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Contents

[1] Text with EEA relevance

EN

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

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

DECISIONS

GUIDELINES

[1] Text with EEA relevance

II

(Non-legislative acts)

REGULATIONS

COMMISSION DELEGATED REGULATION (EU) 2015/560

of 15 December 2014

supplementing Regulation (EU) No 1308/2013 of the European Parliament and of the Council as regards the scheme of authorisations for vine plantings

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 ([1]), and in particular Article 69 thereof,

Having regard to Regulation (EU) No 1306/2013 of the European Parliament and of the Council of 17 December 2013 on the financing, management and monitoring of the common agricultural policy and repealing Council Regulations (EEC) No 352/78, (EC) No 165/94, (EC) No 2799/98, (EC) No 814/2000, (EC) No 1290/2005 and (EC) No 485/2008 ([2]), and in particular Article 64(6) thereof,

Whereas:

(1) Regulation (EU) No 1308/2013 contains in Chapter III of Title I of Part II rules on a scheme of authorisations for vine plantings which repeal and replace the transitional planting rights regime set out in Subsection II of Section IVa of Chapter III of Title I of Part II of Council Regulation (EC) No 1234/2007 ([3]) as from 1 January 2016. This Chapter lays down rules concerning duration, management and control of the scheme of authorisations for vine plantings and empowers the Commission to adopt delegated acts concerning the management of the scheme. The transitional planting rights regime set out in Subsection II of Section IVa of Chapter III of Title I of Part II of Regulation (EC) No 1234/2007 remains applicable until 31 December 2015 in accordance with Article 230(1)(b)(ii) of Regulation (EU) No 1308/2013.

(2) Article 62 of Regulation (EU) No 1308/2013 lays down the general requirement for the Member States to grant an authorisation for vine planting upon submission of an application by producers intending to plant or replant vines. However, paragraph 4 of that Article provides that certain areas are exempted from the scheme of authorisations for vine plantings and therefore from this general requirement. It is necessary to lay down rules concerning the conditions of application of that exemption. The areas intended for experimental purposes or for graft nurseries should only be used for the specified purposes in order to avoid the circumvention of the new scheme, and grapevine products made from such areas should not be marketed unless Member States consider there are no risks of market disturbance. Existing wine-growing experiments and graft nurseries should be allowed to continue, subject to the existing rules in order to ensure a smooth transition between the plantings

([1]) OJ L 347, 20.12.2013, p. 671.
([2]) OJ L 347, 20.12.2013, p. 549.
([3]) 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) (OJ L 299, 16.11.2007, p. 1).

rights regime and the new scheme of authorisations for vine plantings. The areas whose wine or vine products are intended solely for the consumption by the wine grower's household should benefit from such exemption since, under certain conditions, they do not contribute to market disturbances. For the same reason, such exemption should also be extended to organisations without a commercial activity complying with the same conditions. The areas established by a producer having lost a certain area planted with vines due to compulsory purchases in the public interest under national law should also benefit from the exemption given that the loss of the land planted with vines in such cases is independent from the will of the producer. A condition as regards the maximum surface of the new area should however be laid down, so as to avoid undermining the general objectives of the scheme of authorisations for vine plantings.

(3) Article 64(1) and (2) of Regulation (EU) No 1308/2013 lays down rules concerning the granting of authorisations for new plantings and sets out eligibility and priority criteria that Member States may apply. Specific conditions associated to some of the eligibility and priority criteria should be established in order to establish a level playing field for their implementation and to avoid the circumvention of the system of authorisations by producers being granted authorisations. In addition, three new criteria should be added: a new eligibility criterion on the misappropriation of reputation of protected geographical indications; a new priority criterion favouring those producers that comply with the rules of the scheme and do not have abandoned vineyards in their holding; and a new priority criterion favouring non-profit organisations with a social purpose having received lands confiscated in case of terrorism and other types of crime. The new eligibility criterion responds to the need of protecting the reputation of specific geographical indications in a similar manner as the reputation of specific designations of origin, ensuring that they are not threatened by new plantings. The first new priority criterion favours certain applicants on the basis of their background that shows their respect for the rules of the authorisations scheme and that they are not applying for authorisations for new plantings while having areas planted with vines out of production which could generate authorisations for replanting. The second new priority criterion aims at favouring non-profit organisations with a social purpose having received lands confiscated in case of terrorism and other types of crime, in order to promote the social use of land that could risk otherwise being out of production.

(4) Taking into account Article 118 of Regulation (EU) No 1306/2013 and in order to address natural and socioeconomic differences and different growth strategies by the economic actors in those different areas within a particular territory, Member States should be permitted to apply the eligibility criteria and priority criteria referred to in Article 64(1) and (2) of Regulation (EU) No 1308/2013, as well as the new eligibility and priority criteria to be added by this Regulation, differently at regional level, for specific areas eligible for protected designation of origin, for specific areas eligible for protected geographical indication or for areas without a geographical indication. Such differences in the application of those criteria in the different areas of a particular territory should always be based on the differences between those areas.

(5) In order to respond to cases of circumvention not anticipated by this act, Member States should adopt measures to avoid the circumvention of eligibility or priority criteria by applicants of authorisations where their actions are not already covered by the specific anti-circumvention provisions laid down in this Regulation with regard to the specific eligibility and priority criteria.

(6) Article 66(2) of Regulation (EU) No 1308/2013 provides for the possibility of co-existence of vines that the producer has undertaken to grub up with newly planted vines. In order to prevent irregularities, Member States should have the possibility to ensure by the appropriate means that the undertaking to grub up is carried out, including the requirement to lodge a security accompanying the granting of an authorisation for anticipated replanting. In addition it is necessary to specify that in case the grubbing up is not carried out within the 4-year deadline set out by that provision the vines planted in the pledged area should be considered as non-authorised.

(7) Article 66(3) of Regulation (EU) No 1308/2013 allows Member States to restrict the replanting in areas eligible for the production of wines with protected designations of origin or protected geographical indications, on the basis of a recommendation from recognised and representative professional organisations. The grounds or reasons for such decisions of restriction should be defined in order to clarify the limits of their scope, while ensuring the coherence of the scheme and avoiding its circumvention. In particular it should be ensured that the automaticity in granting authorisations for replantings established in Article 66(1) of Regulation (EU) No 1308/2013 does not hinder the possibility of Member States to limit the issuing of authorisations for specific areas in accordance with Article 63(2)(b) and Article 63(3). Nevertheless it should be clarified that certain specific cases may not be considered as a circumvention of the scheme.

(8) Article 64 of Regulation (EU) No 1306/2013 provides for administrative penalties in cases of non-compliance in relation to eligibility criteria, commitments and other obligations resulting from the application of sectoral agricultural legislation. In order to ensure the deterrent effect, Member States should be able to graduate these penalties according to the commercial value of the wines produced in the vineyards concerned. In accordance with Article 71(4) of Regulation (EU) No 1308/2013 administrative penalties should be provided for in relation to non-authorised plantings, in order to provide a deterrent effect. The minimum value of those penalties should correspond to the average yearly income per hectare of vine areas at Union level, measured in gross margin per hectare of vine areas. A progressive graduation should be established from this minimum value, depending of the time of non-compliance. Member States should also be given the possibility to apply higher minimum penalties to producers in a certain area, where the minimum value established at Union level represents less than the estimated average yearly income per hectare of the area concerned. Such increase in the minimum value of penalties should be proportional to the estimated average yearly income per hectare for the area where the non-authorised vine area is located,

HAS ADOPTED THIS REGULATION:

Article 1

Areas exempted from the scheme of authorisations for vine plantings

1. The scheme of authorisations for vine plantings laid down in Chapter III of Title I of Part II of Regulation (EU) No 1308/2013 shall not apply to the planting or replanting of areas referred to in Article 62(4) of that Regulation fulfilling the relevant conditions set out in paragraphs 2, 3 and 4 of this Article.

2. The planting or replanting of areas intended for experimental purposes or for graft nurseries shall be subject to a prior notification to the competent authorities. The notification shall include all relevant information in respect of those areas and the period during which the experiment will take place or the period during which the graft nursery will be in production. Extensions of such periods shall also be notified to the competent authorities.

Where no risks of market disturbance are considered to exist, Member States may decide that during the periods referred to in the first subparagraph the grapes produced in those areas and the grapevine products obtained from those grapes may be marketed. At the end of such periods, the producer shall either:

(a) obtain an authorisation in accordance with Article 64 or 68 of Regulation (EU) No 1308/2013 for the area concerned, so that the grapes produced in that area and the grapevine products obtained from those grapes can be marketed; or

(b) grub up such an area at his own cost in accordance with Article 71(1) of Regulation (EU) No 1308/2013.

Any areas intended for experiments or graft nurseries planted before 1 January 2016 following the granting of new planting rights shall continue to comply after that date with any conditions defined for the use of such rights until the end of the period of the experiment or the period of production of the graft nursery for which they were granted. After the expiry of such periods, the rules laid down in the first and second subparagraphs shall apply.

3. The planting or replanting of areas whose wine or vine products are intended solely for the consumption by the wine grower's household shall be subject to the following conditions:

(a) such area does not exceed 0,1 ha;

(b) the wine grower concerned is not involved in commercial wine production or in the commercial production of other grapevine products.

For the purpose of this paragraph, Member States may consider certain organisations without a commercial activity as equivalent to the wine grower's household.

Member States may decide that the plantings referred to in the first subparagraph are subject to a notification.

4. A producer having lost a certain area planted with vines due to compulsory purchases in the public interest under national law shall be entitled to plant a new area provided that such newly planted area does not exceed 105 % in terms of pure crop of the area lost. The newly planted area shall be registered in the vineyard register.

5. The grubbing up of areas benefiting from the exemption referred to in paragraphs 2 and 3 shall not give rise to an authorisation to replant under Article 66 of Regulation (EU) No 1308/2013. However, such authorisation shall be granted in the event of grubbing up of areas newly planted under the exemption referred to in paragraph 4.

Article 2

Criteria for granting authorisations

1. Where Member States apply the eligibility criterion listed in Article 64(1)(c) of Regulation (EU) No 1308/2013, the rules laid down in Part A of Annex I to this Regulation shall apply.

Member States may also apply the additional objective and non-discriminatory criterion that the application shall not pose a significant risk of misappropriation of the reputation of specific protected geographical indications, which shall be presumed unless the existence of such risk is demonstrated by the public authorities. The rules in relation to the application of this additional criterion are laid down in Part B of Annex I.

2. Where Member States decide to apply one or more of the eligibility criteria referred to in Article 64(1)(a) to (c) of Regulation (EU) No 1308/2013 and the additional criterion referred to in paragraph 1 of this Article, in the granting of authorisations for new plantings, they may apply such criteria at national level or at a lower territorial level.

3. Where Member States apply one or more of the priority criteria listed in Article 64(2) of Regulation (EU) No 1308/2013, the rules laid down in Parts A to H of Annex II to this Regulation shall apply.

Member States may also apply the additional objective and non-discriminatory criteria of the prior behaviour of the producer and non-profit organisations with a social purpose that have received lands confiscated in cases of terrorism and other types of crime. The rules in relation to the application of these additional criteria are laid down in Part I of Annex II.

4. Where Member States decide to apply one or more of the priority criteria referred to in Article 64(2)(a) to (h) of Regulation (EU) No 1308/2013 and the additional criteria provided for in paragraph 3 of this Article, in the granting of authorisations for new plantings, they may apply such criteria uniformly at national level or with varying degrees of importance in different areas of the Member States.

5. The use of one or more of the criteria listed in Article 64(2) of Regulation (EU) No 1308/2013 as eligibility criteria at one of the geographical levels mentioned in Article 63(2) shall be considered duly justified for the purposes of point (d) of paragraph 1 of Article 64 if the use aims at addressing a specific problem affecting the wine growing sector at that specific geographic level which can only be addressed by such a restriction.

6. Without prejudice to the rules laid down in Annexes I and II with regard to specific eligibility and priority criteria, Member States shall adopt additional measures, where necessary, to avoid that applicants of authorisations circumvent the eligibility and priority criteria included in those Annexes.

Article 3

Authorisations for anticipated replanting

Member States may make the granting of an authorisation to a producer undertaking to grub up an area planted with vines in accordance with Article 66(2) of Regulation (EU) No 1308/2013 subject to the requirement to lodge a security.

In any case, if the grubbing up is not carried out by the producers by the end of the fourth year from the date on which new vines were planted, Article 71 of Regulation (EU) No 1308/2013 shall apply in respect of the the pledged area which has not been grubbed up.

Article 4

Replanting restrictions

Member States may restrict the replantings on the basis of Article 66(3) of Regulation (EU) No 1308/2013, where the specific area to be replanted is located in an area for which the issuing of authorisations for new plantings is limited in accordance with Article 63(2)(b) of Regulation (EU) No 1308/2013 and provided that the decision is justified by the need to avoid a well-demonstrated risk of significant devaluation of a specific protected designation of origin or protected geographical indication.

The risk of significant devaluation referred to in the first paragraph does not exist if:

(a) the specific area to be replanted is located in the same area of protected designation of origin or geographical indication as the area grubbed up and the replanting of vines complies with the same protected designation of origin or geographical indication specification as the area grubbed up;

(b) the replanting is aimed at the production of wines without a geographical indication provided that the applicant undertakes the same commitments as those laid down in point (2) of Parts A and B of Annex I to this Regulation in relation to new plantings.

Article 5

Penalties and cost recovery

Member States shall impose financial penalties on producers who do not comply with the obligation laid down in Article 71(1) of Regulation (EU) No 1308/2013.

The minimum amount of the financial penalty shall be:

(a) EUR 6 000 per hectare, if the producer grubs up the totality of the non-authorised planting within the 4 months from the date on which he is notified of the irregularity, as referred to in Article 71(2) of Regulation (EU) No 1308/2013;

(b) EUR 12 000 per hectare, if the producer grubs up the totality of the non-authorised planting during the first year following the expiry of the 4-month period;

(c) EUR 20 000 per hectare, if the producer grubs up the totality of the non-authorised planting after the first year following the expiry of the 4-month period.

Where the yearly income obtained in the area where the vineyards concerned are located is estimated to exceed EUR 6 000 per hectare, Member States may increase the minimum amounts set in the second subparagraph proportionally to the average yearly income per hectare estimated for that area.

If the Member State ensures the grubbing up of the non-authorised planting by its own means, the relevant cost charged to the producer pursuant to Article 71(2) of Regulation (EU) No 1308/2013 shall be calculated in an objective way taking into account the costs of labour, use of machinery and transport or other costs incurred. Such cost shall be added to the applicable penalty.

Article 6

Entry into force

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

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

Done at Brussels, 15 December 2014.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX I

Rules relating to the eligibility criterion listed in Article 64(1)(c) of Regulation (EU) No 1308/2013 and the additional criterion referred to Article 2(1) of this Regulation

A. **Criterion referred to in Article 64(1)(c) of Regulation (EU) No 1308/2013**

The criterion referred to in Article 64(1)(c) of Regulation (EU) No 1308/2013 shall be considered as being fulfilled if one of the following conditions is met:

(1) the area(s) to be newly planted is/are intended for the production of wines with the specific protected designation of origin of the area concerned; or

(2) where the area(s) to be newly planted is/are not intended for the production of wines with the specific protected designation of origin, the applicant shall undertake the following commitments:

(a) not to use or market any of the grapes produced in those newly planted areas for the production of wines with a protected designation of origin, where those areas are located within areas eligible for that purpose;

(b) not to grub up and replant with the aim of making the replanted area become eligible for the production of grapes for wines with the specific protected designation of origin.

The applicants shall undertake the commitments referred to in point (2) of the first subparagraph during a limited period of time to be fixed by the Member State, which may not go beyond 31 December 2030.

B. **Additional criterion referred to in Article 2(1) of this Regulation**

The additional criterion referred to in Article 2(1) of this Regulation shall be considered as being fulfilled if one of the following conditions is met:

(1) the area(s) to be newly planted is/are intended for the production of wines with the specific protected geographical indication of the area concerned; or

(2) where the area(s) to be newly planted is/are not intended for the production of wines with the specific protected geographical indication, the applicant shall undertake the following commitments:

(a) not to use or market any of the grapes produced in those newly planted areas for the production of wines with a protected geographical indication, where those areas are located within areas eligible for that purpose;

(b) not to grub up and replant with the aim of making the replanted area become eligible for the production of grapes for wines with the specific protected geographical indication.

The applicants shall undertake the commitments referred to in point (2) of the first subparagraph during a limited period of time to be fixed by the Member State, which may not go beyond 31 December 2030.

ANNEX II

Rules relating to the priority criteria listed in Article 64(2)(a) to (h) of Regulation (EU) No 1308/2013 and the additional criteria referred to in Article 2(3) of this Regulation

A. Criterion referred to in Article 64(2)(a) of Regulation (EU) No 1308/2013

(1) Legal persons, irrespective of their legal form, shall be considered to comply with this criterion, if one of the following conditions is met:

(a) a natural person who is setting up vine plantings for the first time and who is established as head of the holding ('new entrant') exercises effective and long-term control over the legal person in terms of decisions related to management, benefits and financial risks. Where several natural persons, including a person(s) who is not a new entrant(s), participate in the capital or management of the legal person, the new entrant shall be capable of exercising such effective and long-term control either solely or jointly together with other persons; or

(b) where a legal person is solely or jointly controlled by another legal person, the conditions set out in point (a) shall apply to any natural person having control over that other legal person.

The conditions laid down in points (a) and (b) of the first subparagraph shall apply *mutatis mutandis* in respect of a group of natural persons regardless the legal status granted to such a group and its members by national law.

(2) Member States may decide to add the additional condition that the applicant shall be a natural person who is no more than 40 years of age in the year of submission of the application ('young producer').

Legal persons referred to in point (1) shall be considered to comply with the additional condition mentioned in the first subparagraph of this point, if the natural person referred to in point (1)(a) and (b) of the first subparagraph is no more than 40 years of age in the year of submission of the application.

The conditions laid down in the second subparagraph shall apply *mutatis mutandis* in respect of a group of natural persons referred to in the second subparagraph of point (1).

(3) Member States may require that the applicants undertake during a period of 5 years not to rent or sell the area(s) newly planted to another natural or legal person.

Where the applicant is a legal person or a group of natural persons, Member States may also require the applicant, during a period of 5 years, not to transfer the exercise of effective and long-term control of the holding in terms of decisions related to management, benefits and financial risks to another person(s) unless that person or those persons met the conditions of points (1) and (2) that applied at the time of granting the authorisations.

B. Criterion referred to in Article 64(2)(b) of Regulation (EU) No 1308/2013

The criterion referred to in Article 64(2)(b) of Regulation (EU) No 1308/2013 shall be considered as being fulfilled if one of the following conditions is met:

(1) The applicant undertakes to comply, for a minimum period of 5 to 7 years, with the rules on organic production laid down in Council Regulation (EC) No 834/2007 ([1]) and where applicable Commission Regulation (EC) No 889/2008 ([2]) for the area(s) to be newly planted or for the entire farm holding. Such period shall not go beyond 31 December 2030.

Member States may consider that the criterion is fulfilled where applicants are already wine growers ([3]) at the time of submitting the application, and have effectively applied the rules on organic production referred to in the first subparagraph to the whole area planted with vines in the respective holding for at least 5 years before the submission of the application.

([1]) Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91 (OJ L 189, 20.7.2007, p. 1).

([2]) Commission Regulation (EC) No 889/2008 of 5 September 2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control (OJ L 250, 18.9.2008, p. 1).

([3]) As defined in Article 2(a) of Commission Regulation (EC) No 436/2009 of 26 May 2009 laying down detailed rules for the application of Council Regulation (EC) No 479/2008 as regards the vineyard register, compulsory declarations and the gathering of information to monitor the wine market, the documents accompanying consignments of wine products and the wine sector registers to be kept (OJ L 128, 27.5.2009, p. 15).

(2) The applicant undertakes to comply with one of the following guidelines or certification schemes going beyond the relevant mandatory standards established pursuant to Chapter I of Title VI of Regulation (EU) No 1306/2013, for a minimum period of 5 to 7 years which in any case shall not go beyond 31 December 2030:

(a) crop or sector-specific guidelines for integrated pest management which are appropriate for wine-growing in accordance with Article 14(5) of Directive 2009/128/EC of the European Parliament and of the Council [1], where such guidelines exist;

(b) national certification schemes for integrated production which are appropriate for wine-growing;

(c) national or regional environmental schemes certifying compliance with environmental legislation in relation with soil and/or water quality, biodiversity, landscape preservation, climate change mitigation and/or adaptation to climate change, and which are relevant for wine-growing.

The certification schemes mentioned in points (b) and (c) of the first subparagraph shall certify that the farmer observes practices on its holding which comply with the nationally defined rules for integrated production or the objectives mentioned in point (c) of the first subparagraph. This certification shall be performed by certification bodies that are accredited in accordance with Chapter II of Regulation (EC) No 765/2008 of the European Parliament and of the Council [2] and comply with the relevant harmonised standards for 'Conformity assessment — Requirements for bodies certifying products, processes and services' or 'Conformity assessment — requirements for bodies providing audit and certification of management systems'.

Member States may consider that the criterion is fulfilled where applicants are already wine growers at the time of submitting the application and have effectively applied the guidelines or certification schemes referred to in the first subparagraph, to the whole area planted with vines in the respective holding for at least 5 years before the submission of the application.

(3) Where the rural development programme(s) of Member States includes a specific 'agri-environment-climate' type of operation(s) laid down in Article 28 of Regulation (EU) No 1305/2013 of the European Parliament and the Council [3] which is applicable to areas planted with vines with relevance to the specific area indicated in the application, and provided that sufficient funds are available, the applicant is eligible and undertakes to apply for that type of operation(s) for the area to be newly planted and to comply with the commitments set in the respective rural development programme(s) for that specific 'agri-environment-climate' type of operation(s).

(4) The specific land parcel(s) identified in such application is located in slopes with terraces.

Member States may also require that producers undertake, during a minimum period of 5 to 7 years, not to grub up and replant in areas not complying with those conditions. Such period shall not go beyond 31 December 2030.

C. **Criterion referred to in Article 64(2)(c) of Regulation (EU) No 1308/2013**

The criterion referred to in Article 64(2)(c) of Regulation (EU) No 1308/2013 shall be considered as being fulfilled if all of the following conditions are met:

(1) the specific land parcel(s) identified in the application came into the possession of the applicant due to exchanges with another land parcel(s) planted with vines in the framework of a land consolidation project;

(2) the land parcel(s) identified in the application is not planted with vines, or is planted with vines occupying a smaller surface than the one(s) lost as a result of the implementation of such land consolidation project;

(3) the total area for which the authorisation is requested does not exceed the difference, if any, between the area planted with vines in the previously owned land parcel(s) and the one identified in the application.

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[1] Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides (OJ L 309, 24.11.2009, p. 71).

[2] Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30).

[3] Regulation (EU) No 1305/2013 of the European Parliament and of the Council of 17 December 2013 on support for rural development by the European Agricultural Fund for Rural Development (EAFRD) and repealing Council Regulation (EC) No 1698/2005 (OJ L 347, 20.12.2013, p. 487).

D. **Criterion referred to in Article 64(2)(d) of Regulation (EU) No 1308/2013**

The criterion referred to in Article 64(2)(d) of Regulation (EU) No 1308/2013 shall be considered as being fulfilled if the specific land parcel(s) identified in the application is located in one of the following types of areas:

(1) areas affected by dryness, with a ratio of the annual precipitation to the annual potential evapotranspiration of less than 0,5;

(2) areas with a shallow rooting depth of less than 30 cm;

(3) areas with unfavourable soil texture and stoniness, according to the definition and thresholds laid down in Annex III to Regulation (EU) No 1305/2013;

(4) areas in steep slopes exceeding at least 15 %;

(5) areas located in mountain areas which are above at least 500 m altitude, excluding high plains;

(6) areas located in the outermost regions of the Union referred to in Article 349 TFEU and in the smaller Aegean islands as defined in Regulation (EU) No 229/2013 of the European Parliament and of the Council [1] or in small islands with a total land area not exceeding 250 km² and characterised by structural or socioeconomic constraints.

Member States may also require that producers undertake, during a minimum period of 5 to 7 years, not to grub up and replant in areas which do not face natural or other specific constraints. Such period shall not go beyond 31 December 2030.

Member States may, at the latest until 2018, decide to exclude one or more of the areas listed in the first subparagraph for the compliance with this priority criterion where they are not in a position to assess such compliance in an effective manner.

E. **Criterion referred to in Article 64(2)(e) of Regulation (EU) No 1308/2013**

The criterion referred to in Article 64(2)(e) of Regulation (EU) No 1308/2013 shall be considered as being fulfilled if the economic sustainability of the respective project is established on the basis of one or more of the following standard methodologies of financial analysis for agricultural investment projects:

(1) Net Present Value (NPV)

(2) Internal Rate of Return (IRR)

(3) Benefit-Cost Ratio (BCR)

(4) Payback Period (PP)

(5) Incremental Net Benefit (INB)

The methodology shall be applied in a way that is adapted to the type of applicant.

Member States shall further require the applicant to establish the new vine planting according to the technical characteristics identified in the application.

F. **Criterion referred to in Article 64(2)(f) of Regulation (EU) No 1308/2013**

The criterion referred to in Article 64(2)(f) of Regulation (EU) No 1308/2013 shall be considered as being fulfilled if the potential for increased competitiveness is established on the basis of one of the following considerations:

(1) the areas to be newly planted by an existing wine grower may generate economies of scale due to a significant decrease in the unit costs specific to the newly planted area in relation to the average of already existing vineyards in the farm holding or the average situation of the region;

(2) the areas to be newly planted by an existing wine grower may generate a better adaptation to the market demand due to an increase of prices obtained for the produce or an increase in market outlets in relation to the already existing vineyards in the farm holding or the average situation of the region;

[1] Regulation (EU) No 229/2013 of the European Parliament and of the Council of 13 March 2013 laying down specific measures for agriculture in favour of the smaller Aegean islands and repealing Council Regulation (EC) No 1405/2006 (OJ L 78, 20.3.2013, p. 41).

(3) the areas to be newly planted by a new entrant into the sector may allow for a farm production model which is more profitable than the average of the region.

Member States may further detail the considerations listed in points (1), (2) and (3) of the first subparagraph.

Member States shall further require the applicant to establish the new vine planting according to the technical characteristics identified in the application.

G. **Criterion referred to in Article 64(2)(g) of Regulation (EU) No 1308/2013**

The criterion referred to in Article 64(2)(g) of Regulation (EU) No 1308/2013 shall be considered as being fulfilled if the land parcel(s) to be planted is located within the geographical area of production of an existing protected designation of origin or a protected geographical indication, if the grapes to be produced are intended for wines with a protected designation of origin or a protected geographical indication, and one of the following conditions is met:

(1) the land parcel(s) to be planted has better pedo-climatic characteristics, comparing to an average of other land parcels with vineyards complying with geographical indication specifications in the same region;

(2) the grape variety(ies) or respective clone(s) to be planted is better adapted to the specific pedo-climatic characteristics of the land parcel(s) to be planted comparing to land parcels with vineyards complying with geographical indication specifications, with similar pedo-climatic characteristics and located in the same region, but established with other varieties or other clones of the same variety(ies);

(3) the grape variety(ies) or respective clone(s) to be planted contribute to increase the diversity of grape varieties or clones of the existing varieties in the same geographical area of production of the protected designation of origin or the protected geographical indication;

(4) the vine training system(s) to be used or the vineyard structure to be established in the newly planted area(s) has the potential to lead to a better quality of the grapes, comparing to the training systems and/or structures predominantly used in the same geographical area of production of the protected designation of origin or the protected geographical indication.

Member States may further detail the conditions referred to in points (1) to (4) of the first subparagraph.

Member States shall further require the applicant to establish the new vine planting according to the technical characteristics identified in the application.

Member States may apply this priority criterion to applications for new plantings in an area that has been demarcated in the technical file accompanying an application for protection of a designation of origin or of a geographical indication which is under the preliminary national procedure or the period of scrutiny of the Commission. In that case, the conditions listed in points (1) to (4) of the first subparagraph apply *mutatis mutandis*.

H. **Criterion referred to in Article 64(2)(h) of Regulation (EU) No 1308/2013**

The criterion referred to in Article 64(2)(h) of Regulation (EU) No 1308/2013 shall be considered as being fulfilled if the size of the applicant's holding at the time of the application complies with thresholds to be established by Member States at national or regional level on the basis of objective criteria. Such thresholds shall be set at:

(1) no less than 0,5 hectares for small size holdings;

(2) no more than 50 hectares for medium size holdings;

Member States may further require compliance with one or more of the following conditions:

(1) the size of the applicant's holding will be increased as a result of the new planting;

(2) the applicant has already an area planted with vines, not benefiting from the exemptions laid down in Article 62(4) of Regulation (EU) No 1308/2013, at the time of submitting the application.

The thresholds referred to in points (1) and (2) of the first subparagraph shall be communicated to the Commission.

I. **Additional criteria referred to in Article 2(3) of this Regulation**

I. *'Prior behaviour of the producer'*

The additional criterion referred to in Article 2(3) of this Regulation shall be considered as being fulfilled if the applicant does not have vines planted without authorisation as referred to in Article 71 of Regulation (EU) No 1308/2013 or without a planting right as referred to in Articles 85a and 85b of Regulation (EC) No 1234/2007.

Member States may further require compliance with one or more of the following conditions:

(1) no authorisation previously granted to the applicant in accordance with Article 64 of Regulation (EU) No 1308/2013 has expired due to non-utilisation;

(2) the applicant has not failed to comply with any of the undertakings referred to in Parts A and B of Annex I, in Parts A, B, D, E, F, G of this Annex and in point II of this Part;

(3) the applicant does not have areas planted with vines which are no longer in production for a period of at least 8 years.

II. *'Non-profit organisations with a social purpose having received lands confiscated in cases of terrorism and other types of crime'*

The additional criterion referred to in Article 2(3) of this Regulation shall be considered as being fulfilled if the applicant is a legal person, irrespective of its legal form, and if the following conditions are met:

(1) the applicant is a non-profit organisation which has solely a social purpose as its activity;

(2) the applicant uses the confiscated land only to serve its social purposes pursuant to Article 10 of Directive 2014/42/EU of the European Parliament and of the Council [1].

Member States may also require that the applicants complying with this criterion shall undertake during a period to be determined by the Member State not to rent or sell the area(s) newly planted to another natural or legal person. Such period shall not go beyond 31 December 2030.

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[1] Directive 2014/42/EU of the European Parliament and of the Council of 3 April 2014 on the freezing and confiscation of instrumentalities and proceeds of crime in the European Union (OJ L 127, 29.4.2014, p. 39).

COMMISSION IMPLEMENTING REGULATION (EU) 2015/561

of 7 April 2015

laying down rules for the application of Regulation (EU) No 1308/2013 of the European Parliament and of the Council as regards the scheme of authorisations for vine plantings

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 ([1]), and in particular Articles 70, 72 and Article 145(3) thereof,

Having regard to Regulation (EU) No 1306/2013 of the European Parliament and of the Council of 17 December 2013 on the financing, management and monitoring of the common agricultural policy and repealing Council Regulations (EEC) No 352/78, (EC) No 165/94, (EC) No 2799/98, (EC) No 814/2000, (EC) No 1290/2005 and (EC) No 485/2008 ([2]), and in particular Article 62(2)(a) thereof,

Whereas:

(1) Regulation (EU) No 1308/2013 contains in Chapter III of Title I of Part II rules on a scheme of authorisations for vine plantings which repeal and replace the transitional planting right regime set out in Subsection II of Section IVa of Chapter III of Title I of Part II of Council Regulation (EC) No 1234/2007 ([3]) as from 1 January 2016. Chapter III of Title I of Part II of Regulation (EU) No 1308/2013 lays down rules concerning duration, management and control of the scheme of authorisations for vine plantings and empowers the Commission to adopt implementing acts concerning the management and also the control of the scheme. The transitional planting right regime set out in Subsection II of Section IVa of Chapter III of Title I of Part II of Regulation (EC) No 1234/2007 remains applicable until 31 December 2015 in accordance with Article 230(1)(b)(ii) of Regulation (EU) No 1308/2013.

(2) Article 62 of Regulation (EU) No 1308/2013 lays down the general requirement for Member States to grant an authorisation for vine planting upon submission of an application by producers intending to plant or replant vines. Article 63 of Regulation (EU) No 1308/2013 provides for a safeguard mechanism for new plantings, whereby Member States have to grant every year authorisations for new plantings corresponding to 1 % of the total area actually planted with vines in their territory, but where lower limits may be decided on the basis of sound justifications. Article 64 of Regulation (EU) No 1308/2013 lays down rules concerning the granting of authorisations for new plantings and sets out eligibility and priority criteria that Member States may apply.

(3) Rules should be established at Union level concerning the procedure to follow by the Member States regarding the decisions on the safeguard mechanism and on the choice of eligibility and priority criteria. Such rules should include time limits for decisions to be taken and implications in case certain decisions are not taken.

(4) In order to provide clarity and a consistent application in all Member States and wine regions, the rules in relation to the granting of authorisations for new plantings should also include the processing of applications, the selection procedure and their granting each year. In that way, producers are subject to similar rules at Union level when applying for authorisations for new plantings. These rules aim at ensuring a transparent, fair, and timely functioning of the system, adapted to the needs of the wine sector. They should also prevent that applicants face unjustified inequalities, excessive delays or disproportionate administrative burden. In particular, since the beginning of the wine year is on 1 August, the granting of authorisations for new plantings by that date seems well adjusted to the needs of the wine sector and ensures that vine plantings can still be undertaken within the same civil year. An appropriate date should be fixed to ensure that all relevant decisions taken by the Member State are made public in due time before the opening of the call for applications and to allow producers to be well aware of the applicable rules before they submit an application.

([1]) OJ L 347, 20.12.2013, p. 671.
([2]) OJ L 347, 20.12.2013, p. 549.
([3]) 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) (OJ L 299, 16.11.2007, p. 1).

(5) Where the total number of hectares requested in the eligible applications largely exceeds the number of hectares made available by Member States, it may lead to a large share of individual applicants obtaining only a fraction of the hectares they applied for and therefore not using the corresponding authorisations and thus being subject to penalties. To address such situations, it is appropriate not to impose such penalties where the authorisations granted correspond to less than a certain percentage of what was applied for. Furthermore, in order to avoid the loss of the corresponding authorisations, it should be made possible for Member States either to transfer them to the following year or to redistribute them within the same year among the applicants who did not see their application fully satisfied and did not reject the authorisations granted.

(6) Article 66 of Regulation (EU) No 1308/2013 and Articles 3 and 4 of the Commission Delegated Regulation (EU) 2015/560 [1] establish rules concerning the granting of authorisations for replantings in the same holding. Rules should also be established at Union level concerning the procedure to follow by the Member States when granting those authorisations for replantings, and the time frame for Member States to grant these authorisations. In order to enable producers to address constraints as regards replanting in the same holding due to phytosanitary, environmental or operational reasons, Member States should have the possibility to allow the producers to submit an application within a reasonable but limited period after the grubbing up. Furthermore, given the administrative burden for Member States and for the producers implied by the submission and processing of applications for authorisations for replanting, it should also be possible to apply a simplified procedure in the specific cases where the area to be replanted corresponds to the area grubbed up or where no restrictions on replantings are decided.

(7) Article 68 of Regulation (EU) No 1308/2013 establishes rules on the granting of authorisations on the basis of conversion of plantings rights granted before 31 December 2015. Rules should also be established at Union level concerning the procedure to be followed by the Member States for the granting of such authorisations. Timeframe for submission and treatment of the requests should be established, so that Member States can receive and process the requests for conversion in an appropriate and timely manner.

(8) Article 62(2) of Regulation (EU) No 1308/2013 establishes that authorisations are to be granted for a specific area of the producer's holding identified in an application. In duly justified cases, applicants should be given the possibility to change such specific area during the period of validity of the authorisation. However, this possibility should be excluded in some cases in order to prevent the circumvention of the scheme of authorisations for vine plantings.

(9) Articles 63(4), 64(3), 71(3) and Article 145 of Regulation (EU) No 1308/2013 establish the obligation for Member States to notify the Commission of certain aspects of the implementation of the scheme of authorisations for vine plantings. Requirements should be established to facilitate the communication of information by Member States on all relevant aspects of the management and control of this scheme, allowing for a proper monitoring of its implementation.

(10) Article 62 of Regulation (EU) No 1306/2013 provides for the need to establish control provisions in relation to the implementation of the scheme of authorisations for vine plantings. General rules on control are needed in order to clarify that the main tool for verifying the compliance with the scheme is the vineyard register, and that controls should be carried out in line with the general principles which are laid down in Article 59 of Regulation (EU) No 1306/2013. Such rules should provide the general framework for Member States to develop more detailed provisions at national level in order to avoid non-authorised plantings and to ensure that the rules of the scheme of authorisations are respected, including the respect of the deadline for using the authorisations and for grubbing up in the case of anticipated replanting as well as the respect of the commitments made by the producers to obtain the authorisations.

(11) The measures provided for in this Regulation are in accordance with the opinion of the Committee for the Common Organisation of Agricultural Markets,

[1] Commission Delegated Regulation (EU) 2015/560 of 15 December 2014 supplementing Regulation (EU) No 1308/2013 of the European Parliament and of the Council as regards the scheme of authorisations for vine plantings (see page 1 of this Official Journal).

HAS ADOPTED THIS REGULATION:

Article 1

Authorisations for vine plantings

Authorisations for vine planting as provided for in Chapter III of Title I of Part II of Regulation (EU) No 1308/2013 shall be granted as from 2016 in accordance with this Regulation.

The authorisations concern new plantings, replantings and plantings rights to be converted.

The authorisations for new plantings referred to in Article 64 of Regulation (EU) No 1308/2013 shall be granted annually.

Article 2

Prior decisions on areas to be made available for new plantings

1. Where Member States decide to limit the total area available for new plantings to be allocated in the form of authorisations in accordance with Article 63(2) and (3) of Regulation (EU) No 1308/2013, they shall make public such decisions and respective justifications by 1 March.

2. Where Member States take into account recommendations from professional organisations or interested groups of producers as referred to in Article 65 of Regulation (EU) No 1308/2013, these recommendations shall be presented with sufficient time for their examination before the decision referred to in paragraph 1 is taken by the Member State concerned. The recommendations shall also be made public.

Article 3

Criteria for the granting of authorisations for new plantings

Where Member States decide to use criteria for the granting of authorisations for new plantings as laid down in Article 64(1) and (2) of Regulation (EU) No 1308/2013, such decisions shall be made public by 1 March.

The decisions referred to in the first paragraph shall concern:

(a) the application of one or more of the criteria listed in the second subparagraph of Article 64(1) of Regulation (EU) No 1308/2013, including the due justification in case Member States decide to apply point (d) of Article 64(1), as well as in Article 2(1) of Delegated Regulation (EU) 2015/560;

(b) the number of hectares available for the granting of authorisations at national level:

   (i) on a pro-rata basis;

   (ii) according to priority criteria listed in Article 64(2) of Regulation (EU) No 1308/2013, as well as in Article 2(3) of Delegated Regulation (EU) 2015/560

Where Member States intend to apply the priority criteria referred to in point (b)(ii) of the second paragraph of this Article, they shall define which of these priority criteria will be applied. Member States may also decide to attribute different importance to each of the priority criteria chosen. Such decisions shall enable Member States to establish a ranking of individual applications at national level for the granting of the number of hectares referred to in point (b)(ii), based on the compliance of these applications with the priority criteria chosen.

Article 4

Default rules for new plantings

Where Member States do not make public the relevant decisions by the deadlines set out in Articles 2 and 3, the following rules for granting of authorisations for new plantings shall apply for the corresponding year:

(a) availability of authorisations for new planting corresponding to 1 % of the total area actually planted with vines in their territory, as specified in Article 63(1) of Regulation (EU) No 1308/2013, and without other limits;

(b) pro-rata distribution of hectares to all eligible applicants on the basis of the area for which they have requested the authorisation, where applications exceed the area made available.

Member States shall ensure that the information relating to the rules applicable pursuant to the first paragraph is made public.

Article 5

Submission of applications for new plantings

1. Once the decisions referred to in Articles 2 and 3 or the information referred to in the second paragraph of Article 4 are made public and not later than 1 May, Member States shall open the period for the submission of individual applications, which shall be at least of 1 month.

2. Applications shall identify the specific size and location of the area in the applicant holding for which the authorisation is to be granted. Where no limits are decided in accordance with Article 2 and no criteria are decided in accordance with Article 3, Member States may exempt applicants from the requirement to indicate in the application the specific location of the area in the applicant holding for which the authorisation is to be granted. Member States may request, where relevant for the implementation of the scheme of authorisations, additional information from applicants.

3. Where Member States decide to use certain criteria for the granting of authorisations for new plantings, the following rules apply:

(a) eligibility criteria referred to in Article 64(1)(c) of Regulation (EU) No 1308/2013 and in Article 2(1) of Delegated Regulation (EU) 2015/560: applications shall indicate the grapevine product(s) the applicant intends to produce in the newly planted area(s) specifying whether the applicant intends to produce one or more of the following:

   (i) wines with a protected designation of origin;

   (ii) wines with a protected geographical indication;

   (iii) wines without geographical indication including with an indication of the wine grape variety;

(b) priority criterion referred to in Article 64(2)(e) of Regulation (EU) No 1308/2013: applications shall include information of an economic nature demonstrating the economic sustainability of the respective project on the basis of on one or more of the standard methodologies of financial analysis for agricultural investment projects mentioned in Part E of Annex II to Delegated Regulation (EU) 2015/560;

(c) priority criterion referred to in Article 64(2)(f) of Regulation (EU) No 1308/2013: applications shall include information of an economic nature demonstrating the potential for increased competitiveness on the basis of the considerations laid down in Part F of Annex II to Delegated Regulation (EU) 2015/560;

(d) priority criterion referred to in Article 64(2)(g) of Regulation (EU) No 1308/2013: applications shall include information demonstrating the potential for the improvement of products with geographical indications on the basis of one of the conditions laid down in Part G of Annex II to Delegated Regulation (EU) 2015/560;

(e) priority criterion referred to in Article 64(2)(h) of Regulation (EU) No 1308/2013: applications shall include information showing that the size of the applicant's holding at the time of the application complies with thresholds to be established by Member States on the basis of the provisions laid down in Part H of Annex II to Delegated Regulation (EU) 2015/560;

(f) where Member States require applicants to undertake the commitments referred to in Parts (A) and (B) of Annex I and Parts (A), (B), (D), (E), (F), (G) and in section II of Part (I) of Annex II to Delegated Regulation (EU) 2015/560 in relation to the respective criteria, applications shall include those commitments.

Where any of the elements mentioned in points (a) to (f) of the first subparagraph may be gathered directly by Member States, Member States may exempt applicants from including such elements in their applications.

4. After the expiry of the submission period referred to in paragraph 1, Member States shall inform the non-eligible applicants on the non-eligibility of their applications pursuant to the decision on the eligibility criteria adopted by Member States in accordance with Article 3. Such applications shall be excluded from the subsequent steps of the procedure.

Article 6

Granting of authorisations for new plantings

1. Where the total area covered by the eligible applications submitted does not exceed the area(s) made available in accordance with Article 2(1), Member States shall grant the authorisations to the full extent applied for by producers.

2. Where the total area covered by the eligible applications submitted exceeds the area(s) made available in accordance with Article 2(1), Member States shall apply the selection procedure laid down in Annex I.

Member States shall, not later than 1 August, grant the authorisations to the selected applicants according to the outcome of such selection procedure. Where eligible applications have not been fully satisfied, applicants shall be informed of the reasons for such decision.

3. Where the authorisation granted corresponds to less than 50 % of the area requested in the respective application, the applicant may refuse such authorisation within 1 month following the date on which the authorisation was granted.

In that case, the applicant shall not be subject to the administrative penalties referred to in Article 62(3) of Regulation (EU) No 1308/2013. Member States may decide that the corresponding number of hectares is made available in the same year, not later than 1 October, for authorisations to be granted to those applicants that were granted only a part of the area they requested in line with the outcome of the selection procedure referred to in paragraph 2, and which did not refuse the corresponding authorisations. Member States may also decide to make available those hectares in the following year on top of the 1 % of the total area planted with vines as provided for in Article 63(1) of Regulation (EU) No 1308/2013.

Article 7

Restrictions of the granting of authorisations for replantings

1. Where Member States decide to restrict the granting of authorisations for replantings in areas eligible for the production of wines with a protected designation of origin or a protected geographical indication in accordance with Article 66(3) of Regulation (EU) No 1308/2013 and Article 4 of Delegated Regulation (EU) 2015/560, they shall make such decisions public by 1 March.

Professional organisations or interested groups of producers referred to in Article 65 of Regulation (EU) No 1308/2013 shall present the recommendations to be taken into account by the Member State pursuant to that Article with sufficient time for their examination before the decision referred to in the first subparagraph is taken. The Member State concerned shall make public those recommendations.

2. The decisions referred to in paragraph 1 shall apply during 1 year from the date on which they were made public.

Where a recommendation from a professional organisation or an interested group of producers is made for a period of time longer than 1 year but no more than 3 years, as provided for in the second subparagraph of Article 65 of Regulation (EU) No 1308/2013, such decisions may also apply for a period of time up to 3 years.

Where such professional organisations or interested groups of producers do not submit the relevant recommendations with sufficient time for their examination as provided for in paragraph 1, or Member States do not make public the relevant decisions by 1 March, Member States shall authorise the replanting automatically as provided for in Article 8.

Article 8

Procedure for granting the authorisations for replantings

1. Applications for authorisations for replantings referred to in Article 66(1) of Regulation (EU) No 1308/2013 may be submitted at any time during the same wine year in which the grubbing up takes place. However, Member States may decide that the submission of applications for authorisations for replantings can be made until the end of second wine year following the one in which the grubbing up took place. Where those time-periods are not respected, Member States shall not grant an authorisation for replanting.

Applications shall identify the specific size and the location of the area(s) grubbed up and of the area(s) to be replanted in the same applicant's holding for which the authorisation is to be granted. Where no restrictions are decided in accordance with Article 7, and the applicant has not undertaken any of the commitments referred to in point (2)(b) of Parts A and B of Annex I and in Parts B(4) and D of Annex II to Delegated Regulation (EU) 2015/560, Member States may exempt applicants from the requirement to indicate in the application the specific location of area(s) to be replanted for which the authorisation is to be granted. Member States may request, where relevant for the implementation of the scheme of authorisations, additional information from applicants.

Member States shall grant authorisations automatically within 3 months as from the submission of the applications. However, Member States may decide to apply the time-periods referred to in Articles 5 and 6 for the submission of applications and granting of authorisations for new plantings respectively.

2. Where the area to be replanted corresponds to the same area grubbed up or where no restrictions are decided in accordance with paragraph 1 of Article 7, a simplified procedure may be applied at national level or for certain areas within the territory of the Member State. In such case, the authorisation for replanting may be considered to have been granted the date the area was grubbed up. To this purpose, the producer concerned shall submit, at the latest by the end of the wine year in which the grubbing up was undertaken, an *ex post* communication which stands as application for authorisation.

3. Applications for authorisations for replantings referred to in Article 66(2) of Regulation (EU) No 1308/2013 may be submitted at any time during the year.

Applications shall identify the specific size and the location of the area(s) to be grubbed up and of the area(s) to be replanted in the same applicant's holding for which the authorisation is to be granted. Applications shall also include the commitment to grub up the area planted with vines at the latest by the end of the fourth year from the date on which new vines have been planted. Member States may request, where relevant for the implementation of the scheme of authorisations, additional information from applicants.

Member States shall grant authorisations automatically within 3 months as from the submission of the application. However, Member States may decide to apply the time-periods referred to in Articles 5 and 6 for the submission of applications and granting of authorisations for new plantings respectively.

Article 9

Procedure for granting the authorisations according to the transitional provisions

1. Producers shall submit the requests for conversion of planting rights into authorisations as referred to in Article 68(1) of Regulation (EU) No 1308/2013 as from 15 September 2015.

Applications shall identify the specific size and location of the area in the applicant holding for which the authorisation is to be granted. Member States may exempt applicants from the requirement to indicate in the application the specific location of the area in the applicant holding for which the authorisation is to be granted. Member States may request, where relevant for the implementation of the scheme of authorisations, additional information from applicants.

2. Where, in accordance with the second subparagraph of Article 68(1) of Regulation (EU) No 1308/2013, Member States decide to extend the time period to submit the request for the conversion of planting rights into authorisations beyond 31 December 2015, they shall make this decision public by 14 September 2015.

In this case, the requests for conversion by the producer may be submitted at any time as from 15 September 2015 and until the end of the time period fixed by Member States pursuant to the first subparagraph.

3. After verifying that the planting rights for which the conversion has been requested in accordance with paragraphs 1 and 2 are still valid, Member States shall grant the authorisations automatically. The period between the submission of the request to convert and the granting of the authorisations shall not exceed 3 months. However, when the request is submitted before 31 December 2015, the 3-month period shall start on 1 January 2016.

Article 10

Modification of the specific area for which the authorisation is granted

In duly justified cases, Member States may decide, at the request of the applicant, that a vine planting may be made in an area of the holding which is different from the specific area for which the authorisation has been granted provided that the new area has the same size in hectares and that the authorisation is still valid in accordance with Article 62(3) of Regulation (EU) No 1308/2013.

The first paragraph shall not apply where authorisations have been granted on the basis of the compliance with specific eligibility or priority criteria linked to the location indicated in the application and the request for modification indicates a new specific area outside such location.

Article 11

Notifications

1. As from 2016, Member States shall submit to the Commission each year by 1 March:

(a) the communication on wine-growing areas referred to in Article 145(3) of Regulation (EU) No 1308/2013, concerning the situation on 31 July of the previous wine year. This communication shall be made in the form set out in Annex II to this Regulation;

(b) the notifications referred to in Articles 63(4) and 64(3) of Regulation (EU) No 1308/2013. These notifications shall be made in the form set out in Annex III to this Regulation;

(c) a notification on the restrictions decided by Member States in relation to replantings in the same holding as referred to in Article 7 of this Regulation. This notification shall be made in the form set out in Annex VI (Table A) to this Regulation;

(d) an updated national list of professional organisations or interested groups of producers referred to in Articles 2 and 7 of this Regulation;

(e) the communication on the total size of the areas ascertained as planted with vines without an authorisation as well as the non-authorised areas grubbed up, as referred to in Article 71(3) of Regulation (EU) No 1308/2013. Such communication shall refer to the previous wine year. The first communication shall be submitted for the first time by 1 March 2017 and shall cover the period between 1 January 2016 and 31 July 2016. The communication shall be made in the form set out in Annex IV to this Regulation;

(f) where Member States decide to apply the priority criterion referred to in Article 64(2)(h) of Regulation (EU) No 1308/2013, the thresholds decided in relation to the minimum and maximum size of holdings as referred to in Part H of Annex II to Delegated Regulation (EU) 2015/560.

2. As from 2016, Member States shall submit to the Commission each year by 1 November:

(a) a notification on the applications for authorisations for new plantings requested, on the authorisations effectively granted during the previous wine year pursuant to Article 6(1) or (2) of this Regulation, and on the authorisations refused by the applicants as well as those granted to other applicants before 1 October pursuant to Article 6(3) of this Regulation. These notifications shall be made in the form set out in Annex V to this Regulation;

(b) a notification on the authorisations for replantings granted during the previous wine year as referred to in Article 8 of this Regulation. The first notification shall be made by 1 November 2016 and shall cover the period between 1 January 2016 and 31 July 2016. The notification shall be made in the form set out in Annex VI (Table B) to this Regulation;

(c) a notification on the authorisations granted during the previous wine year on the basis of the conversion of valid planting rights as referred to in Article 9 of this Regulation. Such notification shall be made in the form set out in Annex VII (Table B), and be made only until the 1 November of the year following the end of the deadline for conversion referred to in Article 68(1) of Regulation (EU) No 1308/2013 or the deadline decided by the Member State in accordance with Article 9(2) of this Regulation.

3. Member States complying with the conditions set out in Article 67(2) of Regulation (EU) No 1308/2013 shall notify the Commission by 31 July 2015 of the decision not to implement the scheme of authorisations for vine plantings pursuant Article 67(2) of Regulation (EU) No 1308/2013.

4. Member States shall notify the Commission by 15 September 2015 of the deadline for conversion of planting rights into authorisations pursuant to Article 9(2) of this Regulation. This notification shall be made in the form set out in Annex VII (Table A) to this Regulation.

5. The notifications, communications and submission of lists referred to in this Article shall be made in accordance with Commission Regulation (EC) No 792/2009 ([1]).

6. If a Member State fails to comply with paragraphs 1 to 4, or if the relevant information appears incorrect, the Commission may suspend part or all of the monthly payments referred to in Article 17 of Regulation (EU) No 1306/2013 as regards the wine sector until the notification is correctly made.

7. Member States shall retain the information submitted in accordance with this Article for at least 10 wine years following the wine year during which it was submitted.

8. The obligations laid down in this Article shall not prejudice the Member States' obligations laid down in Regulation (EU) No 1337/2011 of the European Parliament and of the Council ([2]).

Article 12

Controls

1. Member States shall apply controls to the extent they are necessary to ensure the proper application of the rules for the scheme of authorisations for vine plantings laid down in Chapter III of title I of Part II of Regulation (EU) No 1308/2013, in Delegated Regulation (EU) 2015/560 and in this Regulation.

2. In order to verify the compliance with the rules referred to in paragraph 1, Member States shall make use of the vineyard register referred to in Article 145 of Regulation (EU) No 1308/2013.

3. Article 59 of Regulation (EU) No 1306/2013 shall apply *mutatis mutandis* to the scheme of authorisations for vine plantings.

([1]) Commission Regulation (EC) No 792/2009 of 31 August 2009 laying down detailed rules for the Member States' notification to the Commission of information and documents in implementation of the common organisation of the markets, the direct payments' regime, the promotion of agricultural products and the regimes applicable to the outermost regions and the smaller Aegean islands (OJ L 228, 1.9.2009, p. 3).

([2]) Regulation (EU) No 1337/2011 of the European Parliament and of the Council of 13 December 2011 concerning European statistics on permanent crops and repealing Council Regulation (EEC) No 357/79 and Directive 2001/109/EC of the European Parliament and of the Council (OJ L 347, 30.12.2011, p. 7).

Article 13

Entry into force

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

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

Done at Brussels, 7 April 2015.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX I

Selection procedure referred to in Article 6(2)

A. ALLOCATION ON A PRO-RATA BASIS

The total number of hectares available for new plantings that Member States have decided to allocate on a pro rata basis to all applicants at national level as referred to in Article 3(b)(i), shall be divided among individual eligible applications according to the following formula, while respecting the possible limits referred to in Article 2:

$$A_1 = A_r * (\%Pr * Tar/Tap)$$

A_1 = authorisation granted to an individual applicant according to pro rata (in hectares)

A_r = area requested by the producer in his application (in hectares)

%Pr = proportion of the total availability to be granted on a pro rata basis

Tar = total area made available in authorisations (in hectares)

Tap = total of all applications by producers (in hectares)

B. ALLOCATION ACCORDING TO THE PRIORITY CRITERIA

The part of the total number of hectares available for new plantings that Member States have decided to allocate at national level according to the priority criteria selected as referred to in Article 3 (b)(ii), shall be divided among individual eligible applications in the following way:

(a) Member States shall select the priority criteria at national level and may give all the criteria selected the same importance or attribute them different weighing. Member States may apply such weighing uniformly at national level or change the weighing of the criteria depending on the area within the territory of the Member State.

Where Member States attribute the same importance to all criteria selected at national level, a value of one (1) shall be associated to each of them.

Where Member States attribute to the criteria selected at national level different weighing, a value varying between zero (0) and one (1) shall be associated to each of those criteria and the sum of all individual values must always be equal to one (1).

Where the weighing of these criteria varies depending on the area within the territory of the Member State, an individual value varying between zero (0) and one (1) shall be associated to each of those criteria for each of the areas. In this case, the sum of all individual weights of the selected criteria for each of those areas must always be equal to one (1).

(b) Member States shall assess each eligible individual application on the basis of the compliance with priority criteria selected. In order to assess the level of such compliance with each of the priority criteria, Member States shall establish a single scale at national level, on the basis of which to attribute a number of points to each application in relation to each of those criteria.

The single scale shall pre-define the number of points to be attributed in relation to the level of compliance with each of the criteria, detailing also the number of points to be attributed in relation to each of the elements of each specific criterion.

(c) Member States shall establish a ranking of individual applications at national level on the basis of the total points attributed to each individual application according to the compliance or the level of compliance referred respectively in point (b) and, where applicable, the importance of the criteria referred to in point (a). For this purpose, they shall use the following formula:

$$Pt = W_1 * Pt_1 + W_2 * Pt_2 + \ldots + W_n * Pt_n$$

Pt = total of points given to a specific individual application

W_1, W_2…, W_n = weight of criteria 1, 2, …, n

Pt_1, Pt_2…, Pt_n = level of compliance of the application with criteria 1, 2, … n

In areas where the weighing is zero for all priority criteria, all eligible applications shall receive the maximum value in the scale for what concerns the level of compliance.

(d) Member States shall grant authorisations to the individual applicants following the order established in the ranking mentioned in point (c) and until the hectares to be allocated according to the priority criteria are exhausted. The full number of hectares requested by an applicant shall be satisfied in the form of authorisations before granting an authorisation to the next applicant according to the ranking.

If the hectares available are exhausted on a position of the ranking where several applications have the same number of points, the remaining hectares shall be allocated on a pro rata basis to these applications.

(e) If the limit for a certain region, or area eligible for a protected designation of origin or protected geographical indication, or area without geographical indication, is reached when granting authorisations pursuant to Part A and points (a), (b), (c) and (d) of Part B, no further applications originating from that region or area shall be satisfied.

ANNEX II

Communication referred to in Article 11(1)(a)

Table

Inventory of wine-growing areas

Member State:						
Date of communication:						
Wine year:						
Areas/Regions	Areas actually planted with vines (ha) which are eligible for the production of (***):					
	wine with Protected Designation of Origin (PDO) (*)	wine with Protected Geographic Indication (PGI) (**)		wine without PDO/PGI and situated in a PDO/PGI area	wine without PDO/PGI and situated outside of a PDO/PGI area	**Total**
		of which are included in column (2)	of which are not included in column (2)			
(1)	(2)	(3)	(4)	(5)	(6)	(7)
1						
2						
…						
Total of Member State						

NB: values to be introduced in column (7) = (2) + (4) + (5) + (6).

(*) Such areas may also be eligible for the production of PGI wine or wine without GI.

(**) Such areas may also be eligible for the production of PDO wine and wine without GI (column (3)), or only PGI wine and wine without GI (column (4)). None of the areas reported in columns (3) and (4) should be included in columns (5) and (6).

(***) The data refers to the 31 July of the previous wine year.

Communication deadline: 1 March (for the first time: by 1 March 2016).

ANNEX III

Notifications referred to in Article 11(1)(b)

Table A

Authorisations for new plantings — percentage

Member State:	
Date of communication:	
Year:	

Total area (ha) actually planted (on last 31 July):	
Percentage to be applied at national level:	
Total area (ha) for new plantings at national level, on the basis of the % decided:	

Justifications on limitation of the percentage at national level (where below 1 %):

Total area (ha) transferred from previous year in accordance with Article 6(3):	
Total area (ha) to be made available for new plantings at national level:	

Notification deadline: 1 March (for the first time: 1 March 2016).

Table B

Authorisations for new plantings — geographical limitations

Member State:	
Date of communication:	
Year:	

Where appropriate, limitations decided at the relevant geographic level:

A. per region, where appropriate	Limited area
region 1	
region 2	
…	

B. per 'sub-region', where appropriate	Limited area
sub-region 1	
sub-region 2	
…	
C. per PDO/PGI area, where appropriate	Limited area
PDO/PGI area 1	
PDO/PGI area 2	
…	
D. per area without a PDO/PGI, where appropriate	Limited area
area without PDO/PGI 1	
area without PDO/PGI 2	
…	

NB: This table shall be accompanied by the related justifications referred to in Article 63(3) of Regulation (EU) No 1308/2013.

Notification deadline: 1 March (for the first time: 1 March 2016).

Table C

Authorisations for new plantings — Decisions on eligibility criteria at the relevant geographical level made public

Member State:	
Date of communication:	
Year:	

Eligibility criteria, where appropriate:

Eligibility criteria Art. 64(1) of Regulation (EU) No 1308/2013 and Article 2(1) second sub-paragraph of Delegated Regulation (EU) 2015/560	Selected by the MS: Y/N	If Yes, indicate the relevant geographic level where appropriate:
Art. 64(1)(a) of Regulation (EU) No 1308/2013		region, sub-region, (non)PDO/PGI area 1; region, sub-region, (non)PDO/PGI area 2; …
Art. 64(1)(b) of Regulation (EU) No 1308/2013		region, sub-region, (non)PDO/PGI area 1; region, sub-region, (non)PDO/PGI area 2; …

Art. 64(1)(c) of Regulation (EU) No 1308/2013		PDO area 1; PDO area 2; …
Art. 2(1) second subparagraph of Delegated Regulation (EU) 2015/560		PGI area 1; PGI area 2; …
Art. 64(1)(d) of Regulation (EU) No 1308/2013	Selected by the MS: Y/N	If yes for Art. 64(1)(d), indicate the specific geographic level where appropriate:
Priority criteria Art. 64(2) of Regulation (EU) No 1308/2013		
Art. 64(2)(a)		region, sub-region, (non)PDO/PGI area 1; region, sub-region, (non)PDO/PGI area 2; …
Art. 64(2)(b)		region, sub-region, (non)PDO/PGI area 1; region, sub-region, (non)PDO/PGI area 2; …
Art. 64(2)(c)		region, sub-region, (non)PDO/PGI area 1; region, sub-region, (non)PDO/PGI area 2; …
Art. 64(2)(d)		region, sub-region, (non)PDO/PGI area 1; region, sub-region, (non)PDO/PGI area 2; …
Art. 64(2)(e)		region, sub-region, (non)PDO/PGI area 1; region, sub-region, (non)PDO/PGI area 2; …
Art. 64(2)(f)		region, sub-region, (non)PDO/PGI area 1; region, sub-region, (non)PDO/PGI area 2; …
Art. 64(2)(g)		region, sub-region, (non)PDO/PGI area 1; region, sub-region, (non)PDO/PGI area 2; …
Art. 64(2)(h)		region, sub-region, (non)PDO/PGI area 1; region, sub-region, (non)PDO/PGI area 2; …

NB: In case of 'Yes' for Art. 64(1)(d), this table shall be accompanied by the related justifications referred to in Article 64(1)(d) of Regulation (EU) No 1308/2013 and in Article 2(5) of Delegated Regulation (EU) 2015/560:

Notification deadline: 1 March (for the first time: 1 March 2016).

Table D

Authorisations for new plantings — Decisions on pro-rata distribution and priority criteria at the relevant geographical level made public

Member State:	
Date of communication:	
Year:	
Total area (ha) to be made available for new plantings at national level:	

1. **Pro-rata distribution, where appropriate:**

Percentage of area to be granted on a pro-rata basis at national level:	
Number of hectares:	

2. **Priority criteria, where appropriate:**

Percentage of area to be granted according to priority criteria at national level:	
Number of hectares:	

Information on the **single scale** established at national level to assess the level of compliance of individual applications with the priority criteria selected (range of values, min and max…):

2.1. **If priority criteria are applied at national level without differentiation by area**

Priority criteria chosen and respective importance:

Priority criteria Art. 64(2) of Regulation (EU) No 1308/2013 and Article 2(3) second subparagraph of Delegated Regulation (EU) 2015/560:	Art. 64 (2)(a) (*)	Art. 64 (2)(a) (**)	Art. 64 (2)(b)	Art. 64 (2)(c)	Art. 64 (2)(d)	Art. 64 (2)(e)	Art. 64 (2)(f)	Art. 64 (2)(g)	Art. 64 (2)(h)	Art. 2(3) second subparagraph of Delegated Regulation (EU) 2015/560 (***)	Art. 2(3) second subparagraph of Delegated Regulation (EU) 2015/560 (****)
Importance (0 to 1):											

(*) New entrant (NB: the criteria 'new entrant' and 'young producer' cannot both be chosen at the same time, only one of them can apply).
(**) Young producer.
(***) Prior behaviour of the producer.
(****) Non-profit organisations with a social purpose having received lands confiscated in cases of terrorism and other types of crime.

2.2. **If priority criteria are applied at national level with differentiation by area**

2.2.1. **Area 1:** (describe what are the territorial limits of the area 1)

Priority criteria chosen and respective importance:

(If no criteria is selected for this specific area, indicate zero in all columns below)

Priority criteria Art. 64(2) of Regulation (EU) No 1308/2013 and Article 2(3) second subparagraph of Delegated Regulation (EU) 2015/560:	Art. 64 (2)(a) (*)	Art. 64 (2)(a) (**)	Art. 64 (2)(b)	Art. 64 (2)(c)	Art. 64 (2)(d)	Art. 64 (2)(e)	Art. 64 (2)(f)	Art. 64 (2)(g)	Art. 64 (2)(h)	Art. 2(3) second sub-paragraph of Delegated Regulation (EU) 2015/560 (***)	Art. 2(3) second sub-paragraph of Delegated Regulation (EU) 2015/560 (****)
Importance (0 to 1):											

(*) New entrant (NB: the criteria 'new entrant' and 'young producer' cannot both be chosen at the same time, only one of them can apply).
(**) Young producer.
(***) Prior behaviour of the producer.
(****) Non-profit organisations with a social purpose having received lands confiscated in cases of terrorism and other types of crime.

…

2.2.n. **Area n:** (describe what are the territorial limits of the area n)

Priority criteria chosen and respective importance:

(If no criteria is selected for this specific area, indicate zero in all columns below)

Priority criteria Art. 64(2) of Regulation (EU) No 1308/2013 and Article 2(3) second subparagraph of Delegated Regulation (EU) 2015/560:	Art. 64 (2)(a) (*)	Art. 64 (2)(a) (**)	Art. 64 (2)(b)	Art. 64 (2)(c)	Art. 64 (2)(d)	Art. 64 (2)(e)	Art. 64 (2)(f)	Art. 64 (2)(g)	Art. 64 (2)(h)	Art. 2(3) second sub-paragraph of Delegated Regulation (EU) 2015/560 (***)	Art. 2(3) second sub-paragraph of Delegated Regulation (EU) 2015/560 (****)
Importance (0 to 1):											

(*) New entrant (NB: the criteria 'new entrant' and 'young producer' cannot both be chosen at the same time, only one of them can apply).
(**) Young producer.
(***) Prior behaviour of the producer.
(****) Non-profit organisations with a social purpose having received lands confiscated in cases of terrorism and other types of crime.

Notification deadline: 1 March (for the first time: 1 March 2016).

ANNEX IV

Communication referred to in Article 11(1)(e)

Table

Areas planted without corresponding authorisations after 31 December 2015 and areas grubbed up according to Article 71(3) of Regulation (EU) No 1308/2013

Member State:			
Date of communication:			
Wine year or period [1]:			
Areas/Regions	Areas (ha) planted without corresponding planting authorisation after 31.12.2015:		
	Areas grubbed up by producers during the wine year	Areas grubbed up by the Member State during the wine year	Inventory of total areas of non-authorised plantings not yet grubbed up at the end of the wine year
(1)	(2)	(3)	(4)
1			
2			
…			
Total of Member State:			

[1] For the first communication, due by 1 March 2017, the data refers to the period between 1.1.2016 and 31.7.2016; for all the subsequent communications, to the wine year preceding the communication.

Communication deadline: 1 March.

ANNEX V

Notifications referred to in Article 11(2)(a)

Table A

Authorisations for new plantings requested by the applicants

Member State:

Date of communication:	
Year:	

Areas/Regions	Number of hectares requested for new plantings which are situated in an area eligible for the production of:			
	PDO wine (*)	PGI wine (**)	only wine without PDO/PGI	**Total**
(1)	(2)	(3)	(4)	(5)
1				
2				
…				
Total of Member State				

If limitations apply at the relevant geographic level (Article 63(2) of Regulation (EU) No 1308/2013):

per relevant (non) PDO/PGI area:	Area requested (ha)
(1)	(2)
(non) PDO/PGI area 1	
(non) PDO/PGI area 2	
…	

(*) Such areas may also be eligible for the production of PGI wine or wine without GI; none of the areas reported in column (2) should be included in column (3).

(**) Such areas may also be eligible for the production of wine without GI, but not PDO wine; none of the areas reported in column (3) should be included in column (4).

Notification deadline: 1 November (for the first time: by 1 November 2016).

Table B

Authorisations for new plantings effectively granted and areas refused

Member State:

Date of communication:	
Concerned year:	

Areas/Regions	Number of hectares effectively granted for new plantings which are situated in an area eligible for the production of:				Area refused by applicants (Article 6(3)) (ha)
	PDO wine (*)	PGI wine (**)	only wine without PDO/PGI	**Total**	
(1)	(2)	(3)	(4)	(5)	(6)
1					
2					
…					
Total of Member State					
Area refused by the applicants (Article 6(3)):					

If limitations apply at the relevant geographic level (Article 63(2) of Regulation (EU) No 1308/2013):

per relevant (non) PDO/PGI area:	Area granted (ha)	Area refused by applicants (Article 6(3)) (ha)	Area requested and not granted by the Member State (ha) because:	
			beyond the limits established	failed to comply with eligibility criteria
(1)	(2)	(3)	(4)	(5)
(non) PDO/PGI area 1				
(non) PDO/PGI area 2				
…				

(*) Such areas may also be eligible for the production of PGI wine or wine without GI; none of the areas reported in column (2) should be included in column (3).

(**) Such areas may also be eligible for the production of wine without GI, but not PDO wine; none of the areas reported in column (3) should be included in column (4).

Notification deadline: 1 November (for the first time: by 1 November 2016).

ANNEX VI

Notifications referred to in Article 11(1)(c) and Article 11(2)(b)

Table A

Authorisations for replantings — restrictions applied

Member State:	
Date of communication:	
Year:	

where appropriate, indicate the restrictions on replantings for the relevant PDO/PGI areas decided by the Member State as referred to in Article 66(3) of Regulation (EU) No 1308/2013 and in Article 4 of Delegated Regulation (EU) 2015/560:

PDO area, where appropriate	Extent of the restriction (T (*)/P (**))
PDO area 1	
PDO area 2	
…	
PGI area, where appropriate	Extent of the restriction (T (*)/P (**))
PGI area 1	
PGI area 2	
…	

Further information deemed useful to clarify the applications of such restrictions:

(*) Total (T): the restriction is absolute, replantings which would conflict with the restrictions decided are completely forbidden.
(**) Partial (P): the restriction is not absolute, replantings which would conflict with the restrictions decided are partially allowed to the extent decided by the Member State.

Notification deadline: 1 March (for the first time: by 1 March 2016).

Table B

Authorisations for replantings effectively granted

Member State:	
Date of communication:	
Wine year:	

Areas/Regions	Number of hectares effectively granted for replantings in areas which are eligible for the production of:			
	PDO wine (*)	PGI wine (**)	wine without PDO/ PGI	**Total**
(1)	(2)	(3)	(4)	(5)
1				
2				
…				
Total of Member State				

(*) Such areas may also be eligible for the production of PGI wine or wine without GI; none of the areas reported in column (2) should be included in column (3).

(**) Such areas may also be eligible for the production of wine without GI, but not PDO wine; none of the areas reported in column (3) should be included in column (4).

Notification deadline: 1 November (for the first time: by 1 November 2016).

NB: For the first communication, due by 1 November 2016, the data refers to the period between 1.1.2016 and 31.7.2016; for all the subsequent communications, to the wine year preceding the communication.

ANNEX VII

Notifications referred to in Article 11(4) and Article 11(2)(c)

Table A

Planting rights granted before 31 December 2015 and converted into authorisations — deadline of conversion

Member State:	
Date of communication:	
Deadline for conversion:	

Notification deadline: only one communication by 15 September 2015.

Table B

Planting rights granted before 31 December 2015 and converted into authorisations — Authorisations effectively granted

Member State:				
Date of communication:				
Wine year:				
Areas/Regions	Number of hectares effectively granted for areas which are eligible for the production of:			
	PDO wine (*)	PGI wine (**)	wine without PDO/PGI	**Total**
(1)	(2)	(3)	(4)	(5)
1				
2				
…				
Total of Member State				

(*) Such areas may also be eligible for the production of PGI wine or wine without GI; none of the areas reported in column (2) should be included in column (3).

(**) Such areas may also be eligible for the production of wine without GI, but not PDO wine; none of the areas reported in column (3) should be included in column (4).

Notification deadline: 1 November (for the first time: 1 November 2016)

NB: This table has to be communicated for each wine year (from 1 August of year n-1 until 31 July of the year of the communication) until the 1 November of the year following the end of the deadline referred to in Article 68(1) of Regulation (EU) No 1308/2013 or the deadline decided by the Member State in accordance with Article 9(2) of this Regulation and indicated in table A of this Annex.

COMMISSION REGULATION (EU) 2015/562

of 8 April 2015

amending Regulation (EU) No 347/2012 implementing Regulation (EC) No 661/2009 of the European Parliament and of the Council with respect to type-approval requirements for certain categories of motor vehicles with regard to advanced emergency braking systems

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 661/2009 of the European Parliament and of the Council of 13 July 2009 concerning type-approval requirements for the general safety of motor vehicles, their trailers and systems, components and separate technical units intended therefor ([1]), and in particular Article 14(1)(a) thereof,

Whereas:

(1) Regulation (EC) No 661/2009 is a separate Regulation for the purposes of the type-approval procedure provided for by Directive 2007/46/EC of the European Parliament and of the Council ([2]).

(2) Regulation (EC) No 661/2009 lays down basic requirements for the type-approval of motor vehicles of categories M_2, M_3, N_2 and N_3 with regard to the installation of advanced emergency braking systems (AEBS). It is necessary to set out the specific procedures, tests and requirements for such type-approval.

(3) Regulation (EC) No 661/2009 lays down a general obligation for vehicles of categories M_2, M_3, N_2 and N_3 to be equipped with an AEBS.

(4) Commission Regulation (EU) No 347/2012 ([3]) lays down the specific procedures, tests and requirements for the type-approval of motor vehicles with regard to AEBS, and provides for the implementation of those requirements in two stages. As part of the first stage, certain new vehicle types were to be subject, as of 1 November 2013, to approval level 1. As part of the second stage, those vehicle types, together with certain other vehicle types that had not been subject to approval level 1, would be required to obtain approval level 2, entailing compliance with further and more extensive requirements. Regulation (EU) No 347/2012 further provided that approval level 2 would be implemented as of 1 November 2016 for new vehicle types.

(5) The time-frame for the implementation of approval level 2 was set to ensure there would be sufficient lead-in time for gaining further experience with AEBS systems and to enable further technical developments in this field. In addition, the time-frame was intended to enable the Commission to take account of international harmonised performance and test requirements that the United Nations Economic Commission for Europe (UNECE) was to adopt with respect to the types of vehicle of the categories covered by UN Regulation No 131 relating to AEBS.

(6) It was therefore envisaged that the Commission would adopt, no later than two years before the implementation date for approval level 2, the warning and braking activation test criteria for types of vehicle of category M_2 and of category N_2 with a gross vehicle mass equal to or less than 8 tonnes, taking into consideration the further developments at UNECE level on this issue.

(7) UNECE has specified the target speed value applicable for the moving target scenario in approval level 2 for the testing of types of vehicles of category M_2 and of category N_2 with a maximum mass not exceeding 8 tonnes. The target speed values have been set conservatively, so as to allow for further experience with AEBS systems to be gained and to enable further technical developments in this field for the vehicle types concerned.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Technical Committee — Motor Vehicles,

([1]) OJ L 200, 31.7.2009, p. 1.

([2]) Directive 2007/46/EC of the European Parliament and of the Council of 5 September 2007 establishing a framework for the approval of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles (Framework Directive)(OJ L 263, 9.10.2007, p. 1).

([3]) Commission Regulation (EU) No 347/2012 of 16 April 2012 implementing Regulation (EC) No 661/2009 of the European Parliament and of the Council with respect to type-approval requirements for certain categories of motor vehicles with regard to advanced emergency braking systems (OJ L 109, 21.4.2012, p. 1).

HAS ADOPTED THIS REGULATION:

Article 1

Annex II to Regulation (EU) No 347/2012 is amended in accordance with the Annex to this Regulation.

Article 2

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

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

Done at Brussels, 8 April 2015.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Annex II of Regulation (EU) No 347/2012 is amended as follows:

(1) Point 2.4.2.1 is replaced by the following:

'2.4.2.1. (a) For approval level 1: at least one haptic or acoustic warning mode shall be provided not later than the values specified in Column B of the table in Appendix 1.

(b) For approval level 2: at least one warning mode shall be provided not later than the values specified in Column B of the table in Appendix 2, as follows:

— in the case of vehicle categories referred to in Row 1 of the table in Appendix 2: the warning shall be haptic or acoustic, and

— in the case of vehicle categories referred to in Row 2 of the table in Appendix 2: the warning shall be haptic, acoustic or optical.'

(2) Point 2.4.2.2. is replaced by the following:

'2.4.2.2. At least two warning modes shall be provided no later than the values specified in:

for approval level 1: Column C of the table in Appendix 1;

for approval level 2: Column C of the table in Appendix 2.'.

(3) The last sentence in points 2.5.2.1 and 2.5.2.2 is deleted.

(4) Appendix 2 is replaced by the following:

'Appendix 2

Approval level 2: warning and activation test requirements — pass/fail values

Row	A	B	C	D	E	F	G	H
0	Vehicle category	Stationary target			Moving target			
		Timing of warning modes		Speed reduction of subject vehicle	Timing of warning modes		Speed reduction of subject vehicle	Target speed
		At least 1	At least 2		At least 1	At least 2		
		(ref. point 2.4.2.1)	(ref. point 2.4.2.2)	(ref. point 2.4.5)	(ref. point 2.5.2.1)	(ref. point 2.5.2.2)	(ref. point 2.5.3)	(ref. point 2.5.1)
1	M_3 [1], N_3 and N_2> 8t	Not later than 1,4 s. before the start of the emergency braking phase	Not later than 0,8 s. before the start of the emergency braking phase	Not less than 20 km/h	Not later than 1,4 s. before the start of the emergency braking phase	Not later than 0,8 s. before the start of the emergency braking phase	Subject vehicle shall not impact with the moving target	12 ± 2 km/h

Row	A	B	C	D	E	F	G	H
0	Vehicle category	Stationary target			Moving target			
		Timing of warning modes		Speed reduction of subject vehicle	Timing of warning modes		Speed reduction of subject vehicle	Target speed
		At least 1	At least 2		At least 1	At least 2		
		(ref. point 2.4.2.1)	(ref. point 2.4.2.2)	(ref. point 2.4.5)	(ref. point 2.5.2.1)	(ref. point 2.5.2.2)	(ref. point 2.5.3)	(ref. point 2.5.1)
2	$N_2 \leq$ 8t (2) (4) and M_2 (2) (4)	Not later than 0,8 s. before the start of the emergency braking phase	Before the start of the emergency braking phase (3)	Not less than 10 km/h	Not later than 0,8 s. before the start of the emergency braking phase	Before the start of the emergency braking phase (3)	Subject vehicle shall not impact with the moving target	67 ± 2 km/h (5)

(1) Vehicles of category M_3 with hydraulic braking system are subject to the requirements of row 2.
(2) Vehicles with pneumatic braking system are subject to the requirements of row 1.
(3) Values shall be specified by the vehicle manufacturer at the time of type-approval (see Annex I, Part 2, Addendum, point 4.4).
(4) Manufacturers of vehicle categories covered by row 2 may elect to gain vehicle type-approval in accordance with the values specified in row 1; in this instance compliance with all the values specified in row 1 shall be demonstrated.
(5) The values for the target speed in cell H2 shall be reviewed before 1 November 2021.'.

COMMISSION IMPLEMENTING REGULATION (EU) 2015/563

of 8 April 2015

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

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 ([1]),

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

Whereas:

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

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

HAS ADOPTED THIS REGULATION:

Article 1

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

Article 2

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

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

Done at Brussels, 8 April 2015.

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

([1]) OJ L 347, 20.12.2013, p. 671.
([2]) OJ L 157, 15.6.2011, p. 1.

ANNEX

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

(EUR/100 kg)

CN code	Third country code (1)	Standard import value
0702 00 00	AL	102,3
	MA	105,2
	TR	122,2
	ZZ	109,9
0707 00 05	MA	39,8
	MK	97,3
	TR	142,0
	ZZ	93,0
0709 93 10	MA	81,5
	TR	165,8
	ZZ	123,7
0805 10 20	CL	64,9
	EG	46,5
	IL	74,2
	MA	64,0
	TN	54,5
	TR	66,7
	ZZ	61,8
0805 50 10	TR	49,5
	ZZ	49,5
0808 10 80	BR	98,4
	CL	96,7
	MK	28,2
	US	238,8
	ZA	123,2
	ZZ	117,1
0808 30 90	AR	133,9
	CL	141,7
	CN	106,3
	ZA	127,4
	ZZ	127,3

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

COMMISSION IMPLEMENTING REGULATION (EU) 2015/564

of 8 April 2015

establishing the allocation coefficient to be applied to the quantities covered by the applications for import licences lodged from 30 to 31 March 2015 under the tariff quota opened by Regulation (EC) No 1918/2006 for olive oil originating in Tunisia and suspending submission of applications for such licences for the month of April 2015

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007, ([1]) and in particular Article 188(1) and (3) thereof,

Whereas:

(1) Commission Regulation (EC) No 1918/2006 ([2]) opened annual tariff quotas for imports of virgin olive oil falling within CN codes 1509 10 10 and 1509 10 90, wholly obtained in Tunisia and transported direct from that country to the European Union. Article 2(2) of Regulation (EC) No 1918/2006 lays down the maximum monthly quantities covered by the import licences to be issued.

(2) The quantities covered by the applications for import licences lodged from 30 to 31 March 2015 for the month of April 2015 exceed those available. The extent to which import licences may be issued should therefore be determined by establishing the allocation coefficient to be applied to the quantities requested, calculated in accordance with Article 7(2) of Commission Regulation (EC) No 1301/2006. ([3]) Submission of new applications should be suspended for the month of April 2015

(3) In order to ensure that the measure is effective, 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

1. The quantities covered by the applications for import licences submitted pursuant to Commission Regulation (EC) No 1918/2006 from 30 to 31 March 2015 shall be multiplied by the allocation coefficient set out in the Annex to this Regulation.

2. Submission of new applications for import licences shall be suspended for the month of April 2015 from 1 April 2015.

Article 2

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

([1]) OJ L 347, 20.12.2013, p. 671.
([2]) Commission Regulation (EC) No 1918/2006 of 20 December 2006 opening and providing for the administration of tariff quotas for olive oil originating in Tunisia (OJ L 365, 21.12.2006, p. 84).
([3]) Commission Regulation (EC) No 1301/2006 of 31 August 2006 laying down common rules for the administration of import tariff quotas for agricultural products managed by a system of import licences (OJ L 238, 1.9.2006, p. 13).

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

Done at Brussels, 8 April 2015.

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

ANNEX

Order No	Allocation coefficient — applications submitted from 30 to 31 March 2015 for the month of April 2015 (in %)
09.4032	4,638403

DIRECTIVES

COMMISSION DIRECTIVE (EU) 2015/565

of 8 April 2015

amending Directive 2006/86/EC as regards certain technical requirements for the coding of human tissues and cells

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 ([1]) on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells, and in particular Article 28 thereof,

Whereas:

(1) Directive 2004/23/EC requires that Member States ensure the traceability of human tissues and cells from the donor to the recipient and vice versa.

(2) In order to facilitate traceability it is necessary to establish a unique identifier applied to tissues and cells distributed in the Union (Single European Code) providing information on the main characteristics and properties of those tissues and cells.

(3) In order to ensure a uniform implementation of the Single European Code throughout the Union, obligations of the Member States competent authorities and of the tissue establishments for the application of the Single European Code should be set out. Only this approach will guarantee a consistent and coherent application of the code in the Union.

(4) Traceability from donor to recipient and vice versa should be ensured through coding of tissues and cells and through accompanying documentation. At the recipient end, the Single European Code provides information on the donation and on the tissue establishment responsible for the procurement of tissues and cells. At the donor end, the tissue establishment responsible for the procurement of tissues and cells may track the tissues and cells distributed for human application by requesting the next operators in the chain to provide data related to the use of the tissues and cells based on the donation identification elements of the Single European Code as contained in the accompanying documentation.

(5) The format of the Single European Code should be harmonised in order to facilitate its application by small and large establishments, whilst allowing some flexibility for establishments to continue using existing codes.

(6) A Single European Code allowing for donation and product identification should be allocated to all tissues and cells distributed for human application, including those imported from third countries. Member States may allow certain exemptions from the application of the code.

(7) Where tissues and cells are excluded or exempted from the application of the Single European Code, the Member States should ensure that appropriate traceability of these tissues and cells is guaranteed throughout the entire chain from donation and procurement to human application.

(8) In situations where tissues and cells are released for circulation, other than for distribution (such as transfer to another operator for further processing with or without return), as a minimum the donation identification sequence should be applied at least in the accompanying documentation. Where tissues and cells are transferred

([1]) OJ L 102, 7.4.2004, p. 48.

from a tissue establishment to another operator just for storage and/or for further distribution, the tissue establishment may already apply the Single European Code on their final label in addition to the donation identification sequence which should be applied at least in the accompanying documentation.

(9) In the case of tissues and cells retrieved from a deceased donor by procurement teams operating for two or more tissue establishments, Member States shall ensure an appropriate traceability system across procurements. This may be ensured by developing a central system for the allocation of the unique donation numbers for each donation event recorded at national level, or by requiring all tissue establishments to ensure robust traceability links between the donation identification numbers allocated by each tissue establishment procuring or receiving tissue and cells originating from the same deceased donor.

(10) The Commission should ensure the implementation of the Single European Code by providing the appropriate tools to the Member States competent authorities and tissue establishments. The Member States competent authorities should update the register for tissue establishments, reflecting any changes in tissue establishment accreditations, designations, authorisations, or licences and the Commission should ensure the update of the register of the tissues and cells whenever new products need to be included. For this the Commission should consult a group of experts, in particular experts nominated by the Member States competent authorities.

(11) For the donation identification sequence in the Single European Code, the importing tissue establishment should use the tissue establishment code allocated to it in the EU Tissue Establishment Compendium and should allocate a unique donation number if the donation number on the imported product is not globally unique.

(12) Pooling of tissues or cells is allowed in some Member States. Therefore, the application of the Single European Code in case of pooling is also addressed by this Directive.

(13) A transitional regime for tissues and cells already in storage at the end of the transposition period should be introduced.

(14) This Directive does not prevent Member States from maintaining or introducing more stringent measures relating to coding of tissues and cells, provided that the provisions of the Treaty are met.

(15) The measures provided for in this Directive are in accordance with the opinion of the Committee established by Article 29 of Directive 2004/23/EC,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Commission Directive 2006/86/EC [1] is hereby amended as follows:

(1) In Article 2, the following points (k) to (y) are added:

'(k) "Single European Code" or "SEC" means the unique identifier applied to tissues and cells distributed in the Union. The Single European Code consists of a donation identification sequence and a product identification sequence, as further specified in Annex VII to this Directive;

(l) "donation identification sequence" means the first part of the Single European Code consisting of the EU tissue establishment code and the unique donation number;

(m) "EU tissue establishment code" means the unique identifier for accredited, designated, authorised, or licensed tissue establishments in the Union. The tissue establishment code consists of an ISO country code and the tissue establishment number set out in the EU Tissue Establishment Compendium, as further specified in Annex VII to this Directive;

(n) "unique donation number" means the unique number attributed to a specific donation of tissues and cells in line with the system in place in each Member State for allocating such numbers, as further specified in Annex VII to this Directive;

[1] Commission Directive 2006/86/EC of 24 October 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells (OJ L 294, 25.10.2006, p. 32).

(o) "product identification sequence" means the second part of the Single European Code consisting of the product code, the split number and the expiry date;

(p) "product code" means the identifier for the specific type of tissue and cell in question. The product code consists of the product coding system identifier indicating the coding system used by the tissue establishment ("E" for the EUTC, "A" for ISBT128, "B" for Eurocode) and the tissues and cells product number foreseen in the respective coding system for the product type, as further defined in Annex VII to this Directive;

(q) "split number" means the number which distinguishes and uniquely identifies tissues and cells having the same unique donation number and the same product code and originating from the same tissue establishment, as further defined in Annex VII to this Directive;

(r) "expiry date" means the date by which the tissues and cells can be applied, as further defined in Annex VII to this Directive;

(s) "EU Coding Platform" means the IT platform hosted by the Commission which contains the EU Tissue Establishment Compendium and the EU Tissue and Cell Product Compendium;

(t) "EU Tissue Establishment Compendium" means the register of all tissue establishments which are authorised, licensed, designated or accredited by the Member States' competent authority or authorities and which contains the information about these tissue establishments as set out in Annex VIII to this Directive;

(u) "EU Tissue and Cell Product Compendium" means the register of all types of tissues and cells circulating in the Union and the respective product codes under the three permitted coding systems (EUTC, ISBT128 and Eurocode);

(v) "EUTC" means the product coding system for tissues and cells developed by the Union consisting of a register of all types of tissues and cells circulating in the Union and their corresponding product codes.

(w) "released for circulation" means distribution for human application or transfer to another operator, e.g. for further processing with or without return.

(x) "within the same centre" means that all steps from procurement to human application are carried out under the same responsible person, quality management system and traceability system, within a healthcare centre comprising at least an accredited, designated, authorised, or licensed tissue establishment and an organisation responsible for human application at the same location;

(y) "pooling" means the physical contact or mixing in a single container, of tissues or cells from more than one procurement from the same donor, or from two or more donors.'

(2) Article 9 is replaced by the following:

'Article 9

Traceability

1. Member States shall ensure that tissues and cells shall be traceable in particular through documentation and the use of the Single European Code from procurement to human application or disposal and vice versa. Tissues and cells used for advanced therapy medicinal products shall be traceable under this Directive at least until transferred to the ATMP manufacturer.

2. Member States shall ensure that tissue establishments and organisations responsible for human application shall retain the data set out in Annex VI for at least 30 years, using an appropriate and readable storage medium.

3. In case of tissues and cells retrieved from a deceased donor by procurement teams operating for two or more tissue establishments, Member States shall ensure an appropriate traceability system across the procurements.'

(3) Article 10 is replaced by the following:

'Article 10

European coding system

1. Without prejudice to paragraphs 2 or 3 of this Article, a Single European Code shall be applied to all tissues and cells distributed for human application. For the other situations where tissues and cells are released for circulation, as a minimum the donation identification sequence shall be applied at least in the accompanying documentation.

2. Paragraph 1 shall not apply to:

(a) reproductive cells from partner donation;

(b) tissues and cells distributed directly for immediate transplantation to the recipient, as referred to in Article 6(5) of Directive 2004/23/EC;

(c) tissues and cells imported into the Union in case of emergency authorised directly by the competent authority or authorities, as referred to in Article 9(3)b of Directive 2004/23/EC.

3. Member States may also allow exemptions from the requirement provided for in paragraph 1 for:

(a) tissues and cells other than reproductive cells for partner donation, when these tissues and cells remain within the same centre;

(b) tissues and cells that are imported into the Union, when these tissues and cells remain within the same centre from importation to application, provided that the centre comprises a tissue establishment authorised, designated, accredited, or licensed to carry out importing activities.'

(4) The following Articles are inserted:

'Article 10a

Format of the Single European Code

1. The Single European Code referred to in Article 10(1) shall comply with the specifications set out in this Article and in Annex VII.

2. The Single European Code shall be in eye-readable format and shall be preceded by the acronym "SEC". The parallel use of other labelling and traceability systems is possible.

3. The Single European Code shall be printed with the Donation Identification Sequence and Product Identification Sequence separated by a single space or as two successive lines.

Article 10b

Requirements related to the application of the Single European Code

1. Member States shall ensure that the following minimum requirements are complied with by tissue establishments, including importing tissue establishments as defined by Commission Directive (EU) 2015/566 (*):

(a) allocate a Single European Code to all tissues and cells requiring application of this code at the latest before their distribution for human application;

(b) allocate a donation identification sequence after procuring the tissues and cells, or when receiving them from a procurement organisation, or when importing tissues and cells from a third country supplier. The donation identification sequence shall include:

(1) their EU tissue establishment code as assigned in the EU Tissue Establishment Compendium;

(2) a unique donation number allocated by the tissue establishment, unless such number is allocated centrally at national level or is a globally unique number as used by the ISBT128 coding system. Where allowed, in case of pooling of tissues and cells, a new donation identification number shall be allocated to the final product; traceability with the individual donations shall be ensured by the tissue establishment in which pooling is carried out;

(c) do not alter the donation identification sequence once it is allocated to tissues and cells released for circulation, unless it is necessary to correct an encoding error; any correction requires proper documentation;

(d) use one of the permitted product coding systems and the corresponding tissue and cell product numbers included in the EU Tissue and Cell Product Compendium at the latest before their distribution for human application;

(e) use an appropriate split number and expiry date. For tissues and cells for which no expiry date is defined, the expiry date shall be 00000000 at the latest before their distribution for human application;

(f) apply the Single European Code on the label of the product concerned in an indelible and permanent manner and mention that code in the relevant accompanying documentation at the latest before its distribution for human application. The tissue establishment may entrust this task to a third party or third parties, provided the tissue establishment ensures compliance with this Directive, in particular in terms of uniqueness of the code. Where the label size precludes the application of the Single European Code on the label, the code shall be unambiguously linked to tissues and cells packaged with such a label through the accompanying documentation;

(g) notify the competent authority or authorities when:

(1) information contained in the EU Tissue Establishment Compendium requires an update or correction;

(2) the EU Tissue and Cell Product Compendium requires an update;

(3) the tissue establishment observes a situation of significant non-compliance with the requirements relating to the Single European Code concerning tissues and cells received from other EU tissue establishments;

(h) take the necessary measures in case of incorrect application of the Single European Code on the label.

2. Member States shall ensure that the following minimum requirements are applied by all competent authorities:

(a) ensure the allocation of a unique tissue establishment number to all tissue establishments authorised, accredited, designated or licensed in its Member State. If a tissue establishment has different physical locations, but has one system for allocating unique donation numbers, it may be deemed to be one and the same tissue establishment. If a tissue establishment uses two or more systems to allocate unique donation numbers, such an entity shall be allocated separate tissue establishment numbers corresponding to the number of allocation systems used;

(b) decide which system or systems shall be used for the allocation of unique donation numbers in their Member State. Permitted systems of allocation include national systems establishing centralised allocation of the nationally unique donation number or systems requiring each tissue establishment to allocate unique donation numbers or international systems that allocate globally unique donation numbers that are compatible with the Single European Code.

(c) monitor and enforce the full implementation of the Single European Code in their Member State;

(d) ensure the validation of the data on the tissue establishments contained in the EU Tissue Establishment Compendium for their Member State and update the Compendium without undue delay in particular in the following situations:

(1) when a new tissue establishment is authorised, designated, accredited, or licensed;

(2) when tissue establishment information changes or is not correctly recorded in the EU Tissue Establishment Compendium;

(3) when the accreditation, designation, authorisation or licence details of a tissue establishment, as listed in Annex VIII to this Directive, change, including:

— accreditation, designation, authorisation or licence for a new tissue or cell type,

— accreditation, designation, authorisation or licence for a new prescribed activity,

— details of any conditions and or exemptions added to an authorisation,

— suspension, in part or in full, of a specific accreditation, designation, authorisation or licence for a particular activity or tissue or cell type;

— revocation, in part or in full, of an accreditation, designation, authorisation or licence for a tissue establishment,

— situations when a tissue establishment voluntarily ceases, in part or in full, the activity or activities for which it is authorised, accredited, designated or licensed.

Without undue delay means in not later than 10 working days for any changes substantially affecting the authorisation, accreditation, designation or licence of the tissue establishments concerned.

When a tissue establishment is authorised by two or more competent authorities for different types of tissues and cells or different activities, each competent authority shall update the information relating to those activities for which it is responsible;

(e) Alert the competent authorities of another Member State when they observe incorrect information in the EU Tissue Establishment Compendium relating to the other Member State or when they observe a situation of significant non-compliance with the provisions relating to the Single European Code relating to the other Member State;

(f) Alert the Commission and the other Competent Authorities when in their assessment the EU Tissue and Cell Product Compendium requires an update.

3. The application of the Single European Code does not preclude the additional application of other codes in accordance with Member States' national requirements.

Article 10c

Accessibility and maintenance of the European coding system

1. The Commission shall host and maintain an IT platform ("EU Coding Platform") which contains:

(a) the EU Tissue Establishment Compendium;

(b) the EU Tissue and Cell Product Compendium.

2. The Commission shall ensure that the information contained in the EU Coding Platform is publicly available before 29 October 2016.

3. The Commission shall update when needed the EUTC and ensure the overall update of the EU Tissue and Cell Product Compendium. The Commission considers that it is necessary that agreements are established with the organisations managing ISBT128 and Eurocode to ensure that updated product codes are regularly made available to the Commission for inclusion in the EU Tissue and Cell Product Compendium. If such organisations do not comply with the terms of the memoranda of understanding, the Commission may suspend, partially or in full, the future use of their respective product codes, having considered the sufficient supply of the concerned type of products in the Member States including a transitional period and having consulted the Member State experts through the Competent Authorities on Substances of Human Origin Expert Group.

Article 10d

Transitional period

Tissues and cells already in storage on 29 October 2016 shall be exempted from the obligations relating to the Single European Code, provided the tissues and cells are released for circulation in the Union within five years following that date and under the condition that full traceability is ensured by alternative means. For tissues and cells which remain in storage and which are only released for circulation after the expiry of this five-year period and for which the application of the Single European Code is not possible, in particular because the tissues and cells are stored under deep-freeze conditions, the tissue establishments shall use the procedures applicable to products with small labels as laid down in Article 10b paragraph 1(f).

(*) Commission Directive (EU) 2015/566 of 8 April 2015 implementing Directive 2004/23/EC as regards the procedures for verifying the equivalent standards of quality and safety of imported tissue (OJ L 93, 9.4.2015, p. 56).'

(5) The Annexes are amended in accordance with Annex I to this Directive.

(6) A new Annex VIII is added, the text of which is set out in Annex II to this Directive.

Article 2

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 29 October 2016 at the latest. They shall forthwith communicate to the Commission the text of those provisions. They shall apply the legislation from 29 April 2017.

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

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

Article 3

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

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 8 April 2015.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX I

The Annexes to Directive 2006/86/EC are amended as follows:

(1) Annex II, Part E, is amended as follows:

(a) in point 1 the following point (g) is added:

'(g) Single European Code as applicable to the tissues and cells being distributed for human application or the donation identification sequence as applicable to the tissues and cells released for circulation, other than distributed for human application';

(b) the second subparagraph of point 1 is replaced by the following:

'If any of the information under points (d), (e) and (g) above cannot be included on the primary container label, it must be provided on a separate sheet accompanying the primary container. This sheet must be packaged with the primary container in a manner that ensures that they remain together.';

(c) in point 2, the following point (j) is added:

'(j) for imported tissues and cells, the country of procurement and the exporting country (if different from the procurement country)'.

(2) Annexes III and IV are replaced by the following:

'ANNEX III

NOTIFICATION OF SERIOUS ADVERSE REACTIONS

PART A

Rapid notification for suspected serious adverse reactions

Tissue establishment
EU tissue establishment code (if applicable)
Report identification
Reporting date (year/month/day)
Individual affected (recipient or donor)
Date and place of procurement or human application (year/month/day)
Unique donation identification number
Date of suspected serious adverse reaction (year/month/day)
Type of tissues and cells involved in the suspected serious adverse reaction
Single European Code of tissues or cells involved in the suspected serious adverse reaction (if applicable)

Type of suspected serious adverse reaction(s)

PART B

Conclusions of Serious Adverse Reactions Investigation

Tissue establishment
EU tissue establishment code (if applicable)
Report identification
Confirmation date (year/month/day)
Date of serious adverse reaction (year/month/day)
Unique donation identification number
Confirmation of serious adverse reaction (Yes/No)
Single European Code of tissues or cells involved in the confirmed serious adverse reaction (if applicable)
Change of type of serious adverse reaction (Yes/No) If YES, specify
Clinical outcome (if known) — Complete recovery — Minor sequelae — Serious sequelae — Death
Outcome of the investigation and final conclusions
Recommendations for preventive and corrective actions

ANNEX IV

NOTIFICATION OF SERIOUS ADVERSE EVENTS

PART A

Rapid notification for suspected serious adverse events

Tissue establishment				
EU tissue establishment code (if applicable)				
Report identification				
Reporting date (year/month/day)				
Date of serious adverse event (year/month/day)				
Serious adverse event, which may affect quality and safety of tissues and cells due to a deviation in:	Specification			
	Tissues and cells defect	Equipment failure	Human error	Other (specify)
Procurement				
Testing				
Transport				
Processing				
Storage				
Distribution				
Materials				
Others (specify)				

PART B

Conclusions of Serious Adverse Events investigation

Tissue establishment
EU tissue establishment code (if applicable)
Report identification
Confirmation date (year/month/day)
Date of serious adverse event (year/month/day)
Root cause analysis (details)
Corrective measures taken (details)'

(3) Annexes VI and VII are replaced by the following:

'ANNEX VI

Minimum data to be kept in accordance with Article 9(2)

A. BY TISSUE ESTABLISHMENTS

(1) Donor identification

(2) Donation identification that will include at least:

— Identification of the procurement organisation (including contact details) or the tissue establishment

— Unique donation number

— Date of procurement

— Place of procurement

— Type of donation (e.g. single v multi-tissue; autologous v allogenic; living v deceased)

(3) Product identification that will include at least:

— Identification of the tissue establishment

— Type of tissue and cell/product (basic nomenclature)

— Pool number (in case of pooling)

— Split number (if applicable)

— Expiry date (if applicable)

— Tissue/cell status (i.e. quarantined, suitable for use, etc.)

— Description and origin of the products, processing steps applied, materials and additives coming into contact with tissues and cells and having an effect on their quality and/or safety.

— Identification of the facility issuing the final label

(4) Single European Code (if applicable)

(5) Human application identification that will include at least:

— Date of distribution/disposal

— Identification of the clinician or end-user/facility

B. BY ORGANISATIONS RESPONSIBLE FOR HUMAN APPLICATION

(1) Identification of the supplier tissue establishment

(2) Identification of the clinician or end-user/facility

(3) Type of tissues and cells

(4) Product identification

(5) Identification of the recipient

(6) Date of application

(7) Single European Code (if applicable)

ANNEX VII

THE STRUCTURE OF THE SINGLE EUROPEAN CODE

DONATION IDENTIFICATION SEQUENCE			**PRODUCT IDENTIFICATION SEQUENCE**			
EU TISSUE ESTABLISHMENT CODE		UNIQUE DONATION NUMBER	PRODUCT CODE		SPLIT NUMBER	EXPIRY DATE (YYYYMMDD)
ISO country code	Tissue establishment number		Product Coding System identifier	Product number		
2 alphabetic characters	6 alpha-numeric characters	13 alpha-numeric characters	1 alphabetic character	7 alpha-numeric characters	3 alpha-numeric characters	8 numeric characters'

ANNEX II

'ANNEX VIII

Data to be recorded in the EU Tissue Establishment Compendium

A. Tissue establishment information

1. Name of the tissue establishment
2. National or international code of tissue establishment
3. Name of the organisation in which the tissue establishment is located (if applicable)
4. Address of the tissue establishment
5. Publishable contact details: functional e-mail address, phone and fax

B. Details on the authorisation, accreditation, designation, or license of the tissue establishment

1. Name of the authorising, accrediting, designating or licensing competent authority or authorities
2. Name of the national competent authority or authorities responsible for maintenance of the EU Tissue Establishment Compendium
3. Name of the authorisation, accreditation, designation or licence holder (if applicable)
4. Tissues and cells for which the authorisation, accreditation, designation or license was granted
5. Activities actually carried out for which the authorisation, accreditation, designation or licence was granted
6. Status of the authorisation, accreditation, designation or license (authorised, suspended, revoked, in part or in full, voluntary cessation of activities)
7. Details of any conditions and exemptions added to the authorisation (if applicable).'

COMMISSION DIRECTIVE (EU) 2015/566

of 8 April 2015

implementing Directive 2004/23/EC as regards the procedures for verifying the equivalent standards of quality and safety of imported tissues and cells

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells ([1]), and in particular Article 9(4) thereof,

Whereas:

(1) Directive 2004/23/EC lays down standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of all human tissues and cells intended for human application, and for the donation, procurement, and testing of human tissues and cells contained in manufactured products intended for human application where those products are covered by other Union legislation, so as to ensure a high level of human health protection in the Union.

(2) Exchanges of tissues and cells increasingly take place on a worldwide basis and Directive 2004/23/EC therefore requires that imports of tissues and cells are undertaken by tissue establishments accredited, designated, authorised or licensed by Member States for that purpose. Exceptions to that requirement are laid down in Article 9(3) of Directive 2004/23/EC allowing competent authorities to directly authorise the import of specific tissues and cells under the conditions laid down in Article 6 of Commission Directive 2006/17/EC ([2]) or in case of emergency. These exceptions are regularly used, but not limited to, allowing the import of haematopoietic stem cells from bone marrow, peripheral blood or cord blood which is used in the treatment of a number of life-threatening conditions.

(3) Directive 2004/23/EC, furthermore, requires Member States and importing tissue establishments to ensure that imports of tissue and cells meet standards of quality and safety equivalent to the ones laid down in Directive 2004/23/EC and calls for the establishment of procedures to verify the equivalency of the quality and safety standards of imports of tissues and cells. Those procedures should be laid down in this Directive without prejudice to the Union legislation on customs.

(4) In particular, it is appropriate to establish authorisation and inspection schemes mirroring the verification process in place for activities related to tissues and cells carried out within the Union. It is also appropriate to lay down the procedures to be followed by importing tissue establishments in their relations with their third country suppliers.

(5) With the exception of imports directly authorised by competent authorities pursuant to Article 9(3) of Directive 2004/23/EC, all imports of tissues and cells from third countries must be undertaken by importing tissue establishments. Where competent authorities do directly authorise imports pursuant to Article 9(3) of Directive 2004/23/EC, the responsibility to ensure that such imports meet quality and safety standards equivalent to those laid down in that Directive falls upon the competent authorities.

(6) Tissues and cells should normally be imported by tissue banks or units of hospitals which are accredited, designated, authorised or licensed as importing tissue establishments for the purpose of their import activities. Tissue banks or units of hospitals should be considered to be importing tissue establishments where they are a party to a contractual agreement with a third country supplier for the import of tissues and cells. Where an organisation offering brokerage services is a party to a contractual agreement with a third country supplier to facilitate the import of tissues and cells but not for the import itself, it should not be considered to be an importing tissue establishment. Member States may choose to regulate such services outside the scope of this Directive.

([1]) OJ L 102, 7.4.2004, p. 48.

([2]) Commission Directive 2006/17/EC of 8 February 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells (OJ L 38, 9.2.2006, p. 40.)

(7) Where other bodies such as organisations responsible for human application, manufacturers of advanced therapy medicinal products, clinical practitioners or individuals are a party to a contractual agreement with a third country supplier for the import of tissues and cells, they should be considered to be an importing tissue establishment. They must comply with the requirements of this Directive as well as with all relevant provisions of Directive 2004/23/EC and be accredited, designated, authorised or licensed as importing tissue establishments for the purpose of their import activities by their relevant competent authorities. Where, subsequent to the import, they also undertake testing, processing, preservation, storage or distribution of the imported tissues and cells they must also be accredited, designated, authorised or licensed by their relevant competent authorities for the purpose of those activities and comply with the requirements of Directive 2004/23/EC. Alternatively they may obtain tissues and cells originating from third countries from tissue banks or units of hospitals located within the Union which are accredited, designated, authorised or licensed as importing tissue establishments by their relevant competent authorities.

(8) Where importing tissue establishments are also accredited, designated, authorised or licensed as tissue establishments for the activities they carry out within the Union, Member States may align their authorisation, inspection and reporting procedures provided the procedures laid down in this Directive are followed.

(9) In order to facilitate the distribution within the Union of imported tissues and cells including where such distribution is cross-border in nature, the competent authority or authorities should issue the certificate attesting the accreditation, designation, authorisation, or licence of the importing tissue establishment.

(10) Inspection measures play an important role in the verification of the equivalency of imported tissues and cells with the quality and safety standards laid down in Directive 2004/23/EC. Member States are therefore encouraged, where appropriate to also inspect third country suppliers and cooperate with other Member States into which imported tissues and cells are likely to be distributed. Member States in which the importing tissue establishments are located retain the responsibility for deciding on the most appropriate measures to be undertaken and for decisions on whether on-site inspections of third country suppliers are needed.

(11) The Operational Manual for Competent Authorities on inspections has been updated to take into account inspections of importing tissue establishments and their third country suppliers and is available to Member States as a guidance document when undertaking such inspection measures.

(12) Importing tissue establishments should verify that the standards of quality and safety of the tissues and cells they import into the Union are equivalent to the standards of quality and safety laid down in Directive 2004/23/EC. Written agreements with third country suppliers and the documentation to be provided and made available to competent authorities are key elements in ensuring such verification takes place and in particular providing traceability back to the donor and ensuring that the principle of voluntary and unpaid donation is adhered to in line with Directive 2004/23/EC. Importing tissue establishments are also encouraged to audit their third country suppliers as part of this verification process.

(13) Importing tissue establishments should ensure that the Single European Code is applied to imported tissues and cells in line with Commission Directive 2006/86/EC [1], either by carrying out this task themselves or delegating it to third country suppliers as part of the terms of their written agreements with such suppliers.

(14) Member States should be allowed to exempt one-off imports from the requirements laid down in this Directive in respect of documentation and written agreements. Such one-off imports should, however, be carried out by accredited, designated, authorised or licensed importing tissue establishments and as a general rule should not take place on a regular or repeated basis from the same third country supplier. The use of such exemptions should be limited to situations where a person or persons has or have had tissues and cells stored in a third country for their future use, in particular in cases of partner donations of reproductive cells, of autologous donations, or donations directed to close relatives, and subsequently, wishes to have such tissues or cells imported into the Union on their behalf. Such an import of any specific type of tissue or cell should normally not occur more than once for any given recipient and should not include tissues or cells for third parties.

[1] Commission Directive 2006/86/EC of 24 October 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells (OJ L 294, 25.10.2006, p. 32.)

(15) This Directive does not prevent Member States from maintaining or introducing more stringent measures relating to imports of tissues and cells, in particular in order to ensure the principle of voluntary and unpaid donation is respected, provided that the provisions of the Treaty are met.

(16) The measures provided for in this Directive are in accordance with the opinion of the Tissues and Cells Regulatory Committee established by Article 29(3) of Directive 2004/23/EC,

HAS ADOPTED THIS DIRECTIVE:

CHAPTER I

GENERAL PROVISIONS

Article 1

Scope

1. This Directive shall apply to the import into the Union of:

(a) human tissues and cells intended for human application; and

(b) manufactured products derived from human tissues and cells intended for human applications, where those products are not covered by other Union legislation.

2. Where the human tissues and cells to be imported are intended to be used exclusively in manufactured products which are covered by other Union legislation, this Directive shall only apply to the donation, procurement and testing which takes place outside of the Union as well as to contributing to ensuring traceability from donor to recipient and vice versa.

3. This Directive shall not apply to:

(a) the import of tissues and cells referred to in Article 9(3)(a) of Directive 2004/23/EC which are directly authorised by the competent authority or authorities;

(b) the import of tissues and cells referred to in Article 9(3)(b) of Directive 2004/23/EC which are directly authorised in case of emergencies;

(c) blood and blood components as defined by Directive 2002/98/EC;

(d) organs or parts of organs, as defined in Directive 2004/23/EC.

Article 2

Definitions

For the purposes of this Directive, the following definitions apply:

(a) 'emergency' means any unforeseen situation in which there is no practical alternative other than to urgently import tissues and cells from a third country into the Union for immediate application to a known recipient or known recipients whose health would be seriously endangered without such an import;

(b) 'importing tissue establishment' means a tissue bank or a unit of a hospital or another body established within the Union which is a party to a contractual agreement with a third country supplier for the import into the Union of tissues and cells coming from a third country intended for human application;

(c) 'one-off import' means the import of any specific type of tissue or cell which is for the personal use of an intended recipient or recipients known to the importing tissue establishment and the third country supplier before the importation occurs. Such an import of any specific type of tissue or cell shall normally not occur more than once for any given recipient. Imports from the same third country supplier taking place on a regular or repeated basis shall not be considered to be 'one-off imports';

(d) 'third country supplier' means a tissue establishment or another body, established in a third country, which is responsible for the export to the Union of tissues and cells it supplies to an importing tissue establishment. A third country supplier may also carry out one or more of the activities, which take place outside of the Union, of donation, procurement, testing, processing, preservation, storage or distribution of tissues and cells imported into the Union.

CHAPTER II

OBLIGATIONS ON MEMBER STATES' AUTHORITIES

Article 3

Accreditation, designation, authorisation or licensing of importing tissue establishments

1. Without prejudice to Article 1(3), Member States shall ensure that all imports of tissues and cells from third countries are undertaken by importing tissue establishments accredited, designated, authorised or licensed by a competent authority or authorities for the purposes of these activities.

2. The competent authority or authorities, having obtained the information set out in Annex I to this Directive and, having verified that the importing tissue establishment complies with the requirements of this Directive, shall accredit, designate, authorise or license the importing tissue establishment to import tissues and cells and indicate any conditions which apply such as any restrictions of the types of tissues and cells to be imported or the third country suppliers to be used. The competent authority or authorities shall issue the accredited, designated, authorised or licensed importing tissue establishment with the certificate set out in Annex II to this Directive.

3. The importing tissue establishment shall not undertake any substantial changes to its import activities without the prior written approval of the competent authority or authorities. In particular, any changes to the type of tissues and cells imported, the activities undertaken in third countries which may have an influence on the quality and safety of imported tissues and cells or the third country suppliers used shall be considered as substantial changes. Where an importing tissue establishment undertakes a one-off import of tissues or cells originating from a third country supplier not covered by its existing accreditation, designation, authorisation or licence, such an import shall not be considered as a substantial change if the importing tissue establishment is authorised to import the same type of tissues or cells from another third country supplier or suppliers.

4. The competent authority or authorities may suspend or revoke the accreditation, designation, authorisation, or licence, in part or in full, of an importing tissue establishment if, in particular, inspections or other control measures demonstrate that such an establishment no longer meets the requirements of this Directive.

Article 4

Inspections and other control measures

1. Member States shall ensure that the competent authority or authorities organise inspections and other control measures of importing tissue establishments and, where appropriate, their third country suppliers and that importing tissue establishments carry out appropriate controls in order to ensure the equivalency of the quality and safety standards of the tissues and cells to be imported with the standards laid down in Directive 2004/23/EC. The interval between inspections of any given importing tissue establishment shall not exceed 2 years.

2. Such inspections shall be carried out by officials representing the competent authority or authorities who shall:

(a) be empowered to inspect importing tissue establishments and, where appropriate, the activities of any third country suppliers;

(b) evaluate and verify the procedures and activities carried out in importing tissue establishments and the facilities of third country suppliers that are relevant to ensuring the equivalency of the quality and safety standards of the tissues and cells to be imported with the standards laid down in Directive 2004/23/EC;

(c) examine any documents or other records that are relevant for this evaluation and verification.

3. Member States shall, upon a duly justified request from another Member State or the Commission, provide information on the results of inspections and other control measures relating to importing tissue establishments and third country suppliers.

4. Member States into which tissues and cells are imported shall, upon a duly justified request from another Member State into which imported tissues and cells are subsequently distributed, consider carrying out inspections or other control measures on importing tissue establishments and the activities of any third country suppliers. The Member State in which the importing tissue establishment is located shall decide on the appropriate measures to take following consultation with the Member State which made such a request.

5. Where an on-site inspection takes place following such a request, the competent authority or authorities of the Member State in which the importing tissue establishment is located shall agree with the competent authority or authorities of the Member State which made such a request on whether and how the Member State which made such a request shall participate in the inspection. The final decision on any such participation shall rest with the Member State in which the importing tissue establishment is located. The reasons for any decision to refuse such participation shall be explained to the Member State which made such a request.

CHAPTER III

OBLIGATIONS ON IMPORTING TISSUE ESTABLISHMENTS

Article 5

Applications for accreditation, designation, authorisation or licensing as an importing tissue establishment

1. Importing tissue establishments, having taken measures to ensure that any imports of tissues and cells meet standards of quality and safety equivalent to the ones laid down in Directive 2004/23/EC and that imported tissues and cells can be traced from the donor to the recipient and vice versa, shall apply for an accreditation, designation, authorisation or licence as an importing tissue establishment by:

(a) providing to the competent authority or authorities the required information and documentation as set out in Annex I to this Directive;

(b) making available and, when requested by the competent authority or authorities, providing the documentation listed in Annex III to this Directive.

2. Member States may choose to not apply the documentation requirements of Annex I, part F and Annex III to this Directive to one-off imports as defined in Article 2 of this Directive, provided they have suitable national measures in place to regulate such imports. Those national measures shall ensure the following:

(a) traceability from donor to recipient and vice versa; and

(b) imported tissues and cells are not applied to anyone other than their intended recipients.

Article 6

Updated information

1. Importing tissue establishments shall seek the prior written approval of the competent authority or authorities for any planned substantial changes to their import activities, and in particular those substantial changes described in Article 3(3), and inform the competent authority or authorities of their decision to cease their import activities in part or in full.

2. Importing tissue establishments shall notify, without delay, the competent authority or authorities of any suspected or actual serious adverse events or reactions, reported to them by third country suppliers and which may influence the quality and safety of the tissues and cells they import. The information laid out in Annexes III and IV to Directive 2006/86/EC shall be included in such notifications.

3. The importing tissue establishment shall notify, without delay, the competent authority or authorities of:

(a) any revocation or suspension, in part or full, of a third country supplier's authorisation to export tissues and cells; and

(b) any other decision taken for reasons of non-compliance by the competent authority or authorities of the country in which the third country supplier is based and which may be relevant to the quality and safety of imported tissues and cells.

Article 7

Written agreements

1. Importing tissue establishments shall have in place written agreements with third country suppliers where any of the activities of donation, procurement, testing, processing, preservation, storage or export to the Union of tissues and cells to be imported into the Union are carried out outside of the Union.

Member States may choose to not apply this requirement to one-off imports as defined in Article 2 of this Directive, provided they have suitable national measures in place to regulate such an imports. Those national measures shall ensure the following:

(a) traceability from donor to recipient and vice versa; and

(b) imported tissues and cells are not applied to anyone other than their intended recipients.

2. The written agreement between the importing tissue establishment and the third country supplier shall specify the quality and safety requirements to be met to ensure the equivalency of the quality and safety standards of the tissues and cells to be imported with the standards laid down in Directive 2004/23/EC. In particular, the written agreement shall include, as a minimum, the contents listed in Annex IV to this Directive.

3. The written agreement shall establish the right of the competent authority or authorities to inspect the activities, including the facilities, of any third country suppliers during the duration of the written agreement and for a period of 2 years following its termination.

4. Importing tissue establishments shall provide copies of written agreements with third country suppliers to the competent authority or authorities as part of their application for accreditation, designation, authorisation or licensing.

Article 8

Register of importing tissue establishments

1. Importing tissue establishments shall keep a record of their activities, including the types and quantities of tissues and cells imported, and on their origin and destination. This record shall also include the same information for any one-off imports carried out. The annual report referred to in Article 10(1) of Directive 2004/23/EC shall include information about those activities.

2. The competent authority or authorities shall include importing tissue establishments in the publicly accessible register of tissue establishments laid down in Article 10(2) of Directive 2004/23/EC.

3. Information on the accreditations, designations, authorisations or licences of importing tissue establishments shall also be made available through the network of registers referred to in Article 10(3) of Directive 2004/23/EC.

CHAPTER IV

FINAL PROVISIONS

Article 9

Transposition

1. Member States shall adopt and publish the laws, regulations and administrative provisions necessary to comply with this Directive by 29 October 2016 at the latest. They shall forthwith communicate to the Commission the text of those provisions.

They shall apply those provisions from 29 April 2017.

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

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

Article 10

Entry into force

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

Article 11

Addresses

This Directive is addressed to the Member States.

Done at Brussels, 8 April 2015.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX I

Minimum requirements concerning the information and documentation to be provided by importing tissue establishment applicants when applying to be accredited, designated, authorised or licensed for the purpose of import activities

When applying for an accreditation, designation, authorisation or licence for the purpose of import activities, the importing tissue establishment applicant shall, unless already provided as part of previous applications for accreditation, designation, authorisation or licensing as a tissue establishment or importing tissue establishment, provide the most up-to-date information and, for part F, documentation on the following:

A. **General Information on the Importing Tissue Establishment (ITE)**

1. Name of the ITE (Company name).
2. Visiting address of the ITE.
3. Postal address of the ITE *(if different)*.
4. Status of the applicant ITE: It should be indicated if this is the first application for accreditation, designation, authorisation or licensing as an ITE or, where applicable, whether this is a renewal application. Where the applicant is already accredited, designated, authorised or licensed as a tissue establishment, the TE compendium code should be provided.
5. Name of the applying unit *(if different from the company name)*.
6. Visiting address of the applying unit.
7. Postal address of the applying unit *(if different)*.
8. Name of the site of reception of imports *(if different from the company name and applying unit)*.
9. Visiting address of the site of reception.
10. Postal address of the site of reception *(if different)*.

B. **Contact Details for the Application**

1. Name of contact person for the application.
2. Telephone number.
3. E-mail address.
4. Name of Responsible Person *(if different from contact person)*.
5. Telephone number.
6. E-mail address.
7. URL of ITE website *(if available)*.

C. **Details of Tissues and Cells to be Imported**

1. A list of the types of tissues and cells to be imported, including one-off imports of specific types of tissues or cells.
2. The product name *(where applicable, in accordance with the EU generic list)* of all types of tissues and cells to be imported.
3. The trade name *(if different to the product name)* of all types of tissues and cells to be imported.
4. The name of the third country supplier for each type of tissue and cell to be imported.

D. **Location of Activities**

1. A list specifying which of the activities of donation, procurement, testing, processing, preservation or storage are carried out prior to import by the third country supplier per type of tissue or cell.

2. A list specifying which of the activities of donation, procurement, testing, processing, preservation or storage are carried out prior to import by sub-contractors of the third country supplier per type of tissue or cell.

3. A list of all activities carried out by the ITE subsequent to import per type of tissue or cell.

4. The names of the third countries in which the activities prior to import take place per type of tissue or cell.

E. **Details of Third Country Suppliers**

1. Name of third country supplier(s) (company name).

2. Name of contact person.

3. Visiting address.

4. Postal address *(if different)*.

5. Telephone number including international dialling code.

6. Emergency contact number *(if different)*

7. E-mail address.

F. **Documentation to Accompany the Application**

1. A copy of the written agreement with the third country supplier(s).

2. A detailed description of the flow of imported tissues and cells from their procurement to their reception at the importing tissue establishment.

3. A copy of the third country supplier's export authorisation certificate or, where a specific export authorisation certificate is not issued, certification from the relevant third country competent authority or authorities authorising the third country supplier's activities in the tissue and cells sector including exports. This documentation shall also include the contact details of the third country competent authority or authorities. In third countries where such documentation is not available, alternative forms of documentation shall be provided such as reports of audits of the third country supplier.

ANNEX II

Certificate of Accreditation, Designation, Authorisation or Licence to be issued by the competent authority or authorities to importing tissue establishments

Certificate of Accreditation, Designation, Authorisation or Licence of an Importing Tissue Establishment								
1. **Importing Tissue Establishment (ITE) Details**								
1.1 Name of ITE								
1.2 EU Tissue Establishment Compendium Code								
1.3 ITE Address and postal address *(if different)*								
1.4 Site of reception of imports *(if different from the above address)*								
1.5 Name of accreditation, designation, authorisation or licence holder								
1.6 Address of accreditation, designation, authorisation or licence holder								
1.7 Telephone number of accreditation, designation, authorisation or licence holder *(optional)*								
1.8 E-mail address of accreditation, designation, authorisation or licence holder *(optional)*								
1.9 URL of ITE website								
2. **Scope of Activities**								
2.1 Type of Tissues and Cells *(list below using categories of tissues and cells listed in the EU Tissue Establishment Compendium adding rows as necessary)*	Activities in third countries						Import Accreditation, Designation, Authorisation or Licence Status	
	Donation	Procurement	Testing	Preservation	Processing	Storage		
	3CS — Third country supplier *SC — Sub-contractor of third country supplier*						*G — Granted* *S — Suspended* *R — Revoked* *C — Cessation*	
2.2 One-off imports							☐	
2.3 Product name(s) of imported tissues and cells								
2.4 Any conditions placed on the import or clarifying remarks								

2.5 Third country or countries of procurement *(per tissue and cell import)*		
2.6 Third country or countries in which other activities take place *(if different)*		
2.7 Name and country of third country supplier(s) *(per tissue and cell import)*		
2.8 EU Member States in which imported tissues and cells will be distributed *(if known)*		
3. **Competent Authority (CA) Accreditation, Designation, Authorisation or Licence**		
3.1 National accreditation, designation, authorisation or licence number		
3.2 Legal basis of accreditation, designation, authorisation or licence		
3.3 Date of expiry of accreditation, designation, authorisation or licence *(if any)*		
3.4 First accreditation, designation, authorisation or licence as ITE or renewal	First time ☐	Renewal ☐
3.5 Additional remarks		
3.6 Name of CA		
3.7 Name of CA Officer		
3.8 Signature of CA Officer *(electronic or otherwise)*		
3.9 Date of accreditation, designation, authorisation or licence		
3.10 CA Stamp		

ANNEX III

Minimum requirements concerning the documentation to be made available to the competent authority or authorities by tissue establishments intending to import tissues and cells from third countries

With the exception of one-off imports as defined in Article 2 of this Directive which have been exempted from these documentation requirements, the applicant importing tissue establishment shall make available and, unless already provided as part of previous applications for accreditation, designation, authorisation or licensing as an importing tissue establishment or tissue establishment, shall provide when requested by the competent authority or authorities the most up-to-date version of the following documents regarding the applicant and its third country supplier(s).

A. **Documentation relating to the importing tissue establishment**

1. A job description of the Responsible Person and details of his/her relevant qualifications and training record as laid down in Directive 2004/23/EC;
2. A copy of the primary label, repackage label, external package and transport container;
3. A list of relevant and up-to-date versions of standard operating procedures (SOPs) relating to the establishment's import activities including SOPs on applying the Single European Code, reception and storage of imported tissues and cells at the importing tissue establishment, management of adverse events and reactions, management of recalls and traceability from donor to recipient.

B. **Documentation relating to the third country supplier or suppliers**

1. A detailed description of the criteria used for donor identification and evaluation, information provided to the donor or donor family, how consent is obtained from the donor or donor family and whether the donation was voluntary and unpaid or not;
2. Detailed information on the testing centre(s) used by third country suppliers and the tests performed by such centres;
3. Detailed information on the methods used during the processing of the tissues and cells including details of the validation for the critical processing procedure;
4. A detailed description of the facilities, critical equipment and materials and criteria used for quality control and control of the environment for each activity carried out by the third country supplier;
5. Detailed information on the conditions for release of tissues and cells by the third country supplier or suppliers;
6. Details of any sub-contractors used by the third country suppliers including the name, location and activity undertaken;
7. A summary of the most recent inspection of the third country supplier by the third country competent authority or authorities including the date of the inspection, type of inspection and main conclusions;
8. A summary of the most recent audit of the third country supplier carried out by, or on behalf of, the importing tissue establishment;
9. Any relevant national or international accreditation.

ANNEX IV

Minimum requirements concerning the contents of written agreements between importing tissue establishments and their third country suppliers

With the exception of one-off imports as defined in Article 2 of this Directive which have been exempted from these requirements, the written agreement between the importing tissue establishment and the third country supplier shall contain at least the following provisions.

1. Detailed information on the specifications of the importing tissue establishment aimed at ensuring that the quality and safety standards laid down in Directive 2004/23/EC are met and the mutually agreed roles and responsibilities of both parties in ensuring that imported tissues and cells are of equivalent standards of quality and safety;
2. A clause ensuring that the third country supplier provides the information set out in Annex III B to this Directive to the importing tissue establishment;
3. A clause ensuring that the third country supplier informs the importing tissue establishment of any suspected or actual serious adverse events or reactions which may influence the quality and safety of tissues and cells imported or to be imported by the importing tissue establishment;
4. A clause ensuring that the third country supplier informs the importing tissue establishment of any substantial changes to its activities, including any revocation or suspension, in part or in full, of its authorisation to export tissue and cells or other such decisions of non-compliance by the third country competent authority or authorities, which may influence the quality and safety of tissues and cells imported or to be imported by the importing tissue establishment;
5. A clause guaranteeing the competent authority or authorities the right to inspect the activities of the third country supplier, including on-site inspections, should it wish to do so as part of its inspection of the importing tissue establishment. The clause should also guarantee the importing tissue establishment the right to regularly audit its third country supplier;
6. The agreed conditions to be met for the transport of tissues and cells between the third country supplier and importing tissue establishment;
7. A clause ensuring that donor records relating to imported tissues and cells are kept by the third country supplier or its sub-contractor, in line with EU data protection rules, for 30 years following procurement and that suitable provision is made for their retention should the third country supplier cease to operate;
8. Provisions for the regular review and, where necessary, revision of the written agreement including in order to reflect any changes in the requirements of the EU quality and safety standards laid out in Directive 2004/23/EC;
9. A list of all standard operating procedures of the third country supplier relating to the quality and safety of imported tissues and cells and a commitment to provide these on request.

DECISIONS

COMMISSION IMPLEMENTING DECISION (EU) 2015/567

of 7 April 2015

amending Annex I to Decision 2003/467/EC as regards the declaration of Lithuania as an officially tuberculosis-free Member State as regards bovine herds

(notified under document C(2015) 2161)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine [1], and in particular paragraph 4 of Annex A.I thereof,

Whereas:

(1) Directive 64/432/EEC applies to trade within the Union in bovine animals. It lays down the conditions whereby a Member State may be declared officially tuberculosis-free as regards bovine herds.

(2) Chapter 1 of Annex I to Commission Decision 2003/467/EC [2] lists the Member States which are declared officially tuberculosis-free as regards bovine herds.

(3) Lithuania has submitted to the Commission documentation demonstrating compliance for its whole territory with the conditions laid down in Directive 64/432/EEC for officially tuberculosis-free status as regards bovine herds. Accordingly, it should be declared an officially tuberculosis-free Member State as regards bovine herds.

(4) The list set out in Chapter 1 of Annex I to Decision 2003/467/EC should therefore be amended to include Lithuania.

(5) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS DECISION:

Article 1

Annex I to Decision 2003/467/EC is amended in accordance with the Annex to this Decision.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 7 April 2015.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

[1] OJ 121, 29.7.1964, p. 1977/64.
[2] Commission Decision 2003/467/EC of 23 June 2003 establishing the official tuberculosis, brucellosis and enzootic-bovine-leukosis-free status of certain Member States and regions of Member States as regards bovine herds (OJ L 156, 25.6.2003, p. 74).

ANNEX

In Annex I to Decision 2003/467/EC, Chapter 1 is replaced by the following:

'CHAPTER 1

Officially tuberculosis-free Member States

ISO code	Member State
BE	Belgium
CZ	Czech Republic
DK	Denmark
DE	Germany
EE	Estonia
FR	France
LV	Latvia
LT	Lithuania
LU	Luxembourg
HU	Hungary
NL	Netherlands
AT	Austria
PL	Poland
SI	Slovenia
SK	Slovakia
FI	Finland
SE	Sweden'

COMMISSION IMPLEMENTING DECISION (EU) 2015/568

of 7 April 2015

amending Annex I to Implementing Decision 2012/725/EU as regards the definition of bovine lactoferrin

(notified under document C(2015) 2173)

(Only the English text is authentic)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients ([1]), and in particular Article 7 thereof,

Whereas:

(1) Commission Implementing Decision 2012/725/EU ([2]) authorises the placing on the market of bovine lactoferrin as a novel food ingredient.

(2) Annex I to Implementing Decision 2012/725/EU lays down the specifications for bovine lactoferrin. Those specifications contain a definition of bovine lactoferrin. This definition should be amended to better describe the authorised novel food ingredient.

(3) Implementing Decision 2012/725/EU should therefore be amended accordingly.

(4) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS DECISION:

Article 1

In Annex I to Implementing Decision 2012/725/EU, the definition of bovine lactoferrin is replaced by the following:

'Bovine lactoferrin (bLF) is a protein that occurs naturally in cow's milk. It is an iron-binding glycoprotein of approximately 77 kDa and consists of a single polypeptide chain of 689 amino acids.

bLF is isolated from skimmed milk or cheese whey via ion exchange and subsequent ultra-filtration steps. Finally it is dried by freeze drying or spraying and the large particles are sieved out.'

Article 2

This Decision is addressed to Morinaga Milk Industry Co., Ltd, 33-1, Shiba 3-chome, Minato-ku, Tokyo 108-8384, Japan.

Done at Brussels, 7 April 2015.

For the Commission

Vytenis ANDRIUKAITIS

Member of the Commission

([1]) OJ L 43, 14.2.1997, p. 1.

([2]) Commission Implementing Decision 2012/725/EU of 22 November 2012 authorising the placing on the market of bovine lactoferrin as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (Morinaga) (OJ L 327, 27.11.2012, p. 46).

COMMISSION IMPLEMENTING DECISION (EU) 2015/569

of 7 April 2015

amending the Annexes to Implementing Decision 2011/630/EU as regards the equivalence between officially tuberculosis-free bovine herds in Member States and in New Zealand and the information in the model animal health certificate on the quantity of semen

(notified under document C(2015) 2187)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 88/407/EEC of 14 June 1988 laying down the animal health requirements applicable to intra-Community trade in and imports of semen of domestic animals of the bovine species [1], and in particular Article 8(1), the first subparagraph of Article 10(2), Article 10(3) and Article 11(2) thereof,

Whereas:

(1) Annex I to Commission Implementing Decision 2011/630/EU [2] sets out a list of third countries or parts thereof from which Member States are to authorise imports of semen of domestic animals of the bovine species ('semen'). New Zealand is included in that list. In addition, in Section A of Part 1 of Annex II to that Implementing Decision the model animal health certificate for imports into and transits through the Union of semen dispatched from the semen collection centre where the semen was collected is set out.

(2) Council Directive 64/432/EEC [3] lays down rules for intra-Union trade in bovine animals and provides for the monitoring and eradication programmes for certain diseases affecting those animals, including tuberculosis. New Zealand has requested for the recognition of its bovine tuberculosis control programme as being equivalent to the monitoring and eradication programmes for bovine tuberculosis that are implemented by the Member States in accordance with the conditions set out in Annex A.I to Directive 64/432/EEC. The information provided by New Zealand on its bovine tuberculosis control programme demonstrates that the bovine tuberculosis status of a bovine herd classified as 'C2', under the National Pest Management Strategy for bovine tuberculosis of New Zealand, is equivalent to the bovine tuberculosis status of a bovine herd that is recognised in a Member State as being an 'officially tuberculosis-free bovine herd' in accordance with the conditions set out in Annex A.I to Directive 64/432/EEC.

(3) Therefore, the list of third countries or parts thereof from which Member States are to authorise imports of semen set out in Annex I and the model animal health certificate set out in Section A of Part 1 of Annex II to Implementing Decision 2011/630/EU should be amended in order to reflect the special conditions by which the Union recognises the equivalence of the classification of bovine herds as 'C2' within the framework of the bovine tuberculosis control programme implemented in New Zealand with the conditions set out in Annex A.I to Directive 64/432/EEC for a bovine herd in a Member State recognised as being an 'officially tuberculosis-free bovine herd'.

(4) To further reduce administrative burdens for the centre veterinarian and for the official veterinarian, it is appropriate to remove information on the total quantity of the straws of semen in the consignment from point I.28. of the model animal health certificate set out in Section A of Part 1 of Annex II to Implementing Decision 2011/630/EU as this information is already stated in point I.20. of that model animal health certificate.

(5) In addition, it is necessary to insert in the table in point I.28. of the model animal health certificate set out in Section A of Part 1 of Annex II to Implementing Decision 2011/630/EU a column where information can be specified as regards the quantity of straws of semen collected on a particular date from an identified donor bull complying with particular conditions for bluetongue and epizootic haemorrhagic disease.

(6) Annexes I and II to Implementing Decision 2011/630/EU should therefore be amended accordingly.

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[1] OJ L 194, 22.7.1988, p. 10.

[2] Commission Implementing Decision 2011/630/EU of 20 September 2011 on imports into the Union of semen of domestic animals of the bovine species (OJ L 247, 24.9.2011, p. 32).

[3] Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine (OJ 121, 29.7.1964, p. 1977/64).

(7) To avoid any disruption of imports into the Union of consignments of semen of domestic animals of the bovine species, the use of animal health certificates issued in accordance with Section A of Part 1 of Annex II to Implementing Decision 2011/630/EU in their version before the entry into force of this Decision should be authorised during a transitional period subject to certain conditions.

(8) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS DECISION:

Article 1

The Annexes to Implementing Decision 2011/630/EU are amended in accordance with the Annex to this Decision.

Article 2

For a transitional period until 30 June 2015, consignments of semen of domestic animals of the bovine species accompanied by the appropriate animal health certificate issued no later than 1 June 2015 in accordance with the model animal health certificate set out in Section A of Part 1 of Annex II to Implementing Decision 2011/630/EU in its version before the entry into force of this Decision, may continue to be introduced into the Union.

Article 3

This Decision is addressed to the Member States.

Done at Brussels, 7 April 2015.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

ANNEX

The Annexes to Implementing Decision 2011/630/EU are amended as follows:

(1) Annex I is replaced by the following:

'ANNEX I

List of third countries or parts thereof from which Member States are to authorise imports of semen of domestic animals of the bovine species

ISO Code	Name of the third country	Remarks	
		Description of the territory (*if appropriate*)	Additional guarantees
AU	Australia		The additional guarantees concerning testing set out in points II.5.4.1 and/or II.5.4.2 of the model animal health certificate in Section A of Part 1 of Annex II are compulsory.
CA	Canada (*)	Territory described as CA-1 in Part 1 of Annex I to Regulation (EU) No 206/2010.	
CH	Switzerland (**)		
CL	Chile		
GL	Greenland		
IS	Iceland		
NZ	New Zealand (***)		
PM	Saint Pierre and Miquelon		
US	United States		The additional guarantees concerning testing set out in points II.5.4.1 and/or II.5.4.2 of the model animal health certificate in Section A of Part 1 of Annex II are compulsory.

(*) The model certificate to be used for imports from Canada is set out in Commission Decision 2005/290/EC of 4 April 2005 on simplified certificates for the importation of bovine semen and fresh pig meat from Canada and amending Decision 2004/639/EC (only for the semen collected in Canada) laid down in accordance with the Agreement between the European Community and the Government of Canada on sanitary measures to protect public and animal health in respect of trade in live animals and animal products, as approved by Council Decision 1999/201/EC.

(**) The model certificates to be used for imports from Switzerland are set out in Annex D to Council Directive 88/407/EEC, with the adaptations set out in point 4 of Chapter VII(B) of Appendix 2 of Annex 11 to the Agreement between the European Community and the Swiss Confederation on trade in agricultural products as approved by Decision 2002/309/EC, Euratom of the Council, and of the Commission as regards the Agreement on Scientific and Technological Cooperation of 4 April 2002 on the conclusion of seven Agreements with the Swiss Confederation.

(***) For the purposes of imports into the Union of semen of domestic animals of the bovine species, the bovine tuberculosis status of a bovine herd classified as "C2", under the National Pest Management Strategy for bovine tuberculosis of New Zealand, is equivalent to the bovine tuberculosis status of a bovine herd that is recognised in a Member State as being an "officially tuberculosis-free bovine herd" in accordance with the conditions laid down in paragraphs 1 and 2 of Annex A.I to Directive 64/432/EEC.'

(2) In Part 1 of Annex II, Section A is replaced by the following:

'SECTION A

Model 1 — Animal health certificate applicable to imports into and transits through the Union of semen of domestic animals of the bovine species collected, processed and stored in accordance with Council Directive 88/407/EEC, dispatched from a semen collection centre where the semen was collected.

COUNTRY: **Veterinary certificate to EU**

Part I: Details of dispatched consignment

I.1. Consignor Name Address Tel.		I.2. Certificate reference No	I.2.a.
		I.3. Central competent authority	
		I.4. Local competent authority	
I.5. Consignee Name Address Postal code Tel.		I.6. Person responsible for the load in EU Name Address Postal code Tel.	
I.7. Country of origin / ISO code	I.8. Region of origin / Code	I.9. Country of destination / ISO code	I.10. Region of destination / Code
I.11. Place of origin Name Approval number Address		I.12. Place of destination Name Address Postal code	
I.13. Place of loading		I.14. Date of departure	
I.15. Means of transport Aeroplane ☐ Ship ☐ Railway wagon ☐ Road vehicle ☐ Other ☐ Identification Documentary references		I.16. Entry BIP in EU	
		I.17.	
I.18. Description of commodity		I.19. Commodity code (HS code) **05 11 10**	
		I.20. Quantity	
I.21.		I.22. Number of packages	
I.23. Seal/Container No		I.24.	
I.25. Commodities certified for: Artificial reproduction ☐			
I.26. For transit through EU to third country ☐ Third country ISO code		I.27. For import or admission into EU ☐	

I.28. Identification of the commodities

Species

(Scientific name)

Donor/s identity	Identification of straw/s	Date/s of collection	Quantity	Information relating to	
				BT ([6])	EHD ([7])

COUNTRY **Bovine semen — Section A**

II.	Health information	II.a.	Certificate reference No	II.b.

Part II: Certification

I, the undersigned official veterinarian, hereby certify that:

II.1. .....

(name of exporting country or part thereof) ([2])

was free from rinderpest and foot-and-mouth disease during the 12 months immediately prior to collection of the semen for export and until its date of dispatch to the Union and no vaccination against these diseases has taken place during the same period.

II.2. The centre ([3]) described in Box. I.11. at which the semen to be exported was collected:

II.2.1. meets the conditions laid down in Chapter I(1) of Annex A to Directive 88/407/EEC;

II.2.2. is operated and supervised in accordance with the conditions laid down in Chapter II(1) of Annex A to Directive 88/407/EEC.

II.3. The centre at which the semen to be exported was collected was free from rabies, tuberculosis, brucellosis, anthrax and contagious bovine pleuropneumonia during 30 days prior to the date of collection of the semen to be exported and the 30 days after collection (in the case of fresh semen until the day of dispatch to the Union).

II.4. The bovine animals standing at the semen collection centre:

([8]) II.4.1. come from herds which satisfy the conditions of paragraph 1(b) of Chapter I of Annex B to Directive 88/407/EEC;

II.4.2. come from herds or were born to dams which comply with the conditions of paragraph 1(c) of Chapter I of Annex B to Directive 88/407/EEC, or were tested at the age of at least 24 months in accordance with paragraph 1(c) of Chapter II of Annex B to that Directive;

II.4.3. underwent the tests required in accordance with paragraph 1(d) of Chapter I of Annex B to Directive 88/407/EEC in the 28 days preceding the quarantine isolation period;

II.4.4. have satisfied the quarantine isolation period and testing requirements laid down in paragraph 1(e) of Chapter I of Annex B to Directive 88/407/EEC;

II.4.5. have undergone, at least once a year, the routine tests referred to in Chapter II of Annex B to Directive 88/407/EEC.

II.5. The semen to be exported was obtained from donor bulls which:

II.5.1. satisfy the conditions laid down in Annex C of Directive 88/407/EEC;

([1]) *either* [II.5.2. have remained in the exporting country for at least the last six months prior to collection of the semen to be exported;

([1]) *or* [II.5.2. have remained in the exporting country for at least 30 days prior to the collection of the semen since entry and they were imported from ..... ([2]) during the period of less than six months prior to the collection of the semen and satisfied the animal health conditions applying to donors of the semen which is intended for export to the European Union;]

II.5.3. comply with at least one of the following conditions as regards bluetongue, as detailed in the table in point I.28.:

([1]) *either* [II.5.3.1. were kept in a bluetongue virus-free country or zone for at least 60 days prior to, and during, collection of the semen;]

([1]) *and/or* [II.5.3.2. were kept during a bluetongue virus seasonally free period in a seasonally free zone for at least 60 days prior to, and during, collection of the semen;]

([1]) *and/or* [II.5.3.3. were kept in a vector-protected establishment for at least 60 days prior to, and during, collection of the semen;]

([1]) *and/or* [II.5.3.4. were subjected to a serological test for the detection of antibody to the bluetongue virus serogroup, carried out in accordance with the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals, with negative results, at least every 60 days throughout the collection period and between 21 and 60 days after the final collection for this consignment of semen;]

COUNTRY **Bovine semen — Section A**

II.	Health information	II.a. Certificate reference No	II.b.

	([1]) *and/or*	[II.5.3.5.	were subjected to an agent identification test for bluetongue virus, carried out in accordance with the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals, with negative results, on blood samples taken at commencement and final collection for this consignment of semen and at least every 7 days (virus isolation test) or at least every 28 days, if carried out as polymerase chain reaction (PCR), during collection for this consignment of semen;]
	II.5.4.	comply with at least one of the following conditions as regards epizootic haemorrhagic disease (EHD), as detailed in the table in point I.28:	
	([1]) *either*	[II.5.4.1.	were resident in the exporting country which according to official findings is free from epizootic haemorrhagic disease (EHD);]
	([1]) ([5]) *and/or*	[II.5.4.2.	were resident in the exporting country in which according to official findings the following serotypes of epizootic haemorrhagic disease (EHD) exist: ..... and were subjected with negative results in each case to the following tests carried out in an approved laboratory:
	([1]) *either*	[II.5.4.2.1.	a serological test ([4]) for the detection of antibody to the EHD virus serogroup, carried out on samples of blood taken on two occasions not more than 12 months apart prior to and not less than 21 days following collection for this consignment of semen;]]
	([1]) *and/or*	[II.5.4.2.2.	a serological test ([4]) for the detection of antibody to the EHD virus serogroup, carried out on samples taken at intervals of not more than 60 days throughout the collection period and between 21 and 60 days after the final collection for this consignment of semen.]]
	([1]) *and/or*	[II.5.4.2.3.	an agent identification test ([4]) carried out on blood samples collected at commencement and conclusion of, and at least every 7 days (virus isolation test) or at least every 28 days, if carried out as PCR, during collection for this consignment of semen.]]
II.6.	The semen to be exported was collected after the date on which the centre was approved by the competent national authorities of the exporting country.		
II.7.	The semen to be exported was processed, stored and transported under conditions which satisfy the terms of Directive 88/407/EEC.		

Notes

Part I:

Box I.6: *Person responsible for the load in the EU*: this box is to be filled in only if it is a certificate for transit commodity.

Box I.11: *Place of origin* shall correspond to the semen collection centre listed in accordance with Article 9(2) of Directive 88/407/EEC on the Commission website:

http://ec.europa.eu/food/animal/semen_ova/bovine/index_en.htm and where the semen was collected.

Box I.22: *Number of packages* shall correspond to the number of containers.

Box I.23: Identification of container and seal number shall be indicated.

Box I.26: Fill in according to whether it is a transit or an import certificate.

Box I.27: Fill in according to whether it is a transit or an import certificate.

Box I.28: *Species*: select amongst '*Bos taurus*', '*Bison bison*' *or* '*Bubalus bubalis*' as appropriate.

Donor identity shall correspond to the official identification of the animal.

Date of collection shall be indicated in the following format: dd/mm/yyyy.

Quantity shall correspond to the number of straws of semen collected on a particular date from an identified donor bull complying with particular conditions for bluetongue and EHD.

COUNTRY **Bovine semen — Section A**

II. Health information	**II.a. Certificate reference No**	**II.b.**

Part II:

(1) Delete as necessary.

(2) Only third countries or parts thereof listed in Annex I to Implementing Decision 2011/630/EU.

(3) Only semen collection centres listed in accordance with Article 9(2) of Directive 88/407/EEC on the Commission website:

http://ec.europa.eu/food/animal/semen_ova/bovine/index_en.htm.

(4) Standards for EHD virus diagnostic tests are described in the Bluetongue Chapter (2.1.3) of the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals.

(5) Compulsory for Australia, Canada and the United States.

(6) Referring to each straw or batch of straws indicate applicable condition (for example II.5.3.1).

(7) Referring to each straw or batch of straws indicate applicable condition (for example II.5.4.1 or II.5.4.2.1).

(8) For New Zealand, appearing with the entry 'XII' in column 6 of Part 1 of Annex I to Commission Regulation (EU) No 206/2010 (OJ L 73, 20.3.2010, p. 1), officially tuberculosis-free bovine herds shall be considered equivalent to officially tuberculosis-free bovine herds in the Member States recognised based on the conditions laid down in paragraphs 1 and 2 of Annex A.I to Council Directive 64/432/EEC.

— The signature and the stamp must be in a different colour to that of the printing.

Official veterinarian

Name (in capital letters): Qualification and title:

Date: Signature:

Stamp:'

COMMISSION IMPLEMENTING DECISION (EU) 2015/570

of 7 April 2015

approving the plans for the eradication of African swine fever in feral pigs in certain areas of Estonia and Latvia

(notified under document C(2015) 2200)

(Only the Estonian and Latvian texts are authentic)

THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 2002/60/EC of 27 June 2002 laying down specific provisions for the control of African swine fever and amending Directive 92/119/EEC as regards Teschen disease and African swine fever ([1]), and in particular Article 16 thereof,

Whereas:

(1) Directive 2002/60/EC introduces the minimum Union measures for the control of African swine fever, including those to be applied in case of confirmation of the presence of African swine fever in feral pigs.

(2) In 2014 Estonia and Latvia confirmed the presence of African swine fever in feral pigs and they have adopted disease control measures as provided for in Directive 2002/60/EC. In order to establish appropriate control measures and to prevent disease spread, a Union list of high risk areas has been established in the Annex to Commission Implementing Decision 2014/709/EU ([2]). Parts I, II and III of that Annex list the areas in Estonia and Latvia where the eradication plans are to be implemented.

(3) In the light of the epidemiological situation and in accordance with Directive 2002/60/EC Estonia and Latvia submitted to the Commission the plans for the eradication of African swine fever in their respective concerned areas.

(4) The plans submitted by Estonia and Latvia have been examined by the Commission and found to comply with Directive 2002/60/EC.

(5) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS DECISION:

Article 1

The plan submitted by Estonia on 11 December 2014 for the eradication of African swine fever in the areas referred to in the Annex to Implementing Decision 2014/709/EU is approved.

Article 2

The plan submitted by Latvia on 26 September 2014 for the eradication of African swine fever in the areas referred to in the Annex to Implementing Decision 2014/709/EU is approved.

Article 3

Estonia and Latvia shall bring into force the laws, regulations and administrative provisions for implementing the plans referred to in Articles 1 and 2.

([1]) OJ L 192, 20.7.2002, p. 27.
([2]) Commission Implementing Decision 2014/709/EU of 9 October 2014 concerning animal health control measures relating to African swine fever in certain Member States and repealing Implementing Decision 2014/178/EU (OJ L 295, 11.10.2014, p. 63).

Article 4

This Decision is addressed to the Republic of Estonia and to the Republic of Latvia.

Done at Brussels, 7 April 2015.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

GUIDELINES

GUIDELINE (EU) 2015/571 OF THE EUROPEAN CENTRAL BANK

of 6 November 2014

amending Guideline ECB/2014/15 on monetary and financial statistics (ECB/2014/43)

THE GOVERNING COUNCIL OF THE EUROPEAN CENTRAL BANK,

Having regard to the Statute of the European System of Central Banks and of the European Central Bank, and in particular Articles 5.1, 12.1 and 14.3 thereof,

Having regard to Council Regulation (EC) No 2533/98 of 23 November 1998 concerning the collection of statistical information by the European Central Bank ([1]),

Having regard to Council Directive 86/635/EEC of 8 December 1986 on the annual accounts and consolidated accounts of banks and other financial institutions ([2]),

Having regard to Guideline ECB/2010/20 of 11 November 2010 on the legal framework for accounting and financial reporting in the European System of Central Banks ([3]),

Whereas:

(1) It is necessary to update the compilation of statistics on the issuance of securities to take into account updates to the European System of Accounts 2010, and to start compiling statistics on the issuance of securities by financial vehicle corporations engaged in securitisation transactions ('FVCs') within this framework.

(2) It is also necessary to amend the reporting requirements for payment transactions involving non-monetary financial institutions laid down in Guideline ECB/2014/15 ([4]), thereby ensuring the appropriate recording of certain national payment instruments and services not explicitly mentioned or covered by Directive 2007/64/EC of the European Parliament and of the Council ([5]),

HAS ADOPTED THIS GUIDELINE:

Article 1

Amendments to Annex II to Guideline ECB/2014/15

Annex II to Guideline ECB/2014/15 is amended as follows:

1. Part 12 is replaced by the text in the Annex to this Guideline;

2. in Part 16, Table 3 is replaced by the following:

	'Sent		Received	
Memo items	Number of transactions	Value of transactions	Number of transactions	Value of transactions
Transactions per type of payment instrument				
Credit transfers				

([1]) OJ L 318, 27.11.1998, p. 8.
([2]) OJ L 372, 31.12.1986, p. 1.
([3]) OJ L 35, 9.2.2011, p. 31.
([4]) Guideline ECB/2014/15 of 4 April 2014 on monetary and financial statistics (OJ L 340, 26.11.2014, p. 1).
([5]) Directive 2007/64/EC of the European Parliament and of the Council of 13 November 2007 on payment services in the internal market amending Directives 97/7/EC, 2002/65/EC, 2005/60/EC and 2006/48/EC and repealing Directive 97/5/EC (OJ L 319, 5.12.2007, p. 1).

	Sent		Received	
Memo items	Number of transactions	Value of transactions	Number of transactions	Value of transactions
Initiated electronically				
of which:				
Initiated on a single payment basis				
of which:				
Online banking based e-payments	Geo 1	Geo 1	—	—
Credits to the accounts by simple book entry	Geo 0	Geo 0	—	—
Debits from the accounts by simple book entry	Geo 0	Geo 0	—	—
			—	—
Money remittances	Geo 3	Geo 3	Geo 2	Geo 2
Transactions via telecommunication, digital or IT device	Geo 1	Geo 1	Geo 2	Geo 2
Other services (not included in the Payment Services Directive)	Geo 4	Geo 4	—	—';

3. in Part 16, the following definition is added:

'*Other services (not included in the Payment Services Directive)* — payment related services other than those services defined in Article 4(3) of Directive 2007/64/EC.'.

Article 2

Taking effect and implementation

1. This Guideline shall take effect on the day of its notification to the national central banks of the Member States whose currency is the euro.

2. The national central banks of the Member States whose currency is the euro shall take the necessary measures to comply with the Annex to this Guideline and apply it from the date of its adoption.

3. The national central banks of the Member States whose currency is the euro shall take the necessary measures to comply with Article 1(2) of this Guideline and apply it from 1 January 2015.

Article 3

Addressees

This Guideline is addressed to the national central banks of the Member States whose currency is the euro.

Done at Frankfurt am Main, 6 November 2014.

For the Governing Council of the ECB
The President of the ECB
Mario DRAGHI

ANNEX

'PART 12

Securities issues statistics

Section 1: Introduction

Securities issues statistics for the euro area provide two main aggregates:

— all issues by euro area residents in any currency, and

— all issues made worldwide in euro, both domestic and international.

A principal distinction must be drawn on the basis of the residency of the issuer whereby the Eurosystem NCBs collectively cover all issues by the residents of the euro area ([1]). The Bank for International Settlements (BIS) reports issues by the "rest of the world" (RoW), referring to all non-euro area residents (including international organisations not resident in the euro area).

The table below summarises the reporting requirements.

	Securities issues		
	By euro area residents (each NCB reporting on its domestic residents)	By RoW residents (BIS/NCB)	
		Non-euro area Member States	Other countries
In euro/national denominations	**Block A**	**Block B**	
In other currencies (*)	**Block C**	**Block D not required**	

(*) "Other currencies" refers to all other currencies, including the national currencies of non-euro area Member States.

Section 2: Reporting requirements

Table 1

Block A reporting form for NCBs

	DOMESTIC RESIDENT ISSUERS//EURO/NATIONAL DENOMINATIONS			
	Outstanding amounts	Gross issues	Redemptions	Net issues (**)
	A1	A2	A3	A4
1. SHORT-TERM DEBT SECURITIES (*)				
Total	S1	S68	S135	S202
ECB/NCB	S2	S69	S136	S203
MFIs other than central banks	S3	S70	S137	S204
OFIs	S4	S71	S138	S205
Of which FVC	S5	S72	S139	S206

([1]) If reporters encounter a methodological issue not expressly covered in this Guideline, they should apply the revised European system of national and regional accounts ("ESA 2010") laid down in Regulation (EU) No 549/2013 of the European Parliament and of the Council of 21 May 2013 on the European system of national and regional accounts in the European Union (OJ L 174, 26.6.2013, p. 1).

	DOMESTIC RESIDENT ISSUERS//EURO/NATIONAL DENOMINATIONS			
	Outstanding amounts	Gross issues	Redemptions	Net issues (**)
	A1	A2	A3	A4
Financial auxiliaries	S6	S73	S140	S207
Captive financial institutions	S7	S74	S141	S208
Insurance corp. and pension funds	S8	S75	S142	S209
Non-financial corporations	S9	S76	S143	S210
Central government	S10	S77	S144	S211
State and local government	S11	S78	S145	S212
Social security funds	S12	S79	S146	S213
2. LONG-TERM DEBT SECURITIES (*)				
Total	S13	S80	S147	S214
ECB/NCB	S14	S81	S148	S215
MFIs other than central banks	S15	S82	S149	S216
OFIs	S16	S83	S150	S217
Of which FVC	S17	S84	S151	S218
Financial auxiliaries	S18	S85	S152	S219
Captive financial institutions	S19	S86	S153	S220
Insurance corp. and pension funds	S20	S87	S154	S221
Non-financial corporations	S21	S88	S155	S222
Central government	S22	S89	S156	S223
State and local government	S23	S90	S157	S224
Social security funds	S24	S91	S158	S225
2.1. of which fixed rate issues:				
Total	S25	S92	S159	S226
ECB/NCB	S26	S93	S160	S227
MFIs other than central banks	S27	S94	S161	S228
OFIs	S28	S95	S162	S229
Of which FVC	S29	S96	S163	S230

	DOMESTIC RESIDENT ISSUERS//EURO/NATIONAL DENOMINATIONS			
	Outstanding amounts	Gross issues	Redemptions	Net issues (**)
	A1	A2	A3	A4
Financial auxiliaries	S30	S97	S164	S231
Captive financial institutions	S31	S98	S165	S232
Insurance corp. and pension funds	S32	S99	S166	S233
Non-financial corporations	S33	S100	S167	S234
Central government	S34	S101	S168	S235
State and local government	S35	S102	S169	S236
Social security funds	S36	S103	S170	S237
2.2. of which floating rate issues:				
Total	S37	S104	S171	S238
ECB/NCB	S38	S105	S172	S239
MFIs other than central banks	S39	S106	S173	S240
OFIs	S40	S107	S174	S241
Of which FVC	S41	S108	S175	S242
Financial auxiliaries	S42	S109	S176	S243
Captive financial institutions	S43	S110	S177	S244
Insurance corp. and pension funds	S44	S111	S178	S245
Non-financial corporations	S45	S112	S179	S246
Central government	S46	S113	S180	S247
State and local government	S47	S114	S181	S248
Social security funds	S48	S115	S182	S249
2.3. of which zero coupon bonds:				
Total	S49	S116	S183	S250
ECB/NCB	S50	S117	S184	S251
MFIs other than central banks	S51	S118	S185	S252
OFIs	S52	S119	S186	S253
Of which FVC	S53	S120	S187	S254

	DOMESTIC RESIDENT ISSUERS//EURO/NATIONAL DENOMINATIONS			
	Outstanding amounts	Gross issues	Redemptions	Net issues (**)
	A1	A2	A3	A4
Financial auxiliaries	S54	S121	S188	S255
Captive financial institutions	S55	S122	S189	S256
Insurance corp. and pension funds	S56	S123	S190	S257
Non-financial corporations	S57	S124	S191	S258
Central government	S58	S125	S192	S259
State and local government	S59	S126	S193	S260
Social security funds	S60	S127	S194	S261
3. LISTED SHARES (***)				
Total	S61	S128	S195	S262
ECB/NCBs	S62	S129	S196	S263
MFIs other than central banks	S63	S130	S197	S264
OFIs	S64	S131	S198	S265
Financial auxiliaries	S65	S132	S199	S266
Insurance corp. and pension funds	S66	S133	S200	S267
Non-financial corporations	S67	S134	S201	S268

(*) Debt securities other than shares refer to "securities other than shares, excluding financial derivatives".
(**) Net issues are only required should NCBs not be able to transmit either gross issues or redemptions.
(***) Listed shares refer to "listed shares excluding investment fund and money market fund shares/units".

Table 2

Block C reporting form for NCBs

	DOMESTIC RESIDENT ISSUERS//OTHER CURRENCIES			
	Outstanding amounts	Gross issues	Redemptions	Net issues
	C1	C2	C3	C4
4. SHORT-TERM DEBT SECURITIES				
Total	S269	S335	S401	S467
ECB/NCB	S270	S336	S402	S468
MFIs other than central banks	S271	S337	S403	S469

	DOMESTIC RESIDENT ISSUERS//OTHER CURRENCIES			
	Outstanding amounts	Gross issues	Redemptions	Net issues
	C1	C2	C3	C4
OFIs	S272	S338	S404	S470
Of which FVC	S273	S339	S405	S471
Financial auxiliaries	S274	S340	S406	S472
Captive financial institutions	S275	S341	S407	S473
Insurance corp. and pension funds	S276	S342	S408	S474
Non-financial corporations	S277	S343	S409	S475
Central government	S278	S344	S410	S476
State and local government	S279	S345	S411	S477
Social security funds	S280	S346	S412	S478
5. LONG-TERM DEBT SECURITIES				
Total	S281	S347	S413	S479
ECB/NCB	S282	S348	S414	S480
MFIs other than central banks	S283	S349	S415	S481
OFIs	S284	S350	S416	S482
Of which FVC	S285	S351	S417	S483
Financial auxiliaries	S286	S352	S418	S484
Captive financial institutions	S287	S353	S419	S485
Insurance corp. and pension funds	S288	S354	S420	S486
Non-financial corporations	S289	S355	S421	S487
Central government	S290	S356	S422	S488
State and local government	S291	S357	S423	S489
Social security funds	S292	S358	S424	S490
5.1. of which fixed rate issues:				
Total	S293	S359	S425	S491
ECB/NCB	S294	S360	S426	S492

	DOMESTIC RESIDENT ISSUERS//OTHER CURRENCIES			
	Outstanding amounts	Gross issues	Redemptions	Net issues
	C1	C2	C3	C4
MFIs other than central banks	S295	S361	S427	S493
OFIs	S296	S362	S428	S494
Of which FVC	S297	S363	S429	S495
Financial auxiliaries	S298	S364	S430	S496
Captive financial institutions	S299	S365	S431	S497
Insurance corp. and pension funds	S300	S366	S432	S498
Non-financial corporations	S301	S367	S433	S499
Central government	S302	S368	S434	S500
State and local government	S303	S369	S435	S501
Social security funds	S304	S370	S436	S502
5.2. of which floating rate issues:				
Total	S305	S371	S437	S503
ECB/NCB	S306	S372	S438	S504
MFIs other than central banks	S307	S373	S439	S505
OFIs	S308	S374	S440	S506
Of which FVC	S309	S375	S441	S507
Financial auxiliaries	S310	S376	S442	S508
Captive financial institutions	S311	S377	S443	S509
Insurance corp. and pension funds	S312	S378	S444	S510
Non-financial corporations	S313	S379	S445	S511
Central government	S314	S380	S446	S512
State and local government	S315	S381	S447	S513
Social security funds	S316	S382	S448	S514
5.3. of which zero coupon bonds:				
Total	S317	S383	S449	S515
ECB/NCB	S318	S384	S450	S516

	DOMESTIC RESIDENT ISSUERS//OTHER CURRENCIES			
	Outstanding amounts	Gross issues	Redemptions	Net issues
	C1	C2	C3	C4
MFIs other than central banks	S319	S385	S451	S517
OFIs	S320	S386	S452	S518
Of which FVC	S321	S387	S453	S519
Financial auxiliaries	S322	S388	S454	S520
Captive financial institutions	S323	S389	S455	S521
Insurance corp. and pension funds	S324	S390	S456	S522
Non-financial corporations	S325	S391	S457	S523
Central government	S326	S392	S458	S524
State and local government	S327	S393	S459	S525
Social security funds	S328	S394	S460	S526
6. LISTED SHARES				
Total	S329	S395	S461	S527
MFIs other than central banks	S330	S396	S462	S528
OFIs	S331	S397	S463	S529
Financial auxiliaries	S332	S398	S464	S530
Insurance corp. and pension funds	S333	S399	S465	S531
Non-financial corporations	S334	S400	S466	S532

Table 3

Block A memorandum items reporting form for NCBs

	DOMESTIC RESIDENT ISSUERS//EURO/NATIONAL DENOMINATIONS			
	Outstanding amounts	Gross issues	Redemptions	Net issues
	A1	A2	A3	A4
6. LISTED SHARES				
Captive financial institutions	S533	S544	S555	S566

	DOMESTIC RESIDENT ISSUERS//EURO/NATIONAL DENOMINATIONS			
	Outstanding amounts	Gross issues	Redemptions	Net issues
	A1	A2	A3	A4
7. UNLISTED SHARES				
Total	S534	S545	S556	S567
MFIs other than central banks	S535	S546	S557	S568
OFIs	S536	S547	S558	S569
Insurance corp. and pension funds	S537	S548	S559	S570
Non-financial corporations	S538	S549	S560	S571
8. OTHER EQUITY				
Total	S539	S550	S561	S572
MFIs other than central banks	S540	S551	S562	S573
OFIs	S541	S552	S563	S574
Insurance corp. and pension funds	S542	S553	S564	S575
Non-financial corporations	S543	S554	S565	S576

1. **Residency of the issuer**

Issues by subsidiaries owned by the reporting country's non-residents operating in the reporting country's economic territory must be classified as issues by the reporting country's resident units.

Issues by head offices located in the reporting country's economic territory which operate internationally must also be considered as issues by resident units. Issues by head offices or subsidiaries located outside the reporting country's economic territory but owned by residents of the reporting country must be considered as issues by non-residents. For example, issues by Volkswagen Brazil are considered to have been carried out by units resident in Brazil and not in the reporting country's territory. In the absence of any physical dimension to an enterprise, its residence is determined according to the economic territory under whose laws the enterprise is incorporated or registered ([1]).

To avoid double counting or gaps, the reporting of issues by special purpose entities (SPEs) must be addressed bilaterally, involving the reporters concerned. The NCBs, and not the BIS, must report issues by SPEs which fulfil the residency criteria of the ESA 2010 and are classified as euro area residents.

2. **Sectoral breakdown of issuers**

Issues must be classified according to the sector incurring the liability for the securities issued. The sectoral classification comprises the following 12 types of issuers:

— ECB/NCBs,

— other MFIs,

— OFIs,

([1]) See paragraph 2.07 of the ESA 2010.

— of which financial vehicle corporations engaged in securitisation,

— financial auxiliaries,

— captive financial institutions,

— insurance corporations and pension funds ([1]),

— non-financial corporations,

— central government,

— State and local government,

— social security funds,

— international institutions.

Securities issued through SPEs where the ultimate liability for the issue is incurred by the parent organisation and not the SPE must be attributed to the parent organisation and not the SPE. For example, issues by an SPE of "AJAX Electronics", a non-financial corporation located in the euro area country "Country A", would have to be allocated to the non-financial corporation sector and reported by Country A. However, the SPE and its parent must be resident in the same country. Hence, where the parent company is not a resident of the reporting country, the SPE must be treated as a notional resident of the reporting country, and the issuing sector must be aligned with the economic function of the SPE. For example, if "ACME Motors" was a non-financial corporation resident in Japan producing automobiles and "ACME Motor Finance" was a subsidiary resident in euro area country "Country B", issues by ACME Motor Finance would have to be attributed to captive financial institutions of Country B, because the parent company ACME Motors is not resident in the same country. The only exception to this is the case of SPEs owned by government, in which case the security is recorded as being issued by the government in the country of the parent organisation ([2]).

A public corporation that becomes privatised by issuing listed shares must be allocated to the non-financial corporation sector. Similarly, a public credit institution (CI) that is privatised must be allocated to the MFIs other than central banks sector. Issues by households or non-profit institutions serving households must be classified as issues by non-financial corporations.

3. **Maturity of issues**

Short-term debt securities comprise securities that have an original maturity of one year or less, even if they are issued under longer-term facilities.

Long-term debt securities comprise securities that have an original maturity of more than one year. Issues with optional maturity dates, the latest of which is more than one year away, and issues with indefinite maturity dates, are classified as long-term.

A two-year maturity split, as in the MFI balance sheet statistics, is not required.

4. **Classification of long-term debt securities by interest rate**

Long-term debt securities are divided into:

Fixed interest rate debt securities, i.e. debt securities which are issued and redeemed at par value and debt securities issued at a discount or premium to their par value.

Variable interest rate debt securities, i.e. debt securities where the coupon rate and/or underlying principal is linked to a general price index for goods and services (such as the consumer price index), an interest rate, or an asset price resulting in a variable nominal coupon payment over the life of the issue. For the purposes of securities issues statistics, mixed interest rate debt securities are classified as variable interest rate ([3]).

Zero coupon bonds issued at discount, i.e. instruments that have no interest payments and are issued at a considerable discount to par value. Most of the discount represents the equivalent of the interest accrued during the life of the bond.

([1]) In practice debt securities are not issued by pension funds.
([2]) See paragraphs 2.17 to 2.20 of the ESA 2010.
([3]) See paragraph 5.102 of the ESA 2010.

5. **Classification of issues**

Issues are analysed under two broad groupings: (a) debt securities ([1]), and (b) listed shares ([2]). Securities issued via private placement are covered as far as possible. Money market paper is included indistinguishably as part of debt securities. Unlisted shares ([3]) and other equity ([4]) may be reported on a voluntary basis as two separate memorandum items. Shares/units issued by money market funds and other investment funds are excluded.

The following is a non-exhaustive list of instruments covered in in the securities issues statistics:

(a) Debt securities

(i) Short-term debt securities

The following instruments are included as a minimum.

— Treasury bills and other short-term paper issued by general government.

— Negotiable short-term paper issued by financial and by non-financial corporations. A variety of terms are used for such paper including commercial paper, commercial bills, promissory notes, bills of trade, bills of exchange and certificates of deposit.

— Short-term securities issued under long-term underwritten note issuance facilities.

— Bankers' acceptances.

(ii) Long-term debt securities

The following instruments are illustrative and included as a minimum.

— Bearer bonds.

— Subordinated bonds.

— Bonds with optional maturity dates, the latest of which is more than one year away.

— Undated or perpetual bonds.

— Variable rate notes.

— Convertible bonds.

— Covered bonds.

— Index-linked securities where the value of the principal is linked to a price index, the price of a commodity or an exchange rate index.

— Deep-discounted bonds, which have small coupon payments and are issued at a discount to face value.

— Zero coupon bonds.

— Euro bonds.

— Global bonds.

— Privately issued bonds.

— Securities resulting from the conversion of loans.

— Loans that have become negotiable de facto.

— Debentures and loan stock convertible into shares, whether shares of the issuing corporation or shares of another company, so long as they have not been converted. Where separable from the underlying bond, the conversion option, which is considered to be a financial derivative, is excluded.

— Shares or stocks that pay a fixed income but do not provide for participation in the distribution of the residual value of the corporation on dissolution, including non-participating preference shares.

— Financial assets issued as part of the securitisation of loans, mortgages, credit card debt, accounts receivable and other assets.

([1]) Category F.3 of the ESA 2010.
([2]) Category F.511 of the ESA 2010.
([3]) Category F.512 of the ESA 2010.
([4]) Category F.519 of the ESA 2010.

The following instruments are excluded:

— transactions in securities as part of repurchase agreements,

— issues of non-negotiable securities,

— non-negotiable loans.

(b) Listed shares

Listed shares include the following.

— Capital shares issued by limited liability companies.

— Redeemed shares in limited liability companies.

— Dividend shares issued by limited liability companies.

— Preferred or preference stocks or shares which provide for participation in the distribution of the residual value on dissolution of a corporation. These may be listed or unlisted on a recognised exchange.

— Private placements where possible.

If a company is privatised and the government keeps part of the shares of the privatised company but the rest are quoted on a regulated market, the whole value of the company's capital is recorded within the outstanding amounts of listed shares, since all shares could potentially be traded at any time at market value. The same applies if part of the shares is sold to large investors and only the remaining part, i.e. the free float, is traded on the stock exchange.

Listed shares exclude:

— shares offered for sale but not taken up on issue,

— debentures and loan stock convertible into shares, which are included once they are converted into shares,

— the equity of partners with unlimited liability in incorporated partnerships,

— government investments in the capital of international organisations that are legally constituted as corporations with share capital,

— issues of bonus shares at the time of issue only and split share issues; bonus shares and split shares are however included indistinguishably in the total stock of listed shares.

6. **Currency of issue**

Dual currency bonds must be classified according to the denomination of the bond. Dual currency bonds are defined as bonds that are scheduled to be redeemed or the coupon paid in a different currency from the denomination of the bond. If a global bond is issued in more than one currency, each portion must be reported as a separate issue, according to its currency of issue. Where issues are denominated in two currencies, e.g. 70 % in euro and 30 % in US dollars, the relevant components of the issue must be reported separately where possible according to the currency denomination. Hence, in the given example 70 % of the issue must be reported as issues in euro/national denominations ([1]) and 30 % as issues in other currencies. Where it is not possible to separately identify the currency components of an issue, the actual breakdown made by the reporting country must be indicated in the national explanatory notes.

7. **Time of recording issue**

An issue is considered to have occurred when the issuer receives payment, and not when the syndicate takes up the commitment.

8. **Reconciliation of stocks and flows**

NCBs must submit information on outstanding amounts, gross issues, redemptions and net issues of short-term and long-term debt securities and on listed shares.

([1]) Block A for NCBs and Block B for the BIS.

The table below illustrates the link between stocks (i.e. outstanding amounts) and flows (i.e. gross issues, redemptions and net issues). In practice, the link is more complex due to price and exchange rate valuation changes, reinvested (i.e. accrued) interest, reclassifications, revisions and other adjustments.

(i)	Outstanding issues at end of reporting period	≈	Outstanding issues at end of previous reporting period	+	Gross issues during reporting period	–	Redemptions during reporting period	+ Reclassifications and other changes
(ii)	Outstanding issues at end of reporting period	≈	Outstanding issues at end of previous reporting period	+	Net issues during reporting period			+ Reclassifications and other changes

(a) Gross issues

Gross issues during the reporting period must include all issues of debt securities and listed shares where the issuer sells newly-created securities for cash. They concern the regular creation of new instruments. The point in time at which issues have been concluded is defined as the time at which payment is made; the recording of issues must therefore reflect as closely as possible the timing of payment for the underlying issue.

For listed shares, gross issues cover newly-created shares which are issued for cash by corporations listed on a stock exchange for the first time, including newly-created companies or private companies becoming public companies. Gross issues also cover newly-created shares which are issued against cash during the privatisation of public corporations when the corporation's shares are listed on a stock exchange. The issue of bonus shares must be excluded ([1]). Gross issues must not be reported in the event of a sole listing of a corporation on a stock exchange where no new capital is raised.

The exchange or transfer of existing securities during a takeover or merger is not covered ([2]) within the reported gross issues or redemptions, except for new instruments which are created and issued against cash by a euro area resident entity.

Issues of securities which can later be converted into other instruments must be recorded as issues in their original instrument category; on conversion they are to be recorded as having been redeemed from this instrument category, with an identical amount then treated as gross issues in a new category ([3]).

(b) Redemptions

Redemptions during the reporting period cover all repurchases of debt securities and listed shares by the issuer, where the investor receives cash for the securities. Redemptions concern the regular deletion of instruments. They cover all debt securities reaching their maturity date, as well as early redemptions. Company share buy-backs are covered if the company either repurchases all shares against cash prior to a change of its legal form, or repurchases part of its shares against cash and subsequently cancels them, leading to a reduction in capital. Company share buy-backs are not covered if they represent investments by a company in its own shares ([4]).

Redemptions must not be reported in the event of a sole delisting from a stock exchange.

(c) Net issues

Net issues are the balance of all gross issues made minus all redemptions that have occurred during the reporting period.

The outstanding amounts of listed shares must cover the market value of all the listed shares of the resident entities. The outstanding amounts of listed shares reported by a euro area country may therefore increase or decrease following relocation of a listed entity. This also applies in the event of a takeover or merger where no instruments are created and issued against cash and/or redeemed against cash and cancelled. To avoid double counting or gaps for debt securities and listed shares in the event of an issuer relocating to another resident country, the relevant NCBs must coordinate the timing of reporting of such an event bilaterally.

([1]) Not defined as a financial transaction; see paragraphs 5.158 and 6.59 of the ESA 2010, and Section 5(b) of this Part.
([2]) Transaction on a secondary market involving a change of the holder not covered by these statistics.
([3]) Considered as two financial transactions; see paragraphs 5.96 and 6.25 of the ESA 2010, and Section 5(a)(ii) of this Part.
([4]) Transaction on a secondary market involving a change of the holder is not covered by these statistics.

9. **Valuation**

The value of a securities issue comprises a price component and, where an issue is denominated in a currency other than the reporting currency, an exchange rate component.

NCBs must report short-term debt securities at face value ([1]) and listed shares at market value. For long-term debt securities different methods may be used for valuation depending on the interest rate type, resulting in a mixed valuation for the total. For example, fixed interest rate and variable interest rate issues are typically valued at face value, and zero coupon bonds at the nominal value. Generally, the relative amount of zero coupon bonds is small, so that no provision for a mixed valuation value is made in the code list; the total amount of long-term debt securities is reported at face value. Where the magnitude of the phenomenon is significant, the value "Z" for "not specified" is used. In general, whenever there is a situation where mixed valuation occurs, details are provided by the NCB at the attribute level in accordance with the attributes in Annex III.

(a) Price valuation

Stocks and flows of listed shares must be reported at market value.

An exception to the recording of stocks and flows of debt securities at face value is made in respect of deep-discounted and zero coupon bonds, where the outstanding amounts and gross issues are recorded at the nominal value, i.e. the discounted price at the time of issue plus accrued interest, and the redemptions at maturity at face value. The nominal value of the outstanding amounts of zero coupon bonds can be calculated as shown below.

$$A = E \times \left(\frac{100}{(E/P) \times 100} \right)^{\left(\frac{t}{T}\right)}$$

where

A = nominal value = effective amount paid and accrued interest

E = discounted price at time at issue (amount paid at the time of issuance)

P = face value (repaid at end of maturity)

T = time to maturity from issue date (in days)

t = time passed since issue date (in days)

There may be certain differences in the price valuation procedure used across countries.

The ESA 2010 price valuation approach, which requires flows for debt securities and shares to be recorded at transaction value and stocks at market value, is not applied in this context.

For deep-discounted and zero coupon bonds, the reporting NCB must calculate accrued interest where feasible.

(b) Reporting currency and exchange rate valuation

NCBs must report all data to the ECB expressed in euro, including historical series. For the conversion into euro of securities issued by domestic residents in other currencies (Block C) ([2]), NCBs must follow as closely as possible the exchange rate valuation principles based on the ESA 2010 ([3]), as set out below.

(i) Outstanding issues must be converted into euro/national denominations at the relevant mid-market exchange rate prevailing at the end of the reporting period, i.e. the close of business on the last working day of the reporting period.

(ii) Gross issues and redemptions must be converted into euro/national denominations using the mid-market exchange rate prevailing at the time of payment. If it is not possible to identify the exact exchange rate applicable for the conversion, an exchange rate that is as close as possible to the mid-market rate at the time of payment may be used.

([1]) For more detail on the definition of "face value", "market value" and "nominal value" see paragraphs 5.90, 7.38 and 7.39 of the ESA 2010.

([2]) Since 1 January 1999, for securities issued by domestic residents in euro (part of Block A) no exchange rate valuation is required, and securities issued by domestic residents in euro/national denominations (remaining part of Block A) are converted into euro applying the irrevocable conversion rates of 31 December 1998.

([3]) See paragraph 6.64 of the ESA 2010.

10. **Conceptual consistency**

Securities issues statistics and MFI balance sheet statistics are linked for the purpose of issues of negotiable instruments by MFIs. The coverage of instruments and of the MFIs that issue them are conceptually consistent, as well as the allocation of instruments to maturity bands and the currency breakdown. Differences between securities issues statistics and MFI balance sheet statistics exist regarding the valuation principles (i.e. with respect to debt securities, face value for the former and market value for the latter). Except for valuation differences and the netting of own holdings of securities on the balance sheet of MFIs for each country, the outstanding amount of securities issued by MFIs reported for securities issues statistics corresponds to item 11 ("debt securities issued") on the liability side of the MFI balance sheet. Short-term debt securities as defined for securities issues statistics correspond to debt securities issued up to one year. Long-term debt securities as defined for securities issues statistics equal the sum of debt securities issued over one and up to two years and debt securities issued over two years.

NCBs must review the coverage of the securities issues statistics and the MFI balance sheet statistics and indicate any conceptual differences to the ECB. Three types of consistency checks are performed in respect of issues by: (a) NCBs in euro/national denominations; (b) MFIs other than central banks in euro/national denominations; and (c) MFIs other than central banks in other currencies. Conceptual differences may arise between securities issue statistics and MFI balance sheet statistics, since the securities issues statistics and the MFI balance sheet statistics are derived from national reporting systems with different purposes.

11. **Data requirements**

Statistical returns are expected from each country for each applicable time series. NCBs must notify the ECB promptly in writing with explanations if a particular item does not apply in a particular country. NCBs may be temporarily exempted from the reporting of a time series if the underlying phenomenon does not exist. NCBs must also notify this occurrence or any other departures from the reporting scheme described in Annex III. Furthermore, they must inform the ECB when revisions are sent together with explanations on the nature of these revisions.

Section 3: National explanatory notes

Each NCB must submit a report describing the data provided in the context of this exercise. The report must cover the topics detailed below and follow the proposed layout as closely as possible. NCBs must provide additional information on instances where data reported do not comply with this Guideline, or where they have not provided the data, and the reasons for this. The report must not be submitted later than the data.

1. Data sources/data collection system: details of the data sources used to compile securities issues statistics must be given: administrative sources for government issues, direct reporting from MFIs and other institutions, newspapers, and data providers such as the International Financial Review etc. NCBs must indicate whether the data are collected and stored on an issue-by-issue basis, and their criteria. Alternatively, NCBs must indicate whether the data are collected and stored indistinguishably as amounts issued by individual issuers during a reporting period, e.g. for direct data collection systems. NCBs must provide information on the criteria used in direct reporting to identify the reporting agents and the information to be submitted.

2. Compilation procedures: the method used to compile data in this exercise must be briefly described, e.g. aggregation of information on individual securities issues, arrangements for existing time series and whether published or not.

3. Residence of the issuer: NCBs must specify whether it is possible to fully apply the ESA 2010 (and IMF) definition of residency in classifying issues. If this is not possible, or only partially possible, NCBs must provide a full explanation of the criteria actually used.

4. Sectoral breakdown of issuers: NCBs must indicate deviations from the classification of issuers according to the sectoral breakdown defined in Section 2 point 2. The notes must explain the identified deviations and any grey areas.

5. Currency of issue: if it is not possible to separately identify the currency components of an issue, NCBs must explain deviations from the rules. Furthermore, NCBs that cannot distinguish for all securities between issues in local denominations, in other euro/national denominations and in other currencies, must describe where such issues have been classified and indicate the total amount of issues that were not properly allocated to illustrate the size of the distortion.

6. Classification of issues: NCBs must provide comprehensive information on the type of securities covered by the national data, including their national terms. If coverage is known to be partial, NCBs must explain existing gaps. In particular, NCBs must provide the information set out below.

   — Private placements: NCBs must indicate whether or not they are covered in the reported data.

   — Bankers' acceptances: if negotiable and included in the reported data for short-term debt securities, the reporting NCB must explain in the national explanatory notes the national procedures for recording these instruments and their nature.

   — Listed shares: NCBs must indicate whether unlisted shares or other equity are covered in the reported data with an estimate of the amount of unlisted shares and/or other equity to illustrate the size of the distortion. NCBs must indicate in the national explanatory notes any known gaps in the coverage of listed shares.

7. Instrument analysis of long-term debt securities: if the sum of fixed rate, variable rate and zero coupon bonds does not add up to the total for long-term debt securities, NCBs must give the type and amount of long-term securities for which no such breakdown is available.

8. Maturity of issues: if the strict application of the short and long-term debt security definitions cannot be followed, NCBs must indicate where the reported data deviate.

9. Redemptions: NCBs must specify how they derive the information on redemptions and whether the information is collected by direct reporting or calculated by residual.

10. Price valuation: NCBs must specify in detail in the national explanatory notes the valuation procedure used for (a) short-term debt securities; (b) long-term debt securities; (c) discounted bonds; and (d) listed shares. Any valuation difference for stocks and flows must be explained.

11. Reporting frequency, timeliness and time range: NCBs must specify the extent to which the data compiled for this exercise has been provided in conformity with the user requirements, i.e. with a timeliness of five weeks for monthly data. The length of the time series provided must also be given. Any breaks in the series must be reported, e.g. differences in the coverage of securities over time.

12. Revisions: NCBs must provide brief explanatory notes for any revisions and clarify the reason for them and their extent.

13. Estimated coverage per instrument issued by domestic residents: NCBs must give national estimates of the coverage of securities for each category of issues by domestic residents, i.e. issues of short-term securities, long-term securities, and listed shares, in local currency, other euro/national denominations including ECU, and other currencies in accordance with the table below. The estimates for "coverage in %" must indicate the share of securities covered in each instrument category as percentages of the total issue, which must be reported under the relevant heading following the reporting rules. Brief descriptions may be provided in "comments". NCBs must also indicate any changes in coverage as a result of joining the monetary union.

			Coverage in %:	Comments:
Issues in euro/national denominations	Local denomination	STS		
		LTS		
		QUS		
	Euro/national denominations other than the local currency including ECU	STS		
		LTS		

		Coverage in %:	Comments:
In other currencies	STS		
	LTS		

STS = short-term debt securities.

LTS = long-term debt securities.

QUS = listed shares.

Section 4: Requirements for the Bank for International Settlements

The reporting requirements for the BIS follow the same principles as those for NCBs outlined in sections 1-3, except for the following:

Table 4

Block B Reporting form for the BIS

	ROW RESIDENT ISSUERS//EURO/NATIONAL DENOMINATIONS		
	Outstanding amounts	Gross issues	Redemptions
	B1	B2	B3
9. **SHORT-TERM DEBT SECURITIES**			
Total	S577	S642	S707
NCB	S578	S643	S708
MFIs other than central banks	S579	S644	S709
OFIs	S580	S645	S710
Of which FVC	S581	S646	S711
Financial auxiliaries	S582	S647	S712
Captive financial institutions	S583	S648	S713
Insurance corp. and pension funds	S584	S649	S714
Non-financial corporations	S585	S650	S715
Central government	S586	S651	S716
State and local government	S587	S652	S717
Social security funds	S588	S653	S718
International organisations	S589	S654	S719
10. **LONG-TERM DEBT SECURITIES**			
Total	S590	S655	S720
NCB	S591	S656	S721

	ROW RESIDENT ISSUERS//EURO/NATIONAL DENOMINATIONS		
	Outstanding amounts	Gross issues	Redemptions
	B1	B2	B3
MFIs other than central banks	S592	S657	S722
OFIs	S593	S658	S723
Of which FVC	S594	S659	S724
Financial auxiliaries	S595	S660	S725
Captive financial institutions	S596	S661	S726
Insurance corp. and pension funds	S597	S662	S727
Non-financial corporations	S598	S663	S728
Central government	S599	S664	S729
State and local government	S600	S665	S730
Social security funds	S601	S666	S731
International organisations	S602	S667	S732
10.1. **of which fixed rate issues:**			
Total	S603	S668	S733
NCB	S604	S669	S734
MFIs other than central banks	S605	S670	S735
OFIs	S606	S671	S736
Of which FVC	S607	S672	S737
Financial auxiliaries	S608	S673	S738
Captive financial institutions	S609	S674	S739
Insurance corp. and pension funds	S610	S675	S740
Non-financial corporations	S611	S676	S741
Central government	S612	S677	S742
State and local government	S613	S678	S743
Social security funds	S614	S679	S744
International organisations	S615	S680	S745

	ROW RESIDENT ISSUERS//EURO/NATIONAL DENOMINATIONS		
	Outstanding amounts	Gross issues	Redemptions
	B1	B2	B3
10.2. **of which floating rate issues:**			
Total	S616	S681	S746
NCB	S617	S682	S747
MFIs other than central banks	S618	S683	S748
OFIs	S619	S684	S749
Of which FVC	S620	S685	S750
Financial auxiliaries	S621	S686	S751
Captive financial institutions	S622	S687	S752
Insurance corp. and pension funds	S623	S688	S753
Non-financial corporations	S624	S689	S754
Central government	S625	S690	S755
State and local government	S626	S691	S756
Social security funds	S627	S692	S757
International organisations	S628	S693	S758
10.3. **of which zero coupon bonds:**			
Total	S629	S694	S759
NCB	S630	S695	S760
MFIs other than central banks	S631	S696	S761
OFIs	S632	S697	S762
Of which FVC	S633	S698	S763
Financial auxiliaries	S634	S699	S764
Captive financial institutions	S635	S700	S765
Insurance corp. and pension funds	S636	S701	S766
Non-financial corporations	S637	S702	S767
Central government	S638	S703	S768
State and local government	S639	S704	S769
Social security funds	S640	S705	S770
International organisations	S641	S706	S771

Maturity of issues

With regard to maturity, the BIS considers all euro commercial paper ECP and other euro notes drawn under a short-term programme as short-term instruments, and all instruments issued under long-term documentation as long-term instruments whatever their original maturity.

Sectoral breakdown of issuers

The BIS follows the mappings between the sectoral breakdown of issuers available in the BIS database and those requested in the report forms, as shown in the table below.

Sectoral breakdown in BIS database		Classification in report forms
Central bank	→	NCB and ECB
Commercial banks	→	MFIs
OFI	→	OFIs
Central government	→	Central government
Other government State agencies	→	State and local government
Corporations	→	Non-financial corporations
International institutions	→	International institutions (RoW)

Classification of issues

The following instruments contained in the BIS database are classified as debt securities in the securities issues statistics:

— certificates of deposit,

— commercial paper,

— treasury bills,

— bonds,

— euro commercial paper,

— medium-term notes,

— other short-term paper.

Valuation

Current BIS valuation rules are face value for debt securities and issue price for listed shares.

The BIS reports to the ECB all issues by RoW residents in euro/national denominations (Block B) in US dollars using the end-of-period exchange rate for amounts outstanding and the period's average exchange rate for issues and redemptions. The ECB converts all data into euro using the same principle as initially applied by the BIS. For periods prior to 1 January 1999, the exchange rate between the ECU and the US dollar must be used as a proxy.'

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