a firm conclusion as to the compatibility of the intergovernmental agreement or amendment under negotiation with Union law, it shall inform the Commission thereof before the closure of the negotiations and submit the draft agreement or amendment together with any annexes to it.

2. The Commission shall, within four weeks of the date of receipt of the draft agreement or amendment, including annexes thereto, inform the Member State concerned of any doubts it may have as to the compatibility of the draft intergovernmental agreement or amendment with Union law. In the absence of a response from the Commission within that period, the Commission shall be deemed not to have any doubts.

3. Where the Commission informs the Member State concerned pursuant to paragraph 2 that it has doubts, it shall inform the Member State concerned of its opinion on the compatibility with Union law of the draft agreement or amendment concerned within 10 weeks of the date of receipt referred to in paragraph 2 (the examination period). With the approval of the Member State concerned, the examination

period may be extended. In the absence of an opinion from the Commission within the examination period, the Commission shall be deemed not to have raised any objections.

4. The time periods referred to in paragraphs 2 and 3 shall be shortened in agreement with the Commission if circumstances so warrant.

#### Article 7

##### Coordination among Member States

The Commission shall facilitate and encourage coordination among Member States with a view to:

- (a) reviewing developments in relation to intergovernmental agreements and striving for consistency and coherence in the Union's external energy relations with producer, transit, and consumer countries;
- (b) identifying common problems in relation to intergovernmental agreements and considering appropriate action to address those problems and, where appropriate, proposing solutions;
- (c) on the basis of best practice and in consultation with Member States, developing optional model clauses, which, if applied, would significantly improve compliance of future intergovernmental agreements with Union law;
- (d) supporting, where appropriate, the development of multi-lateral intergovernmental agreements involving several Member States or the Union as a whole.

#### Article 8

##### Reporting and review

1. By 1 January 2016, the Commission shall submit a report on the application of this Decision to the European Parliament, the Council and the European Economic and Social Committee.

2. The report shall, in particular, assess the extent to which this Decision promotes compliance of intergovernmental agreements with Union law and a high level of coordination between Member States with regard to intergovernmental agreements. It shall also assess the impact that this Decision has on Member States' negotiations with third countries and whether the scope of this Decision and the procedures it lays down are appropriate.

3. After submission of the first report referred to in paragraph 1 of this Article, the Commission shall report every three years to the European Parliament and the Council on the information received pursuant to Article 3, having due regard to the confidentiality provisions of this Decision.

#### Article 9

##### Entry into force

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

#### Article 10

##### Addressees

This Decision is addressed to the Member States.

Done at Strasbourg, 25 October 2012.

For the European Parliament

The President

M. SCHULZ

For the Council

The President

A. D. MAVROYIANNIS

## II

(Non-legislative acts)

## REGULATIONS

## COMMISSION IMPLEMENTING REGULATION (EU) No 995/2012

of 26 October 2012

**laying down detailed rules for the implementation of Decision No 1608/2003/EC of the European Parliament and of the Council concerning the production and development of Community statistics on science and technology**

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Decision No 1608/2003/EC of the European Parliament and of the Council of 22 July 2003 concerning the production and development of Community statistics on science and technology<sup>(1)</sup> and in particular Article 3 thereof,

Whereas:

- (1) In order to take into account the developments in the area of statistics on science and technology, as well as requests for new and more detailed and frequent statistics, new implementing measures of Decision No 1608/2003/EC should be laid down.
- (2) Existing statistical support for decisions in current policy areas should be continued and additional requirements arising from new policy initiatives should be satisfied, with a view to making best use of available resources and minimising the response burden.
- (3) Regulation (EC) No 223/2009 of the European Parliament and of the Council<sup>(2)</sup> on European statistics provides a reference framework, in particular with regard to rules on access to administrative data sources and statistical confidentiality.
- (4) It is necessary to ensure that European statistics on science and technology are consistent with other international standards. To that end, work carried out by the Organisation for Economic Cooperation and Development (OECD) and other international organisations should be taken into account. In particular, the Frascati Manual on research and development statistics, the Canberra Manual on statistics on human resources devoted to science and technology, the OECD Patent Statistics Manual, published by the OECD, as well as

the Oslo Manual on innovation statistics, published jointly by the OECD and the European Commission (Eurostat), should provide a reference framework.

- (5) For the sake of clarity, Commission Regulation (EC) No 753/2004 of 22 April 2004 implementing Decision No 1608/2003/EC of the European Parliament and of the Council as regards statistics on science and technology<sup>(3)</sup> and Commission Regulation (EC) No 1450/2004 of 13 August 2004 implementing Decision No 1608/2003/EC of the European Parliament and of the Council concerning the production and development of Community statistics on innovation<sup>(4)</sup> should be repealed.

- (6) 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*

This Regulation lays down detailed rules concerning the production of European statistics on science and technology.

*Article 2*

1. This Regulation shall cover the following domains:

- (a) statistics on research and development (R & D);
- (b) statistics on government budget appropriations or outlays on research and development (GBAORD);
- (c) innovation statistics;
- (d) statistics on human resources in science and technology, including gender and mobility statistics, statistics on

<sup>(1)</sup> OJ L 230, 16.9.2003, p. 1.

<sup>(2)</sup> OJ L 87, 31.3.2009, p. 164.

<sup>(3)</sup> OJ L 118, 23.4.2004, p. 23.

<sup>(4)</sup> OJ L 267, 14.8.2004, p. 32.

patents, statistics on high-technology industries and knowledge-based services and other statistics on science and technology.

The lists of statistical variables, the activities and sectors covered, breakdowns of the results, frequency, deadlines for data provision and the reference period shall be as specified in Annexes I and II.

For the domains referred to in point (d) of first subparagraph, the necessary data shall be obtained from existing statistical or other data sources, as specified in section 3 of Annex I.

2. The lists of statistical variables, the activities and sectors covered, breakdowns of the results, frequency, deadlines for data provision, and other characteristics set out in Annexes I and II shall, where appropriate, be reviewed at regular intervals.

#### Article 3

Member States shall acquire the necessary data using a combination of different sources, such as sample surveys, administrative data sources or other data sources. As far as the quality or statistical estimation procedures are concerned, the other data sources shall be at least equivalent to sample surveys or administrative data sources.

#### Article 4

The statistics referred to in Annexes I and II shall be based on harmonised concepts and definitions, notably those contained in the most recent versions of the Frascati Manual (R & D statistics), the Canberra Manual (statistics on human resources in science and technology), OECD Patent Statistics Manual (patent statistics), Oslo Manual (innovation statistics) or other harmonised standards.

#### Article 5

Member States shall provide the variables listed in Annexes I and II, including confidential data, to the Commission (Eurostat), using the technical standard determined by the Commission (Eurostat) in cooperation with the Member States.

Member States may provide the Commission (Eurostat) with individual data records on innovation statistics on a voluntary basis using the technical standard determined by the Commission (Eurostat).

#### Article 6

1. Member States shall take all necessary measures to ensure the quality of the data provided.

2. Member States shall provide the Commission (Eurostat) with standard quality reports concerning the data on:

- (a) research and development (R & D);
- (b) government budget appropriations or outlays on research and development (GBAORD);
- (c) innovation.

As far as research and development statistics are concerned, separate quality reports shall be drawn up for the business enterprise sector, government sector and higher education sector. Quality reports for the private non-profit sector shall be drawn up only if its R & D expenditure as a share of the total national R & D expenditure is more than 5 %.

3. Quality reports shall be drawn up by the Member States in accordance with the rules laid down in Annex III and shall cover the quality criteria defined in Article 12(1) of Regulation (EC) No 223/2009.

4. The first quality reports on R & D and GBAORD shall be drawn up for the data concerning the reference year 2011 and shall be submitted by 31 October 2013. For innovation statistics, the first quality reports shall be drawn up for the data concerning the reference year 2012 and shall be submitted by 31 October 2014. Subsequent quality reports shall be provided to the Commission (Eurostat) every second year within 22 months after the end of the reference year for which the data were collected.

#### Article 7

Regulations (EC) No 753/2004 and (EC) No 1450/2004 are repealed.

However, Regulation (EC) No 753/2004 shall continue to apply as regards R & D and GBAORD statistics for the reference year 2011.

References to the repealed Regulations shall be construed as references to this Regulation.

#### Article 8

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, 26 October 2012.

For the Commission  
The President  
José Manuel BARROSO

## ANNEX I

**STATISTICS ON SCIENCE AND TECHNOLOGY***Section 1***Statistics on Research and Development**

1. The statistics are to be compiled for R & D activity performed in the whole economy. The results shall relate to the population of all R & D performing units classified in Sections A to U of the common statistical classification of economic activities as established by Regulation (EC) No 1893/2006 of the European Parliament and of the Council <sup>(1)</sup> (NACE Rev.2).
2. The statistical units to be used in order to compile the statistics listed in paragraph 3 are: (a) enterprises for the statistics to be compiled at national level and (b) local units for the statistics to be compiled at regional level (NUTS 2). The definitions of the statistical units to be used ('enterprise' and 'local unit') are as set out in Council Regulation (EEC) No 696/93 of 15 March 1993 on the statistical units for the observation and analysis of the production system in the Community <sup>(2)</sup>.
3. The list of statistics (including their breakdowns) to be compiled is set out below.

<sup>(1)</sup> OJ L 393, 30.12.2006, p. 1.

<sup>(2)</sup> OJ L 76, 30.3.1993, p. 1.

Code	Title	All sectors	By sector of performance				Comments
			Business enterprise sector	Higher education sector	Government sector	Private non-profit sector	
1.11	<b>Number of R &amp; D personnel in head count (HC)</b>						
	Without breakdown	1.11.0.0	1.11.0.1	1.11.0.2	1.11.0.3	1.11.0.4	
	By occupation and sex	1.11.1.0	1.11.1.1	1.11.1.2	1.11.1.3	1.11.1.4	
	By qualification and sex	1.11.2.0	1.11.2.1	1.11.2.2	1.11.2.3	1.11.2.4	Optional
	By principal economic activity (NACE)		1.11.3.1				
	By major field of science and sex			1.11.4.2	1.11.4.3		
	By region (NUTS 2)	1.11.5.0	1.11.5.1	1.11.5.2	1.11.5.3	1.11.5.4	
	By region (NUTS 2) and sex	1.11.6.0	1.11.6.1	1.11.6.2	1.11.6.3	1.11.6.4	Optional
	By principal economic activity (NACE) and sex		1.11.7.1				
1.12	<b>Number of researchers in head Count (HC)</b>						
	Without breakdown	1.12.0.0	1.12.0.1	1.12.0.2	1.12.0.3	1.12.0.4	
	By sex	1.12.1.0	1.12.1.1	1.12.1.2	1.12.1.3	1.12.1.4	
	By qualification and sex	1.12.2.0	1.12.2.1	1.12.2.2	1.12.2.3	1.12.2.4	Optional
	By principal economic activity (NACE) and sex		1.12.3.1				
	By major field of science and sex			1.12.4.2	1.12.4.3		
	By region (NUTS 2)	1.12.5.0	1.12.5.1	1.12.5.2	1.12.5.3	1.12.5.4	
	By region (NUTS 2) and sex	1.12.6.0	1.12.6.1	1.12.6.2	1.12.6.3	1.12.6.4	Optional
	By age group and sex	1.12.7.0	1.12.7.1	1.12.7.2	1.12.7.3	1.12.7.4	Optional
	By citizenship and sex	1.12.8.0	1.12.8.1	1.12.8.2	1.12.8.3	1.12.8.4	Optional

Code	Title	All sectors	By sector of performance				Comments
			Business enterprise sector	Higher education sector	Government sector	Private non-profit sector	
1.13	<b>Number of R &amp; D personnel in full-time equivalent (FTE)</b>						
	Without breakdown	1.13.0.0	1.13.0.1	1.13.0.2	1.13.0.3	1.13.0.4	Yearly
	By occupation	1.13.1.0	1.13.1.1	1.13.1.2	1.13.1.3	1.13.1.4	
	By qualification	1.13.2.0	1.13.2.1	1.13.2.2	1.13.2.3	1.13.2.4	Optional
	By principal economic activity (NACE)		1.13.3.1				
	By major field of science and sex			1.13.4.2	1.13.4.3		Optional
	By region (NUTS 2)	1.13.5.0	1.13.5.1	1.13.5.2	1.13.5.3	1.13.5.4	
	By size class		1.13.6.1				Optional for the size classes 0 and one to nine employees
1.14	<b>Number of researchers in full-time equivalent (FTE)</b>						
	Without breakdown	1.14.0.0	1.14.0.1	1.14.0.2	1.14.0.3	1.14.0.4	Yearly
	By sex	1.14.1.0	1.14.1.1	1.14.1.2	1.14.1.3	1.14.1.4	Optional
	By qualification	1.14.2.0	1.14.2.1	1.14.2.2	1.14.2.3	1.14.2.4	Optional
	By principal economic activity (NACE)		1.14.3.1				
	By major field of science and sex			1.14.4.2	1.14.4.3		Optional
	By region (NUTS 2)	1.14.5.0	1.14.5.1	1.14.5.2	1.14.5.3	1.14.5.4	
	By region (NUTS 2) and sex	1.14.6.0	1.14.6.1	1.14.6.2	1.14.6.3	1.14.6.4	Optional
	By size class		1.14.7.1				Optional for the size classes 0 and one to nine employees
1.20	<b>Intramural R &amp; D expenditure</b>						
	Without breakdown	1.20.0.0	1.20.0.1	1.20.0.2	1.20.0.3	1.20.0.4	Yearly

Code	Title	All sectors	By sector of performance				Comments
			Business enterprise sector	Higher education sector	Government sector	Private non-profit sector	
	By source of funds	1.20.1.0	1.20.1.1	1.20.1.2	1.20.1.3	1.20.1.4	
	By type of R & D	1.20.3.0	1.20.3.1	1.20.3.2	1.20.3.3	1.20.3.4	Optional for HES and for all sectors
	By type of costs	1.20.4.0	1.20.4.1	1.20.4.2	1.20.4.3	1.20.4.4	
	By principal economic activity (NACE)		1.20.5.1.1				
	By product field (NACE)		1.20.5.1.2				Optional
	By size class		1.20.6.1				Optional for the size classes 0 and one to nine employees
	By source of funds and size class		1.20.7.1				Optional for the size classes 0 and one to nine employees
	By major field of science			1.20.8.2	1.20.8.3		
	By socioeconomic objective (SEO)				1.20.9.3		Optional
	By region (NUTS 2)	1.20.10.0	1.20.10.1	1.20.10.2	1.20.10.3	1.20.10.4	

4. All variables shall be provided every two years in each odd year, except those where the tables in paragraph 3 stipulate that they shall be provided annually.
5. The first reference year for which the statistics listed in paragraph 3 are to be compiled is the calendar year 2012.
6. The results are to be provided within 18 months of the end of the calendar year of the reference period. In addition, preliminary results for the variables with an annual frequency are to be provided within 10 months of the end of the calendar year of the reference period.
7. Production of results
  - 7.1. The results of the statistics by occupation are to be broken down into 'researchers' and 'other R & D personnel'.
  - 7.2. The results of the statistics by qualification are to be broken down into 'PhD holders (ISCED 2011 level 8)', 'other university degrees and other tertiary diplomas (ISCED 2011 levels 5, 6 and 7)' and 'other qualifications'.
  - 7.3. The results of the statistics by major field of science are to be broken down into 'natural sciences', 'engineering and technology', 'medical sciences', 'agricultural sciences', 'social sciences' and 'humanities'.
  - 7.4. The results of the statistics by size class are to be broken down into the following size classes: '0 employees', 'one to nine employees', '10 to 49 employees', '50 to 249 employees', '250 to 499 employees', '500 and more employees'.
  - 7.5. The results of the statistics by source of funds are to be broken down into the 'business enterprise sector', 'government sector', 'private non-profit sector', 'higher education sector' and 'abroad'. The category 'abroad' is to be further broken down into: 'foreign business enterprises', 'European Commission', 'international organisations' and 'other sources'. For the business enterprise sector category 'foreign business enterprises' is to be further broken down into 'foreign enterprises within the same group' and 'other foreign enterprises'.
  - 7.6. The results of the statistics by type of R & D are to be broken down into 'basic research', 'applied research' and 'experimental development'.
  - 7.7. The results of the statistics by type of costs are to be broken down into 'current costs (labour costs and other costs)' and 'capital expenditure'.
  - 7.8. The results of the statistics by socioeconomic objective (SEO) are to be broken down in accordance with the nomenclature for the analysis and comparison of scientific programmes and budgets (NABS) at chapter level.
  - 7.9. The results of the statistics by age group are to be broken down into the following age classes (in years): 'up to 25', '25 to 34', '35 to 44', '45 to 54', '55 to 64', '65 and more'.
  - 7.10. The results of the statistics by citizenship are to be broken down into the following categories: 'national citizenship', 'citizenship of other EU Member States', 'citizenship of other European countries', 'citizenship of North America', 'citizenship of Central and South America', 'citizenship of Asia', 'citizenship of Africa', 'other citizenship'.
  - 7.11. The results of the statistics by principal economic activity and by product field (NACE Rev. 2) are to be broken down into the following NACE Rev. 2 divisions, groups and aggregates:  
  
 '01, 02, 03', '05, 06, 07, 08, 09', '10 to 33', '10, 11, 12', '10, 11', '12', '13, 14, 15', '13', '14', '15', '16, 17, 18', '16', '17', '18', '19', '20', '21', '22', '23', '24', '25, 26, 27, 28, 29, 30', '25', '25.4', '26', '26.1', '26.2', '26.3', '26.4', '26.5', '26.6', '26.7', '27', '28', '29', '30', '30.1', '30.2', '30.3', '30.4', '31', '32', '32.5', '33', '35, 36, 37, 38, 39', '35, 36', '37, 38, 39', '41, 42, 43', '45, 46, 47, 49, 50, 51, 52, 53, 55, 56, 58, 59, 60, 61, 62, 63, 64, 65, 66, 68, 69, 70, 71, 72, 73, 74, 75, 77, 78, 79, 80, 81, 82', '45, 46, 47', '49, 50, 51, 52, 53', '55, 56', '58, 59, 60, 61, 62, 63', '61', '62', '63', '64, 65, 66', '68', '69, 70, 71, 72, 73, 74, 75', '71', '72', '72.1', '72.2', '77, 78, 79, 80, 81, 82', '84, 85', '86, 87, 88', '86', '87, 88', '90, 91, 92, 93', '94, 95, 96, 97, 98, 99', '01 to 99'.
8. The concepts and definitions related to the statistics defined in this section are laid down in the Frascati Manual.

9. On a voluntary basis, pilot studies will be undertaken by the Commission and/or Member States on additional variables and breakdowns of R & D statistics with a view to strengthening the scientific evidence base of R & D policy-making. The pilot studies are to be carried out in order to assess the relevance and feasibility of obtaining data, taking into account the benefits of the availability of the data in relation to the cost of collection and the burden on business. Topics of the pilot studies will be decided in close cooperation with the Member States.

#### Section 2

#### Statistics on government budget appropriations or outlays on research and development (GBAORD)

1. The following statistics are to be compiled:

Code	Title
21.0	Government R & D appropriations in the provisional budget (as approved by the Parliament at the beginning of the budget year)
21.1	Government R & D appropriations in the final budget (revised budget approved during the budget year)
22.0	National public funding to transnationally coordinated R & D

2. All variables shall be provided annually.
3. The first reference year for which the statistics are to be compiled is the calendar year 2012.
4. The results are to be provided within six months of the end of the calendar year of the reference period for variable 21.0 (including all breakdowns) and within 12 months for variables 21.1 and 22.0 (including all breakdowns).
5. Production of results
- 5.1. The results of the statistics compiled for the variables 21.0 and 21.1 are to be broken down in accordance with the nomenclature for the analysis and comparison of scientific programmes and budgets (NABS 2007) at chapter level.
- 5.2. The results of the statistics compiled for the variable 21.1 are to be broken down:
- (a) in accordance with the nomenclature for the analysis and comparison of scientific programmes and budgets (NABS 2007) at subchapter level — optional;
- (b) into 'project funding' and 'institutional funding' — optional.
- 5.3. The results of the statistics compiled for the variable 22.0 are to be broken down into 'national contributions to transnational public R & D performers', 'national contributions to Europe-wide transnational public R & D programmes' and 'national contributions to bilateral or multilateral public R & D programmes established between Member State governments (and with candidate countries and EFTA countries)'.
6. The concepts and definitions related to the statistics defined in this section are laid down in the Frascati Manual or other harmonised standards.

#### Section 3

#### Other statistics on science and technology

The work relating to the other areas of statistics on science and technology shall refer in particular to the following domains:

- (a) statistics on human resources in science and technology (including gender and mobility statistics) (HRST): development and implementation of a comprehensive framework for statistics on HRST principally by exploiting existing national and international data sources more effectively (also within the European statistical system). Particular attention is to be paid to gender aspects;
- (b) statistics on patents: development and implementation of a comprehensive framework for statistics on patents by regularly producing international and national patent statistics and indicators based on the information available at national and international patent offices;

- (c) statistics on high-technology industries and knowledge-based services: development and implementation of a comprehensive framework for statistics on high-technology industries and knowledge-based services, principally by exploiting existing national and international data sources more effectively (also within the European statistical system). This work also comprises the identification and classification of activities and products, the measurement of economic performance of these activities and their contribution to performance of the economy as a whole;
- (d) other statistics on science and technology: the additional development and implementation work is related, inter alia, to statistics on biotechnology, nanotechnology or other areas where science and technology is vital for meeting European Union priorities (like health, security, environment and climate change).

For the domains listed in this section, the necessary data will mostly be acquired through existing statistical or other data sources (e.g. in the area of social or economic statistics).

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## ANNEX II

## INNOVATION STATISTICS

## Section 1

The enterprise is the statistical unit to be used for the compilation of the statistics listed in Section 2. The definitions of the statistical units to be used ('enterprise') are as set out in Regulation (EEC) No 696/93.

## Section 2

Member States shall compile the following innovation statistics:

Variable	Title	Comments
1	Number of innovation active enterprises	As absolute value and as a percentage of all enterprises
2	Number of innovating enterprises that introduced new or significantly improved products, new to the market/new to enterprise	As absolute value, as a percentage of all enterprises and as a percentage of all innovation active enterprises
3	Turnover from innovation, related to new or significantly improved products, new to the market	As absolute value, as a percentage of total turnover and as a percentage of total turnover from innovation active enterprises
4	Turnover from innovation, related to new or significantly improved products, new to the firm, but not new to the market	As absolute value, as a percentage of total turnover and as a percentage of total turnover from innovation active enterprises
5	Number of innovation active enterprises involved in innovation cooperation	As absolute value and as a percentage of innovation active enterprises
6	Innovation expenditure	As absolute value, as a percentage of total turnover and as a percentage of total turnover from innovation active enterprises
7	Number of innovation active enterprises that indicated highly important objectives of innovation	As absolute value and as a percentage of all innovation active enterprises — optional
8	Number of innovation active enterprises that indicated highly important sources of information for innovation	As absolute value and as a percentage of all innovation active enterprises — optional
9	Number of enterprises facing important hampering factors	As absolute value, as a percentage of all enterprises, as a percentage of all innovation active enterprises and as a percentage of non-innovation active enterprises — optional
10	Number of innovating enterprises that developed the innovations itself or together with the other enterprises/institutions	As absolute value and as a percentage of all innovation active enterprises

Beyond the statistics listed above, Member States may compile additional statistics (including their breakdowns) in accordance with the main themes listed in the Oslo Manual. Inclusion of these additional statistics will be decided in close cooperation with Member States and incorporated in the harmonised survey questionnaire.

## Section 3

Market activity enterprises in the NACE Rev. 2 sections B, C, D, E, H, J, K and in the NACE Rev. 2 divisions 46 and divisions 71, 72 and 73 are to be covered. Member States have the option of further extending the coverage.

## Section 4

All variables shall be provided every two years in each even year.

## Section 5

The first reference year for which the statistics are to be compiled is the calendar year 2012.

## Section 6

1. All results are to be broken down by economic activity by NACE Rev. 2 sections, divisions or other aggregates and by the employment size classes as follows:

NACE category/ size category	10-49 employees	50-249 employees	above 249 employees	total
'B-C-D-E-46-H-J-K-71-72-73'	x	x	x	x
'B-C-D-E'	x	x	x	x
'B'	x	x	x	x
'C'	x	x	x	x
'10 to 12'				x
'13 to 15'				x
'16 to 18'				x
'19 to 22'				x
'20'				x
'21'				x
'23'				x
'24'				x
'25 to 30'				x
'25'				x
'26'				x
'31 to 33'				x
'D'	x	x	x	x
'E'	x	x	x	x
'36'				x
'37 to 39'				x
'46-H-J-K-71-72-73'	x	x	x	x
'46'	x	x	x	x
'H'	x	x	x	x
'49 to 51'				x
'52 to 53'				x
'J'	x	x	x	x
'58'				x
'61'				x
'62'				x
'63'				x

NACE category/ size category	10-49 employees	50-249 employees	above 249 employees	total
'K'	x	x	x	x
'64'				x
'65'				x
'66'				x
'71-72-73'	x	x	x	x
'71'				x
'72'				x
'73'				x

2. The results of variable 1 shall cover and be broken down into four types of innovations: process, product, organisational and marketing innovations. The results of variables 5 to 10 shall cover enterprises with process and/or product innovation activities. Coverage and breakdown by four types of innovations for the variables other than 1 will be decided in close cooperation with Member States and incorporated in the harmonised survey questionnaire.
3. The results of variable 5 are to be broken down by type of innovation cooperation. The results of variable 6 are to be broken down by type of innovation expenditures. The results of variable 7 are to be broken down by type of objectives of innovation. The results of variable 8 are to be broken down by type of sources of information. The results of variable 9 are to be broken down by type of hampering factors. The results of variable 10 are to be broken down by type of developers. These breakdowns will be decided in close cooperation with Member States and incorporated in the harmonised survey questionnaire.

#### *Section 7*

1. All results are to be provided within 18 months of the end of the calendar year of the reference period.
2. Member States may, on a voluntary basis, provide the Commission (Eurostat) with individual data records covering all statistical units surveyed as part of the national innovation surveys.

#### *Section 8*

1. The survey questionnaire, which is used for the innovation surveys carried out every two years and starting with the reference year 2012, shall cover the main themes listed in the Oslo Manual with regard to the measurement of innovation in enterprises.
2. In close cooperation with the Member States, methodological recommendations for the innovation surveys shall be drawn up by the Commission (Eurostat) leading to a high level of harmonisation of the survey results. These recommendations shall cover at least the target population, the survey methodology (including regional aspects), the harmonised survey questionnaire, the collection, processing and provision of the data, and data quality requirements.
3. Member States shall provide the Commission (Eurostat) with the necessary information concerning the national methodology used in national innovation statistics.

*ANNEX III***REQUIREMENTS FOR QUALITY REPORTS***Section 1***Introduction**

The quality reports shall contain both quantitative and qualitative indicators of the quality of the data, in the standard structure determined by the Commission in cooperation with the Member States. The Commission (Eurostat) shall provide the results for those quantitative indicators which can be calculated on the basis of data provided by Member States. Member States shall interpret and comment on them, in the light of their collection methodology and provide the remaining quantitative indicators as well as qualitative information.

*Section 2***Timeline**

Every second year, the Commission (Eurostat) shall, within 20 months after the end of the reference year (by the end of August), supply the Member States with draft standard quality reports, pre-filled with quality indicators and other information available to the Commission (Eurostat).

Every second year, Member States shall supply the Commission (Eurostat) within 22 months after the end of the reference year (by the end of October) with the completed standard quality reports.

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## 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**

(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 <sup>(1)</sup>, 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 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 <sup>(2)</sup> was adopted. That Regulation was replaced by Commission Implementing Regulation (EU) No 961/2011 <sup>(3)</sup> which was later replaced by Commission Implementing Regulation (EU) No 284/2012 <sup>(4)</sup>.
- (3) Implementing Regulation (EU) No 284/2012 has been amended several times to take into account the development of the situation. Since now further amendments are required, it is appropriate to replace Implementing Regulation (EU) No 284/2012 by a new Regulation.
- (4) The existing measures have been reviewed taking into account more than 26 000 occurrence data on radioactivity in feed and food provided by the Japanese authorities concerning the second growing season after the accident.

- (5) It is appropriate to exclude personal consignments from the application of the provisions of this Regulation. For food and feed of animal origin reference should be made to the provisions provided for in 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) 136/2004 <sup>(5)</sup>. For other feed and food, it should be provided that consignments can only be considered as personal consignments if they are non-commercial and are destined to a private person for personal consumption or use.
- (6) The Japanese authorities have provided extensive information to the Commission that in addition to the already exempted alcoholic beverages (sake, whiskey and shochu) also other alcoholic beverages do not contain measurable levels of radioactivity. The process of polishing and fermentation reduces the radioactivity in the alcoholic beverage to a significant extent. It is therefore appropriate to exclude certain other alcoholic beverages from the scope of this Regulation in order to reduce the administrative burden for the Japanese authorities and the competent authorities of the importing Member States.
- (7) 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 Yamanashi and Shizuoka on the presence of radioactivity before export to the Union. The requirement for sampling and analyses should only be maintained for tea from Shizuoka and mushrooms from Shizuoka and Yamanashi.
- (8) Since non-compliant or significant levels of radioactivity continue to be found in feed and food originating in the prefecture of Fukushima, it is appropriate to maintain the existing requirement of sampling and analysis before export to the Union for all feed and food originating in that prefecture. However, the general exemptions, such as for alcoholic beverages and personal consignments, should continue to apply in relation to such feed and food.
- (9) As regards the prefectures of Gunma, Ibaraki, Tochigi, Miyagi, Saitama, Tokyo, Iwate, Chiba and Kanagawa for which it is currently required to sample and analyse all feed and food before export to the Union, it is appropriate to limit that requirement to mushrooms, tea, fishery products, certain edible wild plants, certain vegetables, certain fruits, rice and soybeans and the processed and derived products thereof. The same

<sup>(1)</sup> OJ L 31, 1.2.2002, p. 1.

<sup>(2)</sup> OJ L 80, 26.3.2011, p. 5.

<sup>(3)</sup> OJ L 252, 28.9.2011, p. 10.

<sup>(4)</sup> OJ L 92, 30.3.2012, p. 16.

<sup>(5)</sup> OJ L 77, 24.3.2009, p. 1.

requirements should apply to compound foodstuffs containing more than 50 % of (an) ingredient(s) for which pretesting before export to the Union is required.

- (10) 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 occurred for more than a year. Therefore it is appropriate to reduce the frequency of controls at import and the reporting of the results to the Commission.
- (11) It is appropriate to foresee a next review of the provisions when the results of sampling and analysis on the presence of radioactivity of feed and food of the third growing season after the accident will be available, i.e. by 31 March 2014. However, for the products for which the harvest is mainly in the second part of the second growing season and therefore all the data of the second growing season are not yet available, it is appropriate to foresee a review of the provisions for these products by 31 March 2013.
- (12) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

#### Article 1

##### Scope

This Regulation shall apply to feed and food within the meaning of Article 1(2) of Council Regulation (Euratom) No 3954/87 <sup>(1)</sup> originating in or consigned from Japan, with the exclusion of:

- (a) products which left Japan before 28 March 2011;
- (b) products which have been harvested and/or processed before 11 March 2011;
- (c) alcoholic beverages falling within CN codes 2203 to 2208;
- (d) personal consignments of feed and food of animal origin which are covered by Article 2 of Regulation (EC) 206/2009;
- (e) personal consignments of feed and food other than of animal origin which are not-commercial and destined to a private person for personal consumption and use only. In case of doubt, the burden of proof lies with the recipient of the consignment.

#### Article 2

##### Definitions

For the purposes of this Regulation, 'transitional measures provided in the Japanese legislation' means the transitional measures adopted by the Japanese authorities on 24 February 2012 as regards the maximum levels for the sum of caesium-134 and caesium-137 as set out in Annex III.

'Consignment' means 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(s) of Japan, within the limits permitted by the declaration referred to in Article 5.

#### Article 3

##### Import into the Union

Feed and food (hereinafter 'the products') referred to in Article 1 may only be imported into the Union if they comply with this Regulation.

#### Article 4

##### Maximum levels of caesium-134 and caesium-137

1. The products referred to in Article 1, except those appearing in Annex III, shall comply with the maximum level for the sum of caesium-134 and caesium-137 as set out in Annex II.
2. Products appearing in Annex III shall comply with the maximum level for radioactive caesium set out in that Annex.

#### Article 5

##### Declaration

1. Each consignment of products referred to in Article 1 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:
  - (a) attest that the products comply with the legislation in force in Japan and
  - (b) specify whether the products are falling or not under the transitional measures provided for in the Japanese legislation.
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, other than tea and mushrooms originating in the prefecture Shizuoka and other than mushrooms originating in the prefecture Yamanashi, originates in and is consigned from a prefecture other than Fukushima, Gunma, Ibaraki, Tochigi, Miyagi, Saitama, Tokyo, Chiba, Kanagawa and Iwate; or
  - (c) the product originates in and is consigned from Gunma, Ibaraki, Tochigi, Miyagi, Saitama, Tokyo, Chiba, Kanagawa and Iwate but is not listed in Annex IV to this Regulation (and consequently no analysis before export is required); or
  - (d) the product is consigned from Fukushima, Gunma, Ibaraki, Tochigi, Miyagi, Saitama, Tokyo, Chiba, Kanagawa and Iwate prefectures, but does not originate in one of those prefectures and has not been exposed to radioactivity during transiting; or

<sup>(1)</sup> OJ L 371, 30.12.1987, p. 11.

- (e) where the product is tea or mushrooms originating in Shizuoka prefecture or mushrooms originating in Yamanashi prefecture, or a derived product thereof or a compound feed or food containing more than 50 % of these products, the product is accompanied by an analytical report containing the results of sampling and analysis; or
- (f) where the product, listed in Annex IV to this Regulation, originates in Fukushima, Gunma, Ibaraki, Tochigi, Miyagi, Saitama, Tokyo, Chiba, Kanagawa and Iwate prefectures, or is a compound feed or food containing more than 50 % of these products, the product is accompanied by an analytical report containing the results of sampling and analysis. The list of products in Annex IV 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 <sup>(1)</sup>; or
- (g) where the origin of the product or of the ingredients present at more than 50 % is unknown, the product is accompanied by an analytical report containing the results of sampling and analysis.

4. Point (f) of paragraph 3 shall apply also to products caught or harvested in the coastal waters of the prefectures referred to therein, 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 I.
2. For the products referred to in the points (a), (b), (c) or (d) 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 the point (e), (f) and (g) of Article 5(3), 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 1 shall be identified by means of a code which shall be indicated on the declaration referred to in Article 5(1), on the analytical report referred to in Article 5(3), on the sanitary certificate and on any commercial documents accompanying the consignment.

#### Article 8

##### Border inspection posts and designated point of entry

Consignments of products referred to in Article 1, except those falling within the scope of Council Directive 97/78/EC <sup>(2)</sup>, 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 <sup>(3)</sup> (hereinafter – 'the designated point of entry').

#### Article 9

##### Prior notification

Feed and food business operators or their representatives shall give prior notification of the arrival of each consignment of the products referred to in Article 1, at least two working days prior to the physical arrival of the consignment to the competent authorities at the border inspection post or at the designated point of entry.

#### Article 10

##### Official controls

1. The competent authorities of the border inspection post or designated point of entry shall carry out:
  - (a) documentary checks on all consignments of products referred to in Article 1;
  - (b) physical checks and identity checks, including laboratory analysis on the presence of caesium-134 and caesium-137, on 5 % of the consignments.
2. Consignments shall be kept under official control, for a maximum of five working days, pending the availability of the results of the laboratory analysis.
3. In case the result of the laboratory analysis provides evidence that the guarantees provided in the declaration are false, the declaration is considered not to be valid and the consignment of feed and food does not comply with the provisions of 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

The consignments may only be released into free circulation if the feed and food business operator or its representative submits to the customs authorities the declaration referred to in Article 5(1), which:

- (a) has been duly endorsed by the competent authority at the border inspection post or designated point of entry; and
- (b) provides evidence that the official controls referred to in Article 10 have been carried out and that the results of those controls have been favourable.

#### Article 13

##### Non-compliant products

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

<sup>(1)</sup> OJ L 43, 14.2.1997, p. 1.

<sup>(2)</sup> OJ L 24, 30.1.1998, p. 9.

<sup>(3)</sup> OJ L 194, 25.7.2009, p. 11.

*Article 14***Reports**

Member States shall inform the Commission every three months through the Rapid Alert System for Food and Feed (RASFF) of all analytical results obtained. That report shall be submitted during the month following each quarter.

*Article 15***Repeal**

Implementing Regulation (EU) No 284/2012 is repealed.

References to the repealed Regulation shall be construed as references to this Regulation.

*Article 16***Transitional measure**

By way of derogation from Article 3, products referred to in Article 1 may be imported into the Union if they comply with Implementing Regulation (EU) No 284/2012 where:

(a) the products left Japan before the entry into force of this Regulation; or

(b) the products are accompanied by a declaration in accordance with Implementing Regulation (EU) No 284/2012 which was issued before 1 November 2012 and the products have left Japan before 1 December 2012.

*Article 17***Entry into force and period of application**

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

It shall apply from the date of entry into force until 31 March 2014.

This Regulation shall be reviewed before 31 March 2013 as regards the products of which the harvest is mainly between August and November and as regards fish and fishery products.

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

Done at Brussels, 26 October 2012.

*For the Commission*

*The President*

José Manuel BARROSO

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## ANNEX I

**Declaration for the import into the Union of**

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

**Batch identification Code** ..... **Declaration Number** .....

According to the provisions of the Commission Implementing Regulation (EU) No 996/2012 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 the

.....  
 (authorised representative referred to in Article 6 (2) or 6(3) of Implementing Regulation (EU) No 996/2012)

DECLARES that the .....

..... (products referred to in Article 1)

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 feed or food

**not falling under the transitional measures** provided in the Japanese legislation (see Annex III to Implementing Regulation (EU) No 996/2012) as regards the maximum level for the sum of caesium-134 and caesium-137

**falling under the transitional measures** provided in the Japanese legislation (see Annex III to Implementing Regulation (EU) No 996/2012) as regards the maximum level for the sum of caesium-134 and caesium-137

DECLARES that the consignment concerns:

feed or food that has been harvested and/or processed before 11 March 2011;

feed or food that originates in and is consigned from a prefecture other than Fukushima, Gunma, Ibaraki, Tochigi, Miyagi, Saitama, Tokyo, Chiba, Kanagawa and Iwate, other than tea and mushrooms originating in Shizuoka prefecture and other than mushrooms originating in Yamanashi prefecture;

feed and food that is consigned from Fukushima, Gunma, Ibaraki, Tochigi, Miyagi, Saitama, Tokyo, Chiba, Kanagawa and Iwate prefectures, but does not originate in one of those prefectures and has not been exposed to radioactivity during transiting;

feed and food not listed in Annex IV to Implementing Regulation (EU) No 996/2012, that originates in and is consigned from Gunma, Ibaraki, Tochigi, Miyagi, Saitama, Tokyo, Chiba, Kanagawa and Iwate;

tea or mushrooms or a compound feed or food containing more than 50 % of these products, originating in Shizuoka prefecture, and has been sampled on ..... (date), 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 or a compound feed or food containing more than 50 % of these products, originating in Yamanashi prefecture, and has been sampled on ..... (date), 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;
- feed and food listed in Annex IV to Implementing Regulation (EU) No 996/2012 or a compound feed or food containing more than 50 % of these products, that originates in Fukushima, Gunma, Ibaraki, Tochigi, Miyagi, Saitama, Tokyo, Chiba, Kanagawa and Iwate prefectures, and has been sampled on ..... (date), 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;
- feed and food of unknown origin or containing more than 50 % of (an) ingredient(s) of unknown origin and has been sampled on ..... (date), 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) No 996/2012,

*Part to be completed by the competent authority at the border inspection post (BIP) or designated point of entry (DPE)*

- The consignment has been accepted to be presented to the custom authorities for release into free circulation in the Union
- The consignment has NOT been accepted to be presented to the custom authorities into release for free circulation in the Union

.....  
(Competent authority, Member State)

.....  
Date Stamp Signature

\_\_\_\_\_

## ANNEX II

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

	Foods for infants and young children	Milk and milk-based drinks	Other food, with the exception of - mineral water and similar drinks - tea brewed from unfermented leaves	Mineral water and similar drinks and tea brewed from unfermented leaves
Sum of caesium-134 and caesium-137	50 <sup>(2)</sup>	50 <sup>(2)</sup>	100 <sup>(2)</sup>	10 <sup>(2)</sup>

<sup>(1)</sup> 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 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.

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

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

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

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

<sup>(2)</sup> In order to ensure consistency with maximum levels currently applied in Japan, this value replaces on a provisional basis the value laid down in Commission Regulation (Euratom) No 770/90 (OJ L 83, 30.3.1990, p. 78).

<sup>(3)</sup> With the exemption of feed for ornamental fish.

## ANNEX III

**Transitional measures provided in Japanese legislation and of application for this Regulation**

- (a) Milk and dairy products, mineral water and similar drinks that are manufactured and/or processed before 31 March 2012 shall not contain radioactive caesium more than 200 Bq/kg. Other foods, except for rice, soybean and processed products thereof that are manufactured, and/or processed before 31 March 2012 shall not contain radioactive caesium more than 500 Bq/kg.
  - (b) Products made from rice that are manufactured, and/or processed before 30 September 2012 shall not contain radioactive caesium more than 500 Bq/kg.
  - (c) Soybean harvested and placed on the market before 31 December 2012 shall not contain radioactive caesium more than 500 Bq/kg.
  - (d) Products made from soybean that are manufactured and/or processed before 31 December 2012 shall not contain radioactive caesium more than 500 Bq/kg.
-

## ANNEX IV

**Feed and food for which a sampling and analysis on the presence of caesium 134 and caesium-137 is required before export to the Union**

- (a) products originating in the prefecture Fukushima:
- all products, taking into account the exemptions provided for in Article 1 of this Regulation.
- (b) products originating in the prefecture Shizuoka:
- tea and processed products thereof falling within CN codes 0902 2101 20 and 2202 90 10;
  - mushrooms and processed 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.
- (c) products originating in the prefecture Yamanashi:
- mushrooms and processed 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.
- (d) products originating in the prefectures Gunma, Ibaraki, Tochigi, Miyagi, Saitama, Tokyo, Chiba, Kanagawa or Iwate:
- tea and processed products thereof falling within CN codes 0902, 2101 20 and 2202 90 10;
  - mushrooms and processed 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 and 0308 (\*);
  - rice and processed 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 processed products thereof falling within CN codes 1201 90, 1208 10, 1507 (\*);
  - Adzuki beans falling within CN codes 0708 20, 0713 32 00 and processed products thereof falling under CN code such as 1106 10 (\*);
  - blueberries and processed products thereof falling within CN codes 0810 40 30, 0810 40 50, 0811 90 50, 0811 90 70, 0812 90 40, 0813 40 95;
  - ginkgo nut falling within CN code 0802 90 85 and processed products thereof falling within CN codes such as 0811 90 19, 0811 90 39, 0811 90 95, 0812 90 98, 0813 40 95;
  - Japanese apricot falling within CN codes 0809 40 05, and processed products thereof falling within CN codes such as 0811 90 19, 0811 90 39, 0811 90 95, 0812 90 98, 0813 40 95;
  - citrus fruit falling within CN code 0805, peel of citrus fruit falling within CN code 0814 00 00 and processed products thereof falling within CN codes such as 0811 90 19, 0811 90 39, 0811 90 95, 0812 90 25, 0812 90 98, 0813 40 95 (\*);
  - Japanese persimmon falling within CN code 0810 70 00 and processed products thereof falling within CN codes such as 0811 90 19, 0811 90 39, 0811 90 95, 0812 90 98, 0813 40 95 (\*);
  - pomegranate falling within CN code 0810 90 75 and processed products thereof falling within CN codes such as 0811 90 19, 0811 90 39, 0811 90 95, 0812 90 98, 0813 40 95 (\*);
  - chocolate vine (*Akebia quinata*) and processed products thereof falling within CN codes 0810 90 75, 0811 90 19, 0811 90 39, 0811 90 95, 0812 90 98 and 0813 40 95;
  - pome fruit (*Chaenomeles*) falling within CN code 0810 90 75 and processed products thereof falling within CN codes such as 0811 90 19, 0811 90 39, 0811 90 95, 0812 90 98, 0813 40 95 (\*);
  - pawpaws (*Asimina triloba*) falling within CN code 0810 90 75 and processed products thereof falling within CN codes such as 0811 90 19, 0811 90 39, 0811 90 95, 0812 90 98, 0813 40 95 (\*);

- pears falling within CN code 0808 30 10 and processed products thereof falling within CN codes such as 0811 90 19, 0811 90 39, 0811 90 95, 0812 90 98, 0813 40 30 (\*);
- chestnuts falling within CN codes 0802 41 00 and 0802 42 00 and processed products thereof falling within CN codes such as 0811 90 19, 0811 90 39, 0811 90 95, 0812 90 98, 0813 40 95 (\*);
- walnuts falling within CN codes 0802 31 00 and 0802 32 00 and processed products thereof falling within CN codes such as 0811 90 19, 0811 90 39, 0811 90 95, 0812 90 98, 0813 40 95 (\*);
- Ashitaba (*Angelica keiskei*) and processed products thereof falling within CN codes 0709 99, 0710 80, 0711 90 and 0712 90;
- giant butterbur (fuki), Japanese butterbur scape (*Petasites japonicus*) and processed products thereof falling within CN codes 0709 99, 0710 80, 0711 90 and 0712 90;
- Japanese ginger (Myoga) falling within CN codes 0709 99, 0710 80, 0711 90, 0712 90 and processed products thereof such as those falling within CN codes 2008 99 49, 2008 99 67;
- edible parts of *Aralia* sp. and processed products thereof falling within CN codes 0709 99, 0710 80, 0711 90 and 0712 90;
- bamboo shoot (*Phyllostachys pubescens*) and processed products thereof falling within CN codes 0709 99, 0710 80, 0711 90, 0712 90, 2004 90 and 2005 91;
- bracken (*Pteridium aquilinum*) and processed products thereof falling within CN codes 0709 99, 0710 80, 0711 90 and 0712 90;
- edible parts of Japanese horseradish or wasabi (*Wasabia japonica*) and processed products thereof falling within CN codes 0709 99, 0710 80, 0711 90, 0712 90 and 0910 99;
- Japanese parsley (*Oenanthe javanica*) and processed products thereof falling within CN codes 0709 99, 0710 80, 0711 90 and 0712 90;
- Japanese pepper (*Zanthoxylum piperitum*) falling within CN code 0910 99;
- Japanese royal fern (*Osmunda japonica*) and processed products thereof falling within CN codes 0709 99, 0710 80, 0711 90 and 0712 90;
- koshiabura (shoot of *Eleuterococcus sciadophylloides*) and processed products thereof falling within CN codes 0709 99, 0710 80, 0711 90 and 0712 90;
- momijigasa (*Parasenecio delphinifolius*) and processed products thereof falling within CN code 0709 99, 0710 80, 0711 90 and 0712 90;
- ostrich fern (*Matteuccia struthiopteris*) and processed products thereof falling within CN codes 0709 99, 0710 80, 0711 90 and 0712 90;
- plantain lily (*Hosta Montana*) and processed products thereof falling within CN codes 0709 99, 0710 80, 0711 90 and 0712 90;
- uwabamisou (*Elatostoma umbellatum* var. *majus*) and processed products thereof falling within CN codes 0709 99, 0710 80, 0711 90 and 0712 90;
- victory onion (*Allium victorialis* subsp. *Platyphyllum*) and processed products thereof falling within CN codes 0703 10, 0710 80, 071190071220 and 0712 90;
- thistle (*Cirsium japonicum*) and processed products thereof falling within CN codes 0709 99, 0710 80, 0711 90 and 0712 90 (\*);
- yobusumaso (Honma) (*Cacalia hastata* ssp. *orientalis*) and processed products thereof falling within CN codes 0709 99, 0710 80, 0711 90 and 0712 90 (\*);
- *Synurus pungens* (Oyamabokuchi) and processed products thereof falling within CN codes 0709 99, 0710 80, 0711 90 and 0712 90 (\*);
- field horsetail (*Equisetum arvense*) and processed products thereof falling within CN codes 0709 99, 0710 80, 0711 90 and 0712 90 (\*);
- *Actinidia polygama* (silver vine) and processed products thereof falling within CN codes 0810 90 75, 0811 90 19, 0811 90 39, 0811 90 95, 0812 90 98 and 0813 40 95 (\*).

- Taro (*Colocasia esculenta*) and processed products thereof falling within CN code 0714 40 (\*);
- Yacon (*Smallanthus sonchifolius*) and processed products thereof falling within CN codes 0709 99, 0710 80, 0711 90, 0712 90 and 0714 90 (\*);

(\* ) the listing of these products will be reviewed before 31 March 2013 taking into account the analytical results obtained in the period from September 2012 until December 2012.

- (e) compound products containing more than 50 % of the products referred to in the headings (a), (b), (c), and (d) of this Annex.

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**COMMISSION IMPLEMENTING REGULATION (EU) No 997/2012****of 26 October 2012****establishing the standard import values for determining the entry price of certain fruit and vegetables**

THE EUROPEAN COMMISSION,

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

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

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 <sup>(2)</sup>, 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 multi-lateral 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, 26 October 2012.

*For the Commission,  
On behalf of the President,  
José Manuel SILVA RODRÍGUEZ  
Director-General for Agriculture and  
Rural Development*

<sup>(1)</sup> OJ L 299, 16.11.2007, p. 1.

<sup>(2)</sup> 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 <sup>(1)</sup>	Standard import value
0702 00 00	AL	38,5
	MA	49,6
	MK	40,5
	ZZ	42,9
0707 00 05	AL	36,9
	MK	32,3
	TR	126,2
	ZZ	65,1
0709 93 10	TR	116,3
	ZZ	116,3
0805 50 10	AR	57,6
	CL	75,4
	TR	83,1
	UY	56,6
	ZA	88,8
	ZZ	72,3
0806 10 10	BR	258,6
	LB	333,4
	MK	87,0
	TR	158,3
	US	225,7
	ZZ	212,6
0808 10 80	CL	148,8
	CN	95,2
	MK	34,4
	NZ	128,3
	US	118,8
	ZA	150,3
	ZZ	112,6
0808 30 90	CN	51,0
	TR	113,5
	ZZ	82,3

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

# DECISIONS

## COUNCIL DECISION

of 25 October 2012

### on the launch of automated data exchange with regard to Vehicle Registration Data (VRD) in Sweden

(2012/664/EU)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to Council Decision 2008/615/JHA of 23 June 2008 on the stepping up of cross-border cooperation, particularly in combating terrorism and cross-border crime <sup>(1)</sup>, in particular Article 25 thereof,

Having regard to Council Decision 2008/616/JHA of 23 June 2008 on the implementation of Decision 2008/615/JHA <sup>(2)</sup>, in particular Article 20 and Chapter 4 of the Annex thereto,

Whereas:

- (1) According to the Protocol on Transitional Provisions annexed to the Treaty on European Union, to the Treaty on the Functioning of the European Union and to the Treaty establishing the European Atomic Energy Community, the legal effects of the acts of the institutions, bodies, offices and agencies of the Union adopted prior to the entry into force of the Treaty of Lisbon are preserved until those acts are repealed, annulled or amended in implementation of the Treaties.
- (2) Accordingly, Article 25 of Decision 2008/615/JHA is applicable and the Council must unanimously decide whether the Member States have implemented the provisions of Chapter 6 of that Decision.
- (3) Article 20 of Decision 2008/616/JHA provides that decisions referred to in Article 25(2) of Decision 2008/615/JHA are to be taken on the basis of an evaluation report based on a questionnaire. With respect to automated data exchange in accordance with Chapter 2 of Decision 2008/615/JHA, the evaluation report is to be based on an evaluation visit and a pilot run.
- (4) According to Chapter 4, point 1.1, of the Annex to Decision 2008/616/JHA, the questionnaire drawn up by the relevant Council Working Group concerns each of the automated data exchanges and has to be answered by

a Member State as soon as it believes it fulfils the prerequisites for sharing data in the relevant data category.

- (5) Sweden has completed the questionnaire on data protection and the questionnaire on Vehicle Registration Data (VRD).
- (6) A successful pilot run has been carried out by Sweden with the Netherlands.
- (7) An evaluation visit has taken place in Sweden and a report on the evaluation visit has been produced by the Belgian/Dutch evaluation team and forwarded to the relevant Council Working Group.
- (8) An overall evaluation report, summarising the results of the questionnaire, the evaluation visit and the pilot run concerning VRD has been presented to the Council,

HAS ADOPTED THIS DECISION:

#### *Article 1*

For the purposes of automated searching of vehicle registration data (VRD), Sweden has fully implemented the general provisions on data protection of Chapter 6 of Decision 2008/615/JHA and is entitled to receive and supply personal data pursuant to Article 12 of that Decision as from the day of the entry into force of this Decision.

#### *Article 2*

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

Done at Luxembourg, 25 October 2012.

*For the Council*  
*The President*  
E. MAVROU

<sup>(1)</sup> OJ L 210, 6.8.2008, p. 1.

<sup>(2)</sup> OJ L 210, 6.8.2008, p. 12.

**COUNCIL DECISION 2012/665/CFSP****of 26 October 2012****amending Decision 2010/638/CFSP concerning restrictive measures against the Republic of Guinea**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union, and in particular Article 29 thereof,

Whereas:

- (1) On 25 October 2010, by Decision 2010/638/CFSP <sup>(1)</sup> the Council imposed restrictive measures against the Republic of Guinea.
- (2) On the basis of a review of Decision 2010/638/CFSP, the restrictive measures should be extended until 27 October 2013.
- (3) It is necessary to amend the measures relating to the arms embargo provided for in Decision 2010/638/CFSP.
- (4) Decision 2010/638/CFSP should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

*Article 1*

Decision 2010/638/CFSP is hereby amended as follows:

(1) Article 2(1) is amended as follows:

(a) the following point is added:

'(g) sale, supply, transfer or export of explosives and related equipment intended solely for civilian use in mining and infrastructure investments and the provision of technical assistance, brokering services and other services as well as the provision

of financing and financial assistance related to such items, provided that the storage and use of the explosives and related equipment and services are controlled and verified by an independent body and that the providers of related services are identified;'

(b) the following subparagraph is added:

'In cases falling within point (g) a Member State shall inform the other Member States two weeks in advance of its intention to grant an approval under that point.'

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

'2. This Decision shall apply until 27 October 2013. It shall be kept under constant review. It may be renewed or amended, as appropriate, if the Council deems that its objectives have not been met.'

*Article 2*This Decision shall enter into force on the day of its publication in the *Official Journal of the European Union*.

Done at Brussels, 26 October 2012.

*For the Council**The President*

A. D. MAVROYIANNIS

<sup>(1)</sup> OJ L 280, 26.10.2010, p. 10.

## COMMISSION IMPLEMENTING DECISION

of 25 October 2012

amending Decision 2008/855/EC as regards animal health control measures relating to classical swine fever in Hungary

(notified under document C(2012) 7433)

(Text with EEA relevance)

(2012/666/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market <sup>(1)</sup>, and in particular Article 9(4) thereof,Having regard to Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market <sup>(2)</sup>, and in particular Article 10(4) thereof,

Whereas:

- (1) Commission Decision 2008/855/EC of 3 November 2008 concerning animal health control measures relating to classical swine fever in certain Member States <sup>(3)</sup> lays down certain control measures in relation to classical swine fever in the Member States or regions thereof listed in the Annex thereto. That list includes the county of Nógrád in Hungary.
- (2) Hungary has informed the Commission about recent developments with regard to classical swine fever in the territory of the county of Nógrád listed in the Annex to Decision 2008/855/EC.
- (3) That information indicates that classical swine fever has been eradicated in the territory of the county of Nógrád. Accordingly, the measures provided for in Decision

2008/855/EC should no longer apply to that county and the reference to the county of Nógrád in the list set out in Part I of the Annex thereto should be deleted.

- (4) Decision 2008/855/EC should therefore be amended accordingly.
- (5) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

*Article 1*

In Part I of the Annex to Decision 2008/855/EC, point 3 is replaced by the following:

**3. Hungary**

The territory of the county of Pest located north and east of the Danube, south of the border with Slovakia, west of the border with the county of Nógrád and north of the motorway E71.'

*Article 2*

This Decision is addressed to the Member States.

Done at Brussels, 25 October 2012.

For the Commission  
Maroš ŠEFČOVIČ  
Vice-President

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<sup>(1)</sup> OJ L 395, 30.12.1989, p. 13.

<sup>(2)</sup> OJ L 224, 18.8.1990, p. 29.

<sup>(3)</sup> OJ L 302, 13.11.2008, p. 19.

## COMMISSION IMPLEMENTING DECISION

of 25 October 2012

## establishing the financial contribution by the Union to the expenditure incurred in the context of the emergency measures taken to combat avian influenza in the Netherlands in 2011

(notified under document C(2012) 7440)

(Only the Dutch text is authentic)

(2012/667/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Council Decision 2009/470/EC of 25 May 2009 on expenditure in the veterinary field <sup>(1)</sup>, and in particular Article 4 thereof,

Whereas:

- (1) In accordance with Article 75 of the Financial Regulation and Article 90(1) of the Implementing Rules, the commitment of expenditure from the Union budget shall be preceded by a financing decision setting out the essential elements of the action involving expenditure and adopted by the institution or the authorities to which powers have been delegated by the institution.
- (2) Decision 2009/470/EC lays down the procedures governing the financial contribution from the Union towards specific veterinary measures, including emergency measures. With a view to helping to eradicate avian influenza as rapidly as possible the Union should contribute financially to eligible expenditure borne by the Member States. Article 4(3) first and second indents of that Decision lays down rules on the percentage that must be applied to the costs incurred by the Member States.
- (3) Article 3 of Commission Regulation (EC) No 349/2005 of 28 February 2005 laying down rules on the Community financing of emergency measures and of the campaign to combat certain animal diseases under Council Decision 90/424/EEC <sup>(2)</sup> sets rules on the expenditure eligible for Union financial support.
- (4) Commission Implementing Decision 2012/132/EU of 15 February 2012 on a financial contribution from the Union towards emergency measures to combat avian influenza in Germany, Italy and the Netherlands in 2011 <sup>(3)</sup> granted a financial contribution by the Union towards emergency measures to combat avian influenza

in the Netherlands in 2011. An official request for reimbursement was submitted by the Netherlands on 13 April 2012, as set out in Article 7(1) and 7(2) of Regulation (EC) No 349/2005.

- (5) The payment of the financial contribution from the Union is to be subject to the condition that the planned activities were actually implemented and that the authorities provided all the necessary information within the set deadlines.
- (6) The Netherlands have in accordance with Article 3(4) of Decision 2009/470/EC without delay informed the Commission and the other Member States of the measures applied in accordance with Union legislation on notification and eradication and the results thereof. The request for reimbursement was, as required in Article 7 of Regulation (EC) No 349/2005, accompanied by a financial report, supporting documents, an epidemiological report on each holding where the animals have been slaughtered or destroyed and the results of respective audits.
- (7) The Commission's observations, method of calculating the eligible expenditure and final conclusions were communicated to the Netherlands on 25 April 2012 and 4 June 2012. The Netherlands agreed by e-mail dated 11 June 2012.
- (8) Consequently the total amount of the financial support from the Union to the eligible expenditure incurred in connection with the eradication of avian influenza in the Netherlands in 2011 can now be fixed.
- (9) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

## Article 1

The financial contribution from the Union towards the expenditure associated with eradicating avian influenza in the Netherlands in 2011 is fixed at EUR 429 425,74.

<sup>(1)</sup> OJ L 155, 18.6.2009, p. 30.

<sup>(2)</sup> OJ L 55, 1.3.2005, p. 12.

<sup>(3)</sup> OJ L 59, 1.3.2012, p. 34.

*Article 2*

This Decision constituting a financing decision in the meaning of Article 75 of the Financial Regulation is addressed to the Kingdom of the Netherlands.

Done at Brussels, 25 October 2012.

*For the Commission*  
Maroš ŠEFČOVIČ  
*Vice-President*

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## COMMISSION IMPLEMENTING DECISION

of 25 October 2012

**establishing the financial contribution by the Union to the expenditure incurred in the context of the emergency measures taken to combat foot-and-mouth disease in Bulgaria in 2011**

(notified under document C(2012) 7454)

(Only the Bulgarian text is authentic)

(2012/668/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Council Decision 2009/470/EC of 25 May 2009 on expenditure in the veterinary field <sup>(1)</sup>, and in particular Article 14 thereof,

Whereas:

- (1) In accordance with Article 75 of the Financial Regulation and Article 90(1) of the Implementing Rules, the commitment of expenditure from the Union budget shall be preceded by a financing decision setting out the essential elements of the action involving expenditure and adopted by the institution or the authorities to which powers have been delegated by the institution.
- (2) Decision 2009/470/EC lays down the procedures governing the financial contribution from the Union towards specific veterinary measures, including emergency measures. With a view to helping to eradicate foot-and-mouth disease as rapidly as possible the Union should contribute financially to eligible expenditure borne by the Member States. Article 14(4) of that Decision lays down rules on the percentage that must be applied to the costs incurred by the Member States.
- (3) Article 3 of Commission Regulation (EC) No 349/2005 of 28 February 2005 laying down rules on the Community financing of emergency measures and of the campaign to combat certain animal diseases under Council Decision 90/424/EEC <sup>(2)</sup> sets rules on the expenditure eligible for Union financial support.
- (4) Commission Implementing Decision 2011/730/EU of 9 November 2011 on a financial contribution from the Union towards emergency measures to combat foot-and-mouth disease in Bulgaria in 2011 <sup>(3)</sup> granted a financial contribution by the Union towards emergency measures to combat foot-and-mouth disease in Bulgaria in 2011. An official request for reimbursement was submitted by Bulgaria on 9 December 2011 and 24 January 2012, as set out in Articles 7(1) and 7(2) of Regulation (EC) No 349/2005.
- (5) The payment of the financial contribution from the Union is to be subject to the condition that the

planned activities were actually implemented and that the authorities provided all the necessary information within the set deadlines.

- (6) Bulgaria has in accordance with Article 14(3) of Decision 2009/470/EC without delay informed the Commission and the other Member States of the measures applied in accordance with Union legislation on notification and eradication and the results thereof. The request for reimbursement was, as required in Article 7 of Regulation (EC) No 349/2005, accompanied by a financial report, supporting documents, an epidemiological report on each holding where the animals have been slaughtered or destroyed and the results of respective audits.
- (7) The Commission's observations, method of calculating the eligible expenditure and final conclusions were communicated to Bulgaria on 19 June 2012. Bulgaria agreed by e-mail dated 20 June 2012.
- (8) Consequently the total amount of the financial support from the Union to the eligible expenditure incurred in connection with the eradication of foot-and-mouth disease in Bulgaria in 2011 can now be fixed.
- (9) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

*Article 1*

The financial contribution from the Union towards the expenditure associated with eradicating foot-and-mouth disease in Bulgaria in 2011 is fixed at EUR 463 583,37.

*Article 2*

This Decision constituting a financing decision in the meaning of Article 75 of the Financial Regulation is addressed to the Republic of Bulgaria.

Done at Brussels, 25 October 2012.

*For the Commission*  
Maroš ŠEFČOVIČ  
Vice-President

<sup>(1)</sup> OJ L 155, 18.6.2009, p. 30.

<sup>(2)</sup> OJ L 55, 1.3.2005, p. 12.

<sup>(3)</sup> OJ L 293, 11.11.2011, p. 36.









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