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⁽¹⁾ Text with EEA relevance.

II

(Non-legislative acts)

INTERNATIONAL AGREEMENTS

COUNCIL DECISION (CFSP) 2017/2322

of 29 May 2017

**concerning the signing and conclusion of the Agreement between Canada and the European Union
on security procedures for exchanging and protecting classified information**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union and in particular Article 37 thereof, in conjunction with Article 218(5) and the first subparagraph of Article 218(6) of the Treaty on the Functioning of the European Union,

Having regard to the proposal from the High Representative of the Union for Foreign Affairs and Security Policy,

Whereas:

- (1) At its meeting on 27 and 28 November 2003, the Council decided to authorise the Presidency assisted by the Secretary-General/High Representative to open negotiations in order to conclude an Agreement on the security of information between the European Union and Canada.
- (2) Following that authorisation, the Presidency negotiated an Agreement with Canada on security procedures for exchanging and protecting classified information.
- (3) That agreement should be approved,

HAS ADOPTED THIS DECISION:

Article 1

The Agreement between Canada and the European Union on security procedures for exchanging and protecting classified information ('the Agreement') is hereby approved on behalf of the Union.

The text of the Agreement is attached to this Decision.

Article 2

The President of the Council is hereby authorised to designate the person(s) empowered to sign the Agreement in order to bind the Union.

Article 3

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

Done at Brussels, 29 May 2017.

For the Council
The President
C. CARDONA

AGREEMENT**between Canada and the European Union on security procedures for exchanging and protecting classified information**

CANADA,

and

the EUROPEAN UNION (the 'EU')

hereinafter referred to as the 'Parties',

CONSIDERING that the Parties share the objective of strengthening all aspects of their security;

CONSIDERING that the Parties believe that they should consult and cooperate on matters of common interest;

CONSIDERING that, for these purposes, the Parties need to exchange information that they have designated by a security classification;

RECOGNISING that the Parties must take appropriate measures to protect the information that they exchange,

HAVE AGREED AS FOLLOWS:

*Article 1***Definitions**

For the purposes of this Agreement:

- (a) 'classified information' means any information that either Party has designated by a security classification and marked as such and which, if disclosed to unauthorised third parties, could cause varying degrees of damage or harm to the interests of that Party. This information may be in oral, visual, electronic, magnetic, or document form, or in the form of material, equipment or technology and includes reproductions, translations, and material in the process of development;
- (b) 'protected information' means any information that Canada has so designated by means of an appropriate marking and which, if disclosed to unauthorised third parties, could cause injury to a Canadian person, entity or public interest. This information may be in oral, visual, electronic, magnetic, or document form, or in the form of material, equipment or technology and includes reproductions, translations, and material in the process of development;
- (c) 'contractor' means an individual or legal entity possessing the legal capacity to enter into contracts; this term may also refer to a subcontractor, but does not include an individual engaged by Canada or the EU under a contract of employment;
- (d) 'need-to-know' means that access to classified information is limited to authorised individuals who need to have access to that classified information in order to perform their official duties;
- (e) 'Federal Government' means the federal government departments of Canada and all divisions and branches of the federal public administration of Canada;
- (f) 'third party' means any person or entity other than the Parties.

*Article 2***Scope**

1. This Agreement applies to classified information provided or exchanged between the Parties.
2. This Agreement also contains provisions on the protection of Canadian protected information provided to the EU. Unless otherwise specified, all references in this Agreement to classified information shall be deemed to refer also to Canadian protected information.

3. The receiving Party shall protect classified information provided to it by the other Party from being lost, compromised or disclosed without authorisation, in accordance with this Agreement. Each Party shall, in accordance with its laws and regulations, take measures to implement its obligations under this Agreement.
4. The receiving Party shall use this classified information only for the purposes established by the providing Party or the purposes for which the classified information has been provided or exchanged.
5. This Agreement does not constitute a basis to compel the release of classified information by the Parties.

Article 3

Application

1. This Agreement applies to the following EU institutions and entities: the European Council, the Council of the European Union (the 'Council'), the General Secretariat of the Council, the European Commission, the High Representative of the Union for Foreign Affairs and Security Policy, and the European External Action Service (the 'EEAS').
2. For Canada, this Agreement applies to the Federal Government.

Article 4

Classified Information and Protected Information

1. Classified information provided by one Party to the other Party shall bear an appropriate classification marking in accordance with paragraph 2. Canadian protected information provided to the EU shall bear an appropriate marking in accordance with paragraph 4.
2. Each Party shall ensure that classified information received from the other Party is afforded the level of protection warranted by the corresponding security classification marking as set out in the following table:

EU	CANADA
TRÈS SECRET UE/EU TOP SECRET	TOP SECRET or TRÈS SECRET
SECRET UE/EU SECRET	SECRET
CONFIDENTIEL UE/EU CONFIDENTIAL	CONFIDENTIAL or CONFIDENTIEL
RESTREINT UE/EU RESTRICTED	No Canadian equivalent

3. Canada shall afford to information classified RESTREINT UE/EU RESTRICTED a level of protection which is at least equivalent to that afforded to it by the EU.
4. The EU shall handle and store Canadian PROTECTED A or PROTÉGÉ A information in the same manner as the EU information classified RESTREINT UE/EU RESTRICTED. The EU shall handle and store Canadian PROTECTED B or PROTÉGÉ B and PROTECTED C or PROTÉGÉ C in accordance with the implementing administrative arrangements referred to in Article 11.
5. The providing Party may also mark classified information to specify any limitations on its use, disclosure, transmittal or access, and additional security requirements for its protection by the receiving Party, including institutions or entities of the receiving Party. Canada may also mark protected information to specify any limitations on its use, disclosure, transmittal or access, and additional security requirements for its protection by the EU, including an institution or entity not mentioned in Article 3(1).

Article 5

Protection of Classified Information

1. The receiving Party shall ensure that classified information received from the providing Party:
 - (a) retains the marking affixed to it by the providing Party in accordance with Article 4;
 - (b) is not downgraded or declassified without the prior consent in writing of the providing Party;

- (c) without prejudice to paragraph 2, is not disclosed or released to third parties, or to any institution or entity of the Parties not mentioned in Article 3 without the prior consent in writing of the providing Party;
- (d) is handled in compliance with any limitations which the providing Party has marked on the classified information in accordance with Article 4(5);
- (e) is safeguarded in accordance with this Agreement and the implementing administrative arrangements referred to in Article 11.

2. The receiving Party shall inform the providing Party of any request by a judicial authority or legislative authority acting in an investigative capacity, to obtain classified information received from the providing Party under this Agreement. In assessing such a request, the receiving Party shall take the views of the providing Party into account to the maximum extent possible. If, by virtue of the receiving Party's laws and regulations, that request entails transmission of the said classified information to the requesting judicial or legislative authority, the receiving Party shall ensure, to the maximum extent possible, that the information is appropriately protected, including from any subsequent disclosure.

Article 6

Personnel Security

1. The Parties shall ensure that classified information provided or exchanged under this Agreement is accessible only on a need-to-know basis.
2. The Parties shall ensure that any individual who is granted access to classified information provided or exchanged under this Agreement is briefed on the security rules and procedures relevant to the protection of that classified information and acknowledges the responsibility to protect that classified information.
3. The Parties shall ensure that access to classified information provided or exchanged under this Agreement is limited to individuals:
 - (a) who are authorised to access that classified information based on their functions; and
 - (b) who have the required personnel security clearance or are specifically empowered or authorised in accordance with the Parties' respective laws and regulations.

Article 7

Security of Location

The receiving Party shall ensure that the classified information provided to it by the other Party is held in a location which is secure, controlled, and protected.

Article 8

Release or Disclosure of Classified Information to Contractors

1. Each Party may provide classified information to a contractor or prospective contractor, with the prior written consent of the providing Party. Before disclosing any classified information to a contractor or prospective contractor, the receiving Party shall ensure that the contractor or prospective contractor has secured its facilities and is able to protect the classified information in accordance with Article 7, and that the contractor or prospective contractor has the required facility security clearance for itself and the appropriate security clearances for its personnel who need access to classified information.
2. The provision of RESTREINT UE/EU RESTRICTED and Canadian PROTECTED A or PROTÉGÉ A information to a contractor or prospective contractor shall not require the issuance of a facility security clearance.
3. The EU shall not provide Canadian PROTECTED B or PROTÉGÉ B and PROTECTED C or PROTÉGÉ C to a contractor or prospective contractor, except in specific cases where Canada has given its prior written consent, including on the measures governing the protection of such information.

*Article 9***Transmission of Classified Information**

1. For the purposes of this Agreement:
 - (a) Canada shall send classified information in electronic, magnetic, or paper document form through the Central Registry of the Council, which will forward it to the EU Member States and to the EU institutions and entities referred to in Article 3(1);
 - (b) the EU shall address classified information in electronic, magnetic, or paper document form, to the registry office of the relevant Canadian Government agency or department, via the Mission of the Government of Canada to the European Union, in Brussels.
2. A Party may send classified information and require that it be made accessible only to specific competent officials, organs, or services of the institutions or entities referred to in Article 3. In sending this classified information, the Party shall designate the specific competent officials, organs, or services of the institutions or entities referred to in Article 3 as the only recipients. In this case, the following shall apply to the transmission of classified information:
 - (a) Canada shall send classified information through the Central Registry of the Council, the Central Registry of the European Commission or the Central Registry of the EEAS, as appropriate;
 - (b) the EU shall address classified information to the registry office of the relevant Canadian Government entity, agency or department, via the Mission of the Government of Canada to the European Union, in Brussels.

*Article 10***Oversight**

The Parties agree that the following entities oversee the implementation of this Agreement:

- (a) for Canada, the entity that is designated by the Government of Canada and whose name is transmitted by diplomatic channel to the EU;
- (b) for the EU, the High Representative of the Union for Foreign Affairs and Security Policy, the Member of the European Commission responsible for security matters, and the Secretary-General of the Council.

*Article 11***Implementing Administrative Arrangements**

1. In order to implement this Agreement, the Parties shall ensure that their competent authorities enter into implementing administrative arrangements, which shall set out the requirements for matters such as:
 - (a) security clearances;
 - (b) procedures for providing or exchanging classified information;
 - (c) information on storage security;
 - (d) procedures for instances in which classified information is lost, compromised, or disclosed without authorisation; and
 - (e) procedures for the protection of classified information in electronic form.
2. The Parties shall conduct reciprocal security consultations and assessment visits to evaluate the effectiveness of the security measures applied by each Party to the classified information provided by the other Party under this Agreement and under the implementing administrative arrangements referred to in paragraph 1. The Parties shall jointly decide on the frequency and timing of those consultations and assessment visits.
3. Before a Party provides classified information to the other Party, the providing Party shall confirm in writing that the receiving Party is able to protect the classified information in a manner that is consistent with this Agreement and with the implementing administrative arrangements referred to in paragraph 1.

*Article 12***Classified Information that is Lost, Compromised or Disclosed without Authorisation**

1. The receiving Party shall immediately inform the providing Party if it discovers that classified information received under this Agreement may have been lost, compromised or disclosed without authorisation, and it shall initiate an investigation to determine how that information was lost, compromised or disclosed. Furthermore, the receiving Party shall forward to the providing Party the results of the investigation and information regarding measures taken to prevent recurrence.
2. The protection by the EU under this Agreement of Canadian protected information shall not oblige any EU Member State to treat any compromise of such information as a criminal offence under its criminal law.

*Article 13***Costs**

Each Party shall bear its own costs for the implementation of this Agreement.

*Article 14***Other Agreements**

This Agreement does not alter existing agreements or arrangements between the Parties, or agreements or arrangements between Canada and EU Member States. It is entirely without prejudice to the content of future agreements or arrangements between Canada and EU Member States. This Agreement does not preclude the Parties from concluding other agreements or arrangements relating to the provision or exchange of classified information.

*Article 15***Dispute Settlement**

The Parties shall deal with any differences arising from the interpretation or application of this Agreement through consultations.

*Article 16***Entry into force, amendment and termination**

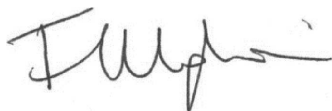
1. This Agreement shall enter into force on the first day of the first month after the Parties have notified each other of the completion of their internal procedures necessary for this purpose.
2. Each Party shall notify the other Party of any changes in its laws and regulations that could affect the protection of classified information provided or exchanged under this Agreement.
3. At any time, either Party may request a review of this Agreement for consideration of possible amendments.
4. This Agreement may be amended by mutual agreement. The Party seeking to amend a provision of this Agreement shall notify the other Party in writing. An amendment shall enter into force in accordance with the procedure described in paragraph 1.

5. A Party may denounce this Agreement by notice in writing to the other Party. This Agreement shall terminate three months after the notification is received by the other Party. Both Parties shall continue to provide the protection described in this Agreement to any classified information provided prior to the termination of this Agreement.

IN WITNESS WHEREOF the undersigned, being duly authorised, have signed this Agreement.

Done in duplicate at Brussels, this fourth day of December in the year two thousand and seventeen, in the English and French languages, each version being equally authentic.

For the European Union



For Canada



REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2017/2323

of 17 November 2017

approving non-minor amendments to the specification for a name entered in the register of protected designations of origin and protected geographical indications ('Ternasco de Aragón' (PGI))

THE EUROPEAN COMMISSION,

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

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

Whereas:

- (1) Pursuant to the first subparagraph of Article 53(1) of Regulation (EU) No 1151/2012, the Commission examined Spain's application for the approval of amendments to the specification for the protected geographical indication 'Ternasco de Aragón', registered under Commission Regulation (EC) No 1107/96 ⁽²⁾ as amended by Commission Implementing Regulation (EU) No 583/2013 ⁽³⁾.
- (2) Since the amendments in question are not minor within the meaning of Article 53(2) of Regulation (EU) No 1151/2012, the Commission published the amendment application in the *Official Journal of the European Union* ⁽⁴⁾ as required by Article 50(2)(a) of that Regulation.
- (3) As no statement of opposition under Article 51 of Regulation (EU) No 1151/2012 has been received by the Commission, the amendments to the specification should be approved,

HAS ADOPTED THIS REGULATION:

Article 1

The amendments to the specification published in the *Official Journal of the European Union* regarding the name 'Ternasco de Aragón' (PGI) are hereby approved.

Article 2

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

⁽¹⁾ OJ L 343, 14.12.2012, p. 1.

⁽²⁾ Commission Regulation (EC) No 1107/96 of 12 June 1996 on the registration of geographical indications and designations of origin under the procedure laid down in Article 17 of Council Regulation (EEC) No 2081/92 (OJ L 148, 21.6.1996, p. 1).

⁽³⁾ Commission Implementing Regulation (EU) No 583/2013 of 18 June 2013 approving non-minor amendments to the specification for a name entered in the register of protected designations of origin and protected geographical indications (Ternasco de Aragón (PGI)) (OJ L 169, 21.6.2013, p. 37).

⁽⁴⁾ OJ C 250, 1.8.2017, p. 24.

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

Done at Brussels, 17 November 2017.

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

COMMISSION IMPLEMENTING REGULATION (EU) 2017/2324**of 12 December 2017****renewing the approval of the active substance glyphosate in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC ⁽¹⁾, and in particular Article 20(1) thereof,

Whereas:

- (1) Commission Directive 2001/99/EC ⁽²⁾ included glyphosate as an active substance in Annex I to Council Directive 91/414/EEC ⁽³⁾.
- (2) Active substances included in Annex I to Directive 91/414/EEC are deemed to have been approved under Regulation (EC) No 1107/2009 and are listed in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011 ⁽⁴⁾.
- (3) The approval of the active substance glyphosate, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 15 December 2017.
- (4) An application for the renewal of the inclusion of the active substance glyphosate in Annex I to Directive 91/414/EEC was submitted in accordance with Article 4 of Commission Regulation (EU) No 1141/2010 ⁽⁵⁾ within the time period provided for in that Article.
- (5) The applicant submitted the supplementary dossiers required in accordance with Article 9 of Regulation (EU) No 1141/2010. The application was found to be complete by the rapporteur Member State.
- (6) The rapporteur Member State prepared a renewal assessment report in consultation with the co-rapporteur Member State and submitted it to the European Food Safety Authority (hereinafter 'the Authority') and the Commission on 20 December 2013.
- (7) The Authority communicated the renewal assessment report to the applicant and to the Member States for comments and forwarded the comments received to the Commission. The Authority also made the supplementary summary dossier available to the public.
- (8) Following the findings of the International Agency for Research on Cancer published on 20 March 2015 as regards the carcinogenic potential of glyphosate, on 29 April 2015 the Commission mandated the Authority to review the underlying information and to include those findings in its conclusion by 13 August 2015.
- (9) To allow for an appropriate evaluation of the information ⁽⁶⁾ from the International Agency for Research on Cancer and of the extraordinarily high number of comments received from Member States and the public, the Commission extended the deadline for the submission of the Authority's conclusion to 30 October 2015.
- (10) On 30 October 2015 ⁽⁷⁾, the Authority communicated to the Commission its conclusion on whether glyphosate can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Commission presented the draft review report for glyphosate to the Standing Committee on Plants, Animals, Food and Feed on 28 January 2016.
- (11) The applicant was given the possibility to submit comments on the draft review report.

- (12) The discussions in the Standing Committee on Plants, Animals, Food and Feed on 18 and 19 May 2016 showed that in the specific situation of glyphosate a number of Member States, in their role as risk managers, considered that it was appropriate to have an opinion of the Committee for Risk Assessment of the European Chemicals Agency (hereinafter 'the Agency') on the harmonised classification as regards carcinogenicity of glyphosate, before taking a decision on a renewal of the approval because such an opinion could be relevant for the approval based on the criteria set out in Regulation (EC) No 1107/2009.
- (13) The possible renewal of the approval of glyphosate was also extensively discussed outside of the Standing Committee on Plants, Animals, Food and Feed. On 13 April 2016 ⁽⁸⁾ and on 24 October 2017 ⁽⁹⁾, the European Parliament adopted Resolutions on the different draft Commission Implementing Regulations renewing the approval of the active substance glyphosate, and on 6 October 2017 the European Commission officially received a successful European Citizens' Initiative (ECI) ⁽¹⁰⁾, referring specifically to glyphosate in one of its three aims, with validated signatures from at least one million European citizens in at least seven Member States.
- (14) As an opinion of the Committee for Risk Assessment of the Agency on the harmonised classification as regards carcinogenicity of glyphosate was deemed necessary, on 17 March 2016, the rapporteur Member State submitted a dossier in accordance with Article 37 of Regulation (EC) No 1272/2008 of the European Parliament and of the Council ⁽¹¹⁾, including for the hazard class on carcinogenicity. In view of the time required to assess such a dossier, the approval period of the active substance was extended until 6 months from the date of receipt of the opinion of the Committee for Risk Assessment of the Agency by the Commission but however until 31 December 2017 at the latest by Commission Implementing Regulation (EU) 2016/1056 ⁽¹²⁾. In the meantime, the conditions of approval of the active substance were amended in the light of new scientific and technical knowledge by Commission Implementing Regulation (EU) 2016/1313 ⁽¹³⁾.
- (15) The Committee for Risk Assessment of the Agency adopted its opinion ⁽¹⁴⁾ on 15 March 2017 and forwarded it to the Commission on 15 June 2017. The Commission published a Notice ⁽¹⁵⁾ confirming the date of its receipt in the *Official Journal of the European Union* on 28 June 2017. In its opinion, the Committee for Risk Assessment of the Agency concluded by consensus that on the basis of the information currently available, no hazard classification for carcinogenicity is justified for glyphosate.
- (16) In its conclusion of October 2015, the Authority identified a data gap to rule out potential endocrine activity observed in one study. Pertinent data became available too late to be included in the peer review. On 27 September 2016 the Commission asked the Authority to assess that additional information. On 7 September 2017 ⁽¹⁶⁾ the Authority communicated to the Commission its conclusion on the potential endocrine disrupting properties of glyphosate. In its conclusion, the Authority confirmed that the data gap had been adequately addressed as the weight of evidence indicates that glyphosate does not have endocrine disrupting properties through oestrogen, androgen, thyroid or steroidogenesis mode of action based on a comprehensive database available in the toxicology area. The available ecotoxicology studies did not contradict this conclusion.
- (17) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance glyphosate that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied. Those approval criteria are therefore deemed to be satisfied.
- (18) It is therefore appropriate to renew the approval of glyphosate.
- (19) While a large amount of information on the active substance glyphosate already exists and has been assessed leading to the conclusion that the approval of the active substance glyphosate should be renewed, additional information on glyphosate is being published at an exceptionally high rate compared to other active substances. Therefore possibilities of rapid future developments in science and technology should be taken into account when deciding on the length of the approval period of glyphosate, also bearing in mind the fact that glyphosate is one of the most widely used herbicides in the Union.
- (20) In light of these specificities and other legitimate factors referred to in the recitals above and bearing in mind the need to ensure a level of safety and protection consistent with the high level of protection that is sought within the Union, from a risk management perspective it is appropriate to provide for a renewal of the approval of glyphosate for a period of five years ensuring a priority re-assessment of glyphosate over other active substances.
- (21) In accordance with Article 14(1) of Regulation (EC) No 1107/2009 in conjunction with Article 6 thereof and in the light of current scientific and technical knowledge, it is necessary to include certain conditions and restrictions.

- (22) In accordance with Article 20(3) of Regulation (EC) No 1107/2009, in conjunction with Article 13(4) thereof, the Annex to Implementing Regulation (EU) No 540/2011 should be amended accordingly.
- (23) Taking into account that the current approval of glyphosate expires on 15 December 2017, this Regulation should enter into force as soon as possible.
- (24) This Regulation should apply from the day after the date of expiry of the approval of the active substance glyphosate as referred to in recital 3.
- (25) The Standing Committee on Plants, Animals, Food and Feed has not delivered an opinion within the time limit laid down by its Chairman. An implementing act was deemed to be necessary and the chair submitted the draft implementing act to the appeal committee for further deliberation. The measures provided for in this Regulation are in accordance with the opinion of the appeal committee,

HAS ADOPTED THIS REGULATION:

Article 1

Renewal of the approval of active substance

The approval of the active substance glyphosate, as specified in Annex I, is renewed subject to the conditions laid down in that Annex.

Article 2

Amendments to Implementing Regulation (EU) No 540/2011

The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with Annex II to this Regulation.

Article 3

Entry into force and date of application

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

It shall apply from 16 December 2017.

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

Done at Strasbourg, 12 December 2017.

For the Commission

The President

Jean-Claude JUNCKER

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

⁽²⁾ Commission Directive 2001/99/EC of 20 November 2001 amending Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market to include glyphosate and thifensulfuron-methyl as active substances (OJ L 304, 21.11.2001, p. 14).

⁽³⁾ Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1).

- (⁴) Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1).
- (⁵) Commission Regulation (EU) No 1141/2010 of 7 December 2010 laying down the procedure for the renewal of the inclusion of a second group of active substances in Annex I to Council Directive 91/414/EEC and establishing the list of those substances (OJ L 322, 8.12.2010, p. 10).
- (⁶) IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Volume 112 (2015). Available online: www.iarc.fr
- (⁷) EFSA (European Food Safety Authority), 2015. Conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate. *EFSA Journal* 2015;13(11):4302, 107 pp. doi:10.2903/j.efsa.2015.4302 Available online: www.efsa.europa.eu
- (⁸) European Parliament resolution of 13 April 2016 on the draft Commission implementing regulation renewing the approval of the active substance glyphosate in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Implementing Regulation (EU) No 540/2011 (D044281/01 — 2016/2624(RSP)). Available online: <http://www.europarl.europa.eu/sides/getDoc.do?type=TA&reference=P8-TA-2016-0119&language=EN&ring=B8-2016-0439>
- (⁹) European Parliament resolution of 24 October 2017 on the draft Commission implementing regulation renewing the approval of the active substance glyphosate in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Implementing Regulation (EU) No 540/2011 (D053565-01 — 2017/2904(RSP)). Available online: <http://www.europarl.europa.eu/sides/getDoc.do?type=TA&reference=P8-TA-2017-0395&language=EN&ring=B8-2017-0567>
- (¹⁰) Commission registration number: ECI(2017)000002, available online: <http://ec.europa.eu/citizens-initiative/public/initiatives/successful/details/2017/000002?lg=en>.
- (¹¹) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).
- (¹²) Commission Implementing Regulation (EU) 2016/1056 of 29 June 2016 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval period of the active substance glyphosate (OJ L 173, 30.6.2016, p. 52).
- (¹³) Commission Implementing Regulation (EU) 2016/1313 of 1 August 2016 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance glyphosate (OJ L 208, 2.8.2016, p. 1).
- (¹⁴) European Chemicals Agency (ECHA) (2017). Opinion of the Committee for Risk Assessment proposing harmonised classification and labelling of glyphosate (ISO); N-(phosphonomethyl)glycine (EC Number: 213-997-4; CAS Number: 1071-83-6).
- (¹⁵) Commission Notice on the date of receipt of the opinion proposing harmonised classification and labelling at EU level of glyphosate of the Committee for Risk Assessment of the European Chemicals Agency (OJ C 204, 28.6.2017, p. 5).
- (¹⁶) EFSA (European Food Safety Authority), 2017. Conclusion on the peer review of the pesticide risk assessment of the potential endocrine disrupting properties of glyphosate. *EFSA Journal* 2017;15(9):4979, 20 pp. <https://doi.org/10.2903/j.efsa.2017.4979>.
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ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
Glyphosate CAS No 1071-83-6 CIPAC No 284	N-(phosphonome- thyl)glycine	≥ 950 g/kg Impurities: Formaldehyde, less than 1 g/kg N-Nitroso-glyphosate, less than 1 mg/kg	16 December 2017	15 December 2022	Only uses as herbicide may be authorised. For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on glyphosate, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the protection of the groundwater in vulnerable areas, in particular with respect to non-crop uses, — the protection of operators and amateur users, — the risk to terrestrial vertebrates and non-target terrestrial plants, — the risk to diversity and abundance of non-target terrestrial arthropods and vertebrates via trophic interactions, — compliance of pre-harvest uses with good agricultural practices. Conditions of use shall include risk mitigation measures, where appropriate. Member States shall ensure that use of plant protection products containing glyphosate is minimised in the specific areas listed in Article 12(a) of Directive 2009/128/EC. Member States shall ensure equivalence between the specifications of the technical material, as commercially manufactured, and those of the test material used in the toxicological studies. Member States shall ensure that plant protection products containing glyphosate do not contain the co-formulant POE-tallowamine (CAS No 61791-26-2).

⁽¹⁾ Further details on identity and specification of active substance are provided in the review report.

The Annex to Implementing Regulation (EU) No 540/2011 is amended as follows:

(1) in Part A, entry 25 on glyphosate is deleted;

(2) in Part B, the following entry is added:

	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
'118	Glyphosate CAS No 1071-83-6 CIPAC No 284	N-(phosphono- methyl)glycine	≥ 950 g/kg Impurities: Formaldehyde, less than 1 g/kg N-Nitroso-glyphosate, less than 1 mg/kg	16 December 2017	15 December 2022	Only uses as herbicide may be authorised. For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on glyphosate, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the protection of the groundwater in vulnerable areas, in particular with respect to non-crop uses, — the protection of operators and amateur users, — the risk to terrestrial vertebrates and non-target terrestrial plants, — the risk to diversity and abundance of non-target terrestrial arthropods and vertebrates via trophic interactions, — compliance of pre-harvest uses with good agricultural practices. Conditions of use shall include risk mitigation measures, where appropriate. Member States shall ensure that use of plant protection products containing glyphosate is minimised in the specific areas listed in Article 12(a) of Directive 2009/128/EC. Member States shall ensure equivalence between the specifications of the technical material, as commercially manufactured, and those of the test material used in the toxicological studies.

	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
						Member States shall ensure that plant protection products containing glyphosate do not contain the co-formulant POE-tallowamine (CAS No 61791-26-2).

⁽¹⁾ Further details on identity and specification of active substance are provided in the review report.'

COMMISSION IMPLEMENTING REGULATION (EU) 2017/2325**of 14 December 2017****concerning the authorisation of preparations of lecithins liquid, lecithins hydrolysed and lecithins de-oiled as feed additives for all animal species and amending Implementing Regulation (EU) 2017/1007****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ⁽¹⁾, and in particular Article 9(2) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC ⁽²⁾.
- (2) Lecithins were authorised without a time limit in accordance with Directive 70/524/EEC as feed additive for all animal species. These additives were subsequently entered in the Register of feed additives as existing products, in accordance with Article 10(1)(b) of Regulation (EC) No 1831/2003.
- (3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 an application was submitted for the re-evaluation of preparations of lecithins as feed additives for all animal species. The applicant requested those additives to be classified in the additive category 'technological additives' and in the functional group 'emulsifiers'. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 13 July 2016 ⁽³⁾ that, under the proposed conditions of use, the preparations of lecithins, lecithins hydrolysed and lecithins de-oiled do not have an adverse effect on animal health, human health or the environment. The Authority also concluded that the preparations are considered efficacious for use in feed as emulsifiers. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the methods of analysis of the feed additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (5) The assessment of lecithins liquid, lecithins hydrolysed and lecithins de-oiled shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of those preparations should be authorised as specified in the Annex I to this Regulation.
- (6) It is considered appropriate to harmonise the characteristics of the lecithins, lecithins liquid, lecithins hydrolysed and lecithins de-oiled and the conditions of use to avoid the distortion of the market, Commission Implementing Regulation (EU) 2017/1007 ⁽⁴⁾ should be amended accordingly.
- (7) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ L 270, 14.12.1970, p. 1).

⁽³⁾ EFSA Journal 2016;14(8):4561.

⁽⁴⁾ Commission Implementing Regulation (EU) 2017/1007 of 15 June 2017 concerning the authorisation of a preparation of lecithins as feed additive for all animal species (OJ L 153, 16.6.2017, p. 13).

HAS ADOPTED THIS REGULATION:

Article 1

Authorisation

The additives specified in Annex I belonging to the additive category 'technological additives' and to the functional group 'emulsifiers', are authorised as additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

Amendment to Implementing Regulation (EU) 2017/1007

The Annex to Implementing Regulation (EU) 2017/1007 is replaced by the text in Annex II to this Regulation.

Article 3

Transitional measures

1. The additives specified in Annex I and premixtures containing those additives which are produced and labelled before 4 July 2018 in accordance with the rules applicable before 4 January 2018 may continue to be placed on the market and used until the existing stocks are exhausted.
2. Compound feed and feed materials containing the additives as specified in Annex I which are produced and labelled before 4 January 2019 in accordance with the rules applicable before 4 January 2018 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.
3. Compound feed and feed materials containing the additives as specified in Annex I which are produced and labelled before 4 January 2020 in accordance with the rules applicable before 4 January 2018 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for non-food-producing animals.

Article 4

Entry into force

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

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

Done at Brussels, 14 December 2017.

For the Commission
The President
Jean-Claude JUNCKER

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						mg of lecithins/kg of complete feedingstuff with a moisture content of 12 %			
Category of technological additives. Functional group: emulsifiers									
1c322i	—	lecithins liquid	<i>Additive composition</i> Preparation of lecithins: phospholipids ≥ 48 %, Moisture ≤ 1 % Liquid form <i>Characterisation of the active substance</i> Liquid lecithins (CAS No 8002-43-5) extracted from rapeseeds, sunflower and/or soybean <i>Analytical method</i> ⁽¹⁾ For the characterisation of feed additive: Commission Regulation (EU) No 231/2012 ⁽²⁾ and the corresponding tests in the FAO JECFA monograph 'Lecithin' ⁽³⁾ ⁽⁴⁾	All animal species	—	—	—		4 January 2028
1c322ii		hydrolysed lecithins	<i>Additive composition</i> preparation of hydrolysed lecithins: phospholipids ≥ 44 %, Moisture ≤ 1 % Liquid form <i>Characterisation of the active substance</i> Liquid hydrolysed lecithins (CAS No 8002-43-5) extracted from sunflowers and/or soybeans	All animal species					4 January 2028

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						mg of lecithins/kg of complete feedingstuff with a moisture content of 12 %			
			<i>Analytical method</i> ⁽¹⁾ For the characterisation of feed additive: Commission Regulation (EU) No 231/2012 ⁽²⁾ and the corresponding tests in the FAO JECFA monograph 'Lecithin' ⁽³⁾ ⁽⁴⁾						
1c322iii	—	Lecithins de-oiled	<i>Additive composition</i> Preparation of de-oiled lecithins having a minimum of: phospholipids ≥ 75 %, Moisture ≤ 2 % Solid form <i>Characterisation of the active substance</i> Solid de-oiled lecithins (CAS No 8002-43-5) extracted from sunflowers and/or soybeans and de-fatted by solvent extraction <i>Analytical method</i> ⁽¹⁾ For the characterisation of feed additive: Commission Regulation (EU) No 231/2012 ⁽²⁾ and the corresponding tests in the FAO JECFA monograph 'Lecithin' ⁽³⁾ ⁽⁴⁾	All animal species	—	—	—		4 January 2028

⁽¹⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>

⁽²⁾ Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).

⁽³⁾ FAO JECFA Combined Compendium of Food Additive Specifications, 'Lecithin', Monograph No 4 (2007), <http://www.fao.org/ag/agn/jecfa-additives/specs/monograph4/additive-250-m4.pdf>

⁽⁴⁾ FAO JECFA Combined Compendium for Food Additive Specifications — Analytical methods, test procedures and laboratory solutions used by and referenced in the food additive specifications, Vol. 4, <http://www.fao.org/docrep/009/a0691e/a0691e00.htm>

ANNEX II

‘ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						mg of lecithins/kg of complete feedingstuff with a moisture content of 12 %			
Category of technological additives. Functional group: emulsifiers									
1c322	—	Lecithins	<i>Additive composition</i> Preparation of lecithins having a minimum of: — phospholipids ≥ 18 %, — lysophospholipids ≥ 11 %, Moisture ≤ 1 % <i>Characterisation of the active substance</i> Lecithins (CAS No 8002-43-5) extracted from soybeans <i>Analytical method</i> ⁽¹⁾ For the characterisation of feed additive: Commission Regulation (EU) No 231/2012 ⁽²⁾ and the corresponding tests in the FAO JECFA monograph “Lecithin” ⁽³⁾ ⁽⁴⁾	All animal species	—	—	—	=	6 July 2027

⁽¹⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>

⁽²⁾ Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).

⁽³⁾ FAO JECFA Combined Compendium of Food Additive Specifications, “Lecithin”, Monograph No 4 (2007), <http://www.fao.org/ag/agn/jecfa-additives/specs/monograph4/additive-250-m4.pdf>

⁽⁴⁾ FAO JECFA Combined Compendium for Food Additive Specifications — Analytical methods, test procedures and laboratory solutions used by and referenced in the food additive specifications, Vol. 4, <http://www.fao.org/docrep/009/a0691e/a0691e00.htm>

COMMISSION IMPLEMENTING REGULATION (EU) 2017/2326**of 14 December 2017****approving imiprothrin as an existing active substance for use in biocidal products of product-type 18****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ⁽¹⁾, and in particular the third subparagraph of Article 89(1) thereof,

Whereas:

- (1) Commission Delegated Regulation (EU) No 1062/2014 ⁽²⁾ establishes a list of existing active substances to be evaluated for their possible approval for use in biocidal products. That list includes imiprothrin.
- (2) Imiprothrin has been evaluated for use in products of product-type 18, insecticides, acaricides and products to control other arthropods, as described in Annex V to Regulation (EU) No 528/2012.
- (3) The United Kingdom was designated as evaluating competent authority and submitted the assessment report together with its recommendations on 20 July 2016.
- (4) In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014, the opinion of the European Chemicals Agency was formulated on 27 June 2017 by the Biocidal Products Committee, having regard to the conclusions of the evaluating competent authority.
- (5) According to that opinion, biocidal products of product-type 18 containing imiprothrin may be expected to satisfy the criteria of Article 19(1)(b) of Regulation (EU) No 528/2012, provided that certain specifications and conditions concerning their use are complied with.
- (6) It is therefore appropriate to approve imiprothrin for use in biocidal products of product-type 18, subject to compliance with certain specifications and conditions.
- (7) A reasonable period should be allowed to elapse before an active substance is approved in order to permit interested parties to take the preparatory measures necessary to meet the new requirements.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS REGULATION:

Article 1

Imiprothrin is approved as an active substance for use in biocidal products of product-type 18, subject to the specifications and conditions set out in the Annex.

Article 2

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

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

⁽²⁾ Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 294, 10.10.2014, p. 1).

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

Done at Brussels, 14 December 2017.

For the Commission

The President

Jean-Claude JUNKER

ANNEX

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance ⁽¹⁾	Date of approval	Expiry date of approval	Product type	Specific conditions
Imiprothrin	IUPAC Name: Reaction mass of: 2,5-dioxo-3-prop-2-ynylimidazolidin-1-ylmethyl (1R)-cis-2,2-dimethyl-3-(2-methylprop-1-enyl)cyclopropanecarboxylate; 2,5-dioxo-3-prop-2-ynylimidazolidin-1-ylmethyl (1R)-trans-2,2-dimethyl-3-(2-methylprop-1-enyl)cyclopropanecarboxylate EC No: 428-790-6 CAS No: 72963-72-5	≥ 870 g/kg	1 July 2019	30 June 2029	18	The authorisations of biocidal products are subject to the following conditions: 1. The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any use covered by an application for authorisation, but not addressed in the Union-level risk assessment of the active substance. 2. In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to surface water, sediment and soil for products used indoors as a spray for surface treatment. 3. For products that may lead to residues in food or feed, the need to set new or to amend existing maximum residue levels (MRLs) in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council ⁽²⁾ or Regulation (EC) No 396/2005 of the European Parliament and of the Council ⁽³⁾ shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded.

⁽¹⁾ The purity indicated in this column was the minimum degree of purity of the active substance evaluated. The active substance in the product placed on the market can be of equal or different purity if it has been proven to be technically equivalent to the evaluated active substance.

⁽²⁾ Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11).

⁽³⁾ Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).

COMMISSION IMPLEMENTING REGULATION (EU) 2017/2327**of 14 December 2017****approving 2-methyl-1,2-benzisothiazol-3(2H)-one as an active substance for use in biocidal products of product-type 6****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ⁽¹⁾, and in particular Article 90(2) thereof,

Whereas:

- (1) Poland received on 26 November 2009 an application, in accordance with Article 11(1) of Directive 98/8/EC of the European Parliament and of the Council ⁽²⁾, for the inclusion of the active substance 2-methyl-1,2-benzisothiazol-3(2H)-one in Annex I to that Directive for use in products of product-type 6, in-can preservatives, as described in Annex V to that Directive, which corresponds to product-type 6 as described in Annex V to Regulation (EU) No 528/2012.
- (2) Poland submitted the assessment report together with its recommendations on 24 March 2016 in accordance with Article 90(2) of Regulation (EU) No 528/2012.
- (3) The opinion of the European Chemicals Agency was formulated on 27 June 2017 by the Biocidal Products Committee, having regard to the conclusions of the evaluating competent authority.
- (4) According to that opinion, biocidal products of product-type 6 containing 2-methyl-1,2-benzisothiazol-3(2H)-one may be expected to satisfy the criteria of Article 19(1)(b) of Regulation (EU) No 528/2012, provided that certain specifications and conditions concerning their use are complied with.
- (5) It is therefore appropriate to approve 2-methyl-1,2-benzisothiazol-3(2H)-one for use in biocidal products of product-type 6, subject to compliance with certain specifications and conditions.
- (6) Since 2-methyl-1,2-benzisothiazol-3(2H)-one meets the criteria for classification as a skin sensitiser sub-category 1A (strong sensitiser) as specified in point 3.4.2.2.1.2 of Annex I to Regulation (EC) No 1272/2008 of the European Parliament and of the Council ⁽³⁾, treated articles treated with or incorporating 2-methyl-1,2-benzisothiazol-3(2H)-one should be labelled appropriately when placed on the market.
- (7) A reasonable period should be allowed to elapse before an active substance is approved in order to permit interested parties to take the preparatory measures necessary to meet the new requirements.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS REGULATION:

Article 1

2-methyl-1,2-benzisothiazol-3(2H)-one is approved as an active substance for use in biocidal products of product-type 6, subject to the specifications and conditions set out in the Annex.

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.⁽²⁾ Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p. 1).⁽³⁾ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

Article 2

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

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

Done at Brussels, 14 December 2017.

For the Commission

The President

Jean-Claude JUNKER

ANNEX

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance ⁽¹⁾	Date of approval	Expiry date of approval	Product type	Specific conditions
2-methyl-1,2-benzisothiazol-3(2H)-one (MBIT)	IUPAC Name: 2-methyl-1,2-benzisothiazol-3(2H)-one EC No: Not available CAS No: 2527-66-4	≥ 997 g/kg	1 July 2018	30 June 2028	6	The authorisations of biocidal products are subject to the following conditions: (1) the product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any use covered by an application for authorisation, but not addressed in the Union-level risk assessment of the active substance; (2) in view of the risks identified for the uses assessed, the product assessment shall pay particular attention to: (a) professional users; (b) surface water and groundwater for the outdoor use of preserved paints and plasters and the use of preserved fluids used in paper, textile or leather production. The placing on the market of treated articles is subject to the following condition: The person responsible for the placing on the market of a treated article treated with or incorporating 2-methyl-1,2-benzisothiazol-3(2H)-one shall ensure that the label of that treated article provides the information listed in the second subparagraph of Article 58(3) of Regulation (EU) No 528/2012.

⁽¹⁾ The purity indicated in this column was the minimum degree of purity of the active substance evaluated. The active substance in the product placed on the market can be of equal or different purity if it has been proven to be technically equivalent to the evaluated active substance.

COMMISSION IMPLEMENTING REGULATION (EU) 2017/2328**of 14 December 2017****conferring protection under Article 99 of Regulation (EU) No 1308/2013 of the European Parliament and of the Council on the name ‘Skalický rubín’ (PDO)**

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 99 thereof,

Whereas:

- (1) In accordance with Article 97(2) and (3) of Regulation (EU) No 1308/2013, the Commission has examined the application to register the name ‘Skalický rubín’ sent by Slovakia and has published it in the *Official Journal of the European Union* ⁽²⁾.
- (2) No statement of objection has been received by the Commission under Article 98 of Regulation (EU) No 1308/2013.
- (3) In accordance with Article 99 of Regulation (EU) No 1308/2013, the name ‘Skalický rubín’ should be protected and entered in the register referred to in Article 104 of that Regulation.
- (4) The measures provided for in this Regulation are in accordance with the opinion of the Committee for the Common Organisation of the Agricultural Markets,

HAS ADOPTED THIS REGULATION:

Article 1

The name ‘Skalický rubín’ (PDO) is hereby protected.

*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, 14 December 2017.

*For the Commission**The President*

Jean-Claude JUNCKER

⁽¹⁾ OJ L 347, 20.12.2013, p. 671.⁽²⁾ OJ C 224, 13.7.2017, p. 9.

COMMISSION IMPLEMENTING REGULATION (EU) 2017/2329**of 14 December 2017****amending and correcting Regulation (EC) No 1235/2008 laying down detailed rules for implementation of Council Regulation (EC) No 834/2007 as regards the arrangements for imports of organic products from third countries****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91 ⁽¹⁾, and in particular Article 33(2) and (3) and Article 38(d) thereof,

Whereas:

- (1) Annex III to Commission Regulation (EC) No 1235/2008 ⁽²⁾ sets out the list of third countries whose systems of production and control measures for organic production of agricultural products are recognised as equivalent to those laid down in Regulation (EC) No 834/2007.
- (2) According to information provided by Costa Rica, the names of the control bodies 'Kiwa BCS Öko-Garantie GmbH', 'Control Union Certifications' and 'Primus lab' have been changed to 'Kiwa BCS Costa Rica Limitada', 'Control Union Perú' and 'PrimusLabs.com CR S.A.' respectively. Costa Rica has also informed the Commission that the 'Servicio Fitosanitario del Estado, Ministerio de Agricultura y Ganadería' is no longer a control body and that the other control bodies are the certification issuing bodies, and not the Ministry of Agriculture.
- (3) Japan has informed the Commission that its competent authority has added two control bodies, namely Japan Food Research Laboratories and Leafearth Company, to the list of control bodies recognised by Japan and that the names of 'Bureau Veritas Japan, Inc.' and 'Hyogo prefectural Organic Agriculture Society (HOAS)' and the internet address of 'Organic Certification Association' have changed.
- (4) According to information provided by New Zealand, the internet address of the competent authority has changed.
- (5) The Republic of Korea has informed the Commission that its competent authority has added the control body 'Industry-Academic Cooperation Foundation, SCNU' to the list of control bodies recognised by the Republic of Korea.
- (6) The duration of the inclusion of the Republic of Korea in the list in Annex III to Regulation (EC) No 1235/2008 ends on 31 January 2018. Given that the Republic of Korea continues to satisfy the conditions laid down in Article 33(2) of Regulation (EC) No 834/2007, the inclusion should be prolonged for an unspecified period.
- (7) Annex IV to Regulation (EC) No 1235/2008 sets out the list of control authorities and control bodies competent to carry out controls and issue certificates in third countries for the purpose of equivalence.
- (8) The duration of the recognition in accordance with Article 33(3) of Regulation (EC) No 834/2007 of the control bodies listed in Annex IV to Regulation (EC) No 1235/2008 ends on 30 June 2018. Based on the results of the continuous supervision carried out by the Commission, the recognition of those control bodies should be extended until 30 June 2021.
- (9) 'Albinspekt' has notified the Commission of the change of its address.

⁽¹⁾ OJ L 189, 20.7.2007, p. 1.

⁽²⁾ Commission Regulation (EC) No 1235/2008 of 8 December 2008 laying down detailed rules for implementation of Council Regulation (EC) No 834/2007 as regards the arrangements for imports of organic products from third countries (OJ L 334, 12.12.2008, p. 25).

- (10) The Commission has received and examined a request from 'BAŞAK Ekolojik Ürünler Kontrol ve Sertifikasyon Hizmetleri Tic. Ltd' to be included in the list in Annex IV to Regulation (EC) No 1235/2008. Based on the information received, the Commission has concluded that it is justified to recognise 'BAŞAK Ekolojik Ürünler Kontrol ve Sertifikasyon Hizmetleri Tic. Ltd' for product categories A and D in respect of Turkey.
- (11) The Commission has received and examined a request from 'BIOCert Indonesia' to be included in the list in Annex IV to Regulation (EC) No 1235/2008. Based on the information received, the Commission has concluded that it is justified to recognise 'BIOCert Indonesia' for Indonesia for product categories A and D.
- (12) The Commission has received and examined a request from 'bio.inspecta AG' to amend its specifications. Based on the information received, the Commission has concluded that it is justified to extend the geographical scope of its recognition for product categories A and D to Afghanistan, China and Nepal.
- (13) The entry of 'Bolicert Ltd' in the list set out in Annex IV to Regulation (EC) No 1235/2008 was suspended by Implementing Regulation (EU) 2017/1473 ⁽¹⁾. In order to lift the temporary suspension, the Commission invited 'Bolicert Ltd' to provide a valid accreditation certificate from IOAS (the accreditation organisation of 'Bolicert Ltd') and to take appropriate and timely remedial action in accordance with the requirements of Regulation (EC) No 834/2007. IOAS has informed the Commission that it has decided to lift the suspension because it had received satisfactory information on corrective actions by 'Bolicert Ltd'. Based on that information, the Commission has concluded that it is justified to include 'Bolicert Ltd' in Annex IV again under the same conditions as before the suspension.
- (14) The Commission has received and examined a request from 'CCPB Srl' to amend its specifications. Based on the information received, the Commission has concluded that it is justified to extend the geographical scope of its recognition for product categories A, B, D, E and F to Albania, Algeria, the United Arab Emirates and South Africa, for product category A to Uganda, for product categories A and D to Afghanistan, Armenia, Ethiopia, Ghana, Nigeria, Senegal and Uzbekistan, for product categories A, D and E to Belarus, Kazakhstan, Moldova, Russia, Serbia, Thailand, Tajikistan and Turkmenistan, for product categories A, B, D and E to Azerbaijan, Kyrgyzstan and Ukraine, for products categories A, B and D to Qatar and for product category D to Tunisia.
- (15) The Commission has received and examined a request from 'Control Union Certifications' to amend its specifications. Based on the information received, the Commission has concluded that it is justified to extend the geographical scope of its recognition for product categories A, B, C, D, E and F to Brunei, Cook Islands, French Polynesia, Georgia, Grenada, Guyana, Jordan, Kuwait, Lebanon, Papua New Guinea, Sao Tome and Principe, Seychelles, Tajikistan, Turkmenistan and Venezuela, for product categories B, C, D (only wine) and E to Australia, for product categories C and E to New Zealand, for product category B to Tonga and Tunisia and for product category F to Tuvalu.
- (16) The Commission has received and examined a request from 'Ecocert SA' to amend its specifications. Based on the information received, the Commission has concluded that it is justified to extend the geographical scope of its recognition for product categories D (wine) and E to Argentina, to extend the recognition for Japan, Kyrgyzstan and Zimbabwe to product category B, the recognition for Georgia and Mozambique to product category E, and the recognition for Paraguay and Uruguay to product category F.
- (17) The Commission has received and examined a request from 'Florida Certified Organic Growers and Consumers, Inc. (FOG), DBA as Quality Certification Services (QCS)' to amend its specifications. Based on the information received, the Commission has concluded that it is justified to extend the geographical scope of its recognition for product categories A and D to Bolivia, Colombia and Laos, for product categories A, C, D and E to Chile, for product category D to Costa Rica and for product categories C and D (processed aquaculture products) to the United States.
- (18) 'IMOswiss AG' has informed the Commission that it will cease its certification activities in all third countries for which it is recognised as of 1 January 2018 and should no longer be listed in Annex IV to Regulation (EC) No 1235/2008 as from that date.
- (19) 'Kiwa BCS Öko-Garantie GmbH' has notified the Commission of the change of its internet address.

⁽¹⁾ Commission Implementing Regulation (EU) 2017/1473 of 14 August 2017 amending Regulation (EC) No 1235/2008 laying down detailed rules for implementation of Council Regulation (EC) No 834/2007 as regards the arrangements for imports of organic products from third countries (OJ L 210, 15.8.2017, p. 4).

- (20) The Commission has received and examined a request from 'Letis S.A' to amend its specifications. Based on the information received, the Commission has concluded that it is justified to extend the geographical scope of its recognition for product categories A and D to Afghanistan, Ethiopia, Iran, Kazakhstan, Moldova, Pakistan, Russia, Tajikistan, Turkey and Ukraine.
- (21) 'Organic agriculture certification Thailand' has notified the Commission of the change of its name to 'Organic Agriculture Certification Thailand (ACT)' and of the change of its address.
- (22) The Commission has received and examined a request from 'Organic Control System' to amend its specifications. Based on the information received, the Commission has concluded that it is justified to extend the geographical scope of its recognition for product categories A and D to Bosnia and Herzegovina.
- (23) The Commission has received and examined a request from 'Organic Standard' to amend its specifications. Based on the information received, the Commission has concluded that it is justified to extend the recognition for Kazakhstan, Kyrgyzstan, Moldova and Russia to product category B and to extend its recognition to wine.
- (24) The Commission has received and examined a request from 'Organska Kontrola' to amend its specifications. Based on the information received, the Commission has concluded that it is justified to extend the geographical scope of its recognition for product categories A, B and D to Kosovo ⁽¹⁾.
- (25) The Commission has received and examined a request from 'ORSER' to amend its specifications. Based on the information received, the Commission has concluded that it is justified to extend the geographical scope of its recognition for product categories A and D to Azerbaijan, Bosnia and Herzegovina, Georgia, Iran, Kazakhstan, Kyrgyzstan and Nepal.
- (26) The Commission has received and examined a request from 'Servicio de Certificación CAAE S.L.U.' to be included in the list in Annex IV to Regulation (EC) No 1235/2008. Based on the information received, the Commission has concluded that it is justified to recognise 'Servicio de Certificación CAAE S.L.U.' for product categories A and D in respect of Bolivia, Ecuador, Mexico, Morocco, Peru and Turkey.
- (27) The Commission has received and examined a request from 'Tse-Xin Organic Certification Corporation' to be included in the list in Annex IV to Regulation (EC) No 1235/2008. Based on the information received, the Commission has concluded that it is justified to recognise 'Tse-Xin Organic Certification Corporation' for product categories A and D in respect of Taiwan.
- (28) The DAkkS, an accreditation organisation in the field of organic agriculture, has informed the Commission that it has decided to suspend its accreditation of 'Egyptian Center of Organic Agriculture (ECOAG)'. Pursuant to Article 12(1)(c) of Regulation (EC) No 1235/2008, the Commission may at any time suspend the entry of a control body from the list in Annex IV to that Regulation, either in the light of the information received or where the control body has not supplied information required. 'Egyptian Center of Organic Agriculture (ECOAG)' was invited by the Commission to provide a valid accreditation certificate and to take appropriate and timely remedial action in accordance with the requirements of Regulation (EC) No 834/2007, but did not reply satisfactorily within the deadline set. The entry of 'Egyptian Center of Organic Agriculture (ECOAG)' should therefore be suspended in Annex IV to Regulation (EC) No 1235/2008 until satisfactory information is provided.
- (29) Annex IV to Regulation (EC) No 1235/2008 as amended by Implementing Regulation (EU) 2017/872 (*) lists 'IMOcert Latinoamérica Ltda' as a recognised control body for product categories A and B in respect of Argentina and for product category A in respect of Costa Rica. Since Argentina and Costa Rica are listed in Annex III to Regulation (EC) No 1235/2008 for product categories A and B and for product category A, respectively, 'IMOcert Latinoamérica Ltda' could not have been recognised for those countries for those product categories in Annex IV to Regulation (EC) No 1235/2008 in accordance with Article 10(2)(b) of Regulation (EC) No 1235/2008. The recognition for those product categories in respect of those countries should therefore be deleted. 'IMOcert Latinoamérica Ltda' had been invited by the Commission not to certify products falling within those product categories on the basis of the erroneous reference to those product categories in respect of Argentina and Costa Rica.

⁽¹⁾ Commission Implementing Regulation (EU) 2017/872 of 22 May 2017 amending Regulation (EC) No 1235/2008 laying down detailed rules for implementation of Council Regulation (EC) No 834/2007 as regards the arrangements for imports of organic products from third countries (OJ L 134, 23.5.2017, p. 6).

(*) This designation is without prejudice to positions on status, and is in line with UNSCR 1244/1999 and the ICJ Opinion on the Kosovo declaration of independence.

- (30) Annex V to Regulation (EC) No 1235/2008 as amended by Implementing Regulation (EU) 2016/1842 ⁽¹⁾ contains the new model of the certificate of inspection for import of organic products under the electronic certification system, to which reference is made in Article 13(2) of Regulation (EC) No 1235/2008. In this Annex, the note corresponding to box 12 of the certificate erroneously refers to box 24 instead of box 21. This error should be corrected.
- (31) Annexes III, IV and V to Regulation (EC) No 1235/2008 should therefore be amended and corrected accordingly.
- (32) The deletion of 'IMOCert Latinoamérica Ltda' should apply retroactively from the date of entry into force of Implementing Regulation (EU) 2017/872 and the deletion of 'IMOSwiss AG' should apply from 1 January 2018.
- (33) The measures provided for in this Regulation are in accordance with the opinion of the Committee on organic production,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 1235/2008 is amended as follows:

- (1) Annex III is amended in accordance with Annex I to this Regulation;
- (2) Annex IV is amended and corrected in accordance with Annex II to this Regulation;
- (3) Annex V is corrected in accordance with Annex III 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*.

Point (12) of Annex II shall apply from 12 June 2017.

Point (13) of Annex II shall apply from 1 January 2018.

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

Done at Brussels, 14 December 2017.

For the Commission
The President
Jean-Claude JUNCKER

⁽¹⁾ Commission Implementing Regulation (EU) 2016/1842 of 14 October 2016 amending Regulation (EC) No 1235/2008 as regards the electronic certificate of inspection for imported organic products and certain other elements, and Regulation (EC) No 889/2008 as regards the requirements for preserved or processed organic products and the transmission of information (OJ L 282, 19.10.2016, p. 19).

ANNEX I

Annex III to Regulation (EC) No 1235/2008 is amended as follows:

(1) The entry relating to **Costa Rica** is amended as follows:

(a) in point 5, the row relating to code number CR-BIO-001 is deleted and the rows relating to code numbers CR-BIO-002, CR-BIO-004 and CR-BIO-006 are replaced by the following:

CR-BIO-002	Kiwa BCS Costa Rica Limitada	www.kiwa.lat
CR-BIO-004	Control Union Perú	www.cuperu.com
CR-BIO-006	PrimusLabs.com CR S.A.	www.primusauditingops.com

(b) point 6 is replaced by the following:

‘6. Certificate issuing bodies: as at point 5.’

(2) In the entry relating to **Japan**, point 5 is amended as follows

(a) the rows relating to code numbers JP-BIO-001, JP-BIO-007 and JP-BIO-018 are replaced by the following:

JP-BIO-001	Hyogo prefectural Organic Agriculture Society, HOAS	www.hyoyuken.org
JP-BIO-007	Bureau Veritas Japan Co., Ltd	http://certification.bureauveritas.jp/cer-business/jas/nintei_list.html
JP-BIO-018	Organic Certification Association	http://yuukinin.org/index.html

(b) the following rows are added:

JP-BIO-036	Japan Food Research Laboratories	http://www.jfrr.or.jp/jas.html
JP-BIO-037	Leafearth Company	http://www.leafearth.jp/

(3) In the entry relating to **New Zealand**, point 4 is replaced by the following:

‘4. Competent authority: Ministry for Primary Industries (MPI)

<http://www.mpi.govt.nz/exporting/food/organics/>’

(4) The entry relating to the **Republic of Korea** is amended as follows:

(a) in point 5, the following row is added:

KR-ORG-024	Industry-Academic Cooperation Foundation, SCNU	http://siacf.scnu.ac.kr/web/siacf/home
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(b) point 7 is replaced by the following:

‘7. **Duration of the inclusion:** unspecified.’

ANNEX II

Annex IV to Regulation (EC) No 1235/2008 is amended and corrected as follows:

- (1) Throughout the Annex, in point 5 of all entries, the date of '30 June 2018' is replaced by '30 June 2021'.
- (2) In the entry relating to '**Albinspekt**', point 1 is replaced by the following:
'1. Address: "Rr. Kavajes", Nd.132, Hy.9, Kati 8, Ap.43 (Perballe pallatit me shigjeta), Tirana, Albania'
- (3) After the entry relating to '**Balkan Biocert Skopje**', the following new entry is inserted:

"BAŞAK Ekolojik Ürünler Kontrol ve Sertifikasyon Hizmetleri Tic. Ltd"

1. Address: Atatürk Mahallesi 1014 Sokak No:9/5, 35920 Selçuk-ZMR, Turkey
2. Internet address: <http://basakekolojik.com.tr>
3. Code numbers, third countries and product categories concerned:

Code number	Third country	Category of products					
		A	B	C	D	E	F
TU-BIO-175	Turkey	x	—	—	x	—	—

4. Exceptions: in-conversion products and wine.
5. Duration of inclusion: until 30 June 2021.'
- (4) After the entry relating to '**Bioagricert S.r.l.**', the following new entry is inserted:

"BIOCert Indonesia"

1. Address: Jl. Perdana Raya Budi Agung Ruko A1 Cimanggu Residence, 16165 Bogor, Indonesia
2. Internet address: <http://www.biocert.co.id>
3. Code numbers, third countries and product categories concerned:

Code number	Third country	Category of products					
		A	B	C	D	E	F
ID-BIO-176	Indonesia	x	—	—	x	—	—

4. Exceptions: in-conversion products and wine.
5. Duration of inclusion: until 30 June 2021.'
- (5) In the entry relating to '**Bio.inspecta AG**', in point 3, the following rows are inserted in the order of the code numbers:

'AF-BIO-161	Afghanistan	x	—	—	x	—	—
CN-BIO-161	China	x	—	—	x	—	—
NP-BIO-161	Nepal	x	—	—	x	—	—'

(6) After the entry relating to '**Bio Latina Certificadora**', the following new entry is inserted:

“Bolicert Ltd”

1. Address: Street Colon 756, floor 2, office 2A, Edif. Valdivia Casilla 13030, La Paz, Bolivia

2. Internet address: <http://www.bolicert.org>

3. Code numbers, third countries and product categories concerned:

Code number	Third country	Category of products					
		A	B	C	D	E	F
BO-BIO-126	Bolivia	x	—	—	x	—	—

4. Exceptions: in-conversion products and wine.

5. Duration of inclusion: until 30 June 2021.'

(7) In the entry relating to '**CCPB Srl**':

(a) in point 3, the following rows are inserted in the order of the code numbers:

'AE-BIO-102	United Arab Emirates	x	x	—	x	x	x
AF-BIO-102	Afghanistan	x	—	—	x	—	—
AL-BIO-102	Albania	x	x	—	x	x	x
AM-BIO-102	Armenia	x	—	—	x	—	—
AZ-BIO-102	Azerbaijan	x	x	—	x	x	—
BY-BIO-102	Belarus	x	—	—	x	x	—
DZ-BIO-102	Algeria	x	x	—	x	x	x
ET-BIO-102	Ethiopia	x	—	—	x	—	—
GH-BIO-102	Ghana	x	—	—	x	—	—
KG-BIO-102	Kyrgyzstan	x	x	—	x	x	—
KZ-BIO-102	Kazakhstan	x	—	—	x	x	—
MD-BIO-102	Moldova	x	—	—	x	x	—
NG-BIO-102	Nigeria	x	—	—	x	—	—
QA-BIO-102	Qatar	x	x	—	x	—	—
RS-BIO-102	Serbia	x	—	—	x	x	—
RU-BIO-102	Russia	x	—	—	x	x	—
SN-BIO-102	Senegal	x	—	—	x	—	—
TH-BIO-102	Thailand	x	—	—	x	x	—
TJ-BIO-102	Tajikistan	x	—	—	x	x	—
TM-BIO-102	Turkmenistan	x	—	—	x	x	—

UA-BIO-102	Ukraine	x	x	—	x	x	—
UG-BIO-102	Uganda	x	—	—	—	—	—
UZ-BIO-102	Uzbekistan	x	—	—	x	—	—
ZA-BIO-102	South Africa	x	x	—	x	x	x'

(b) in the row concerning Tunisia, a cross is added in column D;

(c) point 4 is replaced by the following:

‘4. Exceptions: in-conversion products and products covered by Annex III.’

(8) The entry relating to ‘**Control Union Certifications**’ is amended as follows:

(a) in point 3, the following rows are inserted in the order of the code numbers:

‘AU-BIO-149	Australia	—	x	x	x	x	—
BN-BIO-149	Brunei	x	x	x	x	x	x
CK-BIO-149	Cook Islands	x	x	x	x	x	x
GD-BIO-149	Grenada	x	x	x	x	x	x
GE-BIO-149	Georgia	x	x	x	x	x	x
GY-BIO-149	Guyana	x	x	x	x	x	x
JO-BIO-149	Jordan	x	x	x	x	x	x
KW-BIO-149	Kuwait	x	x	x	x	x	x
LB-BIO-149	Lebanon	x	x	x	x	x	x
NZ-BIO-149	New Zealand	—	—	x	—	x	—
PF-BIO-149	French Polynesia	x	x	x	x	x	x
PG-BIO-149	Papua New Guinea	x	x	x	x	x	x
SC-BIO-149	Seychelles	x	x	x	x	x	x
ST-BIO-149	Sao Tome and Principe	x	x	x	x	x	x
TJ-BIO-149	Tajikistan	x	x	x	x	x	x
TM-BIO-149	Turkmenistan	x	x	x	x	x	x
TN-BIO-149	Tunisia	—	x	—	—	—	—
TO-BIO-149	Tonga	—	x	—	—	—	—
TV-BIO-149	Tuvalu	—	—	—	—	—	x
VE-BIO-149	Venezuela	x	x	x	x	x	x'

(b) point 4 is replaced by the following:

‘4. Exceptions: in-conversion products and products covered by Annex III.’

(9) In the entry relating to '**Ecocert SA**', point 3 is amended as follows:

(a) the following row is inserted in the order of the code numbers:

'AR-BIO-154	Argentina	—	—	—	x	x	—'
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(b) in the rows concerning Georgia and Mozambique, a cross is added in column E;

(c) in the rows concerning Japan, Kyrgyzstan and Zimbabwe, a cross is added in column B;

(d) in the rows concerning Paraguay and Uruguay, a cross is added in column F.

(10) The entry relating to '**Florida Certified Organic Growers and Consumers, Inc. (FOG), DBA as Quality Certification Services (QCS)**' is amended as follows:

(a) in point 3, the following rows are inserted in the order of the code numbers:

'BO-BIO-144	Bolivia	x	—	—	x	—	—
CL-BIO-144	Chile	x	—	x	x	x	—
CO-BIO-144	Colombia	x	—	—	x	—	—
CR-BIO-144	Costa Rica	—	—	—	—	x	—
LA-BIO-144	Laos	x	—	—	x	—	—
US-BIO-144	United States	—	—	x	x	—	—'

(b) point 4 is replaced by the following:

'4. Exceptions: in-conversion products, wine and products covered by Annex III.'

(11) The entry relating to the 'Egyptian Center of Organic Agriculture (ECOAG)' is deleted.

(12) In the entry relating to '**IMOCert Latinoamérica Ltda.**', in point 3, the rows relating to Argentina and Costa Rica are replaced by the following:

'AR-BIO-123	Argentina	—	—	—	x	—	—
CR-BIO-123	Costa Rica	—	x	—	x	—	—'

(13) The entry relating to '**IMOSwiss AG**' is deleted.

(14) In the entry relating to '**Kiwa BCS Öko-Garantie GmbH**', point 2 is replaced by the following:

'2. Internet address: www.kiwabcs-oeko.com'

(15) In the entry relating to '**Letis S.A.**', in point 3, the following rows are inserted in the order of the code numbers:

'AF-BIO-135	Afghanistan	x	—		x	—	—
ET-BIO-135	Ethiopia	x	—		x	—	—
IR-BIO-135	Iran	x	—		x	—	—
KZ-BIO-135	Kazakhstan	x	—		x	—	—

MD-BIO-135	Moldova	x	—		x	—	—
PK-BIO-135	Pakistan	x	—		x	—	—
RU-BIO-135	Russia	x	—		x	—	—
TJ-BIO-135	Tajikistan	x	—		x	—	—
TR-BIO-135	Turkey	x	—		x	—	—
UA-BIO-135	Ukraine	x	—		x	—	—'

(16) The entry relating to '**Organic agriculture certification Thailand**', is amended as follows:

(a) the name is replaced by the following:

'Organic Agriculture Certification Thailand (ACT)'

(b) point 1 is replaced by the following:

'1. Address: 102 Moo 2, Soi Ngamwongwan 23, Ngamwongwan Road, Muang District, Nonthaburi 11000, Thailand'

(17) In the entry relating to '**Organic Control System**', in point 3, the following row is inserted in the order of the code numbers:

'BA-BIO-162	Bosnia and Herzegovina	x	—	—	x	—	—'
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(18) The entry relating to '**Organic Standard**' is amended as follows:

(a) in point 3, in the rows concerning Kyrgyzstan, Kazakhstan, Moldova and Russia, a cross is added in column B;

(b) point 4 is replaced by the following:

'4. Exceptions: in-conversion products.'

(19) In the entry relating to '**Organska Kontrola**', in point 3, the following row is inserted in the order of the code numbers:

'XK-BIO-101	Kosovo (*)	x	x	—	x	—	—
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(*) This designation is without prejudice to positions on status, and is in line with UNSCR 1244/1999 and the ICJ Opinion on the Kosovo declaration of independence.'

(20) In the entry relating to '**ORSER**', in point 3, the following rows are inserted in the order of the code numbers:

'AZ-BIO-166	Azerbaijan	x	—	—	x	—	—
BA-BIO-166	Bosnia and Herzegovina	x	—	—	x	—	—
GE-BIO-166	Georgia	x	—	—	x	—	—
IR-BIO-166	Iran	x	—	—	x	—	—
KG-BIO-166	Kyrgyzstan	x	—	—	x	—	—
KZ-BIO-166	Kazakhstan	x	—	—	x	—	—
NP-BIO-166	Nepal	x	—	—	x	—	—'

(21) After the entry relating to ‘**Quality Partner**’, the following new entry is inserted:

“Servicio de Certificación CAAE S.L.U.”

1. Address: Avenida Emilio Lemos, 2 mod. 603, 41020 Seville, Spain
2. Internet address: <http://www.caae.es>
3. Code numbers, third countries and product categories concerned:

Code number	Third country	Category of products					
		A	B	C	D	E	F
BO-BIO-178	Bolivia	x	—	—	x	—	—
EC-BIO-178	Ecuador	x	—	—	x	—	—
MA-BIO-178	Morocco	x	—	—	x	—	—
MX-BIO-178	Mexico	x	—	—	x	—	—
PE-BIO-178	Peru	x	—	—	x	—	—
TR-BIO-178	Turkey	x	—	—	x	—	—

4. Exceptions: in-conversion products.
5. Duration of inclusion: until 30 June 2021.’

(22) After the entry relating to ‘**Suolo e Salute srl**’, the following new entry is inserted:

“Tse-Xin Organic Certification Corporation”

1. Address: 7F., No 75, Sec.4, Nanjing E. R., Songshan Dist., Taipei City 105, Taiwan (R.O.C.)
2. Internet address: <http://www.tw-toc.com/en>
3. Code numbers, third countries and product categories concerned:

Code number	Third country	Category of products					
		A	B	C	D	E	F
TW-BIO-174	Taiwan	x	—	—	x	—	—

4. Exceptions: in-conversion products and wine.
5. Duration of inclusion: until 30 June 2021.’

ANNEX III

In Annex V to Regulation (EC) No 1235/2008, in the note relating to box 12, the reference to 'box 24' is replaced by 'box 21'.

COMMISSION IMPLEMENTING REGULATION (EU) 2017/2330**of 14 December 2017**

concerning the authorisation of Iron(II) carbonate, Iron(III) chloride hexahydrate, Iron(II) sulphate monohydrate, Iron(II) sulphate heptahydrate, Iron(II) fumarate, Iron(II) chelate of amino acids hydrate, Iron(II) chelate of protein hydrolysates and Iron(II) chelate of glycine hydrate as feed additives for all animal species and of Iron dextran as feed additive for piglets and amending Regulations (EC) No 1334/2003 and (EC) No 479/2006

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ⁽¹⁾, and in particular Article 9(2) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC ⁽²⁾.
- (2) The iron compounds Ferric chloride hexahydrate, Ferric oxide, Ferrous carbonate, Ferrous chelate of amino acids hydrate, Ferrous chelate of glycine hydrate, Ferrous fumarate, Ferrous sulphate heptahydrate and Ferrous sulphate monohydrate were authorised without a time limit by Commission Regulation (EC) No 1334/2003 ⁽³⁾ and Commission Regulation (EC) No 479/2006 ⁽⁴⁾ in accordance with Directive 70/524/EEC. Those substances were subsequently entered in the Register of feed additives as existing products, in accordance with Article 10(1) of Regulation (EC) No 1831/2003.
- (3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, applications were submitted for the re-evaluation of Ferric chloride hexahydrate, Ferric oxide, Ferrous carbonate, Ferrous chelate of amino acids hydrate, Ferrous chelate of glycine hydrate, Ferrous fumarate, Ferrous sulphate heptahydrate and Ferrous sulphate monohydrate as feed additives for all animal species. Additionally, in accordance with Article 7 of that Regulation, an application was submitted for Iron dextran as feed additive for piglets. The applicants requested that those additives be classified in the additive category 'nutritional additives'. The applications were accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (4) Due to scientific considerations, the European Food Safety Authority ('the Authority') recommended in its opinions of 19 June 2013 ⁽⁵⁾, 30 January 2014 ⁽⁶⁾, 5 March 2014 ⁽⁷⁾, 28 April 2014 ⁽⁸⁾ and 27 January 2016 ⁽⁹⁾ to rename Ferric as Iron(III) and Ferrous as Iron(II), in order to avoid potential misunderstandings. The Authority also recommended splitting Iron(II) chelate of amino acids into the following two groups, in view of its chemical characteristics: Iron(II) chelate of amino acids hydrate and Iron(II) chelate of protein hydrolysates.
- (5) The Authority concluded that, under the proposed conditions of use, Iron(II) carbonate, Iron(III) chloride hexahydrate, Iron(II) sulphate monohydrate, Iron(II) sulphate heptahydrate, Iron(II) fumarate, Iron(II) chelate of amino acids hydrate, Iron(II) chelate of protein hydrolysates and Iron(II) chelate of glycine hydrate do not have an

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ Council Directive 70/524/EEC of 23 November 1970 concerning additives in feeding-stuffs (OJ L 270, 14.12.1970, p. 1).

⁽³⁾ Commission Regulation (EC) No 1334/2003 of 25 July 2003 amending the conditions for authorisation of a number of additives in feedingstuffs belonging to the group of trace elements (OJ L 187, 26.7.2003, p. 11).

⁽⁴⁾ Commission Regulation (EC) No 479/2006 of 23 March 2006 as regards the authorisation of certain additives belonging to the group compounds of trace elements (OJ L 86, 24.3.2006, p. 4).

⁽⁵⁾ EFSA Journal 2013;11(7):3287.

⁽⁶⁾ EFSA Journal 2014;12(2):3566.

⁽⁷⁾ EFSA Journal 2014;12(3):3607.

⁽⁸⁾ EFSA Journal 2015;13(5):4109.

⁽⁹⁾ EFSA Journal 2016;14(2):4396.

adverse effect on animal health, consumer safety and the environment. Considering the capacities to be respiratory, eye and skin irritants due to the presence of Nickel in each iron (II) and iron (III) compound, appropriate protective measures should be taken with respect to the handling of the additives concerned and premixtures containing them, in order to avoid that safety concerns for the users would arise.

- (6) In its opinions of 24 January 2017 ⁽¹⁾, the Authority concluded that, under the proposed conditions of use, Iron dextran does not have an adverse effect on animal health, consumer safety and the environment, and that no safety concerns for users would arise provided that appropriate protective measures are taken.
- (7) The Authority further concluded that Iron(II) carbonate, Iron(III) chloride hexahydrate, Iron(II) sulphate monohydrate, Iron(II) sulphate heptahydrate, Iron(II) fumarate, Iron(II) chelate of amino acids hydrate, Iron(II) chelate of protein hydrolysates, Iron(II) chelate of glycine hydrate and Iron dextran are effective sources of iron; however, the bioavailability of Iron(II) carbonate varies significantly and is considered to be lower than that for Iron(II) sulphate. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the reports on the method of analysis of the feed additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (8) The assessment of Iron(II) carbonate, Iron(III) chloride hexahydrate, Iron(II) sulphate monohydrate, Iron(II) sulphate heptahydrate, Iron(II) fumarate, Iron(II) chelate of amino acids hydrate, Iron(II) chelate of protein hydrolysates and Iron(II) chelate of glycine hydrate as feed additives for all animal species and of Iron dextran for piglets shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied, except for water for drinking. Accordingly, the use of these substances should be authorised as specified in the Annex to this Regulation and their use via water for drinking should be prohibited.
- (9) As a result of the granting new authorisations for 'Ferric chloride hexahydrate', 'Ferrous carbonate', 'Ferrous chelate of amino acids hydrate', 'Ferrous fumarate', 'Ferrous sulphate heptahydrate', 'Ferrous sulphate monohydrate' and 'Ferrous chelate of glycine, hydrate' by this Regulation and of the denial of the authorisation for 'Ferric oxide', the entries of these substances in Regulations (EC) No 479/2006 and (EC) No 1334/2003 should be deleted.
- (10) As the Authority could not conclude in its opinions of 24 May 2016 ⁽²⁾ on the safety of ferric oxide for the target species, the additive and feed containing it should be withdrawn from the market as soon as possible. For practical reasons, however, a limited transitional period should be allowed for the withdrawal from the market of the products concerned in order to enable operators to comply properly with the withdrawal obligation.
- (11) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation for Ferric chloride hexahydrate, Ferrous carbonate, Ferrous chelate of amino acids hydrate, Ferrous chelate of glycine hydrate, Ferrous fumarate, Ferrous sulphate heptahydrate and Ferrous sulphate monohydrate as authorised by Regulation (EC) No 1334/2003 and Regulation (EC) No 479/2006, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.
- (12) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Authorisation

The substances specified in the Annex, belonging to the additive category 'nutritional additives' and to the functional group 'compounds of trace elements', are authorised as feed additives in animal nutrition, subject to the conditions laid down in that Annex.

⁽¹⁾ EFSA Journal 2017;15(2):4701.

⁽²⁾ EFSA Journal 2016;14(6):4508.

*Article 2***Special conditions of use**

The authorised substances specified in the Annex as additives belonging to the additive category 'nutritional additives' and to the functional group 'compounds of trace elements' shall not be used in water for drinking.

*Article 3***Denial**

The authorisation for ferric oxide is hereby denied and the substance shall no longer be used as nutritional feed additive.

*Article 4***Amendment to Regulation (EC) No 1334/2003**

In the Annex to Regulation (EC) No 1334/2003, from the entry E1 on the element Iron-Fe the following additives, their chemical formulas and descriptions are deleted: 'Ferric chloride hexahydrate', 'Ferrous carbonate', 'Ferrous chelate of amino acids hydrate', 'Ferrous fumarate', 'Ferrous sulphate heptahydrate', 'Ferrous sulphate monohydrate' and 'Ferric oxide'.

*Article 5***Amendment to Regulation (EC) No 479/2006**

In the Annex to Regulation (EC) No 479/2006, the entry E1 on the additive 'Ferrous chelate of glycine, hydrate' is deleted.

*Article 6***Transitional measures**

1. The substances 'Ferric chloride hexahydrate', 'Ferrous carbonate', 'Ferrous chelate of amino acids hydrate', 'Ferrous chelate of glycine hydrate', 'Ferrous fumarate', 'Ferrous sulphate heptahydrate', 'Ferric oxide' and 'Ferrous sulphate monohydrate' as authorised by Commission Regulation (EC) No 1334/2003 and Commission Regulation (EC) No 479/2006, and premixtures containing those substances, which are produced and labelled before 4 July 2018 in accordance with the rules applicable before 4 January 2018 may continue to be placed on the market and used until the existing stocks are exhausted.
2. Feed materials and compound feed containing the substances referred to in paragraph 1 which are produced and labelled before 4 January 2019 in accordance with the rules applicable before 4 January 2018 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.
3. Feed materials and compound feed containing the substances referred to in paragraph 1 which are produced and labelled before 4 January 2020 in accordance with the rules applicable before 4 January 2018 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for non-food-producing animals.

*Article 7***Entry into force**

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

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

Done at Brussels, 14 December 2017.

For the Commission

The President

Jean-Claude JUNKER

COMMISSION IMPLEMENTING REGULATION (EU) 2017/2331**of 14 December 2017****conferring protection under Article 99 of Regulation (EU) No 1308/2013 of the European Parliament and of the Council on the name 'La Clape' (PDO)**

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 99 thereof,

Whereas:

- (1) In accordance with Article 97(2) and (3) of Regulation (EU) No 1308/2013, the Commission has examined the application to register the name 'La Clape' sent by France and has published it in the *Official Journal of the European Union* ⁽²⁾.
- (2) No statement of objection has been received by the Commission under Article 98 of Regulation (EU) No 1308/2013.
- (3) In accordance with Article 99 of Regulation (EU) No 1308/2013, the name 'La Clape' should be protected and entered in the register referred to in Article 104 of that Regulation.
- (4) The measures provided for in this Regulation are in accordance with the opinion of the Committee for the Common Organisation of the Agricultural Markets,

HAS ADOPTED THIS REGULATION:

Article 1

The name 'La Clape' (PDO) is hereby protected.

*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, 14 December 2017.

*For the Commission**The President*

Jean-Claude JUNCKER

⁽¹⁾ OJ L 347, 20.12.2013, p. 671.⁽²⁾ OJ C 259, 9.8.2017, p. 3.

COMMISSION IMPLEMENTING REGULATION (EU) 2017/2332**of 14 December 2017****on the minimum selling price for skimmed milk powder for the 15th partial invitation to tender within the tendering procedure opened by Implementing Regulation (EU) 2016/2080**

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) 2016/1240 of 18 May 2016 laying down rules for the application of Regulation (EU) No 1308/2013 of the European Parliament and of the Council with regard to public intervention and aid for private storage ⁽²⁾, and in particular Article 32 thereof,

Whereas:

- (1) Commission Implementing Regulation (EU) 2016/2080 ⁽³⁾ has opened the sale of skimmed milk powder by a tendering procedure.
- (2) In the light of the tenders received for the 15th partial invitation to tender, a minimum selling price should not be fixed.
- (3) The measures provided for in this Regulation are in accordance with the opinion of the Committee for the Common Organisation of the Agricultural Markets,

HAS ADOPTED THIS REGULATION:

Article 1

For the 15th partial invitation to tender for the selling of skimmed milk powder within the tendering procedure opened by Implementing Regulation (EU) 2016/2080, in respect of which the period during which tenders were to be submitted ended on 12 December 2017, a minimum selling price has not been fixed.

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, 14 December 2017.

*For the Commission,
On behalf of the President,
Jerzy PLEWA*

*Director-General
Directorate-General for Agriculture and Rural Development*

⁽¹⁾ OJ L 347, 20.12.2013, p. 671.

⁽²⁾ OJ L 206, 30.7.2016, p. 71.

⁽³⁾ Commission Implementing Regulation (EU) 2016/2080 of 25 November 2016 opening the sale of skimmed milk powder by a tendering procedure (OJ L 321, 29.11.2016, p. 45).

DECISIONS

COMMISSION IMPLEMENTING DECISION (EU) 2017/2333

of 13 December 2017

determining quantitative limits and allocating quotas for substances controlled under Regulation (EC) No 1005/2009 of the European Parliament and of the Council on substances that deplete the ozone layer, for the period 1 January to 31 December 2018

(notified under document C(2017) 8317)

(Only the Croatian, Czech, Dutch, English, French, German, Greek, Italian, Latvian, Maltese, Polish, Portuguese, and Spanish texts are authentic)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer ⁽¹⁾, and in particular to Articles 10(2) and 16(1) thereof,

Whereas:

- (1) The release for free circulation in the Union of imported controlled substances is subject to quantitative limits.
- (2) The Commission is required to determine those limits and allocate quotas to undertakings.
- (3) Furthermore, the Commission is required to determine the quantities of controlled substances other than hydrochlorofluorocarbons that may be used for essential laboratory and analytical uses, and the companies that may use them.
- (4) The determination of the allocated quotas for essential laboratory and analytical uses has to ensure that the quantitative limits set out in Article 10(6) of Regulation (EC) No 1005/2009 are respected, applying Commission Regulation (EU) No 537/2011 ⁽²⁾. As those quantitative limits include quantities of hydrochlorofluorocarbons licensed for laboratory and analytical uses, the production and import of hydrochlorofluorocarbons for those uses should also be covered by that allocation.
- (5) The Commission has published a notice to undertakings intending to import or export controlled substances that deplete the ozone layer to or from the European Union in 2018 and to undertakings intending to produce or import these substances for laboratory and analytical uses ⁽³⁾ in 2018, and has thereby received declarations on intended imports in 2018.
- (6) The quantitative limits and quotas should be determined for the period 1 January to 31 December 2018, in line with the annual reporting cycle under the Montreal Protocol on Substances that Deplete the Ozone Layer.
- (7) The measures provided for in this Decision are in accordance with the opinion of the Committee established by Article 25(1) of Regulation (EC) No 1005/2009,

⁽¹⁾ OJ L 286, 31.10.2009, p. 1.

⁽²⁾ Commission Regulation (EU) No 537/2011 of 1 June 2011 on the mechanism for the allocation of quantities of controlled substances allowed for laboratory and analytical uses in the Union under Regulation (EC) No 1005/2009 of the European Parliament and of the Council on substances that deplete the ozone layer (OJ L 147, 2.6.2011, p. 4).

⁽³⁾ OJ C 43, 10.2.2017, p. 5.

HAS ADOPTED THIS DECISION:

Article 1

Quantitative limits for release for free circulation

The quantities of controlled substances subject to Regulation (EC) No 1005/2009 which may be released for free circulation in the Union in 2018 from sources outside the Union shall be the following:

Controlled substances	Quantity (in ozone-depleting potential (ODP) kilograms)
Group I (chlorofluorocarbons 11, 12, 113, 114 and 115) and group II (other fully halogenated chlorofluorocarbons)	2 616 350,00
Group III (halons)	18 566 550,00
Group IV (carbon tetrachloride)	22 330 561,00
Group V (1,1,1-trichloroethane)	1 700 000,00
Group VI (methyl bromide)	480 720,00
Group VII (hydrobromofluorocarbons)	4 630,35
Group VIII (hydrochlorofluorocarbons)	5 635 808,00
Group IX (bromochloromethane)	324 024,00

Article 2

Allocation of quotas for release for free circulation

1. The allocation of quotas for chlorofluorocarbons 11, 12, 113, 114 and 115 and other fully halogenated chlorofluorocarbons during the period 1 January to 31 December 2018 shall be for the purposes and to the undertakings indicated in Annex I.
2. The allocation of quotas for halons during the period 1 January to 31 December 2018 shall be for the purposes and to the undertakings indicated in Annex II.
3. The allocation of quotas for carbon tetrachloride during the period 1 January to 31 December 2018 shall be for the purposes and to the undertakings indicated in Annex III.
4. The allocation of quotas for 1,1,1-trichloroethane during the period 1 January to 31 December 2018 shall be for the purposes and to the undertakings indicated in Annex IV.
5. The allocation of quotas for methyl bromide during the period 1 January to 31 December 2018 shall be for the purposes and to the undertakings indicated in Annex V.
6. The allocation of quotas for hydrobromofluorocarbons during the period 1 January to 31 December 2018 shall be for the purposes and to the undertakings indicated in Annex VI.
7. The allocation of quotas for hydrochlorofluorocarbons during the period 1 January to 31 December 2018 shall be for the purposes and to the undertakings indicated in Annex VII.
8. The allocation of quotas for bromochloromethane during the period 1 January to 31 December 2018 shall be for the purposes and to the undertakings indicated in Annex VIII.
9. The individual quotas for undertakings shall be as set out in Annex IX.

*Article 3***Quotas for laboratory and analytical uses**

The quotas for importing and producing controlled substances for laboratory and analytical uses in the year 2018 shall be allocated to the undertakings listed in Annex X.

The maximum quantities that may be produced or imported in 2018 for laboratory and analytical uses allocated to those undertakings are set out in Annex XI.

*Article 4***Period of validity**

This Decision shall apply from 1 January 2018 and shall expire on 31 December 2018.

*Article 5***Addressees**

This Decision is addressed to the following undertakings:

1	2D Technologies Ltd Fletton Avenue Peterborough United Kingdom	2	Abcr GmbH Im Schleht 10 76187 Karlsruhe Germany
3	AGC Chemicals Europe, Ltd York House, Hillhouse International FY5 4QD Thornton Cleveleys United Kingdom	4	Albemarle Europe SPRL Parc Scientifique Einstein, Rue du Bosquet 9 B-1348 Louvain-la-Neuve Belgium
5	ARKEMA FRANCE Rue Estienne d'Orves 420 92705 COLOMBES Cedex France	6	ATELIERS BIGATA SASU RUE JEAN-BAPTISTE PERRIN 10 33320 EYSINES France
7	BASF Agri-Production S.A.S. Rue de Verdun 32 76410 Saint-Aubin Les Elbeuf France	8	Baxter S.A. Boulevard René Branquart 80 7860 Lessines Belgium
9	Bayer CropScience AG Alfred-Nobel-Str. 50 40789 Monheim Germany	10	Biovit d.o.o. Matka Laginje 13 HR-42000 Varazdin Croatia
11	Blue Cube Germany Assets GmbH & Co. KG Buetzflether Sand 2 21683 Stade Germany	12	Butterworth Laboratories Ltd Waldegrave Road 54-56 TW118NY LONDON United Kingdom
13	Ceram Optec SIA Skanstes street 7 K-1 LV-1013 Riga Latvia	14	Chemours Netherlands B.V. Baanhoekweg 22 3313LA Dordrecht Netherlands

15	Daikin Refrigerants Europe GmbH Industriepark Höchst 65926 Frankfurt am Main Germany	16	DIVERCHIM SA RUE DU NOYER, ZAC du Moulin 6 95700 Roissy en France France
17	Dyneon GmbH Industrieparkstr. 1 84508 Burgkirchen Germany	18	EAF protect s.r.o. Karlovarská 131/50 35002 Cheb 2 Czech Republic
19	ESTO Cheb s.r.o. Palackého 2087/8A 35002 Cheb Czech Republic	20	F-Select GmbH Grosshesseloherstr. 18 81479 Munich Germany
21	Fire Fighting Enterprises Ltd Hunting Gate 9 SG4 0TJ Hitchin United Kingdom	22	GHC Gerling, Holz & Co. Handels GmbH Ruhrstr. 113 22761 Hamburg Germany
23	GIELLE DI LUIGI GALANTUCCI VIA FERRI ROCCO 32 70022 ALTAMURA Italy	24	GlaxoSmithKline Cobden Street DD10 8EA Montrose United Kingdom
25	Halon & Refrigerant Services Ltd J Reid Trading Estate, Factory Road CH5 2QJ Sandycroft United Kingdom	26	Honeywell Fluorine Products Europe BV Laarderhoogtweg 18 1101 EA Amsterdam Netherlands
27	Honeywell Speciality Chemicals Seelze GmbH Wunstorfer Str. 40 30926 Seelze Germany	28	Hovione FarmaCiencia SA Quinta de S. Pedro — Sete Casas 2674-506 Loures Portugal
29	Hudson Technologies Europe S.r.l. Via delle Macere 20 00060 Formello Italy	30	ICL EUROPE COOPERATIEF U.A. Koningin Wilhelminaplein 30 1062 KR Amsterdam Netherlands
31	INTERGEO LTD INDUSTRIAL PARK OF THERMI 57001 THESSALONIKI Greece	32	Labmix24 GmbH Jonas-Elkan-Weg 4 46499 Hamminkeln Germany
33	LABORATORIOS MIRET S.A. Geminis 4 08228 Terrassa Spain	34	LGC Standards GmbH Mercatorstr. 51 46485 Wesel Germany
35	Ludwig-Maximilians-University Butenadtstr. 5-13 (HAUS D) DE-81377 Munich Germany	36	Lyontech Engineering Ltd Manor Industrial Estate 39 CH6 5UY Flint United Kingdom

37	Mebrom NV Antwerpsesteenweg 45 2830 Willebroek Belgium	38	Merck KGaA Frankfurter Strasse 250 64293 Darmstadt Germany
39	Meridian Technical Services Limited Hailey Road 14 DA18 4AP Erith United Kingdom	40	Mexichem UK Limited The Heath Business and Technical Park WA7 4QX Runcorn, Cheshire United Kingdom
41	Ministry of Defense — Chemical Laboratory — Den Helder Bevesierweg 4 1780CA Den Helder Netherlands	42	P.U. POZ-PLISZKA Sp. z o.o. Szczecinska 45 80-392 Gdansk Poland
43	PANREAC QUIMICA S.L.U. C/Garraf 2 E08210 Barcelona Spain	44	R.P. CHEM s.r.l. Via San Michele 47 31032 Casale sul Sile (TV) Italy
45	Rutherford Appleton Laboratory Chilton, Didcot, Oxon OX11 0QX Didcot United Kingdom	46	Savi Technologie sp. z o.o. Psary Wolnosci 20 51-180 Wroclaw Poland
47	SIGMA ALDRICH CHIMIE sarl Rue de Luzais 80 38070 SAINT QUENTIN FALLAVIER France	48	Sigma-Aldrich Chemie GmbH Riedstraße 2 89555 Steinheim Germany
49	SIGMA-ALDRICH COMPANY LTD The Old Brickyard, New Road SP8 4XT Gillingham, DORSET United Kingdom	50	Solvay Fluor GmbH Hans-Boeckler-Allee 20 30173 Hannover Germany
51	Solvay Specialty Polymers France SAS Avenue de la Republique 39501 Tavaux Cedex France	52	Solvay Specialty Polymers Italy SpA Viale Lombardia 20 20021 Bollate Italy
53	SPEX CertiPrep LTD Dalston Gardens 2 HA7 1BQ Stanmore United Kingdom	54	Sterling Chemical Malta Limited V. Dimech Street 4 1504 FLORIANA Malta
55	Sterling SpA Via della Carboneria 30 06073 Solomeo — Corciano (PG) Italy	56	Syngenta Limited Priestley Road Surrey Research Park 30 GU2 7YH Guildford United Kingdom
57	Tazzetti SAU Calle Roma 2 28813 Torres de la Alameda Spain	58	Tazzetti SpA Corso Europa 600/A 10088 Volpiano Italy

59	TEGA — Technische Gase und Gasetechnik GmbH Werner-von-Siemens-Str. 18 D-97076 Würzburg Germany	60	Thomas Swan & Co. Ltd Rotary Way DH8 7ND Consett County Durham United Kingdom
61	VALLISCOR EUROPA LIMITED 3rd Floor Kilmore House Park Lane Spencer Dock D01 YE64 Dublin 1 Ireland		

Done at Brussels, 13 December 2017.

For the Commission
Miguel ARIAS CAÑETE
Member of the Commission

ANNEX I

GROUPS I and II

Import quotas for chlorofluorocarbons 11, 12, 113, 114 and 115 and other fully halogenated chlorofluorocarbons allocated to importers in accordance with Regulation (EC) No 1005/2009 for feedstock uses and process agent uses during the period 1 January to 31 December 2018.

Company

Abcr GmbH (DE)

Honeywell Fluorine Products Europe BV (NL)

Solvay Specialty Polymers Italy SpA (IT)

Syngenta Limited (UK)

Tazzetti SAU (ES)

Tazzetti SpA (IT)

TEGA — Technische Gase und Gasetechnik GmbH (DE)

ANNEX II

GROUP III

Import quotas for halons allocated to importers in accordance with Regulation (EC) No 1005/2009 for feedstock uses and critical uses during the period 1 January to 31 December 2018.

Company

Abcr GmbH (DE)
ARKEMA FRANCE (FR)
ATELIERS BIGATA SASU (FR)
BASF Agri-Production S.A.S. (FR)
EAF protect s.r.o. (CZ)
ESTO Cheb s.r.o. (CZ)
Fire Fighting Enterprises Ltd (UK)
GIELLE DI LUIGI GALANTUCCI (IT)
Halon & Refrigerant Services Ltd (UK)
INTERGEO LTD (EL)
Lyontech Engineering Ltd (UK)
Meridian Technical Services Limited (UK)
P.U. POZ-PLISZKA Sp. z o.o. (PL)
Savi Technologie sp. z o.o. (PL)

ANNEX III

GROUP IV

Import quotas for carbon tetrachloride allocated to importers in accordance with Regulation (EC) No 1005/2009 for feedstock uses and process agent uses for the period 1 January to 31 December 2018.

Company

Abcr GmbH (DE)

ARKEMA FRANCE (FR)

Blue Cube Germany Assets GmbH & Co. KG (DE)

Ceram Optec SIA (LV)

ANNEX IV

GROUP V

Import quotas for 1,1,1-trichloroethane allocated to importers in accordance with Regulation (EC) No 1005/2009 for feedstock uses for the period 1 January to 31 December 2018.

Company

ARKEMA FRANCE (FR)

ANNEX V

GROUP VI

Import quotas for methyl bromide allocated to importers in accordance with Regulation (EC) No 1005/2009 for feedstock uses for the period 1 January to 31 December 2018.

Company

Abcr GmbH (DE)

GHC Gerling, Holz & Co. Handels GmbH (DE)

ICL EUROPE COOPERATIEF U.A. (NL)

Mebrom NV (BE)

Sigma-Aldrich Chemie GmbH (DE)

ANNEX VI

GROUP VII

Import quotas for hydrobromofluorocarbons allocated to importers in accordance with Regulation (EC) No 1005/2009 for feedstock uses for the period 1 January to 31 December 2018.

Company

Abcr GmbH (DE)

GlaxoSmithKline (UK)

Hovione FarmaCiencia SA (PT)

R.P. CHEM s.r.l. (IT)

Sterling Chemical Malta Limited (MT)

Sterling SpA (IT)

VALLISCOR EUROPA LIMITED (IE)

ANNEX VII

GROUP VIII

Import quotas for hydrochlorofluorocarbons allocated to importers in accordance with Regulation (EC) No 1005/2009 for feedstock uses for the period 1 January to 31 December 2018.

Company

Abcr GmbH (DE)
AGC Chemicals Europe, Ltd. (UK)
ARKEMA FRANCE (FR)
Bayer CropScience AG (DE)
Chemours Netherlands B.V. (NL)
Dyneon GmbH (DE)
Honeywell Fluorine Products Europe BV (NL)
Solvay Fluor GmbH (DE)
Solvay Specialty Polymers France SAS (FR)
Solvay Specialty Polymers Italy SpA (IT)
Tazzetti SAU (ES)
Tazzetti SpA (IT)

ANNEX VIII

GROUP IX

Import quotas for bromochloromethane allocated to importers in accordance with Regulation (EC) No 1005/2009 for feedstock uses for the period 1 January to 31 December 2018.

Company

Albemarle Europe SPRL (BE)
ICL EUROPE COOPERATIEF U.A. (NL)
LABORATORIOS MIRET S.A. (ES)
Sigma-Aldrich Chemie GmbH (DE)
Thomas Swan & Co. Ltd. (UK)
VALLISCOR EUROPA LIMITED (IE)

ANNEX IX

(Commercially sensitive — in confidence — not to be published)

ANNEX X

Undertakings entitled to produce or import for laboratory and analytical uses in 2018

The quota of controlled substances which may be used for laboratory and analytical uses, are allocated to:

Company

2D Technologies Ltd (UK)
Abcr GmbH (DE)
ARKEMA FRANCE (FR)
Baxter S.A. (BE)
Biovit d.o.o. (HR)
Butterworth Laboratories Ltd (UK)
Daikin Refrigerants Europe GmbH (DE)
DIVERCHIM SA (FR)
F-Select GmbH (DE)
Honeywell Fluorine Products Europe BV (NL)
Honeywell Speciality Chemicals Seelze GmbH (DE)
Hudson Technologies Europe S.r.l. (IT)
Labmix24 GmbH (DE)
LGC Standards GmbH (DE)
Ludwig-Maximilians-University (DE)
Merck KGaA (DE)
Mexichem UK Limited (UK)
Ministry of Defense — Chemical Laboratory — Den Helder (NL)
PANREAC QUIMICA S.L.U. (ES)
Rutherford Appleton Laboratory (UK)
SIGMA ALDRICH CHIMIE sarl (FR)
Sigma-Aldrich Chemie GmbH (DE)
SIGMA-ALDRICH COMPANY LTD (UK)
Solvay Fluor GmbH (DE)
Solvay Specialty Polymers France SAS (FR)
SPEX CertiPrep LTD (UK)
VALLISCOR EUROPA LIMITED (IE)

ANNEX XI

(Commercially sensitive — in confidence — not to be published)

COMMISSION IMPLEMENTING DECISION (EU) 2017/2334
of 14 December 2017
postponing the expiry date of approval of creosote for use in biocidal products of product-type 8
(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ⁽¹⁾, and in particular Article 14(5) thereof,

After consulting the Standing Committee on Biocidal Products,

Whereas:

- (1) The active substance creosote was included into Annex I to Directive 98/8/EC of the European Parliament and of the Council ⁽²⁾ for use in biocidal products for product-type 8, and pursuant to Article 86 of Regulation (EU) No 528/2012 is therefore considered approved under that Regulation subject to the specifications and conditions set out in Annex I to that Directive.
- (2) The approval of creosote will expire on 30 April 2018. In accordance with Article 13(1) of Regulation (EU) No 528/2012, an application has been submitted for the renewal of the approval of this active substance on 27 October 2016.
- (3) The United Kingdom, as the evaluating competent authority, has informed the Commission services on 14 July 2017 that a full evaluation will have to be performed. A 365-day period is allowed to perform a full evaluation pursuant to Article 14(2) of Regulation (EU) No 528/2012. During this evaluation, the evaluating competent authority may, as appropriate, request the applicant to provide sufficient data to carry out the evaluation, in accordance with Article 8(2) of that Regulation. In such case, the 365-day period is suspended for a period that may not exceed 180 days in total unless it is justified by the nature of the data requested or by exceptional circumstances.
- (4) Within 270 days of receipt of a recommendation from the evaluating competent authority, the European Chemicals Agency ('the Agency') is to prepare and submit to the Commission an opinion on renewal of the approval of the active substance in accordance with Article 14(3) of that Regulation.
- (5) In addition, as creosote is classified as carcinogen category 1B and meets the criteria for being a persistent, bioaccumulative and toxic substance (PBT substance), or a very persistent and very bioaccumulative substance (vPvB substances) (PBT or vPvB) according to Annex XIII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council ⁽³⁾, it meets the exclusion criteria set out in points (a) and (e) of Article 5(1) of Regulation (EU) No 528/2012. Further examination will therefore be necessary to define whether at least one of the conditions of the first subparagraph of Article 5(2) of that Regulation is fulfilled, and whether the approval of creosote may therefore be renewed.
- (6) Consequently, for reasons beyond the control of the applicant, the approval of creosote is likely to expire before a decision has been taken on its renewal. It is therefore appropriate to postpone the expiry date of approval of creosote for a period of time sufficient to enable the examination of the application. Considering the periods of time allowed for the evaluation by the evaluating competent authority and for the preparation and submission of the opinion by the Agency, and the period of time necessary to decide if at least one of the conditions of the first subparagraph of Article 5(2) of that Regulation is fulfilled and whether the approval of creosote may therefore be renewed, it is appropriate to postpone the expiry date of approval of creosote to 31 October 2020.

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

⁽²⁾ Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p. 1).

⁽³⁾ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

- (7) Except for the expiry date of the approval, creosote should remain approved subject to the specifications and conditions set out in Annex I to Directive 98/8/EC,

HAS ADOPTED THIS DECISION:

Article 1

The expiry date of approval of creosote for use in biocidal products of product-type 8 is postponed to 31 October 2020.

Article 2

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

Done at Brussels, 14 December 2017.

For the Commission

The President

Jean-Claude JUNCKER

GUIDELINES

GUIDELINE (EU) 2017/2335 OF THE EUROPEAN CENTRAL BANK

of 23 November 2017

on the procedures for the collection of granular credit and credit risk data (ECB/2017/38)

THE GOVERNING COUNCIL OF THE EUROPEAN CENTRAL BANK,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 127(2) and (5) thereof,

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,

Whereas:

- (1) The European System of Central Banks (ESCB) is establishing a common granular analytical credit database (hereinafter 'AnaCredit'), comprising credit data from all Member States whose currency is the euro. AnaCredit will support the Eurosystem, the ESCB and the European Systemic Risk Board (ESRB) in the performance of their tasks, including monetary policy analysis and monetary policy operations, risk management, financial stability surveillance as well as macroprudential policy and research, and banking supervision.
- (2) Regulation (EU) 2016/867 of the European Central Bank (ECB/2016/13) ⁽¹⁾ provides that reporting agents resident in a reporting Member State must report credit data and counterparty reference data to the national central bank (NCB) of that Member State. NCBs of the reporting Member States are required to transmit these data to the European Central Bank (ECB). It is therefore necessary to define the procedures for such transmissions in accordance with the requirements under Regulation (EU) 2016/867 (ECB/2016/13). In particular, it is necessary for NCBs to provide counterparty reference data, and, where applicable, register counterparties in the Register of Institutions and Affiliates Database (RIAD), the central repository that holds attributes on individual organisational units as well as various types of relationships between them which, inter alia, permit the derivation of group structures by reference to different definitions in RIAD, in a timely manner.
- (3) Furthermore, it is necessary to allocate clearly the NCBs' responsibilities for the reporting to the ECB of credit data and counterparty reference data of observed agents which are reporting Member State foreign branches, in order to facilitate the reduction of double-reporting and thereby ensure that effective and efficient statistical procedures are implemented throughout the statistical production chain.
- (4) AnaCredit may also comprise credit data from Member States whose currency is not the euro, but which decide to become a reporting Member State by incorporating the provisions of Regulation (EU) 2016/867 (ECB/2016/13) into their national law or otherwise imposing relevant reporting requirements in accordance with their national law. Those Member States may also incorporate the provisions of this Guideline into their national law or otherwise implement measures pursuant to their national law to ensure they fulfil applicable obligations to transmit data to the ECB in a harmonised manner.
- (5) Pursuant to Article 24 of Guideline ECB/2014/15 ⁽²⁾, NCBs communicate and maintain all reference data describing institutional units or legal units, where applicable, that are required for statistical purposes via RIAD. RIAD data are also used to prepare the official lists of monetary financial institutions (MFIs), investment funds, financial vehicle corporations, payment statistics relevant institutions and insurance corporations.
- (6) RIAD should be the repository of reference data on all counterparties defined in Regulation (EU) 2016/867 (ECB/2016/13). The unique identification of all counterparties is a prerequisite for the correct functioning of AnaCredit.

⁽¹⁾ Regulation (EU) 2016/867 of the European Central Bank of 18 May 2016 on the collection of granular credit and credit risk data (ECB/2016/13) (OJ L 144, 1.6.2016, p. 44).

⁽²⁾ Guideline ECB/2014/15 of 4 April 2014 on monetary and financial statistics (OJ L 340, 26.11.2014, p. 1).

- (7) It is necessary to define the scope of data to be provided in accordance with Article 11 of Regulation (EU) 2016/867 (ECB/2016/13), pursuant to which NCBs may establish feedback loops or enrich existing feedback loops to reporting agents using a subset of credit data collected under that Regulation. These feedback loops help to provide reporting agents with a broader basis for their creditworthiness assessments, in particular of cross-border debtors, as well as to improve credit institutions' and other lenders' risk management. A feedback loop may enhance the ESCB's contribution to the prudential supervision of credit institutions and the stability of the financial system.
- (8) The ECB, in collaboration with the NCBs of the reporting Member States, should establish, at a subsequent stage, a legal framework setting out details on the scope and implementation of the feedback loops. This legal framework should not prevent NCBs from exchanging counterparty reference data with their respective reporting agents, if this is deemed necessary for improving the efficiency and consistency of the reporting procedure and contributing to a better quality of the counterparty reference data stored in RIAD.
- (9) It is necessary to establish a procedure for making technical amendments to the annexes to this Guideline in an effective manner, provided they neither change the underlying conceptual framework nor affect the reporting burden. Account should be taken of the views of the Statistics Committee of the ESCB (hereinafter the 'STC') when following this procedure. NCBs and other ESCB Committees may propose such technical amendments to the annexes through the STC,

HAS ADOPTED THIS GUIDELINE:

CHAPTER I

GENERAL PROVISIONS

Article 1

Scope

This Guideline provides details on the NCBs' obligations to transmit credit data and counterparty reference data collected pursuant to Regulation (EU) 2016/867 (ECB/2016/13) to the ECB, including the NCBs' responsibilities for registering counterparties in RIAD, and on the procedures for the transmission of such data.

Article 2

Definitions

The terms used in this Guideline have the same meaning as those defined in Regulation (EU) 2016/867 (ECB/2016/13).

For the purposes of this Guideline, the following definitions also apply:

- (1) 'credit data' means granular credit data and credit risk data;
- (2) 'reporting Member State foreign branch' or 'RMS foreign branch' means a foreign branch resident in a reporting Member State which is a legally dependent part of a credit institution resident in another reporting Member State;
- (3) 'head office undertaking' means the legal entity of which a foreign branch is a legally dependent part;
- (4) 'home NCB' means the NCB of the reporting Member State in which the credit institution of which a foreign branch is a legally dependent part is resident;
- (5) 'host NCB' means the NCB of the reporting Member State in which a foreign branch is resident;
- (6) 'RIAD code' means the unique counterparty identifier for all counterparties when reported from the NCBs to the ECB;
- (7) 'competent NCB' means, for the purpose of defining roles and responsibilities in the field of counterparty reference data, the NCB of the reporting Member State in which the counterparty is resident. The ECB is to be considered as the competent NCB for those counterparties not resident in a reporting Member State;

- (8) 'originating NCB' means, for the purpose of defining roles and responsibilities in the field of counterparty reference data, the NCB of the reporting Member State which reports to the ECB reference data on counterparties resident in a different Member State;
- (9) 'output data' means data created by the ECB within the scope of credit data and counterparty reference data;
- (10) 'Data quality management' or 'DQM' means ensuring, verifying and maintaining the quality of output data through the use and application of DQM targets, DQM metrics and DQM thresholds;
- (11) 'DQM target' means a benchmark for assessing the quality of output data;
- (12) 'DQM metric' means a statistical indicator measuring the level to which a certain DQM target has been reached;
- (13) 'DQM threshold' means the minimum level of verification work to be conducted in order to satisfy the requirements of the DQM framework for a DQM target.

CHAPTER II

NCBs' REPORTING OBLIGATIONS FOR CREDIT DATA AND COUNTERPARTY REFERENCE DATA

Article 3

NCBs' general reporting obligations for credit data and counterparty reference data

NCBs shall compile and report to the ECB credit data and counterparty reference data in accordance with the schemes laid down in Annexes I to IV to Regulation (EU) 2016/867 (ECB/2016/13), subject to the NCBs' rights to grant derogations or to allow a reduced reporting frequency in accordance with Article 16 of that Regulation.

Article 4

NCBs' specific reporting obligations, frequency and timeliness

1. NCBs shall transmit to the ECB credit data and counterparty reference data collected in accordance with Regulation (EU) 2016/867 (ECB/2016/13), as specified in Article 13(4) to (8) of that Regulation.
2. NCBs shall identify each credit data attribute which is:
 - (a) not applicable: this means a data attribute which does not apply to the instrument, protection or counterparty that it refers to; or
 - (b) not required: this means a data attribute which is either explicitly specified as information which is not required to be reported in accordance with Regulation (EU) 2016/867 (ECB/2016/13), or which the NCB has decided not to collect in accordance with that Regulation.
3. NCBs shall ensure that, for each reporting reference date, all relevant counterparties are registered in RIAD and have counterparty reference data which are valid at that reporting reference date. Although the same transmission date applies both for credit data and counterparty reference data in accordance with Article 13(8) of Regulation (EU) 2016/867 (ECB/2016/13), NCBs shall make reasonable efforts to provide counterparty reference data, and, where applicable, to register the counterparty in RIAD, at least one day before the relevant credit data are transmitted.

Article 5

Actual reporting population

1. NCBs shall identify and review the actual reporting population on the basis of:
 - (a) the definition of 'actual reporting population' in Article 3 of Regulation (EU) 2016/867 (ECB/2016/13);

- (b) the derogations granted by NCBs pursuant to Article 16 of Regulation (EU) 2016/867 (ECB/2016/13), considering the total outstanding amount of loans to all sectors as reported to the NCBs for end-December of the previous calendar year pursuant to Regulation (EU) No 1071/2013 of the European Central Bank (ECB/2013/33) ⁽¹⁾;
- (c) information provided by reporting agents to the NCB on any merger, division or reorganisation that could affect the fulfilment of their statistical obligations;
- (d) any arrangements made between the relevant NCBs with the aim of avoiding double reporting for foreign branches in accordance with Articles 6(3) and 16(3) of Regulation (EU) 2016/867 (ECB/2016/13);
- (e) any arrangements made between the relevant NCBs for the allocation of responsibilities with regard to RMS foreign branches in accordance with Article 6 of this Guideline.

2. Without prejudice to the inclusion in the actual reporting population of new reporting agents established in reporting Member States after the first reporting under Regulation (EU) 2016/867 (ECB/2016/13), NCBs shall check the fulfilment of the conditions set out in Article 16 of that Regulation for granting or withdrawing any derogation. NCBs shall perform this exercise in the first quarter of each year, based on the status of the actual reporting population in the month of December of the previous year. NCBs may decide to postpone this exercise until the first quarter of 2021.

3. NCBs shall ensure that for each reporting reference date the following counterparties are registered in RIAD:

- (a) reporting agents in accordance with point 8 of Article 1 of Regulation (EU) 2016/867 (ECB/2016/13), resident in the same reporting Member State as the NCB;
- (b) observed agents which are foreign branches of reporting agents as referred to in point (a) in accordance with point 9 of Article 1 of Regulation (EU) 2016/867 (ECB/2016/13);
- (c) head office undertakings of observed agents as referred to in point (b).

NCBs shall register these counterparties as soon as they meet the criteria to become: (i) a reporting agent; (ii) an observed agent; or (iii) the head office undertaking of an observed agent, and always prior to the first reporting reference date after which they meet the criteria to become such counterparties.

4. NCBs shall ensure that for each reporting reference date the following information is registered in RIAD for each observed agent:

- (a) the relationship between the observed agent and the legal entity of which the observed agent is a part;
- (b) the reference date on which observed agents shall report information to AnaCredit;
- (c) any derogations that apply, by indicating whether:
 - (i) a derogation has been granted in accordance with Article 16(1) of Regulation (EU) 2016/867 (ECB/2016/13);
 - (ii) a derogation covers some or all reporting requirements as defined in Article 16(1) of Regulation (EU) 2016/867 (ECB/2016/13); or
 - (iii) a derogation has been granted to foreign branches pursuant to an arrangement made between the relevant NCBs to avoid double reporting in accordance with Articles 6(3) and 16(3) of Regulation (EU) 2016/867 (ECB/2016/13);
- (d) confirmation of whether the NCB has decided not to collect information in accordance with Article 6(4) of Regulation (EU) 2016/867 (ECB/2016/13);
- (e) confirmation of whether the obligation to report credit data only on a quarterly basis in accordance with Article 16(2) of Regulation (EU) 2016/867 (ECB/2016/13) applies; and
- (f) confirmation of whether the observed agent has to report the counterparty risk data only on a quarterly basis in accordance with Template 2 of Annex I to Regulation (EU) 2016/867 (ECB/2016/13).

5. The home NCB shall register in RIAD the decision not to collect any, or to collect only part, of the data attributes listed in Template 1 of Annex I to Regulation (EU) 2016/867 (ECB/2016/13) of a foreign branch from the legal entity of which it is a part, when such instruments are held or serviced by a foreign branch resident in another reporting Member State in accordance with Article 6(3)(a) of that Regulation.

⁽¹⁾ Regulation (EU) No 1071/2013 of the European Central Bank of 24 September 2013 concerning the balance sheet of the monetary financial institutions sector (ECB/2013/33) (OJ L 297, 7.11.2013, p. 1).

6. The host NCB shall register in RIAD the decision not to collect any, or to collect only part, of the data attributes listed in Template 2 of Annex I to Regulation (EU) 2016/867 (ECB/2016/13) from a foreign branch which is part of a legal entity resident in another reporting Member State in accordance with Article 6(3)(b) of that Regulation.
7. The relevant NCB shall inform the ECB of the procedures that are planned pursuant to Article 15 of Regulation (EU) 2016/867 (ECB/2016/13) for fulfilling the statistical reporting requirements set out in that Regulation in the event of a merger, division or reorganisation involving one or more reporting agents that could affect the fulfilment of those reporting agents' statistical reporting requirements.

Article 6

Allocation of responsibilities for RMS foreign branches

1. Where both a legal entity and any of its foreign branches are resident in different reporting Member States, NCBs shall make reasonable efforts to avoid double reporting of the same data in accordance with Article 6(3) of Regulation (EU) 2016/867 (ECB/2016/13) by coordinating their collection of data attributes listed in Templates 1 and 2 of Annex I to that Regulation from the respective reporting agent and its foreign branches.
2. Annex II to this Guideline defines the allocation of responsibilities for NCBs that report credit data and counterparty reference data of RMS foreign branches to the ECB, taking into account the derogations granted to reporting agents.
3. The home NCB and the host NCB involved in the collection of data from an RMS foreign branch may agree on a different allocation of responsibilities for the reporting of credit data and counterparty reference data to the ECB which overrides the allocation of responsibilities set out in Annex II to this Guideline, subject to paragraph 4. In accordance with any such arrangement, the home NCB or the host NCB shall inform the ECB and register in RIAD the following information:
 - (a) the NCB responsible for the transmission to the ECB of the information set out in Template 1 of Annex I to Regulation (EU) 2016/867 (ECB/2016/13); and
 - (b) the NCB responsible for the transmission to the ECB of the information set out in Template 2 of Annex I to Regulation (EU) 2016/867 (ECB/2016/13).

Both NCBs shall register in RIAD the corresponding counterparty reference data.

4. The arrangement to override the allocation of responsibilities to transmit Templates 1 and 2 of Annex I to Regulation (EU) 2016/867 (ECB/2016/13) may not result in the transmission of less credit data to the ECB compared to the arrangement specified in Annex II, without prejudice to an NCB's decision not to collect specific data attributes in accordance with Article 7 of that Regulation.
5. If there is an arrangement between two relevant NCBs pursuant to Article 6(3) of Regulation (EU) 2016/867 (ECB/2016/13) which results in only one of them collecting and transmitting all the data (Templates 1 and 2) from an RMS foreign branch to the ECB, then:
 - (a) the NCB not transmitting data to the ECB may decide not to collect any data from this RMS foreign branch in accordance with Articles 8(5) and 16(3) of Regulation (EU) 2016/867 (ECB/2016/13) to avoid double reporting; and
 - (b) the ECB shall send the data transmitted in relation to the RMS foreign branch to the NCB not transmitting data to the ECB for use in accordance with Article 10(1) of Regulation (EU) 2016/867 (ECB/2016/13).

Article 7

Transitional provisions regarding the transmission of credit data and counterparty reference data

1. Where NCBs exercise their rights in accordance with Article 19 of Regulation (EU) 2016/867 (ECB/2016/13) to postpone the first transmission to the ECB of credit data relating to all reporting reference dates prior to 1 February 2019, the first transmission shall take place not later than 31 March 2019.
2. Without prejudice to Article 2(2) of Regulation (EU) 2016/867 (ECB/2016/13), if an NCB makes use of the transitional provision for credit data referred to in paragraph 1, it may postpone the first transmission to the ECB of counterparty reference data provided that it transmits such data to the ECB six months before the first reporting of credit data, and in any case no later than 30 September 2018.

3. Without prejudice to Article 19 of Regulation (EU) 2016/867 (ECB/2016/13), NCBs shall register in RIAD their decision to postpone the first transmission of credit data to the ECB by 30 June 2018. Such information may be updated before the first reporting of credit data and counterparty reference data, in the event that NCBs need to postpone the first transmission.

4. In relation to the first reporting of monthly and quarterly credit data, NCBs shall inform the ECB by 31 March 2018 of their respective selected actual reporting population, by registering this information in RIAD.

CHAPTER III

SPECIFIC REPORTING OBLIGATIONS RELATING TO COUNTERPARTY REFERENCE DATA IN RIAD

Article 8

Identification of counterparties in RIAD

1. NCBs shall identify each counterparty whose data they report, whether resident or non-resident, by its unique RIAD code, taking into account the conditions set out in this Guideline.

2. NCBs shall take all possible measures to correctly identify relevant counterparties in RIAD and refer to such counterparties, irrespective of their country of residence, by means of the respective RIAD code. This shall also apply when an NCB only uses Template 2 of Annex I to Regulation (EU) 2016/867 (ECB/2016/13) to collect and transmit to the ECB credit data and counterparty reference data in cases where another NCB uses Template 1 of Annex I to that Regulation to collect and transmit data in respect of the same counterparty, and when partial derogations are granted to reporting agents.

3. NCBs shall use the correct RIAD codes to refer to all counterparties consistently over time, and shall update them in a timely manner if there are changes, such as when the competent NCB intervenes to replace a temporary code by an official RIAD code.

4. NCBs may require reporting agents to use a specific set of counterparty identifiers. Annex IV to Regulation (EU) 2016/867 (ECB/2016/13) provides that the relevant NCB may allow reporting agents to use a reporting agent-specific counterparty identifier to refer to counterparties for the primary transmission. In this case, the NCB using Template 1 of Annex I to Regulation (EU) 2016/867 (ECB/2016/13) to collect credit data and counterparty reference data shall create mappings between the various counterparty identifiers used by reporting agents to refer to the same counterparty and the corresponding RIAD code, to be used for the secondary transmission.

5. NCBs shall ensure that all counterparties linked to instruments reported to AnaCredit, irrespective of the role and of the country of residence of the counterparty itself, are registered in RIAD at the relevant reporting reference date. NCBs shall make reasonable efforts to register a new counterparty in RIAD at least one day before transmitting to the ECB the credit data on instruments to which the counterparty is linked.

Article 9

Transmission of counterparty reference data to RIAD

1. NCBs shall report to the ECB counterparty reference data in accordance with the counterparty reference dataset in Template 1 of Annex I and in Tables 2 and 3 of Annex III to Regulation (EU) 2016/867 (ECB/2016/13).

2. NCBs may obtain counterparty reference data, including identifiers, from respective reporting agents or via memoranda of understanding entered into with national statistical institutes, national competent authorities and other national institutions, provided that such information can be used for the purposes defined in Council Regulation (EC) No 2533/98 ⁽¹⁾.

3. NCBs shall update the counterparty reference data that they transmit to the ECB as soon as they become aware of a change to one or more data attributes. This applies to both resident and non-resident counterparties.

⁽¹⁾ Council Regulation (EC) No 2533/98 of 23 November 1998 concerning the collection of statistical information by the European Central Bank (OJ L 318, 27.11.1998, p. 8).

4. Although NCBs may decide not to collect certain counterparty reference data attributes from individual reporting agents, e.g. when the attribute is marked 'N' in Tables 2 and 3 of Annex III to Regulation (EU) 2016/867 (ECB/2016/13), pursuant to Article 9(1) of Regulation (EU) 2016/867 (ECB/2016/13) NCBs shall always report to RIAD, irrespective of the role and of the country of residence of the counterparty itself, a Legal Entity Identifier (LEI). If no LEI has been assigned to the counterparty, NCBs shall report a national identifier from the list of national identifiers published on the ECB website as an annex to the AnaCredit Reporting Manual.

5. In addition to the mandatory entity identifiers required by Regulation (EU) 2016/867 (ECB/2016/13), NCBs shall report to RIAD any other national identifier available for a given counterparty, provided that this information can be used in accordance with the confidentiality regime set out in Regulation (EC) No 2533/98.

6. NCBs shall not be required to report any counterparty reference information to RIAD if the counterparty is included in the list of international organisations published on the ECB website as an annex to the AnaCredit Reporting Manual and regularly updated by the ECB in cooperation with NCBs. In those cases, NCBs shall only use the correct RIAD code to identify the international organisation in the transmission of credit data to the ECB. This shall also apply to counterparties in the list of MFIs, except where the counterparty is acting as a debtor, in which case the NCBs shall comply with the general reporting requirements for counterparty reference data.

Article 10

NCBs' responsibility for the identification of resident counterparties registered in RIAD

1. NCBs shall be responsible for the unique identification of all resident counterparties in RIAD and shall take all possible measures to avoid that two or more distinct records in RIAD refer to the same resident counterparty.

2. Detailed information on the steps NCBs shall take to ensure the unique identification of counterparties in RIAD and the management of their reference data is set out in Annex I.

3. Once a resident counterparty has been registered in RIAD with a temporary RIAD code, the competent NCB shall assess, by the last working day of the second month following the date of the receipt of the list of potential duplicates from the central identification service, at the latest, whether the new temporary counterparty is a duplicate of an existing resident counterparty or a genuinely new counterparty. In the former case, i.e. where there is a match, the competent NCB shall select the preferred match out of the proposed list, hence invalidating ('freezing') the new temporary counterparty in favour of the corresponding existing resident counterparty ('living' counterparty). In the latter case, i.e. where there is no match, the competent NCB shall assign an official RIAD code to the new temporary counterparty.

4. In resolving a duplication, NCBs shall first address those cases which involve new temporary resident counterparties with the largest exposures according to the credit data reported to the ECB.

5. NCBs shall use all available information at the national level to ensure, to the extent possible, that reference information on resident counterparties registered in RIAD is complete, accurate and up to date. To this end, NCBs shall assess all reliable sources of information provided such information can be used in accordance with the confidentiality regime set out in Regulation (EC) No 2533/98, with a view to entering in RIAD the best possible reference information on all relevant counterparties.

6. In the case of counterparties resident in a country for which there is no competent NCB to provide counterparty reference data, the ECB shall provide for the unique identification and reference data of those counterparties, on a reasonable efforts basis and based on available information, following the steps that are required to be taken by the 'competent NCB/ECB' in Annex I to this Guideline. In so doing, the ECB shall first address those cases which involve counterparties with the largest exposures according to the information available in AnaCredit.

7. For each counterparty, RIAD calculates the authoritative record of each data attribute according to pre-defined compounding rules, allocating a priority to all potential candidate sources. If the standard compounding rules (ranking between all potential sources) defined by the ECB are not considered appropriate, NCBs shall define and communicate to the ECB in writing the compounding rules to be applied in RIAD for calculating the authoritative record of the reference data of all resident counterparties. The competent NCB may define a different method for each counterparty reference data attribute and may change such method from time to time as it deems appropriate.

8. NCBs shall ensure that the list of national identifiers and the list of legal forms published as an annex to the AnaCredit Reporting Manual on the ECB website are kept up to date for the respective Member State. NCBs shall inform the ECB in writing and in a timely manner of any change deemed necessary.

CHAPTER IV

PROCEDURES AND STANDARDS FOR TRANSMISSION TO RIAD

Article 11

Assignment of the RIAD code

1. At the time of the first registration in RIAD, NCBs shall assign an official RIAD code to each resident counterparty and a temporary RIAD code to non-resident counterparties, with the required format.
2. NCBs shall ensure that the RIAD codes they assign to counterparties, both resident and non-resident, are exclusive, i.e. that they are not associated with more than a single counterparty, and do not change over time.
3. NCBs shall be responsible for assigning an official RIAD code to all resident counterparties which were initially registered in RIAD with a temporary RIAD code by an originating NCB or by the ECB.
4. The ECB shall inform NCBs of reporting Member States if a counterparty's RIAD code changes, irrespective of their country of residence. NCBs shall use the current RIAD code for all counterparties from the date that the following applicable credit data and counterparty reference data are transmitted.

Article 12

Transmission standards in relation to RIAD

1. NCBs shall transmit counterparty reference data to the ECB using RIAD. Any regular upload of information shall be organised by means of a file transfer via the standard ESCB facility. Alternatively, for small volumes, NCBs may process acquisition acknowledgement messages or update attributes online.
2. In order to minimise operational errors and ensure the accuracy and consistency of the updates reported to RIAD, prior to the transmission of data to the ECB, NCBs shall carry out validation checks matching the relevant data exchange specifications.

Article 13

Acquisition and error acknowledgements

1. On receipt of the updates, the ECB shall promptly carry out checks to validate the quality of the information provided.
2. Pursuant to Article 24(5) of Guideline ECB/2014/15, the ECB shall provide NCBs with:
 - (a) an acquisition acknowledgement containing summary information on the updates which have been processed and implemented successfully in the relevant dataset; and/or
 - (b) an error acknowledgement containing detailed information on the updates and the validation checks which have failed.
3. NCBs shall take action to transmit corrected information promptly.

Article 14

First transmission of counterparty reference data to RIAD

1. NCBs shall transmit to the ECB a first set of the counterparty reference data no later than six months prior to the first transmission of credit data in accordance with Article 2(2) of Regulation (EU) 2016/867 (ECB/2016/13) and shall make reasonable efforts to do so before the relevant deadline set out in Article 7(2) of this Guideline.
2. As regards the content of the first transmission of counterparty reference data under paragraph 1, NCBs shall transmit, at a minimum, counterparty reference data which, based on available information, can be reasonably assessed to be relevant.

3. The same minimum common standards for transmission, accuracy and compliance with concepts and revisions specified in Annex V to Regulation (EU) 2016/867 (ECB/2016/13) shall apply to the first transmission of counterparty reference data to the ECB under paragraph 1.

4. Where applicable, the first set of counterparty reference data to be reported by NCBs shall comprise the following data attributes:

- (a) counterparty identifier (RIAD code);
- (b) LEI;
- (c) if the LEI is not available: a national identifier from the list of national identifiers published on the ECB website, as composed by two distinct variables, namely: the identifier type (or its description, when relevant) and the respective code (unless the identifier type is 'not applicable');
- (d) name;
- (e) address: country;
- (f) address: city/town/village;
- (g) address: street;
- (h) legal form;
- (i) institutional sector.

5. The actual list of reference data attributes that NCBs shall provide for each counterparty at the first transmission of counterparty reference data to RIAD may vary subject to the applicability of the various attributes to the specific role and category of the counterparty as described in Tables 2 and 3 of Annex III to Regulation (EU) 2016/867 (ECB/2016/13).

CHAPTER V

COLLECTION OF CREDIT AND COUNTERPARTY REFERENCE DATA BY NCBs

Article 15

Derogations and reduced reporting frequency

1. For the purposes of Article 16(1) and (2) of Regulation (EU) 2016/867 (ECB/2016/13), when calculating the total outstanding amount of loans to all sectors reported pursuant to Regulation (EU) No 1071/2013 (ECB/2013/33) by all reporting agents resident in the reporting Member State, NCBs shall only have regard to the total outstanding amount of loans of all reporting agents captured in the actual reporting population provided for in Article 3(1) of Regulation (EU) 2016/867 (ECB/2016/13), including the total outstanding amount of loans of all reporting agents granted a derogation. For the avoidance of doubt, an NCB shall not have regard to the total outstanding amount of loans of foreign branches not resident in the reporting Member State of that NCB.

2. For the purposes of Article 16(2) of Regulation (EU) 2016/867 (ECB/2016/13), when allowing small reporting agents to report credit data relating to reporting reference dates prior to 1 January 2021 on a quarterly instead of monthly basis, NCBs shall take into account the combined contribution of:

- (a) the small reporting agents that are granted a derogation pursuant to Article 16(1) of Regulation (EU) 2016/867 (ECB/2016/13), and
- (b) the reporting agents eligible for reporting on a quarterly basis pursuant to Article 16(2) of Regulation (EU) 2016/867 (ECB/2016/13),

to the total outstanding amount of loans reported pursuant to Regulation (EU) No 1071/2013 (ECB/2013/33) by all reporting agents resident in the reporting Member State, and ensure such combined contribution does not exceed 4 %.

3. Pursuant to Articles 6(3) and 16(3) of Regulation (EU) 2016/867 (ECB/2016/13), a relevant NCB may grant derogations to reporting agents that are RMS foreign branches to the extent that the NCBs obtain data from other sources of the quality and timeliness required under Article 14(3) of that Regulation. The NCBs' right to grant such derogations is subject to coordination between the relevant NCBs on the basis of the arrangements made for avoiding double reporting in accordance with Article 6 of this Guideline. For the avoidance of doubt, any reporting agent which is granted a derogation pursuant to Article 16(3) shall not be considered a small reporting agent which is granted a derogation pursuant to Article 16(1) or a small reporting agent which may report on a quarterly or monthly basis pursuant to Article 16(2).

4. In exercising their powers pursuant to Article 16(1) of Regulation (EU) 2016/867 (ECB/2016/13), the relevant NCB may grant derogations to small reporting agents which cover some or all of the reporting requirements, including those which relate exclusively to specific observed agents that are part of a reporting agent that is a legal entity.

Article 16

Cooperation with competent authorities

1. Where all or part of the data described in Regulation (EU) 2016/867 (ECB/2016/13) can be obtained from competent authorities other than NCBs, and these data can be used to the extent and for the purposes defined in Regulation (EC) No 2533/98, NCBs may establish appropriate cooperation arrangements with these authorities to ensure a permanent structure for receiving such data.

2. The NCBs shall ensure that the data referred to in paragraph 1 meet the requirements set out in Regulation (EU) 2016/867 (ECB/2016/13) before transmitting them to the ECB.

CHAPTER VI

DATA QUALITY MANAGEMENT

Article 17

Transmission standards using the ESCB-Net

1. The NCBs shall use the ESCB-Net provided by the ESCB for the electronic transmission of the credit data and counterparty reference data as required by the ECB. The NCBs shall make that data available to the ECB in accordance with the SDMX ⁽¹⁾ reporting standards laid down separately.

2. Subject to the ECB's prior consent, the NCBs may use other means to transmit the credit data and counterparty reference data.

Article 18

Data quality management

1. Without prejudice to the ECB's verification rights under Regulation (EC) No 2533/98 and Regulation (EU) 2016/867 (ECB/2016/13), the NCBs shall monitor and ensure the quality and reliability of credit data and counterparty reference data made available to the ECB and cooperate closely with the ECB as part of overall data quality management.

2. NCBs shall define the conditions that trigger the rejection of data received from the reporting agents.

3. NCBs shall monitor the observed agents for which information has been rejected and the progress achieved from one reporting period to another. NCBs shall inform the ECB of the results of such monitoring.

4. NCBs shall ensure, verify and maintain the quality of credit data and counterparty reference data to ensure: (i) the quality of aggregate output data; (ii) the consistency of credit data and counterparty reference data; and (iii) consistency with other statistics. In particular, prior to the transmission of credit data and counterparty reference data to the ECB, NCBs shall verify that:

- (a) the files transmitted to the ECB comply with the technical specifications for transmission to the ECB;
- (b) each record is uniquely identified;
- (c) the contract identifier is unique for each contract that generates credit risk for the same observed agent and that such an identifier is not reused at any point in time to identify a different contract with the same observed agent;
- (d) each instrument identifier is unique for each contract of an observed agent, and that this identifier is not reused at any point in time to identify a different instrument for the same contract and observed agent;
- (e) the protection identifier is unique for each protection received by the same observed agent and that this identifier is not reused at any point in time to identify a different protection with the same observed agent;

⁽¹⁾ Statistical Data and Metadata eXchange.

- (f) the credit data and counterparty reference data to be transmitted are complete and consistent;
 - (g) all counterparties are linked to instruments that are registered in the RIAD system and referred to by the corresponding counterparty identifier (RIAD code) based on the information provided by the reporting agents.
5. Prior to the transmission of credit data to the ECB, the NCBs transmitting Template 1 or Template 2 of Annex I to Regulation (EU) 2016/867 (ECB/2016/13) shall verify and ensure that for each instrument to be reported for each counterparty linked to the instrument, the required counterparty reference data for all counterparties are registered in RIAD.
6. The credit data and counterparty reference data transmitted by NCBs shall be consistent with the data stored in national databases as a result of any data quality management activities exercised at national level.
7. Where credit data are transmitted by two NCBs to the ECB for observed agents which are RMS foreign branches in accordance with Article 6, each NCB shall be responsible for the quality of the data it reports. In particular, if two NCBs make an arrangement to share the responsibilities for secondary reporting, the relevant NCBs shall ensure that the credit data and counterparty reference data reported by one NCB are consistent with the credit data and counterparty reference data reported by the other relevant NCB. To this end and after the information is loaded in AnaCredit, the ECB shall send to the relevant NCBs the information transmitted in order to ensure that the credit data and counterparty reference data reported to each of them is consistent.
8. NCBs shall verify the consistency and accuracy of the credit data and counterparty reference data by comparing them with other datasets collected at national level under national or Union law and at the time they are available. NCBs shall take into account differences in the methodology and the timeliness of the datasets used for the assessment of the quality of data in AnaCredit.
9. For each transmission of credit data for an observed agent, reporting reference date and type of reporting, i.e. monthly data attributes in Templates 1 and 2 of Annex I to Regulation (EU) 2016/867 (ECB/2016/13), and quarterly data attributes in Template 2 of Annex I to that Regulation, an acknowledgement message to the NCB transmitting the information indicating whether the file has been loaded or rejected by the system shall be automatically transmitted by AnaCredit. In the latter case, the message shall indicate the reason for the rejection.
10. The ECB shall assess credit data and counterparty reference data by applying a set of validation checks, in close cooperation with the NCBs. The assessment shall be carried out in a timely manner. The ECB and the NCBs may jointly coordinate the data quality management efforts taking into account the significance of the discrepancy between the DQM metrics and the DQM targets both at national and euro area level.
11. For each transmission of credit data for an observed agent, reporting reference date and type of reporting which is loaded into AnaCredit, an acknowledgement message shall be automatically transmitted via AnaCredit with the results of the validation checks. This message shall detail the data that failed to comply with the AnaCredit validation checks and the validation check that triggered the error.
12. If the observed agent is an RMS foreign branch and two NCBs report information for the observed agent:
- (a) the messages indicated in paragraph 11 shall be transmitted to the two relevant NCBs; and
 - (b) each NCB shall be responsible for the data quality of the information included in the template. In particular, each NCB shall be responsible for the validation checks verifying the consistency and integrity of the information reported in Templates 1 and 2 of Annex I to Regulation (EU) 2016/867 (ECB/2016/13). For this purpose, each NCB shall ensure the correctness of the information reported in the template for which each NCB is responsible.
13. NCBs shall establish and monitor the necessary mechanisms for reporting agents to revise and correct any credit data and counterparty reference data reported which do not comply with the AnaCredit validation checks, in order for NCBs to be able to submit available revisions promptly.
14. To monitor the implementation of appropriate procedures for the collection, verification, processing and dissemination of information that ensure the quality of the data collected, the ECB and NCBs shall submit a quality report on a biennial basis to the Governing Council. The quality reports shall cover both credit data and counterparty reference data, and also provide information on the methods and procedures established by NCBs for the unique identification of resident counterparties. The first quality report shall be prepared in December 2020, with September 2020 as reporting reference date.

*Article 19***Revision policy**

1. NCBs shall transmit to the ECB all revisions received from reporting agents as soon as they have been processed.
2. NCBs shall establish arrangements with reporting agents so that revisions to the data identified in the acknowledgement messages referred to in Article 18(11) as not complying with the AnaCredit validation checks may be transmitted promptly and not later than the next date on which information for that observed agent is due.
3. NCBs shall transmit revisions at any time after the reporting reference date.
4. NCBs shall transmit revisions, where they exist, for all reference periods.
5. The ECB shall automatically process revisions and store them in the shared database without undue delay after they have been received from NCBs. The ECB shall inform the NCBs concerned of the outcome of additional quality assessment after further processing the revisions.

CHAPTER VII

FINAL PROVISIONS*Article 20***Simplified amendment procedure**

The ECB's Executive Board may make any technical amendments to the annexes to this Guideline, taking into account the views of the STC, provided that such amendments neither change the underlying conceptual framework nor affect the reporting burden on reporting agents or NCBs. The Executive Board shall inform the Governing Council of any such amendment without undue delay.

*Article 21***Taking effect**

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.

*Article 22***Addressees**

This Guideline is addressed to all Eurosystem central banks.

Done at Frankfurt am Main, 23 November 2017.

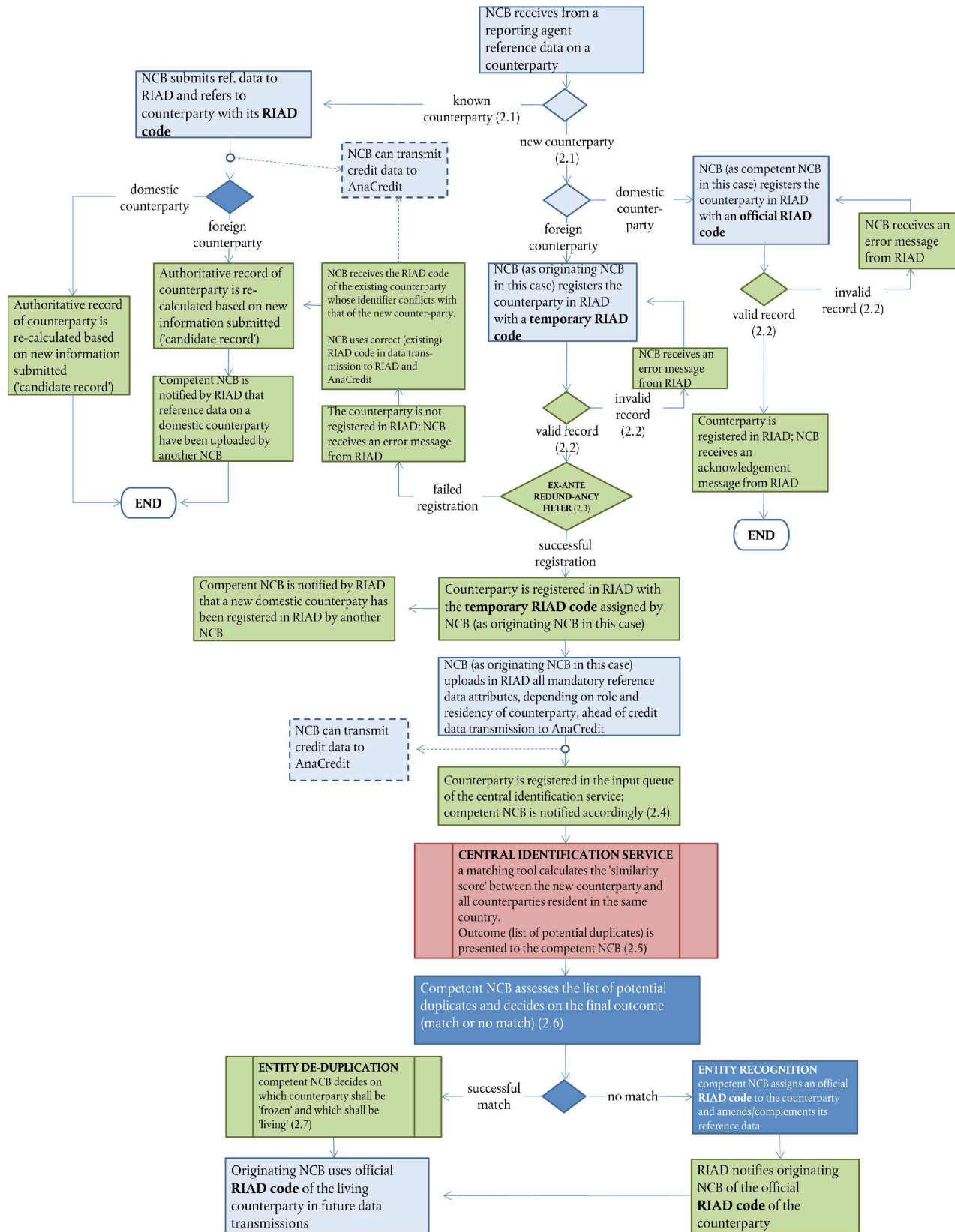
For the Governing Council of the ECB

The President of the ECB

Mario DRAGHI

ANNEX I

Identification and reference data management of counterparties in the Register of Institutions and Affiliates Database (RIAD)



1. General assumptions underlying the process flow chart

- 1.1. It is assumed that all NCBs maintain a national reference dataset in which counterparties (both domestic and non-resident) are uniquely identified and there are no duplications at the national level (i.e. they have a unique and exclusive internal NCB identifier). That means that even though different reporting agents in the same Member State might be using different counterparty identifiers to refer to the counterparty in their communications with the relevant NCB, the NCB eventually ensures that all such identifiers are associated with the actual unique counterparty.
- 1.2. If necessary, to avoid duplications (e.g. the same counterparty registered twice in the national reference dataset), the counterparty identifiers used by reporting agents when reporting to the NCB are mapped by the NCB into unique internal NCB identifiers. When transmitting information to RIAD and AnaCredit, NCBs eventually map such internal NCB identifiers into a unique RIAD code, if necessary.

2. Notes to the flow chart:

- 2.1. A 'known' counterparty is a counterparty which is already registered in RIAD and for which the originating NCB knows the RIAD code.
 - 2.2. A new counterparty can be registered in RIAD only provided that the necessary minimum set of reference data attributes are provided ('valid record'), as provided for in the RIAD requirements.
 - 2.3. RIAD does not allow a new counterparty to be registered with the same identifiers (LEI and/or national identifier) of an existing counterparty.
 - 2.4. Each NCB can decide to determine whether a domestic counterparty registered by another NCB is a duplicate of an existing counterparty or not also outside the central identification service (CIS), e.g. using their own internal process (matching algorithm) for this purpose.
 - 2.5. The CIS is a functionality in RIAD which searches for potential duplicates among existing counterparties resident in the same country via a dedicated 'matching tool' every time a new counterparty is registered in the system with a temporary RIAD code. Counterparties to be processed by the matching tool are stacked into an 'input queue', while the outcome of the matching process is accumulated in the 'output queue' and presented to the competent NCB, via a dedicated automated backflow, for its final assessment.
 - 2.6. The competent NCB reviews the list of potential duplicates received from RIAD and, for each counterparty with a temporary RIAD code, selects the preferred candidate from the list (match) or determines that no option is eventually selected from the list (no match).
 - 2.7. The counterparty 'de-duplication' is a process whereby the competent NCB decides, following the successful matching between two counterparties registered in RIAD, which counterparty is to be invalidated ('frozen counterparty'), and which one is to be maintained in the system ('living counterparty').
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ANNEX II

Allocation of responsibilities for RMS foreign branches

The table sets out the allocation of responsibilities for the reporting by NCBs to the ECB of credit data and counterparty reference data of observed agents which are RMS foreign branches on the basis of the information on derogations granted to reporting agents.

Allocation of responsibilities for RMS foreign branches

		Reporting agents reporting to the home NCB				
		No derogation	Only collect T2	Quarterly reporting	Partial derogation	Full derogation
Reporting agents reporting to the host NCB	No derogation	Home NCB: T1&T2	Host NCB: T1&T2	Host NCB: T1&T2	Host NCB: T1&T2	Host NCB: T1&T2
	Only collect T1	Home NCB: T1&T2	Host NCB: T1 Home NCB: T2	T2 required ⁽¹⁾ Host NCB: T1&T2	T2 required ⁽¹⁾ Host NCB: T1&T2	T2 required ⁽¹⁾ Host NCB: T1&T2
	Quarterly reporting	Home NCB: T1&T2	T1 required ⁽²⁾ Home NCB: T1&T2	Home NCB: T1&T2 (Q)	Host NCB: T1&T2 (Q)	Host NCB: T1&T2 (Q)
	Partial derogation	Home NCB: T1&T2	T1 required ⁽²⁾ Home NCB: T1&T2	Home NCB: T1&T2 (Q)	—	—
	Full derogation	Home NCB: T1&T2	T1 required ⁽²⁾ Home NCB: T1&T2	Home NCB: T1&T2 (Q)	—	—

⁽¹⁾ If the home NCB:

- (a) grants a derogation in accordance with Article 16(1) of Regulation (EU) 2016/867 (ECB/2016/13); or
- (b) allows data reporting on a quarterly basis in accordance with Article 16(2) of Regulation (EU) 2016/867 (ECB/2016/13); and the host NCB:
- (c) does not grant a derogation in accordance with Article 16(1) of Regulation (EU) 2016/867 (ECB/2016/13); and
- (d) does not allow data reporting on a quarterly basis in accordance with Article 16(2) of Regulation (EU) 2016/867 (ECB/2016/13); then the host NCB cannot decide not to collect any, or to collect only part, of the data attributes listed in Template 2 in accordance with Article 6(3)(b) of Regulation (EU) 2016/867 (ECB/2016/13), and will transmit Templates 1 and 2 to the ECB.

⁽²⁾ If the host NCB:

- (a) grants a derogation in accordance with Article 16(1) of Regulation (EU) 2016/867 (ECB/2016/13); or
- (b) allows data reporting on a quarterly basis in accordance with Article 16(2) of Regulation (EU) 2016/867 (ECB/2016/13); and the home NCB:
- (c) does not grant a derogation in accordance with Article 16(1) of Regulation (EU) 2016/867 (ECB/2016/13); and
- (d) does not allow data reporting on a quarterly basis in accordance with Article 16(2) of Regulation (EU) 2016/867 (ECB/2016/13); then the home NCB cannot decide not to collect any, or to collect only part, of the data attributes listed in Template 1 in accordance with Article 6(3)(a) of Regulation (EU) 2016/867 (ECB/2016/13), and will transmit Templates 1 and 2 to the ECB.

Note:

- (i) T1: means Template 1 as defined in Annex I to Regulation (EU) 2016/867 (ECB/2016/13).
- (ii) T2: means Template 2 as defined in Annex I to Regulation (EU) 2016/867 (ECB/2016/13).

