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⁽¹⁾ Text with EEA relevance.

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⁽¹⁾ Text with EEA relevance.

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⁽¹⁾ Text with EEA relevance.

II

(Non-legislative acts)

REGULATIONS

COUNCIL IMPLEMENTING REGULATION (EU) 2019/1292

of 31 July 2019

implementing Article 21(2) of Regulation (EU) 2016/44 concerning restrictive measures in view of the situation in Libya

THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to Council Regulation (EU) 2016/44 of 18 January 2016 concerning restrictive measures in view of the situation in Libya and repealing Regulation (EU) No 204/2011 ⁽¹⁾, and in particular Article 21(2) thereof,

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

Whereas:

- (1) On 18 January 2016 the Council adopted Regulation (EU) 2016/44.
- (2) In accordance with Article 21(6) of Regulation (EU) 2016/44, the Council has reviewed the list of designated persons and entities set out in Annex III to that Regulation.
- (3) The entries for two persons should be removed from the list of persons and entities set out in Annex III to Regulation (EU) 2016/44.
- (4) Annex III to Regulation (EU) 2016/44 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Annex III to Regulation (EU) 2016/44 is amended in accordance with the Annex to this Regulation.

*Article 2*This Regulation shall enter into force on the 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, 31 July 2019.

*For the Council**The President*

T. TUUPURAINEN

⁽¹⁾ OJ L 12, 19.1.2016, p. 1.

ANNEX

In Annex III (List of natural and legal persons, entities or bodies referred to in Article 6(2)) to Regulation (EU) 2016/44, entries 1 (concerning ABDUSSALAM, Abdussalam Mohammed) and 14 (concerning AL-BAGHDADI, Dr Abdulqader Mohammed) are deleted from the list set out in Part A (Persons) and the remaining entries are renumbered accordingly.

COMMISSION IMPLEMENTING REGULATION (EU) 2019/1293**of 29 July 2019****amending Implementing Regulation (EU) No 577/2013 as regards the list of territories and third countries in Annex II and the model of animal health certificate for dogs, cats and ferrets set out in Annex IV****(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 576/2013 of the European Parliament and of the Council of 12 June 2013 on the non-commercial movement of pet animals and repealing Regulation (EC) No 998/2003 ⁽¹⁾, and in particular Articles 13(2) and 25(2) thereof,

Whereas:

- (1) Commission Implementing Regulation (EU) No 577/2013 ⁽²⁾ provides, amongst others, for the lists of territories and third countries referred to in Article 13 of Regulation (EU) No 576/2013 and for the animal health certificate required for the non-commercial movement into a Member State of dogs, cats and ferrets from territories and third countries.
- (2) Implementing Regulation (EU) No 577/2013 was incorporated into the European Economic Area (EEA) Agreement by the Decision of the EEA Joint Committee No 66/2016 ⁽³⁾ and is fully applicable to Norway in the same manner as to the EU Member States.
- (3) Norway is listed in Part 1 of Annex II to Implementing Regulation (EU) No 577/2013. Decision of the EEA Joint Committee No 66/2016 regulates the non-commercial movement into a Member State of dogs, cats and ferrets from Norway. Therefore, it is necessary to delete Norway from the list of territories and third countries set out in Part 1 of Annex II to Implementing Regulation (EU) No 577/2013.
- (4) It is also necessary to reflect the new name of the former Yugoslav Republic of Macedonia in the list of territories and third countries set out in Part 2 of Annex II to Implementing Regulation (EU) No 577/2013.
- (5) Regulation (EU) No 576/2013 provides, amongst others, that dogs, cats and ferrets moved into a Member State from a territory or a third country for non-commercial purposes are to comply with any preventive health measures for diseases or infections other than rabies adopted pursuant to Article 19(1) thereof and be accompanied by an identification document in the format of an animal health certificate. Part 1 of Annex IV to Commission Implementing Regulation (EU) No 577/2013 sets out the model for the animal health certificate.
- (6) In addition, following the mandatory review of Commission Delegated Regulation (EU) No 1152/2011 ⁽⁴⁾, the Commission adopted Delegated Regulation (EU) 2018/772 ⁽⁵⁾ which lays down, inter alia, the rules for the categorisation of Member States, or parts thereof, in view of their eligibility to apply preventive health measures for the control of *Echinococcus multilocularis* infection in dogs. Delegated Regulation (EU) 2018/772 repealed Delegated Regulation (EU) No 1152/2011 with effect from 1 July 2018.

⁽¹⁾ OJ L 178, 28.6.2013, p. 1.

⁽²⁾ Commission Implementing Regulation (EU) No 577/2013 of 28 June 2013 on the model identification documents for the non-commercial movement of dogs, cats and ferrets, the establishment of lists of territories and third countries and the format, layout and language requirements of the declarations attesting compliance with certain conditions provided for in Regulation (EU) No 576/2013 of the European Parliament and of the Council (OJ L 178, 28.6.2013, p. 109).

⁽³⁾ Decision of the EEA Joint Committee No 66/2016 of 29 April 2016 amending Annex I (Veterinary and phytosanitary matters) to the EEA Agreement [2017/2017] (OJ L 300, 16.11.2017, p. 1).

⁽⁴⁾ Commission Delegated Regulation (EU) No 1152/2011 of 14 July 2011 supplementing Regulation (EC) No 998/2003 of the European Parliament and of the Council as regards preventive health measures for the control of *Echinococcus multilocularis* infection in dogs (OJ L 296, 15.11.2011, p. 6).

⁽⁵⁾ Commission Delegated Regulation (EU) 2018/772 of 21 November 2017 supplementing Regulation (EU) No 576/2013 of the European Parliament and of the Council with regard to preventive health measures for the control of *Echinococcus multilocularis* infection in dogs and repealing Delegated Regulation (EU) No 1152/2011 (OJ L 30, 28.5.2018, p. 1).

- (7) The list of Member States complying with the rules for categorisation laid down in Delegated Regulation (EU) 2018/772 for the whole of their territory or parts thereof is set out in the Annex to Commission Implementing Regulation (EU) 2018/878 ⁽¹⁾.
- (8) It is therefore appropriate to replace the references to Delegated Regulation (EU) No 1152/2011 by references to Delegated Regulation (EU) 2018/772 and to Implementing Regulation (EU) 2018/878 in the model health certificate in Annex IV to Implementing Regulation (EU) No 577/2013.
- (9) Annexes II and IV to Implementing Regulation (EU) No 577/2013 should therefore be amended accordingly.
- (10) To avoid any disruption of movements of dogs, cats and ferrets, the use of the animal health certificates issued in accordance with Part 1 of Annex IV to Implementing Regulation (EU) No 577/2013 as amended by Commission Implementing Regulation (EU) 2016/561 ⁽²⁾ should be authorised until 28 February 2020.
- (11) 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

Implementing Regulation (EU) No 577/2013 is amended as follows:

- (1) Part 1 of Annex II is replaced by the text set out in Annex I to this Regulation.
- (2) Part 2 of Annex II is replaced by the text set out in Annex II to this Regulation.
- (3) Part 1 of Annex IV is replaced by the text set out in Annex III to this Regulation.

Article 2

For a transitional period until 28 February 2020, Member States shall authorise the entry of dogs, cats and ferrets moved into a Member State from a territory or a third country for non-commercial purposes and accompanied by an animal health certificate issued not later than 31 October 2019 in accordance with the model set out in Part 1 of Annex IV to Implementing Regulation (EU) No 577/2013 as amended by Implementing Regulation (EU) 2016/561.

Article 3

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

It shall apply from 1 November 2019.

⁽¹⁾ Commission Implementing Regulation (EU) 2018/878 of 18 June 2018 adopting the list of Member States, or parts of the territory of Member States, that comply with the rules for categorisation laid down in Article 2(2) and (3) of Delegated Regulation (EU) 2018/772 concerning the application of preventive health measures for the control of *Echinococcus multilocularis* infection in dogs (OJ L 155, 19.6.2018, p. 1).

⁽²⁾ Commission Implementing Regulation (EU) 2016/561 of 11 April 2016 amending Annex IV to Implementing Regulation (EU) No 577/2013 as regards the model of animal health certificate for dogs, cats and ferrets moved into a Member State from a territory or a third country for non-commercial purposes (OJ L 96, 12.4.2016, p. 26).

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

Done at Brussels, 29 July 2019.

For the Commission

The President

Jean-Claude JUNKER

ANNEX I

PART 1

List of territories and third countries referred to in Article 13(1) of Regulation (EU) No 576/2013

ISO code	Territory or third country
AD	Andorra
CH	Switzerland
FO	Faeroe Islands
GI	Gibraltar
GL	Greenland
IS	Iceland
LI	Liechtenstein
MC	Monaco
SM	San Marino
VA	Vatican City State'

ANNEX II

PART 2

List of territories and third countries referred to in Article 13(2) of Regulation (EU) No 576/2013

ISO code	Territory or third country	Included territories
AC	Ascension Island	
AE	United Arab Emirates	
AG	Antigua and Barbuda	
AR	Argentina	
AU	Australia	
AW	Aruba	
BA	Bosnia and Herzegovina	
BB	Barbados	
BH	Bahrain	
BM	Bermuda	
BQ	Bonaire, Sint Eustatius and Saba (the BES Islands)	
BY	Belarus	
CA	Canada	
CL	Chile	
CW	Curaçao	
FJ	Fiji	
FK	Falkland Islands	
HK	Hong Kong	
JM	Jamaica	
JP	Japan	
KN	Saint Kitts and Nevis	
KY	Cayman Islands	
LC	Saint Lucia	
MS	Montserrat	
MK	North Macedonia	
MU	Mauritius	
MX	Mexico	
MY	Malaysia	

ISO code	Territory or third country	Included territories
NC	New Caledonia	
NZ	New Zealand	
PF	French Polynesia	
PM	Saint Pierre and Miquelon	
RU	Russia	
SG	Singapore	
SH	Saint Helena	
SX	Sint Maarten	
TT	Trinidad and Tobago	
TW	Taiwan	
US	United States of America	AS — American Samoa GU — Guam MP — Northern Mariana Islands PR — Puerto Rico VI — US Virgin Islands'
VC	Saint Vincent and the Grenadines	
VG	British Virgin Islands	
VU	Vanuatu	
WF	Wallis and Futuna	

ANNEX III

PART 1

Model animal health certificate for the non-commercial movement into a Member State from a territory or third country of dogs, cats or ferrets in accordance with Article 5(1) and (2) of Regulation (EU) No 576/2013

COUNTRY:

Veterinary certificate to EU

Part I: Details of dispatched consignment	I.1. Consignor Name Address Tel.				I.2. Certificate reference No		I.2. a.			
					I.3. Central competent authority					
					I.4. Local competent authority					
	I.5. Consignee Name Address Postal code Tel.				I.6. Operator responsible for the consignment in the EU					
	I.7. Country of origin		ISO code	I.8. Region of origin	Code	I.9. Country of destination		ISO code	I.10. Region of destination	Code
	I.11. Place of origin				I.12. Place of destination					
	I.13. Place of loading				I.14. Date of departure					
	I.15. Means of transport				I.16. Entry BIP in EU					
					I.17. No.(s) of CITES					
	I.18. Description of commodity						I.19. Commodity code (HS code) 010619			
						I.20. Quantity				
I.21. Temperature of products						I.22. Total number of packages				
I.23. Seal/Container No						I.24. Type of packaging				

COUNTRY:

Veterinary certificate to EU

I.25. Commodities certified for:

Pets

I.26. For transit to 3rd Country

I.27. For import or admission into EU

I.28. Identification of the commodities

Species (Scientific name)	Sex	Colour	Breed	Identification number	Identification system	Date of birth [dd/mm/yyyy]
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Non-commercial movement into a Member State from a territory or third country of dogs, cats or ferrets in accordance with Article 5(1) and (2) of Regulation (EU) No 576/2013

COUNTRY

II.	Health information	II.a. Certificate reference No	II.b.
I, the undersigned official veterinarian ⁽¹⁾/veterinarian authorised by the competent authority ⁽¹⁾ of (insert name of territory or third country) certify that: <u>Purpose/nature of journey attested by the owner:</u> II.1. the attached declaration ⁽²⁾ by the owner or the natural person who has authorisation in writing from the owner to carry out the non-commercial movement of the animals on behalf of the owner, supported by evidence ⁽³⁾, states that the animals described in Box I.28 will accompany the owner or the natural person who has authorisation in writing from the owner to carry out the non-commercial movement of the animals on behalf of the owner within not more than five days of his movement and are not subject to a movement that aims at their sale or a transfer of ownership, and during the non-commercial movement will remain under the responsibility of (¹) either [the owner;] (¹) or [the natural person who has authorisation in writing from the owner to carry out the non-commercial movement of the animals on behalf of the owner;] (¹) or [the natural person designated by a carrier contracted by the owner to carry out the non-commercial movement of the animals on behalf of the owner;] (¹) either II.2. the animals described in Box I.28 are moved in a number of five or less;] (¹) or II.2. the animals described in Box I.28 are moved in a number of more than five, are more than six months old and are going to participate in competitions, exhibitions or sporting events or in training for those events, and the owner or the natural person referred to in point II.1 has provided evidence ⁽³⁾ that the animals are registered (¹) either [to attend such event;] (¹) or [with an association organising such events;] <u>Attestation of rabies vaccination and rabies antibody titration test:</u> (¹) either II.3. the animals described in Box I.28 are less than 12 weeks old and have not received an anti-rabies vaccination, or are between 12 and 16 weeks old and have received an anti-rabies vaccination, but 21 days at least have not elapsed since the completion of the primary vaccination against rabies carried out in accordance with the validity requirements set out in Annex III to Regulation (EU) No 576/2013 ⁽⁴⁾, and II.3.1 the territory or third country of provenance of the animals indicated in Box I.1 is listed in Annex II to Implementing Regulation (EU) No 577/2013 and the Member State of destination indicated in Box I.5 has informed the public that it authorises the movement of such animals into its territory, and they are accompanied by (¹) either II.3.2 the attached declaration ⁽⁵⁾ of the owner or the natural person referred to in point II.1 stating that from birth until the time of the non-commercial movement the animals have had no contact with wild animals of species susceptible to rabies;] (¹) or II.3.2 their mother, on whom they still depend, and it can be established that the mother received before their birth an anti-rabies vaccination which complied with the validity requirements set out in Annex III to Regulation (EU) No 576/2013;] (¹) or/and II.3. the animals described in Box I.28 were at least 12 weeks old at the time of vaccination against rabies and at least 21 days have elapsed since the completion of the primary anti-rabies vaccination ⁽⁴⁾ carried out in accordance with the validity requirements set out in Annex III to Regulation (EU) No 576/2013 and any subsequent revaccination was carried out within the period of validity of the preceding vaccination ⁽⁶⁾; and (¹) either II.3.1 the animals described in Box I.28 come from a territory or a third country listed in Annex II to Implementing Regulation (EU) No 577/2013, either directly, through a territory or a third country listed in Annex II to Implementing Regulation (EU) No 577/2013 or through a territory or a third country other than those listed in Annex II to Implementing Regulation (EU) No 577/2013 in accordance with point (c) of Article 12(1) of Regulation (EU) No 576/2013 ⁽⁷⁾, and the details of the current anti-rabies vaccination are provided in the table below;]			

Non-commercial movement into a Member State from a territory or third country of dogs, cats or ferrets in accordance with Article 5(1) and (2) of Regulation (EU) No 576/2013

COUNTRY

II. Health information		II.a. Certificate reference No		II.b.			
(1) or		[II.3.1 the animals described in Box I.28 come from, or are scheduled to transit through, a territory or third country other than those listed in Annex II to Implementing Regulation (EU) No 577/2013 and a rabies antibody titration test ⁽⁸⁾ , carried out on a blood sample taken by the veterinarian authorised by the competent authority on the date indicated in the table below not less than 30 days after the preceding vaccination and at least three months prior to the date of issue of this certificate, proved an antibody titre equal to or greater than 0,5 IU/ml ⁽⁹⁾ and any subsequent revaccination was carried out within the period of validity of the preceding vaccination ⁽⁶⁾ , and the details of the current anti-rabies vaccination and the date of sampling for testing the immune response are provided in the table below:					
Transponder or tattoo		Date of vaccination [dd/mm/yyyy]	Name and manufacturer of vaccine	Batch number	Validity of vaccination		Date of the blood sampling [dd/mm/yyyy]
Alphanumeric code of the animal	Date of implantation and/or reading ⁽¹⁰⁾ [dd/mm/yyyy]				From [dd/mm/yyyy]	to [dd/mm/yyyy]	
]]							
Attestation of anti-parasite treatment:							
(1) either		[II.4. the dogs described in Box I.28 are destined for a Member State listed in the Annex to Commission Implementing Regulation (EU) 2018/878 and have been treated against <i>Echinococcus multilocularis</i> , and the details of the treatment carried out by the administering veterinarian in accordance with Article 6 of Commission Delegated Regulation (EU) 2018/772 ⁽¹¹⁾ ⁽¹²⁾ ⁽¹³⁾ are provided in the table below.]					
(1) or		[II.4. the dogs described in Box I.28 have not been treated against <i>Echinococcus multilocularis</i> ⁽¹¹⁾ .]					
Transponder or tattoo number of the dog	Anti-echinococcus treatment		Administering veterinarian				
	Name and manufacturer of the product	Date [dd/mm/yyyy] and time of treatment [00:00]	Name in capitals, stamp and signature				
]]							

**Non-commercial movement into a Member State from a territory
or third country of dogs, cats or ferrets in accordance with
Article 5(1) and (2) of Regulation (EU) No 576/2013**

COUNTRY

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

(a) This certificate is meant for dogs (*Canis lupus familiaris*), cats (*Felis silvestris catus*) and ferrets (*Mustela putorius furo*).

(b) This certificate is valid for 10 days from the date of issue by the official veterinarian until the date of the documentary and identity checks at the designated Union travellers' point of entry (available at http://ec.europa.eu/food/animal/liveanimals/pets/pointentry_en.htm).

In the case of transport by sea, that period of 10 days is extended by an additional period corresponding to the duration of the journey by sea.

For the purpose of further movement into other Member States, this certificate is valid from the date of the documentary and identity checks for a total of four months or until the date of expiry of the validity of the anti-rabies vaccination or until the conditions relating to animals less than 16 weeks old referred to in point II.3 cease to apply, whichever date is earlier. Please note that certain Member States have informed that the movement into their territory of animals less than 16 weeks old referred to in point II.3 is not authorised. You may wish to inquire at http://ec.europa.eu/food/animal/liveanimals/pets/index_en.htm.

Part I:

Box I.5: *Consignee*: indicate Member State of first destination.

Box I.28: *Identification system*: select of the following: transponder or tattoo.

Identification number: indicate the transponder or tattoo alphanumeric code.

Date of birth/breed: as stated by the owner.

Part II:

(¹) Keep as appropriate.

(²) The declaration referred to in point II.1 shall be attached to the certificate and comply with the model and additional requirements set out in Part 3 of Annex IV to Implementing Regulation (EU) No 577/2013.

(³) The evidence referred to in point II.1 (e.g. boarding pass, flight ticket) and in point II. 2 (e.g. receipt of entry to the event, proof of membership) shall be surrendered on request by the competent authorities responsible for the checks referred to in point (b) of the Notes.

(⁴) Any revaccination must be considered a primary vaccination if it was not carried out within the period of validity of a previous vaccination.

(⁵) The declaration referred to in point II.3.2 to be attached to the certificate complies with the format, layout and language requirements laid down in Parts 1 and 3 of Annex I to Implementing Regulation (EU) No 577/2013.

(⁶) A certified copy of the identification and vaccination details of the animals concerned shall be attached to the certificate.

(⁷) The third option is subject to the condition that the owner or the natural person referred to in point II.1 provides, on request by the competent authorities responsible for the checks referred to in point (b), a declaration stating that the animals have had no contact with animals of species susceptible of rabies and remain secure within the means of transport or the perimeter of an international airport during the transit through a territory or a third country other than those listed in Annex II to Implementing Regulation (EU) No 577/2013. This declaration shall comply with the format, layout and language requirements set out in Parts 2 and 3 of Annex I to Implementing Regulation (EU) No 577/2013.

**Non-commercial movement into a Member State from a territory
or third country of dogs, cats or ferrets in accordance with
Article 5(1) and (2) of Regulation (EU) No 576/2013**

COUNTRY

II. Health information	II.a. Certificate reference No	II.b.										
(⁸) The rabies antibody titration test referred to in point II.3.1: — must be carried out on a sample collected by a veterinarian authorised by the competent authority, at least 30 days after the date of vaccination and three months before the date of import; — must measure a level of neutralising antibody to rabies virus in serum equal to or greater than 0,5 IU/ml; — must be performed by a laboratory approved in accordance with Article 3 of Council Decision 2000/258/EC (list of approved laboratories available at http://ec.europa.eu/food/animal/liveanimals/pets/approval_en.htm); — does not have to be renewed on an animal, which following that test with satisfactory results, has been revaccinated against rabies within the period of validity of a previous vaccination. A certified copy of the official report from the approved laboratory on the results of the rabies antibody test referred to in point II.3.1 shall be attached to the certificate. (⁹) By certifying this result, the official veterinarian confirms that he has verified, to the best of his ability and where necessary with contacts with the laboratory indicated in the report, the authenticity of the laboratory report on the results of the antibody titration test referred to in point II.3.1. (¹⁰) In conjunction with footnote (6), the marking of the animals concerned by the implantation of a transponder or by a clearly readable tattoo applied before 3 July 2011 must be verified before any entry is made in this certificate and must always precede any vaccination, or where applicable, testing carried out on those animals. (¹¹) The treatment against <i>Echinococcus multilocularis</i> referred to in point II.4 must: — be administered by a veterinarian within a period of not more than 120 hours and not less than 24 hours before the time of the scheduled entry of the dogs into one of the Member States or parts thereof listed in the Annex to Implementing Regulation (EU) 2018/878; — consist of an approved medicinal product which contains the appropriate dose of praziquantel or pharmacologically active substances, which alone or in combination, have been proven to reduce the burden of mature and immature intestinal forms of <i>Echinococcus multilocularis</i> in the host species concerned. (¹²) The table referred to in point II.4 must be used to document the details of a further treatment if administered after the date the certificate was signed and prior to the scheduled entry into one of the Member States or parts thereof listed in the Annex to Implementing Regulation (EU) 2018/878. (¹³) The table referred to in point II.4 must be used to document the details of treatments if administered after the date the certificate was signed for the purpose of further movement into other Member States described in point (b) of the Notes and in conjunction with footnote (11).												
Official veterinarian/Authorised veterinarian <table border="0"> <tr> <td>Name (in capital letters):</td> <td>Qualification and title:</td> </tr> <tr> <td>Address</td> <td></td> </tr> <tr> <td>Telephone:</td> <td></td> </tr> <tr> <td>Date:</td> <td>Signature:</td> </tr> <tr> <td>Stamp:</td> <td></td> </tr> </table>			Name (in capital letters):	Qualification and title:	Address		Telephone:		Date:	Signature:	Stamp:	
Name (in capital letters):	Qualification and title:											
Address												
Telephone:												
Date:	Signature:											
Stamp:												

Non-commercial movement into a Member State from a territory or third country of dogs, cats or ferrets in accordance with Article 5(1) and (2) of Regulation (EU) No 576/2013

COUNTRY

II.	Health information	II.a. Certificate reference No	II.b.
Endorsement by the competent authority (not necessary when the certificate is signed by an official veterinarian)			
Name (in capital letters):		Qualification and title:	
Address			
Telephone:			
Date:		Signature:	
Stamp:			
Official at the travellers' point of entry (for the purpose of further movement into other Member States)			
Name (in capital letters):		Title:	
Address			
Telephone:			
Email address:			
Date of completion of the documentary and identity checks:		Signature:	Stamp:

COMMISSION IMPLEMENTING REGULATION (EU) 2019/1294**of 1 August 2019****authorising the placing on the market of betaine as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 ⁽¹⁾, and in particular Article 12 thereof,

Whereas:

- (1) Regulation (EU) 2015/2283 provides that only novel foods authorised and included in the Union list may be placed on the market within the Union.
- (2) Pursuant to Article 8 of Regulation (EU) 2015/2283, Commission Implementing Regulation (EU) 2017/2470 ⁽²⁾ was adopted, which establishes a Union list of authorised novel foods.
- (3) Pursuant to Article 12 of Regulation (EU) 2015/2283, the Commission is to decide on the authorisation and on the placing on the Union market of a novel food and on the updating of the Union list.
- (4) On 12 June 2015, the company DuPont Nutrition Biosciences ApS. ('the Applicant') made a request to the competent authority of Finland to place betaine on the Union market as a novel food ingredient within the meaning of point (e) of Article 1(2) of Regulation (EC) No 258/97 of the European Parliament and of the Council ⁽³⁾. The application requests for betaine to be used in cereal and protein bars, drink powders, isotonic ready-to-drink beverages for persons above the age of 10 engaging in sports activities, and in cereal and protein bars, and foods for special medical purposes and/or total diet replacement as defined in Regulation (EU) No 609/2013 ⁽⁴⁾ of the European Parliament and of the Council, excluding food for infants and young children.
- (5) Pursuant to Article 35(1) of Regulation (EU) 2015/2283, any request for placing a novel food on the market within the Union submitted to a Member State in accordance with Article 4 of Regulation (EC) No 258/97 and for which the final decision has not been taken before 1 January 2018 shall be treated as an application submitted under Regulation (EU) 2015/2283.
- (6) While the request for placing betaine on the market as a novel food within the Union was submitted to a Member State in accordance with Article 4 of Regulation (EC) No 258/97, the application also meets the requirements laid down in Regulation (EU) 2015/2283.
- (7) On 21 October 2015, the competent authority of Finland issued its initial assessment report. In that report, it came to the conclusion that betaine meets the criteria for novel food ingredient set out in Article 3(1) of Regulation (EC) No 258/97.

⁽¹⁾ OJ L 327, 11.12.2015, p. 1.

⁽²⁾ Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods (OJ L 351, 30.12.2017, p. 72).

⁽³⁾ Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (OJ L 43, 14.2.1997, p. 1).

⁽⁴⁾ Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 (OJ L 181, 29.6.2013, p. 35).

- (8) On 23 October 2015, the Commission forwarded the initial assessment report to the other Member States. Reasoned objections were raised by other Member States within the 60-day period laid down in the first subparagraph of Article 6(4) of Regulation (EC) No 258/97 with regard to adverse effects being observed at the no-observed-adverse-effect level (NOAEL) proposed by the Applicant for the chronic oral toxicity and carcinogenicity study, the small margin of exposure between the betaine doses at which effects were observed in the toxicological studies, and the proposed daily intake of betaine.
- (9) In view of those reasoned objections, the Commission consulted the European Food Safety Authority ('the Authority') on 4 April 2016, asking it to carry out an additional assessment for betaine as novel food ingredient in accordance with Regulation (EC) No 258/97.
- (10) On 25 October 2017, the Authority adopted its scientific opinion 'Safety of Betaine as a novel food pursuant to Regulation (EC) No 258/97 ⁽⁵⁾'. That opinion, although elaborated and adopted by the Authority under Regulation (EC) No 258/97 is in line with the requirements of Article 11 of Regulation (EU) 2015/2283.
- (11) In its scientific opinion, the Authority, using the Benchmark Dose Approach (BMD) ⁽⁶⁾, concluded that betaine is safe for the intended population groups when added to foods at a maximum daily dose of 400 mg/day (6 mg/kg body weight per day). In that opinion, the Authority concluded that the safety of betaine, at the proposed uses and use levels as proposed by the Applicant, which would result in intakes of 2 500 mg of betaine per day, has not been established.
- (12) On 25 January 2018, the Applicant made a request to the Commission for protection of proprietary data for nine studies submitted in support of the application, namely reports of the acute oral toxicity study ⁽⁷⁾, two sub-acute (14-day ⁽⁸⁾ and 28-day ⁽⁹⁾), and one sub-chronic ⁽¹⁰⁾ (42-day) oral toxicity studies, three mutagenicity and genotoxicity studies ⁽¹¹⁾, a chronic oral toxicity and carcinogenicity study ⁽¹²⁾, and a chronic (six-month) human dietary study ⁽¹³⁾.
- (13) On 18 February 2018, the Authority considered ⁽¹⁴⁾ that, in elaborating its opinion on betaine as a novel food, the data from the chronic oral toxicity and carcinogenicity study served as a basis for the BMD analysis and for deriving safe intake levels of betaine for the target population, the data from the chronic human dietary study served as a basis to derive the safe intake of betaine for the target population, and the data from three genotoxicity studies served as a basis to alleviate concerns with respect to the potential genotoxicity of betaine. Therefore, it is considered that the conclusions on the safety of betaine, could not have been reached without the data from the unpublished reports of these studies.
- (14) Following the receipt of the Authority's considerations, the Commission requested the applicant to further clarify the justification provided with regard to their proprietary claim over the chronic oral toxicity and carcinogenicity study, the chronic human dietary study, and the three mutagenicity and genotoxicity studies, and to clarify their claim to an exclusive right of reference to these studies, as referred to in Article 26(2)(b) of Regulation (EU) 2015/2283.
- (15) The Applicant declared that, at the time the application was submitted, it held proprietary exclusive rights to the studies under national law and that therefore third parties could not lawfully access or use these studies.
- (16) The Commission assessed all the information provided by the Applicant and considered that the Applicant has sufficiently substantiated the fulfilment of the requirements laid down in Article 26(2) of Regulation (EU) 2015/2283. Therefore, the chronic oral toxicity and carcinogenicity study, the chronic human dietary study, and the three genotoxicity studies contained in the Applicant's file should not be used by the Authority for the benefit of a subsequent applicant for a period of five years from the date of entry into force of this Regulation. Accordingly, the placing on the market within the Union of betaine authorised by this Regulation should be restricted to the Applicant for that period.

⁽⁵⁾ EFSA Journal 2017; 15(11):5057.

⁽⁶⁾ EFSA Journal 2017; 15(1):4658.

⁽⁷⁾ Life Science Research Limited, 1990, unpublished.

⁽⁸⁾ TNO BIBRA, 2001, unpublished.

⁽⁹⁾ TNO BIBRA, 2001, unpublished.

⁽¹⁰⁾ Imasde Agglomenteria, 2012 unpublished.

⁽¹¹⁾ Asquith 1989 a, b, c. Unpublished.

⁽¹²⁾ Hatano Research Institute. 2002, unpublished studies.

⁽¹³⁾ Unpublished report, undated.

⁽¹⁴⁾ EFSA Scientific Panel on Dietetic Products, Nutrition and Allergies, Minutes of the 83rd Plenary held on 7-8 February 2018 and agreed on 18 February 2018 (<https://www.efsa.europa.eu/sites/default/files/event/180207-1-m.pdf>).

- (17) However, restricting the authorisation of betaine and of the reference to the studies contained in the Applicant's file for the sole use of the Applicant does not prevent other applicants from applying for an authorisation to place on the market the same novel food provided that, their application is based on legally obtained information supporting the authorisation under this Regulation.
- (18) On 2 November 2018 the Applicant made a request to the Commission within the meaning of Article 10(1) of Regulation (EU) 2015/2283 for the change in the conditions of use of betaine which were included in the 12 June 2015 request of the Applicant to the competent authority of Finland to place betaine on the Union market as a novel food ingredient. The requested changes concern modifications in the intended uses and use levels of betaine in drink powders, isotonic drinks, protein and cereal bars and meal replacement foods intended for sportsmen, and in the uses of betaine in total diet replacement foods for weight control and in foods for special medical purposes as defined in Regulation (EU) No 609/2013, excluding foods for infants and young children. Those requested changes would ensure that the intake of betaine by the general population will not exceed the 400 mg/day (6 mg/kg body weight per day) deemed by the Authority in its 2017 opinion to be safe.
- (19) On 12 December 2018, the Commission consulted the Authority asking it to carry out an additional assessment for the changes in the intended uses and use levels of betaine as a novel food in accordance with Article 10(3) of Regulation (EU) 2015/2283.
- (20) On 14 March 2019, the Authority adopted its scientific opinion 'Safety of Betaine as a novel food pursuant to Regulation (EU) 2015/2283' ⁽¹⁵⁾. That scientific opinion is in accordance with the requirements of Article 11 of Regulation (EU) 2015/2283.
- (21) In that opinion the Authority concluded that betaine is safe under the new proposed conditions of use. Therefore that scientific opinion gives sufficient grounds to establish that betaine, under the proposed uses and use levels, when used as an ingredient in drink powders, isotonic drinks, protein and cereal bars and meal replacement foods intended for sportsmen, and in total diet replacement foods for weight control, and foods for special medical purposes as defined in Regulation (EU) No 609/2013, excluding foods for infants and young children, complies with Article 12(1) of Regulation (EU) 2015/2283.
- (22) The safe level of intake of betaine could be exceeded when foods containing betaine are used in conjunction with food supplements containing betaine. It is therefore necessary to inform the consumers with an appropriate label that foods containing betaine should not be used if food supplements containing betaine are also consumed on the same day.
- (23) The use of betaine should be authorised without prejudice to Regulation (EU) No 609/2013 laying down requirements on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control.
- (24) 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

1. Betaine as specified in the Annex to this Regulation shall be included in the Union list of authorised novel foods established in Implementing Regulation (EU) 2017/2470.
2. For a period of five years from the date of entry into force of this Regulation only the initial Applicant:

Company: DuPont Nutrition Biosciences ApS;

Address: Langebrogade 1 DK-1411 Copenhagen K, Denmark,

is authorised to place on the market within the Union the novel food referred to in paragraph 1, unless a subsequent applicant obtains authorisation for the novel food without reference to the data protected pursuant to Article 2 of this Regulation or with the agreement of DuPont Nutrition Biosciences ApS.

⁽¹⁵⁾ EFSA Journal 2019; 17(4):5658.

3. The entry in the Union list referred to in paragraph 1 shall include the conditions of use and labelling requirements laid down in the Annex to this Regulation.
4. The authorisation provided for in this Article shall be without prejudice to the provisions of Regulation (EU) No 609/2013.

Article 2

The studies contained in the application file on the basis of which the novel food referred to in Article 1 has been assessed by the Authority, claimed by the Applicant as proprietary and without which the novel food could not have been authorised, shall not be used for the benefit of a subsequent applicant for a period of five years from the date of entry into force of this Regulation without the agreement of DuPont Nutrition Biosciences ApS.

Article 3

The Annex to Implementing Regulation (EU) 2017/2470 is amended in accordance with the Annex to this Regulation.

Article 4

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, 1 August 2019.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

The Annex to Implementing Regulation (EU) 2017/2470 is amended as follows:

(1) in Table 1 (Authorised novel foods), the following entry is inserted in alphabetical order:

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	Data Protection
Betaine	<i>Specified food category</i>	<i>Maximum levels (*)</i>	The designation of the novel food on the labelling of the foodstuffs containing it shall be “betaine”. The labelling of foods containing betaine shall bear a statement that the foods should not be used if food supplements containing betaine are consumed the same day.		Authorised on 22 August 2019. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: DuPont Nutrition Biosciences ApS, Langebrogade 1 Copenhagen K, DK-1411, Denmark. During the period of data protection, the novel food betaine is authorised for placing on the market within the Union only by DuPont Nutrition Biosciences ApS unless a subsequent applicant obtains authorisation for the novel food without reference to the proprietary scientific evidence or scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283 or with the agreement of DuPont Nutrition Biosciences ApS, End date of the data protection: 22 August 2024.
	Drink powders, isotonic and energy drinks intended for sportsmen	60 mg/100 g			
	Protein and cereal bars intended for sportsmen	500 mg/100 g			
	Meal replacements intended for sportsmen	20 mg/100 g			
	Total diet replacement for weight control as defined under Regulation (EU) No 609/2013	500 mg/100 g (bar) 136 mg/100 g (soup) 188 mg/100 g (porridge) 60 mg/100 g (beverages)			
	Foods for Special Medical Purposes as defined under Regulation (EU) No 609/2013 for adults	400 mg/day			

(*) Maximum use levels in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer.;

(2) the following entry is inserted in Table 2 (Specifications) in alphabetical order:

Authorised Novel Food	Specification
Betaine	Description/Definition: Betaine (N,N,N-trimethylglycine or carboxy-N,N,N-trimethylmethanaminium), in anhydrous $(\text{CH}_3)_3\text{N}^+\text{CH}_2\text{COO}^-$ (CAS No: 107-43-7) and monohydrate $(\text{CH}_3)_3\text{N}^+\text{CH}_2\text{COO}^-\cdot\text{H}_2\text{O}$ (CAS No: 590-47-6) forms is obtained from processing of sugar beets (i.e. molasses, vinasses or betaine-glycerol). Characteristics/Composition Appearance: Free-flowing white crystals Betaine: $\geq 99,0 \%$ (w/w on dry weight basis) Moisture: $\leq 2,0 \%$ (anhydrous); $\leq 15,0 \%$ (monohydrate) Ash: $\leq 0,1 \%$ pH: 5,0-7,0 Residual protein: $\leq 1,0 \text{ mg/g}$ Heavy metals: Arsenic: $< 0,1 \text{ mg/kg}$ Mercury: $< 0,005 \text{ mg/kg}$ Cadmium: $< 0,01 \text{ mg/kg}$ Lead: $< 0,05 \text{ mg/kg}$ Microbiological criteria: Total viable count: $\leq 100 \text{ CFU/g}$ Coliforms: Negative/10 g <i>Salmonella</i> sp.: Negative/25 g Yeast: $\leq 10 \text{ CFU/g}$ Mould: $\leq 10 \text{ CFU/g}$

CFU: Colony Forming Units.'

COMMISSION IMPLEMENTING REGULATION (EU) 2019/1295**of 1 August 2019****amending Implementing Regulation (EU) 2018/1469 imposing a definitive anti-dumping duty on imports of certain seamless pipes and tubes, of iron or steel, originating in Russia and Ukraine, following a partial interim review pursuant to Article 11(3) of Regulation (EU) 2016/1036**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2016/1036 of the European Parliament and of the Council of 8 June 2016 on protection against dumped imports from countries not members of the European Union ⁽¹⁾ ('basic Regulation'), and in particular Article 11(3) thereof,

Whereas:

1. PROCEDURE**1.1. Measures in force**

- (1) By Regulation (EC) No 954/2006 ⁽²⁾ the Council, following an investigation ('the original investigation'), imposed a definitive anti-dumping duty on imports of certain seamless pipes and tubes, of iron or steel, originating in Croatia, Russia and Ukraine. The measures consisted of an *ad valorem* anti-dumping duty ranging between 12,3 % and 25,7 % imposed on imports from individually named exporting producers in Ukraine, with a residual duty rate of 25,7 % on imports from all other companies in Ukraine. The definitive anti-dumping duty imposed on the exporting producer subject to the current review investigation, CJSC Nikopolsky Seamless Tubes Plant Niko Tube and OJSC Nizhnedneprovsky Tube Rolling Plant, now named LLC Interpipe Niko Tube and OJSC Interpipe Nizhnedneprovsky Tube Rolling Plant ('the applicant' or 'Interpipe') was 25,1 %.
- (2) Following an application by Interpipe for the annulment of Council Regulation (EC) No 954/2006, the General Court of the European Union annulled Article 1 of Council Regulation (EC) No 954/2006 in so far as the anti-dumping duty fixed for Interpipe exceeded that which would have been applicable had the export price not been adjusted for a commission when sales took place through the intermediary of the affiliated trader, Sepco SA ⁽³⁾. On 16 February 2012 the Court of Justice of the European Union upheld the judgment of the General Court ⁽⁴⁾.
- (3) Following these judgments, the Council amended Council Regulation (EC) No 954/2006 by Implementing Regulation (EU) No 540/2012 ⁽⁵⁾ to correct the anti-dumping duty imposed on Interpipe in so far as it had been erroneously established. As a consequence, the duty applicable to Interpipe was amended to 17,7 %.
- (4) By Implementing Regulation (EU) No 585/2012 ⁽⁶⁾ the Council, following an expiry review, maintained the measures imposed by Council Regulation (EC) No 954/2006 on imports of seamless pipes and tubes, of iron or steel, originating in Russia and Ukraine.

⁽¹⁾ OJ L 176, 30.6.2016, p. 21.

⁽²⁾ Council Regulation (EC) No 954/2006 of 27 June 2006 imposing definitive anti-dumping duty on imports of certain seamless pipes and tubes, of iron or steel originating in Croatia, Romania, Russia and Ukraine, repealing Council Regulations (EC) No 2320/97 and (EC) No 348/2000, terminating the interim and expiry reviews of the anti-dumping duties on imports of certain seamless pipes and tubes of iron or non-alloy steel originating, inter alia, in Russia and Romania and terminating the interim reviews of the anti-dumping duties on imports of certain seamless pipes and tubes of iron or non-alloy steel originating, inter alia, in Russia and Romania and in Croatia and Ukraine (OJ L 175, 29.6.2006, p. 4).

⁽³⁾ Judgment of 10 March 2009 in case T-249/06, *Interpipe Niko Tube and Interpipe NTRP v Council*, EU:T:2009:62.

⁽⁴⁾ Judgment of 16 February 2012 in joined cases C-191/09 P and C-200/09 P, *Council and Commission v Interpipe Niko Tube and Interpipe NTRP*, EU:C:2012:78.

⁽⁵⁾ Council Implementing Regulation (EU) No 540/2012 of 21 June 2012 amending Regulation (EC) No 954/2006 imposing a definitive anti-dumping duty on imports of certain seamless pipes and tubes, of iron or steel originating in Croatia, Romania, Russia and Ukraine (OJ L 165, 26.6.2012, p. 1).

⁽⁶⁾ Council Implementing Regulation (EU) No 585/2012 of 26 June 2012 imposing a definitive anti-dumping duty on imports of certain seamless pipes and tubes, of iron or steel, originating in Russia and Ukraine, following an expiry review pursuant to Article 11(2) of Regulation (EC) No 1225/2009, and terminating the expiry review proceeding concerning imports of certain seamless pipes and tubes, of iron or steel, originating in Croatia (OJ L 174, 4.7.2012, p. 5).

- (5) Following an application by Interpipe pursuant to Article 11(3) of the basic Regulation, the Council, by Implementing Regulation (EU) No 795/2012 ⁽⁷⁾ amended the definitive measures imposed by Implementing Regulation (EU) No 585/2012 as far as Interpipe is concerned ('the last interim review'). As a consequence, the duty applicable to Interpipe was amended to 13,8 %.
- (6) By Implementing Regulation (EU) 2018/1469 ⁽⁸⁾ the Commission, following an expiry review, maintained the measures imposed by Implementing Regulation (EU) No 585/2012 as last amended by Implementing Regulation (EU) No 795/2012 and Council Implementing Regulation (EU) No 1269/2012 ⁽⁹⁾ on imports of seamless pipes and tubes, of iron or steel, originating in Russia and Ukraine ('the expiry review investigation').
- (7) The anti-dumping duties currently in force range from 35,8 % to 24,1 % for imports originating in Russia, and 25,7 % to 12,3 % for imports originating in Ukraine.

1.2. Request for a partial interim review

- (8) On 7 May 2018, the Commission announced by a notice published in the *Official Journal of the European Union* the initiation of a partial interim review ('Notice of initiation') ⁽¹⁰⁾ of the anti-dumping measures applicable to imports of certain seamless pipes and tubes, of iron or steel, originating in Ukraine pursuant to Article 11(3) of the basic Regulation.
- (9) The review, which is limited in scope to the examination of dumping of the exporting producer Interpipe, was initiated following a substantiated request lodged by the company. In the request Interpipe provided sufficient evidence that the circumstances on the basis of which the existing measures were imposed have changed and that these changes are of a lasting nature.

1.3. Investigation

- (10) The investigation of the level of dumping covered the period from 1 April 2017 to 31 March 2018 ('the review investigation period').
- (11) The Commission officially informed the applicant, the authorities of the exporting country and the Union industry of the initiation of the partial interim review. Interested parties were given the opportunity to make their views known in writing and to request a hearing within the time-limit set out in the Notice of initiation.
- (12) In order to obtain the information necessary for its investigation, the Commission sent a questionnaire to the applicant, which responded within the given deadline.
- (13) The Commission sought and verified all information it deemed necessary for the purpose of determining the level of dumping. Verification visits were carried out at the premises of the applicant and at its related trading companies LLC Interpipe Ukraine, Interpipe Europe SA and Interpipe Central Trade GmbH.

2. PRODUCT UNDER REVIEW AND LIKE PRODUCT

2.1. Product under review

- (14) The product under review is the same as that defined in Implementing Regulation (EU) 2018/1469 of 1 October 2018 which imposed the measures currently in force, *i.e.* seamless pipes and tubes of iron or steel ('SPT'),

⁽⁷⁾ Council Implementing Regulation (EU) No 795/2012 of 28 August 2012 amending Implementing Regulation (EU) No 585/2012 imposing a definitive anti-dumping duty on imports of certain seamless pipes and tubes, of iron or steel, originating in Russia and Ukraine, following a partial interim review pursuant to Article 11(3) of Regulation (EC) No 1225/2009 (OJ L 238, 4.9.2012, p. 1).

⁽⁸⁾ Commission Implementing Regulation (EU) 2018/1469 of 1 October 2018 imposing a definitive anti-dumping duty on imports of certain seamless pipes and tubes, of iron or steel, originating in Russia and Ukraine, following an expiry review pursuant to Article 11(2) of Regulation (EU) 2016/1036 of the European Parliament and of the Council (OJ L 246, 2.10.2018, p. 20).

⁽⁹⁾ Council Implementing Regulation (EU) No 1269/2012 of 21 December 2012 amending Implementing Regulation (EU) No 585/2012 imposing a definitive anti-dumping duty on imports of certain seamless steel pipes, of iron or steel, originating, *inter alia*, in Russia, following a partial interim review pursuant to Article 11(3) of Regulation (EC) No 1225/2009 (OJ L 357, 28.12.2012, p. 1).

⁽¹⁰⁾ OJ C 159, 7.5.2018, p. 18.

of circular cross-section, of an external diameter not exceeding 406,4 mm with a Carbon Equivalent Value (CEV) not exceeding 0,86 according to the International Institute of Welding (IIW) formula and chemical analysis ⁽¹⁾, originating in *inter alia* Ukraine, currently falling within CN codes ex 7304 11 00, ex 7304 19 10, ex 7304 19 30, ex 7304 22 00, ex 7304 23 00, ex 7304 24 00, ex 7304 29 10, ex 7304 29 30, ex 7304 31 80, ex 7304 39 58, ex 7304 39 92, ex 7304 39 93, ex 7304 51 89, ex 7304 59 92 and ex 7304 59 93 ('the product under review').

2.2. Like product

- (15) As established in the original investigation as well as in the subsequent reviews, the current investigation confirmed that the product produced in Ukraine and exported to the EU, the product produced and sold on the domestic market of Ukraine, and the product produced and sold in the EU by the Union producers have the same basic physical and technical characteristics and end uses. These products are therefore considered to be like products within the meaning of Article 1(4) of the basic Regulation.

3. LASTING NATURE OF CHANGED CIRCUMSTANCES

- (16) In accordance with Article 11(3) of the basic Regulation, it was examined whether the changed circumstances regarding dumping could be considered to be of a lasting nature.
- (17) During the original antidumping investigation in 2006, as well as in the most recent interim review investigation of Interpipe in 2012, covering the review investigation period from 1 October 2010 to 30 September 2011, the main raw material for the production of the product under review, i.e. round steel billets, was procured by Interpipe from independent suppliers.
- (18) In its request for a partial interim review, the applicant claimed that the vertical integration of LLC Metallurgical Plant 'Dneprosteel' in 2013 has led to in-house production of the key raw material (steel billets) leading to a significant cost reduction and change in product portfolio. The applicant also claimed that, in comparison with the product types produced and exported in the review investigation period of the last interim review investigation, i.e. 'standard' steel grade, it has now added new and more sophisticated products ('high-alloy', 'line pipe and mechanical pipe' grades) to its product portfolio, which represented an important share of the total exports to the EU during the current review investigation period from 1 April 2017 to 31 March 2018.
- (19) The investigation confirmed that the key raw material was produced in-house by the applicant and that this change resulted in a significant change in costs and in product portfolio. The investigation confirmed that the product types exported by Interpipe to the EU were to a very large extent different from those exported during the review investigation period of the last interim review investigation. On this basis and given the structural nature of these changes, it was concluded that the changes described in recital (17) were of a lasting nature and unlikely to change in the near future. Consequently, it was considered that the application of the existing measures at their current level should be reassessed.
- (20) A further change claimed by the applicant after the initiation of this review, i.e. the existence / setting up of a joint venture between Interpipe and Vallourec Tubes, was not taken into account since it took place after the initiation of the present interim review.

4. DUMPING

4.1.1. Company structure and methodology used for calculating dumping

- (21) During the review investigation period, Interpipe had two fully-owned and controlled exporting producers ('the manufacturing entities'), LLC Interpipe Niko Tube ('NIKO') and OJSC Interpipe Nizhnedneprovsky Tube Rolling Plant ('NTRP').

⁽¹⁾ The CEV shall be determined in accordance with Technical Report, 1967, IIW doc. IX-555-67, published by the International Institute of Welding (IIW).

- (22) In the original investigation, as the accounting system of the applicant did not allow the identification of the relevant production company with respect to sales, a common dumping margin was calculated by aggregating all data relating to production, profitability and sales in the EU of the two producing entities.
- (23) As of the last interim review, following a marked change in the corporate structure of the group enabling the identification of the relevant production company with respect to sales and production and in accordance with Article 2(11) and (12) of the basic regulation, the Commission no longer aggregated the data for the production companies, but used the standard methodology. This standard methodology consisted in calculating one common dumping margin for the two exporting producers by first calculating the amount of dumping for each individual exporting producer before determining a single weighted average rate of dumping for both companies.
- (24) In the current investigation it was also possible to identify the relevant production company with respect to sales. Thus, in accordance with Article 2(11) and (12) of the basic regulation and in line with the Union institutions' consistent practice, the same methodology as in the last interim review was applied.

4.1.2. Normal value

- (25) In accordance with Article 2(2) of the basic Regulation, the Commission first examined whether each of the exporting producers' total volume of domestic sales of the like product to independent customers was representative in comparison with its total volume of export sales to the EU, i.e. whether the total volume of such sales represented at least 5 % of the total volume of export sales of the product under review to the EU. The examination established that the domestic sales were representative for both exporting producers.
- (26) The Commission then examined whether the domestic sales of Interpipe on its domestic market for the product type that is identical or comparable with the product type sold for export to the Union were representative, in accordance with Article 2(2) of the basic Regulation. The domestic sales of a product type are representative if the total volume of domestic sales of that product type to independent customers during the investigation period represents at least 5 % of the total volume of export sales of the identical or comparable product type to the Union. The Commission established that the domestic sales of the product type identical or comparable with the product type sold for export to the Union were to a large extent representative during the investigation period as 60 to 80 % ⁽¹²⁾ of the exported models were found to be sold in representative quantities on the domestic market.
- (27) In accordance with Article 2(4) of the basic Regulation, it was subsequently examined whether the domestic sales of each product type that had been sold in representative quantities could be regarded as being made in the ordinary course of trade. This was done by establishing the proportion of profitable domestic sales to independent customers on the domestic market for each exported type of the product under review during the review investigation period.
- (28) For those product types where more than 80 % by volume of sales on the domestic market of the product type were above cost and the weighted average sales price of that type was equal to or above the unit cost of production, normal value, by product type, was calculated as the weighted average of the actual domestic prices of all sales of the product type in question, irrespective of whether those sales were profitable or not.
- (29) Where the volume of profitable sales of a product type represented 80 % or less of the total sales volume of that product type, or where the weighted average price of that product type was below the unit cost of production, the normal value was based on the actual domestic price, which was calculated as a weighted average price of only the profitable domestic sales of that product type made during the review investigation period.
- (30) The analysis of domestic sales showed that 35 to 55 % ⁽¹³⁾ of all domestic sales of the product type that were identical or comparable with the product type sold for export to the Union were profitable and that the weighted average sales price was higher than the cost of production. Accordingly, the normal value was calculated as a weighted average of the profitable sales only.

⁽¹²⁾ The exact figure is not provided as this is the company specific data.

⁽¹³⁾ The exact figure is not provided as this is the company specific data.

- (31) The normal value for the non-representative product types (i.e. those of which domestic sales constituted less than 5 % of export sales to the EU or were not sold at all in the domestic market) was calculated on the basis of the cost of manufacturing per product type plus an amount for selling, general and administrative costs and for profits. In case of existing domestic sales, the profit of transactions in the ordinary course of trade on the domestic market per product type for the product types concerned was used. In case of no domestic sales, an average profit was used ⁽¹⁴⁾.
- (32) Following the final disclosure, the Interpipe Group contested some of the elements used by the Commission in the calculation of the normal value. The claims pertained to the following issues: (i) calculation of SG&A; (ii) the alleged exclusion of other operating costs; (iii) use of financial costs; (iv) double counting in respect of the adjustments of SG&A costs.
- (33) After reviewing the elements on the file, the Commission decided to accept the above claims (ii) and (iv) and reject the above claims (i) and (iii). Due to the confidential nature of business information contained in Interpipe Group's claims and the Commission's analysis of these arguments, the Commission provided Interpipe Group with an additional disclosure on the adoption date of this regulation, containing a detailed reasoning.
- (34) Having accepted claims (ii) and (iv), the Commission revised Interpipe's dumping margin. The company was provided with an additional disclosure describing the impact on the dumping margin and was invited to comment. The Commission also informed the EU industry of the changes in the company's dumping margin.
- (35) Following the additional disclosure, Interpipe maintained the claims which the Commission had rejected, without adding any new elements which could change the Commission's conclusions disclosed to the company.

4.1.3. Export price

- (36) Export sales of the product under review to the EU involved various entities within the Interpipe group; i.e. the plants, a coordination company based in Ukraine ('Interpipe Ukraine' or 'IPU'), a related importer based in Germany ('Interpipe Central Trade GmbH' or 'IPCT') and an affiliated trader based in Switzerland ('Interpipe Europe SA' or 'IPE').
- (37) The export price was established in accordance with Article 2(8) of the basic Regulation, except for transactions through the related company acting as an importer, IPCT. In this case, the export price was established on the basis of the price at which the imported product was first resold to independent customers in the EU in accordance with Article 2(9) of the basic Regulation. Thus, adjustments to the price were made for all costs incurred between importation and resale as well as for a reasonable profit. These adjustments were calculated on the basis of the selling, general and administrative costs of IPE and a notional profit as achieved by an unrelated importer (2,5 % of turnover).

4.1.4. Comparison

- (38) The normal value and the export price of the two exporting producers were compared on an ex-works basis. For the purpose of ensuring a fair comparison between the normal value and the export price, due allowance in the form of adjustments was made for differences affecting prices and price comparability in accordance with Article 2(10) of the basic Regulation. On this basis, adjustments were made in respect of transport, insurance, handling, loading and ancillary costs, import charges, customs duties, commissions and credit costs.
- (39) During the review investigation period, Interpipe exported the product under review to the EU through two different sales channels; i.e. through the same affiliated trader located in Switzerland as in the last interim review (IPE) and through an related importer company located in the EU (IPCT), established in 2014. The latter channel of distribution did not exist in the last interim review. Due to the confidential nature of business information contained in the Commission's analysis, the Commission provided Interpipe Group with an additional disclosure on the adoption date of this regulation, containing a detailed reasoning.

⁽¹⁴⁾ This change in methodology is due to the fact that following the original investigation, a WTO Panel issued, and the WTO Dispute Settlement Body adopted, the report in case *European Communities — Anti-dumping Measure on Farmed Salmon from Norway*, which provides that the actual profit margin established for the transactions in the ordinary course of trade of the relevant product types for which normal value has to be constructed cannot be disregarded. See WT/DS337/R of 16 November 2007 — adopted by the Dispute Settlement Body on 15 January 2008, para 7.289 to 7.319.

- (40) Consequently, the Commission considered that an adjustment under Article 2(10)(i) of the basic Regulation was warranted. This adjustment was calculated by deducting the selling, general and administrative costs of the affiliated trader, which were not reported as allowances, and a notional profit as achieved by an unrelated trader (2,5 % of turnover) from the selling price to the first unrelated customer.
- (41) Following the final disclosure, the Interpipe Group contested the Commission's conclusion not to treat IPE as part of a single economic entity together with the other entities NIKO, NTRP and IPU. After reviewing the elements on the file, the Commission decided to reject the this claim. As mentioned in recital (34) the company was provided with an additional disclosure describing the impact on the dumping margin and was invited to comment. In its response Interpipe maintained the claims which the Commission had rejected. No further comments were received in this regard.
- (42) Due to the confidential nature of business information contained in Interpipe Group's claim and the Commissions analysis of these arguments, the Commission provided Interpipe Group with an additional disclosure on the adoption date of this regulation, containing a detailed reasoning.

4.1.5. Dumping margin

- (43) Pursuant to Article 2(11) and (12) of the basic Regulation, the weighted average normal value was compared with the weighted average export price per product type on an ex-work basis separately for each of the two exporting producers. One common dumping margin was subsequently established for Interpipe by calculating a single weighted average rate of dumping for both exporting producers within Interpipe.
- (44) On this basis the dumping margin, expressed as a percentage of the CIF Union frontier price, duty unpaid, is 8,1 %.
- (45) Following the additional disclosure, ESTA submitted that the reduction of the dumping margin of Interpipe would create additional injury to the seamless steel tube industry in the EU. The Commission notes that, in accordance with Article 9(4) of the basic Regulation, the amount of anti-dumping duty cannot exceed the margin of dumping, which in this case was established at 8,1 %.
- (46) The Committee established by Article 15(1) of the basic regulation did not deliver an opinion,

HAS ADOPTED THIS REGULATION:

Article 1

The entry concerning LLC Interpipe Niko Tube and OJSC Interpipe Nizhnedneprovsky Tube Rolling Plant (Interpipe NTRP) in the table of Article 1(2) of Implementing Regulation (EU) No 585/2012 shall be replaced by the following:

‘LLC Interpipe Niko Tube and OJSC Interpipe Nizhnedneprovsky Tube Rolling Plant (Interpipe NTRP)	8,1 %	A743’
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Article 2

This Regulation shall enter into force on the 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, 1 August 2019.

For the Commission

The President

Jean-Claude JUNKER

DECISIONS

COUNCIL DECISION (CFSP) 2019/1296

of 31 July 2019

in support of strengthening biological safety and security in Ukraine in line with the implementation of United Nations Security Council Resolution 1540 (2004) on non-proliferation of weapons of mass destruction and their means of delivery

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union, and in particular Articles 28(1) and 31(1) thereof,

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

Whereas:

- (1) On 12 December 2003, the European Council adopted the EU strategy against the Proliferation of Weapons of Mass Destruction, Chapter II of which contains a list of measures to combat such proliferation. Such measures need to be taken both within the Union and in third countries.
- (2) The Union is actively implementing that strategy and is giving effect to the measures listed in Chapter III thereof, in particular by releasing financial resources to support specific projects conducted by multilateral institutions, providing States with technical assistance and expertise with regard to a wide range of non-proliferation measures, and fostering the role of the United Nations Security Council (UNSC).
- (3) On 28 April 2004, the UNSC adopted Resolution 1540 (2004) ('UNSCR 1540 (2004)'), which was the first international instrument to deal in an integrated and comprehensive manner with weapons of mass destruction, their means of delivery and related materials. UNSCR 1540 (2004) established binding obligations for all States, and those obligations aimed to prevent and deter non-State actors from obtaining access to such weapons and weapon-related material. The UNSC also decided that all States are to take and enforce effective measures to establish domestic controls to prevent the proliferation of nuclear, chemical or biological weapons and their means of delivery, including by establishing appropriate controls over related materials.
- (4) On 11 May 2017, the Council adopted Decision (CFSP) 2017/809 ⁽¹⁾ in support of the implementation of UNSCR 1540 (2004). The technical implementation of the activities under Decision (CFSP) 2017/809 is entrusted to the UN Office for Disarmament Affairs (UNODA) in cooperation with relevant regional international organisations, and in particular the Organisation for Security and Cooperation in Europe (OSCE).
- (5) On 11 July 2017, the Council adopted Decision (CFSP) 2017/1252 ⁽²⁾ in support of the strengthening of chemical safety and security in Ukraine in line with the implementation of UNSCR 1540 (2004). The technical implementation of the activities under Decision (CFSP) 2017/1252 is entrusted to the OSCE Secretariat.
- (6) Universal adherence to and full implementation of the Biological and Toxin Weapons Convention (BTWC) and UNSCR 1540 (2004) are among the main priorities of Ukraine in the area of non-proliferation of weapons of mass destruction.

⁽¹⁾ Council Decision (CFSP) 2017/809 of 11 May 2017 in support of the implementation of United Nations Security Council Resolution 1540 (2004) on the non-proliferation of weapons of mass destruction and their means of delivery (OJ L 121, 12.5.2017, p. 39).

⁽²⁾ Council Decision (CFSP) 2017/1252 of 11 July 2017 in support of the strengthening of chemical safety and security in Ukraine in line with the implementation of United Nations Security Council Resolution 1540 (2004) on the non-proliferation of weapons of mass destruction and their means of delivery (OJ L 179, 12.7.2017, p. 8).

- (7) On 21 March and 27 June 2014, the Union and Ukraine signed an Association Agreement ⁽¹⁾ which provides, inter alia, for expedited harmonisation of Ukrainian national legislation with relevant Union legislation, including in relation to the elimination of any obstacles to the comprehensive implementation in Ukraine of UNSCR 1540 (2004). Parts of the EU-Ukraine Association Agreement have been provisionally applied since 1 November 2014. The EU-Ukraine Association Agreement entered into force on 1 September 2017.
- (8) According to the Ukrainian Government's Action Plan on the implementation of the EU-Ukraine Association Agreement for the years 2018-2020, Ukraine committed to develop and improve regulations and mechanisms in the field of biological safety and security in line with Ukraine's obligations under the BTWC and UNSCR 1540 (2004) as well as under international norms and standards, and in particular relevant EU legislation.
- (9) In this context, three project proposals were prepared by the OSCE Secretariat in close cooperation with the competent authorities in Ukraine with a view to strengthening overall biological safety and security in Ukraine.
- (10) The OSCE Secretariat should be entrusted with the technical implementation of the projects to be carried out under this Decision.
- (11) The projects should be implemented in line with the respective provisions of the Ukrainian Government's Action Plan on the implementation of the EU-Ukraine Association Agreement. The activities should take into account relevant good practice and lessons learned, identified during the implementation of Decision (CFSP) 2017/1252.
- (12) The OSCE Secretariat should ensure efficient cooperation with relevant international organisations and bodies such as the BTWC Implementation Support Unit, the UNSC Committee established pursuant to UNSCR 1540 (2004), the World Organisation for Animal Health (OIE), and the Global Partnership Against the Spread of Weapons and Materials of Mass Destruction. The OSCE Secretariat should also ensure the complementarity and synergy of projects undertaken further to this Decision with relevant past and ongoing projects and activities in Ukraine supported by individual EU Member States, and with other Union-sponsored programmes in this field including the Instrument contributing to Stability and Peace and the EU Centres of Excellence on Chemical, Biological, Radiological and Nuclear Risk Mitigation,

HAS ADOPTED THIS DECISION:

Article 1

1. For the purpose of promoting peace and security, and effective multilateralism at global and regional levels, the Union shall pursue the following objectives:

- strengthening biological safety and security in Ukraine by improving Ukraine's legislative and regulatory basis and its human and animal health systems, as well as by raising the awareness of life scientists;
- underpinning effective multilateralism at regional level by supporting the action of the OSCE to enhance the capabilities of the competent authorities in Ukraine in the field of biological safety and security in line with obligations under UNSCR 1540 (2004) and the BTWC.

2. In order to achieve the objectives referred to in paragraph 1, the Union shall undertake the following projects:

- harmonization of existing Ukrainian regulations on biosafety and biosecurity with international standards;
- establishing veterinary surveillance system sustainability in Ukraine for diseases related to especially dangerous pathogens ('EDP-related diseases');
- awareness-raising, education and training for life scientists on biosafety and biosecurity.

A detailed description of the projects referred to above is set out in the Annex.

⁽¹⁾ Association Agreement between the European Union and the European Atomic Energy Community and their Member States, of the one part, and Ukraine, of the other part (OJ L 161, 29.5.2014, p. 3).

Article 2

1. The High Representative of the Union for Foreign Affairs and Security Policy (the 'High Representative') shall be responsible for the implementation of this Decision.
2. The technical implementation of the projects referred to in Article 1(2) shall be carried out by the OSCE Secretariat. It shall perform this task under the control of the High Representative. For this purpose, the High Representative shall enter into the necessary arrangements with the OSCE Secretariat.

Article 3

1. The financial reference amount for the implementation of the projects referred to in Article 1(2) shall be EUR 1 913 900.
2. The expenditure financed by the amount set out in paragraph 1 shall be managed in accordance with the procedures and rules applicable to the general budget of the Union.
3. The Commission shall supervise the proper management of the expenditure referred to in paragraph 1. For that purpose, it shall conclude a financing agreement with the OSCE Secretariat. That agreement shall stipulate that the OSCE Secretariat is to ensure visibility of the Union's contribution, appropriate to the size of that contribution.
4. The Commission shall endeavour to conclude the financing agreement referred to in paragraph 3 as soon as possible after the entry into force of this Decision. The Commission shall inform the Council of any difficulties in that process and of the date of conclusion of the financing agreement.

Article 4

The High Representative shall report to the Council on the implementation of this Decision, and shall do so on the basis of regular reports prepared by the OSCE Secretariat. Those reports shall form the basis for the evaluation carried out by the Council. The Commission shall provide information on the financial aspects of the projects referred to in Article 1(2).

Article 5

1. This Decision shall enter into force on the date of its adoption.
2. This Decision shall expire 36 months after the conclusion of the financing agreement referred to in Article 3(3), or six months after the date of its adoption if no financing agreement has been concluded within that period.

Done at Brussels, 31 July 2019.

For the Council
The President
T. TUPPURAINEN

ANNEX

Strengthening Biological Safety and Security in Ukraine in line with UNSCR 1540 (2004)

1. Background

The Ukrainian legislation prohibiting biological weapons is detailed and comprehensive. However, a significant part of this legislation and regulation is outdated and fails to meet international norms and standards. It therefore requires urgent revision and updating to increase harmonisation with the respective world standards.

There is no framework law on biosafety and biosecurity in Ukraine that outlines establishment of a biosafety and biosecurity system and its proper functioning (for example, which would legally identify the central executive body dealing with biosafety and biosecurity and carrying out expert and monitoring functions). Further, there is not currently comprehensive cooperation between all involved ministries, agencies and organizations for preventing and responding to emergency situations related to biological threats.

Mechanisms for state control of adherence to biosecurity requirements during work with biological agents are also absent. There is no register of economic and non-economic actors working with hazardous biological agents in the territory of Ukraine. Furthermore, those actors that work with hazardous biological agents are not obliged by law to have relevant permits. In fact, elimination of the permit system resulted in a situation where there is no reporting and control of adherence to the biosafety and biosecurity requirements in microbiological laboratories, the actual number of which is unknown. A normative document that regulated accounting, transportation, storage and transfer of hazardous biological materials was annulled. The applicable documents pay little attention to other aspects of biosecurity, such as verification of staff reliability and protection of confidential information.

Against the background of the pace of growth of agricultural production, bio-production, transport and external trade relations in the modern world, human and veterinary medicine face many problems specifically associated with the risk of proliferation of biological materials, in particular infectious and parasitic diseases common among people and animals.

Today the main threats relating to biological and food security in Ukraine are associated with African swine fever, bird flu, foot and mouth disease, and multidrug-resistant bacterial pathogens. There are natural focal risks of outbreaks of anthrax, rabies, classical swine fever and tularaemia. Ensuring food and biological security is a sensitive issue that cannot be solved without the involvement of reliable means of monitoring, forecasting and early diagnosis of emergent and economically significant infections of animals, including zoonotic infections. Biological and food security in Ukraine can only be addressed via integration of basic research in genetics and molecular biotechnology in veterinary and human medicine and diagnosis.

Staff of the majority of Ukrainian life sciences laboratories are experienced in handling dangerous biological materials. However, modern biosafety and biosecurity principles and approaches, modern techniques and practices, and codes of conduct linked to modern practices are very rare in laboratories. A number of life science laboratories possess moderate amounts of modern equipment but, due to the lack of operational training on such equipment, the laboratory personnel do not use it or use it in an inappropriate manner. In addition, the existing system of advanced training for some categories of life scientists does not cover all appropriate biosafety and biosecurity issues. All these factors can result in a decrease in the level of biosafety and biosecurity at laboratories where dangerous biological materials are handled.

As a result of the above analysis, three projects have been prepared by the OSCE with a view to strengthening overall biological safety and security in Ukraine. These projects have been developed in cooperation with the relevant Ukrainian authorities. All projects would be implemented in line with the respective provisions of the Ukrainian Government's Action Plan on the implementation of the EU-Ukraine Association Agreement.

The projects would also be implemented taking into account relevant good practice and lessons learned, identified during the ongoing implementation of Decision (CFSP) 2017/1252 in support of the strengthening of chemical safety and security in Ukraine.

2. Objective

The overall objective of this Decision is to support OSCE projects aiming at strengthening biological safety and security in Ukraine in line with Ukraine's obligations under the BTWC and UNSCR 1540 (2004), as well as in accordance with the EU-Ukraine Association Agreement.

3. Description of the projects

3.1. Harmonisation of existing Ukrainian regulations on biosafety and biosecurity with international standards

3.1.1. Objective of the project

- To improve the legislative and regulatory basis of Ukraine on biological safety and security in line with obligations under UNSCR 1540 (2004), namely the adoption and enforcement of appropriate effective laws which prohibit any non-State actor from manufacturing, acquiring, possessing, developing, transporting, transferring or using biological weapons and their means of delivery, in particular for terrorist purposes.

3.1.2. Description of the project

- Specific measures related to legislative and regulatory improvements in the field of biosafety and biosecurity requiring priority implementation and which will be directly supported by this project include:
 - Development and submission to the Verkhovna Rada of Ukraine of the draft Law of Ukraine on Biosafety and Biosecurity;
 - Development and adoption of a resolution of the Cabinet of Ministers of Ukraine on regulation of issues related to control of compliance with the biosecurity and biosecurity requirements in institutions and establishments working with pathogenic microorganisms;
 - Development and adoption of the Biosafety and Biosecurity Concept, the Ukrainian national action plan for responding to outbreaks of dangerous and especially dangerous diseases, and identification of the critical infrastructure that ensures appropriate response to the risks of outbreaks or to outbreaks of dangerous and especially dangerous diseases;
 - Introduction of a uniform system of biological safety of Ukraine as well as plans for protection of biological agents from accidental or deliberate dissemination and for their proper and safe storage and transportation, including their in-house security;
 - Reorganization of the public health and veterinary medicine system to comply with international requirements.

3.1.3. Expected results of the project

- To improve the Ukrainian biosafety and biosecurity system by enhancing the national legislative and regulatory framework in this field;
- To promote collaboration of the different agencies responsible for biosafety and biosecurity;
- To ensure sustainability of the biosafety and biosecurity system in Ukraine.

3.1.4. Project beneficiaries

- Ministry of Health.

3.2. Establishing veterinary surveillance system sustainability in Ukraine for EDP-related diseases

3.2.1. Objective of the project

- To improve biosafety and biosecurity by strengthening human and animal health systems in Ukraine, in line with obligations under UNSCR 1540 (2004), and in particular the enforcement of effective measures to establish domestic controls to prevent the proliferation of biological weapons and their means of delivery, including by establishing appropriate controls over related materials.

3.2.2. Description of the project

- Implementation of effective monitoring of human and animal diseases by establishment of a common use centre for sequencing and genetic characterization of selected agents and equipping of the participating institutions with reverse transcription polymerase chain reaction (RT-PCR) machines;
- Establishing rapid-response measures in emergency situations and the introduction of rapid diagnosis of particularly dangerous animal diseases by development of RT-PCR-based diagnostics tools for PCR-based detection of selected agents (agents of avian influenza, Newcastle disease, multi-resistant tuberculosis, lumpy skin disease, tularemia, African swine fever, classical swine fever, foot-and-mouth disease, brucellosis, multi-resistant salmonellas and anthrax) based on in-house protocols developed in Ukraine;
- Development of safe storage of pathogens, including zoonotic, viral and bacterial pathogens, in laboratories and depositories by development of registration dossiers for RT-PCR-based kits;
- Providing a unified technical policy in the field of conformity assessment for testing laboratories, securing national and international trust, providing conditions for mutual recognition of performance and transparency, and ensuring awareness and competence in the field of biological protection;
- Capacity building in EDP-related disease molecular diagnostics.

3.2.3. Expected results of the project

- Strengthening of national capacity for surveillance and forecasting in veterinary medicine;
- Development of effective national diagnostics and surveillance tools, based on RT-PCR and isothermal PCR instruments (R&D, validation and implementation in the laboratories);
- Implementation of effective monitoring of diseases of animals (including zoonotic diseases);
- Creation of human capacity in molecular diagnostics of EDP-related diseases (PCR techniques laboratory trainings).

3.2.4. Project beneficiaries

- State Service of Ukraine on Food Safety and Consumer Protection;
- Recipient of assistance: National Scientific Center 'Institute for Experimental and Clinical Veterinary Medicine' (Kharkiv, Ukraine).

3.3. Awareness-raising, education and training for life scientists on biosafety and biosecurity

3.3.1. Objective of the project

- Improving biological safety, security and bioethics in Ukraine by raising the awareness of life scientists in the field of biosafety and biosecurity, in line with obligations under UNSCR 1540 (2004), including the enforcement of effective domestic measures to prevent the proliferation of biological weapons and their means of delivery.

3.3.2. Description of the project

- Creation of a team of trainers from different Ukrainian life sciences institutions who will be able to disseminate modern knowledge on biosafety, biosecurity and bioethics principles, best laboratory practices, and techniques and methods for biorisk management in laboratories;
- Improvement of current resources for further dissemination of knowledge and awareness-raising on biosafety, biosecurity and bioethics amongst teachers, students and researchers in life sciences and other relevant stakeholders taking full account of Project P633 of the Science and Technology Center in Ukraine, 'Education and awareness-raising in Ukraine';
- Ensuring sustainability of training capacities after completion of the project.

3.3.3. Expected results of the project

- Increased awareness of national and local stakeholders in the field of biological safety and security;
- Increased capacity of life scientists to safely handle dangerous biological materials;

- Increased capacity of Ukrainian life scientists to reduce risks of possible misuse of materials and equipment being used during their research as well as misuse of their knowledge and results;
- Establishing a strong team of trainers on biosafety and biosecurity for life scientists;
- Improved and sustainable resource for distance knowledge dissemination on biosafety, biosecurity and bioethics.

3.4. Project beneficiaries

- Ministry of Health.

4. Administrative support for the implementation of the projects

Dedicated personnel in the OSCE Secretariat and in the office of the OSCE Project Coordinator in Ukraine will coordinate and manage the implementation of the project activities set out in Section 3 in order to further develop the collaborative framework between the Ukrainian partners, including through the development of relevant new project proposals and national measures.

The supporting personnel will perform the following tasks:

- Managing projects through all steps of the project cycle;
- Carrying out day-to-day financial oversight of the projects;
- Providing technical and legal expertise, supporting larger procurement, engaging with other international organisations, carrying out quality assurance and quality control of the approved projects' deliverables, and reporting to the European Union.

5. Duration

The total estimated duration of the projects will be 36 months.

6. Technical implementing entity

The technical implementation of this Decision will be entrusted to the Conflict Prevention Centre of the OSCE Secretariat and the OSCE Project Coordinator in Ukraine. The OSCE will implement the activities under this Decision in cooperation with other international organisations and agencies, in particular with a view to ensuring effective synergies and avoiding duplication.

7. Reporting

The OSCE Secretariat will prepare regular reports, as well as reports after the completion of each of the activities described. The final reports should be submitted to the European Union no later than six weeks after the completion of the relevant activities.

8. Steering Committee

The Steering Committee for these projects will be composed of a representative of the High Representative and a representative of the implementing entity referred to in section 6 of this Annex. The Steering Committee will review the implementation of this Decision regularly, at least once every 6 months, including through the use of electronic means of communication.

9. Estimated total cost of the projects and European Union financial contribution

The total cost of the projects is EUR 1 913 900.

COUNCIL DECISION (CFSP) 2019/1297**of 31 July 2019****amending Decision (CFSP) 2016/2382 establishing a European Security and Defence College (ESDC)**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union, and in particular Articles 28(1), 42(4) and 43(2) thereof,

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

Whereas:

- (1) On 21 December 2016, the Council adopted Decision (CFSP) 2016/2382 ⁽¹⁾, establishing a European Security and Defence College (ESDC).
- (2) On 14 May 2018, the Council adopted Decision (CFSP) 2018/712 ⁽²⁾, entrusting the ESDC with the creation of the Cyber Education, Training, Evaluation and Exercise platform, while noting the need to ensure complementarity with other Union efforts and initiatives.
- (3) On 6 November 2018, the Council adopted Decision (CFSP) 2018/1655 ⁽³⁾, amending Decision (CFSP) 2016/2382 and establishing a financial reference amount for the period from 1 January 2019 to 31 December 2019.
- (4) On 20 September 2018, the Political and Security Committee adopted the Terms of Reference for the EU Civilian Training Group as a special configuration of the Committee for Civilian Aspects of Crisis Management.
- (5) On 15 March 2019, during the meeting of the EU Civilian Training Group, Member States expressed the need for Union financial support for the Civilian Coordinators for Training (CCT).
- (6) On 3 June 2019, the ESDC Steering Committee decided that the ESDC should administer and manage the costs relating to travel and accommodation expenses of the CCT.
- (7) Decision (CFSP) 2016/2382 should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

In Article 4(3) of Decision (CFSP) 2016/2382, the following point is added:

- ‘(j) support the Committee for Civilian Aspects of Crisis Management and the EU Civilian Training Group by administering and managing the travel and accommodation costs relating to the activities of the Civilian Coordinators for Training.’.

Article 2

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

Done at Brussels, 31 July 2019.

For the Council

The President

T. TUPPURAINEN

⁽¹⁾ Council Decision (CFSP) 2016/2382 of 21 December 2016 establishing a European Security and Defence College (ESDC) and repealing Decision 2013/189/CFSP (OJ L 352, 23.12.2016, p. 60).

⁽²⁾ Council Decision (CFSP) 2018/712 of 14 May 2018 amending Decision (CFSP) 2016/2382 establishing a European Security and Defence College (ESDC) (OJ L 119, 15.5.2018, p. 37).

⁽³⁾ Council Decision (CFSP) 2018/1655 of 6 November 2018 amending Decision (CFSP) 2016/2382 establishing a European Security and Defence College (ESDC) (OJ L 276, 7.11.2018, p. 9).

COUNCIL DECISION (CFSP) 2019/1298**of 31 July 2019****in support of an Africa-China-Europe dialogue and cooperation on preventing the diversion of arms and ammunition in Africa**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union, and in particular Articles 28(1) and 31(1) thereof,

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

Whereas:

- (1) The Arms Trade Treaty (ATT) entered into force on 24 December 2014, and all Member States are party to it. The ATT aims to establish the highest possible common international standards to regulate the legal trade in conventional weapons and to prevent and eradicate the illicit trade in conventional arms and prevent their diversion.
- (2) On 19 November 2018, the Council adopted the EU Strategy against illicit Firearms, Small Arms & Light Weapons and their Ammunition 'Securing Arms, Protecting Citizens' (the 'Strategy'). The full and effective implementation of the 2001 UN Programme of Action to prevent, combat and eradicate the illicit trade in small arms and light weapons in all its aspects is the main objective of the Strategy. The Strategy states that the EU will continue to promote responsible and effective arms export control and that it will continue supporting the universalisation and implementation of the ATT. The Strategy also states that the EU will continue to support the African Union and relevant regional economic communities in their efforts against the illicit trade in small arms and light weapons and their ammunition.
- (3) In January 2017, the 28th Ordinary Session of the Assembly of the African Union adopted the 'African Union Master Roadmap of Practical Steps to Silence the Guns in Africa by Year 2020' thereby committing Member States of the African Union to: curb the illegal inflow and circulation of illicit arms; impede access to arms by rebels/insurgents; and cut links with suppliers and recipients of illicit arms, including imposing bans, in line with the ATT.
- (4) In its conclusions on an EU Strategy for China of 18 July 2016, the Council supported the establishment of regular and substantial EU dialogue with China to seek, in conjunction with Member States, greater common ground on disarmament, non-proliferation, counterterrorism, migration and cyber-security.
- (5) On 30 June 2018, the third United Nations Conference to Review Progress Made in the Implementation of the UN Programme of Action against illicit Small Arms and Light Weapons adopted an outcome document in which States renew their commitment to preventing and combating the diversion of small arms and light weapons. States reaffirm their willingness to pursue international cooperation and to reinforce regional cooperation, through improved coordination, consultation, information exchange and operational cooperation, involving relevant regional and sub-regional organizations, as well as law enforcement, border control and export and import licensing authorities. States also commit to exchanging and, in accordance with States' national legal frameworks and security requirements, applying experiences, lessons learned and best practices relating to small arms and light weapons export, import and transit control, including certification processes and end-user certificates.
- (6) The 2030 Agenda for Sustainable Development affirms that combating the illicit trade in small arms and light weapons is necessary for the achievement of many sustainable development goals, including those relating to peace, justice and strong institutions, poverty reduction, economic growth, health, gender equality and safe cities. Therefore, in Sustainable development Goal 16.4, all States have committed to significantly reducing illicit financial and arms flows.

- (7) On 27 February 2012, the Council adopted Decision 2012/121/CFSP ⁽¹⁾, in support of activities to promote an EU-China-Africa dialogue and cooperation on conventional arms control. That project was successfully implemented by Saferworld, but more efforts in this field are needed to reach the objectives set out in that Decision.
- (8) Since 2008, the Council has adopted eleven Decisions in support of outreach for responsible arms export control in accordance with the ATT and with Council Common Position 2008/944/CFSP ⁽²⁾, but engagement with China on this topic has been limited,

HAS ADOPTED THIS DECISION:

Article 1

1. The purpose of this Decision is to contribute to preventing and combating the diversion of arms and ammunition in Africa.
2. Pursuant to paragraph 1, the Union shall support the following objectives:
 - (a) to raise awareness of stakeholders in Africa, China and the Union on how the illicit flow of arms, particularly small arms and light weapons (SALW) and their ammunition, to unauthorised actors contributes significantly towards exacerbating insecurity and violence in various parts of Africa, thereby undermining social cohesion, public security, socio-economic development and the effective functioning of state institutions;
 - (b) to promote accountability and responsibility with regard to the legal arms trade and by demonstrating to stakeholders in Africa, China and the Union how effective arms export control can contribute to mitigating the risk of diversion of arms into the illicit market.
3. To achieve those objectives, this Decision shall support the establishment and development of a joint non-governmental Africa-China-Europe Expert Working Group on conventional arms control (the 'EWG'), the main tasks of which will be to increase awareness and engagement and bring about action by the policy communities in Africa, China, and the Union, and to strengthen regional and international cooperation to prevent the diversion of arms and ammunition in Africa.
4. The expected outcomes of this Decision are the following:
 - (a) better understanding of the impact of arms diversion and misuse in Africa resulting from joint research and action-oriented analysis by African, Chinese and Union researchers and academics, with recommendations for specific projects supported by China;
 - (b) increased awareness by stakeholders in Africa, China and the Union of the role of effective arms export control in mitigating the risk of diversion and negative impacts of illicit arms and ammunition in Africa;
 - (c) increased contribution of China to relevant international and regional initiatives, including the African Union's Silencing the Guns in Africa by 2020 initiative and the implementation of the ATT;
 - (d) the consideration of small arms control on the agenda of the Forum on China-Africa Cooperation (FOCAC) dialogue;
 - (e) creation of new fora bringing together experts from government, civil society, business and academia from Africa, China and the Union, who will help inform the EU-China High-level Strategic Dialogue.
5. The direct beneficiaries of the projects will be an estimated 500 policy community actors in Africa, China and the Union, including non-governmental organisations, think tanks, industry representatives, government officials in charge of conventional arms control, and parliamentarians. The indirect beneficiaries will be the population, communities, groups and individuals in Africa who are adversely affected by the proliferation of illicit arms and ammunition in the continent.
6. A detailed description of the project is set out in the Annex to this Decision.

⁽¹⁾ Council Decision 2012/121/CFSP of 27 February 2012 in support of activities to promote EU-China-Africa dialogue and cooperation on conventional arms controls (OJ L 54, 28.2.2012, p. 8).

⁽²⁾ Council Common Position 2008/944/CFSP of 8 December 2008 defining common rules governing control of exports of military technology and equipment (OJ L 335, 13.12.2008, p. 99).

Article 2

1. The High Representative of the Union for Foreign Affairs and Security Policy ('HR') shall be responsible for implementing this Decision.
2. The technical implementation of the project referred to in Article 1 shall be carried out by the non-governmental organisation Saferworld.
3. Saferworld shall perform its tasks under the responsibility of the HR. For that purpose, the HR shall enter into the necessary arrangements with Saferworld.

Article 3

1. The financial reference amount for the implementation of the project financed by the Union referred to in Article 1 shall be EUR 994 007.
2. The expenditure financed by the reference amount set out in paragraph 1 shall be managed in accordance with the procedures and rules applicable to the Union budget.
3. The Commission shall supervise the proper management of the expenditure referred to in paragraph 1. For that purpose, it shall conclude the necessary financing agreement with Saferworld. The financing agreement shall provide that Saferworld is to ensure the visibility of the Union's contribution, appropriate to its size.
4. The Commission shall endeavour to conclude the financing agreement referred to in paragraph 3 as soon as possible after the entry into force of this Decision. It shall inform the Council of any difficulties in that process and of the date of conclusion of the financing agreement.

Article 4

1. The HR shall report to the Council on the implementation of this Decision on the basis of regular quarterly reports prepared by Saferworld. Those reports shall form the basis of the evaluation to be carried out by the Council.
2. The Commission shall report on the financial aspects of the project referred to in Article 1.

Article 5

1. This Decision shall enter into force on the date of its adoption.
2. This Decision shall expire 36 months after the date of conclusion of the financing agreement referred to in Article 3(3). However, it shall expire six months after the date of its entry into force if no agreement has been concluded within that period.

Done at Brussels, 31 July 2019.

For the Council
The President
T. TUPPURAINEN

ANNEX

AFRICA-CHINA-EUROPE DIALOGUE AND COOPERATION ON PREVENTING THE DIVERSION OF ARMS AND AMMUNITION IN AFRICA

1. Description of project and activities

The project will consist of two main phases, as summarised below under sections 1.1 on the establishment of an EWG and 1.2 on outreach to stakeholders in Africa, China and the Union promoting actions to be undertaken in preventing diversion of arms and ammunition in Africa.

1.1. Phase 1: Establishment and development of a joint non-governmental Africa-China-Europe Expert Working Group on preventing diversion of arms and ammunition in Africa

1.1.1. Objectives

To establish a joint non-governmental Africa-China-Europe Expert Working Group (EWG) bringing together African, Chinese and Union non-governmental experts who will engage in outreach to stakeholders in Africa, China and the Union and will support trilateral dialogue and cooperation on preventing diversion of arms and ammunition in Africa, with a view to:

- (a) illustrating the security, socio-economic and humanitarian cost of the diversion of arms, especially small arms and light weapons and their ammunition, in Africa and to demonstrate the ways in which improved arms transfer control, also on the supply side, can contribute to reducing the risk of diversion of arms in the hands of unauthorised actors;
- (b) helping to inform the EU-China High-level Strategic Dialogue, especially on security and arms control cooperation in Africa;
- (c) sharing information, ideas, expertise and research amongst its members and assessing the effectiveness of current policies and initiatives;
- (d) actively approaching and making recommendations to governmental stakeholders. African, Chinese, Union and Member State officials will be invited to observe and contribute to the work of the EWG.

1.1.2. Activities

Activities to be supported in the implementation of tasks referred to under Phase 1 will include:

- (a) mapping out and development by Saferworld of an engagement approach to key partners and stakeholders in governments, business sector, civil society organisations, academic institutions, multilateral agencies, as well as regional and community level actors, who will be crucial for the success and sustainability of the project;
- (b) building upon the achievements of the Union project supported under Decision 2012/121/CFSP:
 - (i) organisation of up to 20 preparatory and follow-up meetings in Africa, China and in Europe to enhance awareness of the project, including the structure and timeline, and ensure the support of relevant authorities
 - (ii) identification of key experts in Africa, China and the Union who will be involved in the EWG;
 - (iii) development of detailed work plans for the establishment and operationalisation of the EWG;
 - (iv) establishment of a project coordination team; (v) delineation and allocation of responsibilities among the team; and (vi) monitoring and evaluation of progress in the implementation of activities;
- (c) creation of the EWG supporting trilateral dialogue and cooperation. The EWG is expected to include nine small arms control experts from Africa, China and Europe to be drawn from think tanks, research centres and academic institutions, who will be chosen on the basis of their interests, expertise and ability to engage in the project;
- (d) creation of an EWG website, which will act as an online platform for the public interface of the EWG;

- (e) three meetings of the EWG (one in Africa, one in China and one in Europe) to enable interaction and shared learning among EWG members and officials from Africa, China, the Union and the Member States, as well as to provide guidance in the implementation of awareness-raising and research activities.

1.1.3. Results

The EWG becomes the bedrock foundation for the dialogue process promoted by this Decision, playing a crucial role in bringing together small arms control experts from Africa, China and Europe, helping bridge the gap between the research and policy communities and ensuring that the project's outputs are effectively transmitted to the governments in Africa, China, Europe and to the institutions of the Union.

1.2. Phase 2: Outreach to governmental stakeholders in Africa, China and the Union on preventing diversion and combating the illegal possession, transfer and use of arms and ammunition in Africa

1.2.1. Objectives

- (a) achieving a reduction in the diversion of arms and ammunition on the African continent, thus reducing threats to human security and contributing to a peaceful and secure environment for African citizens and fostering development;
- (b) supporting African States with the implementation of the African Union Master Roadmap of Practical Steps to Silence the Guns in Africa by 2020 and the relevant strategies of the Regional Economic Communities;
- (c) fostering synergies with the implementation of other relevant international and regional initiatives, including the ATT, the UN Programme of Action on SALW and the UN Firearms Protocol;
- (d) coordinating and synergizing with relevant Union supported initiatives in Africa, including the EU's arms export control and ATT outreach projects supported by Council Decisions (CFSP) 2018/299 ⁽¹⁾ and (CFSP) 2018/101 ⁽²⁾ and Conflict Armament Research Ltd. (CAR)'s iTrace project supported by Council Decision (CFSP) 2017/2283 ⁽³⁾;
- (e) engaging with the multi-year legal review process that is currently underway in China, which will result in the adoption of a new Export Control Law;
- (f) supporting small arms control work at the community level by reaching out to people at the grassroots level and providing opportunities for them to express themselves and offer ways to reduce the human cost of illicit arms and ammunition;
- (g) supporting joint research and action oriented analysis by African, Chinese and Union experts on the problems associated with arms and ammunition diversion and misuse in Africa, with recommendations for specific actions that help address and reduce the threats associated with illicit arms and ammunition. These may include, but are not limited to: export control; safe and secure arms and ammunition storage; destruction of surplus arms and ammunition; marking, record-keeping and tracing, including cooperation with United Nations missions tasked with identification and tracing of illicit arms; monitoring and enforcement of arms embargoes; and the exchange of operational information to disrupt arms-trafficking networks.

1.2.2. Activities

Activities to be supported in the implementation of tasks referred to under Phase 2 will include:

- (a) two seminars (one in Africa and one in China) on 'Promoting accountability and responsibility with regard to the arms trade and preventing the diversion of arms and ammunition to unauthorised and destabilising actors in Africa' to be held under the aegis of the EWG, whose members will assist Saferworld and will also participate in the events;
- (b) production and dissemination of a briefing paper on 'Combating the proliferation of illicit arms and ammunition in Africa: Recommendations to FOCAC', in advance of the 2021 FOCAC summit;

⁽¹⁾ Council Decision (CFSP) 2018/299 of 26 February 2018 promoting the European network of independent non-proliferation and disarmament think tanks in support of the implementation of the EU Strategy against proliferation of weapons of mass destruction (OJ L 56, 28.2.2018, p. 46).

⁽²⁾ Council Decision (CFSP) 2018/101 of 22 January 2018 on the promotion of effective arms export controls (OJ L 17, 23.1.2018, p. 40).

⁽³⁾ Council Decision (CFSP) 2017/2283 of 11 December 2017 in support of a global reporting mechanism on illicit small arms and light weapons and other illicit conventional weapons and ammunition to reduce the risk of their illicit trade ('iTrace III') (OJ L 328, 12.12.2017, p. 20).

- (c) production and dissemination of a briefing paper in English and Chinese on 'Proliferation of illicit arms and ammunition in Africa: what can supplier states do to mitigate the risk of diversion?';
- (d) three field research visits by the EWG each lasting ten days in three selected African countries to address issues related to the proliferation and uncontrolled circulation of illicit arms and ammunition (including the complexity of diversion processes from authorised transfers or holdings; and problematic trans-border phenomena, such as cattle rustling, that are nurtured by the proliferation of illicit arms and ammunition);
- (e) production of three research papers (in Chinese, English and French) by the EWG on the field research, with recommendations on practical actions required to address illicit arms and ammunition, with a special focus on the role of arms suppliers in Africa, China and the Union in reducing the risk of diversion;
- (f) around 20 bilateral meetings with African, Chinese and Member States' officials to share and effectively communicate the EWG recommendations, build awareness and political traction for cooperative projects at the official level;
- (g) production and dissemination of one research report (in Chinese, English and French) on illicit arms and ammunition proliferation in Africa, which will assess the effectiveness of current actions and will include recommendations for actionable projects that will help to better tackle illicit arms and ammunition, thus reducing their harmful impact, and contributing to improved national, regional and international peace and security. The report will include a special focus on the role of arms suppliers in Africa, China and the Union in reducing the risk of diversion of arms in Africa;
- (h) conduct one closing seminar in China to communicate the recommendations from the research and dialogue process and demonstrate the benefits of cooperation among Africa, China, the Union and the Member States and participation in joint activities, as well as establishing processes to sustain the dialogue in the future.

1.2.3. Results

- Increased awareness, knowledge and understanding of 500 African, Chinese and Union policy community actors, including officials in charge of conventional arms export controls, scholars, parliamentarians, non-governmental organisations, industry representatives and journalists, of the factors contributing to the widespread availability of illicit arms and ammunition in Africa, the key issues and impacts on the ground and the role and responsibility of arms supplier states in mitigating the risk of diversion when transferring arms.
- Improved dialogue, interaction, and cooperation on preventing and combating diversion of arms and ammunition amongst 60 African, Chinese, Union and Member States' officials and civil society actors, including through the identification of areas for practical cooperation between Africa, China and the Union, which will help reduce the diversion of arms and ammunition in Africa.
- Reduction in the number of occurrences and cases of arms and ammunition being diverted to unauthorised and destabilising actors in Africa.
- Support for the implementation of the African Union Master Roadmap of Practical Steps to Silence the Guns in Africa by Year 2020 and the UN Programme of Action against illicit SALW.
- Greater alignment of national norms and regulations in Africa and China with international arms export control standards, such as the ATT, with a view to mitigating the risk of diversion when trading in arms.
- The return of arms control on the agenda of FOCAC as a vital entry point for enhancing dialogue and cooperation between Africa and China on preventing diversion of arms to unauthorised and destabilising actors in Africa.
- Production of a body of evidence-based analysis of the problem of illicit arms and ammunition in Africa, drawing from joint field research by African, Chinese and Union experts that will contribute to a better all-round understanding of the diversion and re-transfer of arms to unauthorised and destabilising actors in Africa and provide stronger common ground for Africa, China and the Union to work together more effectively to tackle the problem.

- The identification of practical means to address the threats associated with the proliferation of illicit arms and ammunition and the need for collective and co-operative international responses, in line with major international and regional commitments and policy initiatives, such as the UN Programme of Action against illicit SALW, the International Tracing Instrument, the 2030 Agenda for Sustainable Development, the Arms Trade Treaty, the African Union Strategy on the Control of Illicit Proliferation, Circulation and Trafficking of small Arms and Light Weapons, the EU-China 2020 Strategic Agenda for Cooperation, the EU Strategy on China, and the EU Strategy Against Illicit Firearms, Small Arms and Light Weapons and their Ammunition and the relevant Strategies and Action Plans of the regional economic communities.
- Enhanced capacity of African national authorities and regional organisations to identify specific needs for technical assistance and identification of suitable platforms in their dialogue with China and the EU to channel resources to meet such needs.

2. Participants and venues of seminars/workshops and closing and opening events

Unless otherwise specified in the text of this Annex, Saferworld will propose potential participants and venues for seminars and other events that are envisaged under the project, which will then be endorsed by the HR, in consultation with the competent Council bodies.

3. Gender

Saferworld will mainstream gender into strategies and activities related to the implementation of this project so that women and men influence, participate in, and benefit equitably from the project. As far as possible, Saferworld will encourage project partners to put forward mixed gender delegations to participate in project activities and ensure that the gender impact of illicit arms and ammunition is included in all seminars and study visits.

4. Partners

It is envisaged that the main project partners will be the China Arms Control and Disarmament Association and the Security Research and Information Centre (Kenya).

5. Steering Committee

The Steering Committee for this project will be composed of a representative of the HR, of the Commission and of Saferworld. The Steering Committee will review the implementation of this Decision once every 6 months, including by the use of electronic means of communication.

6. Reporting

Saferworld will provide narrative reports on a six monthly basis to review progress towards project results. Saferworld will also submit annual narrative and financial reports and a final report within 6 months of the end of the implementation period.

7. Union visibility and availability of assistance material

Material produced in the context of the project and the dedicated website will ensure the visibility of the Union, based in particular on the logo and graphic chart of the Communication and Visibility Manual for European Union External Actions. Union Delegations should be involved in events in third countries to enhance political follow-up and visibility.

COUNCIL IMPLEMENTING DECISION (CFSP) 2019/1299
of 31 July 2019
implementing Decision (CFSP) 2015/1333 concerning restrictive measures in view of the situation
in Libya

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union, and in particular Article 31(2) thereof,

Having regard to Council Decision (CFSP) 2015/1333 of 31 July 2015 concerning restrictive measures in view of the situation in Libya, and repealing Decision 2011/137/CFSP ⁽¹⁾, and in particular Article 12(2) thereof,

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

Whereas:

- (1) On 31 July 2015 the Council adopted Decision (CFSP) 2015/1333.
- (2) In accordance with Article 17(2) of Decision (CFSP) 2015/1333, the Council has reviewed the lists of designated persons and entities set out in Annexes II and IV to that Decision.
- (3) The entry for one person should be removed from Annex II to Decision (CFSP) 2015/1333, and the entries for two persons should be removed from Annex IV to that Decision.
- (4) Decision (CFSP) 2015/1333 should be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

Annexes II and IV to Decision (CFSP) 2015/1333 are amended in accordance with the Annex to this Decision

Article 2

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

Done at Brussels, 31 July 2019.

For the Council
The President
T. TUPPURAINEN

⁽¹⁾ OJ L 206, 1.8.2015, p. 34.

ANNEX

Decision (CFSP) 2015/1333 is amended as follows:

- (1) in Annex II (List of persons and entities referred to in Article 8(2)), entry 1 (concerning ABDUSSALAM, Abdussalam Mohammed) is deleted from the list set out in Part A (Persons);
 - (2) in Annex IV (List of persons and entities referred to in Article 9(2)), entries 1 (concerning ABDUSSALAM, Abdussalam Mohammed) and 14 (concerning AL-BAGHDADI, Dr Abdulqader Mohammed) are deleted from the list set out in Part A (Persons).
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COMMISSION IMPLEMENTING DECISION (EU) 2019/1300**of 26 July 2019****as regards the placing on the market of a genetically modified carnation (*Dianthus caryophyllus* L., line FLO-40685-2)***(notified under document C(2019) 5496)***(Only the Dutch text is authentic)****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC ⁽¹⁾, and in particular the first subparagraph of Article 18(1) thereof,

After consulting the European Food Safety Authority,

Whereas:

- (1) Pursuant to Directive 2001/18/EC, the placing on the market of a product containing or consisting of a genetically modified organism or a combination of genetically modified organisms is subject to written consent being granted by the competent authority of the Member State that received the notification for the placing on the market of that product.
- (2) In October 2013, a notification concerning the placing on the market of a genetically modified carnation (*Dianthus caryophyllus* L., line FLO-40685-2) was submitted by Suntory Holdings Limited, Osaka, Japan, to the competent authority of the Netherlands.
- (3) The notification covers import, distribution and retailing of cut flowers of the genetically modified carnation *Dianthus caryophyllus* L., line FLO-40685-2.
- (4) In accordance with Article 14 of Directive 2001/18/EC, the competent authority of the Netherlands prepared an assessment report, which concluded that there are no reasons on the basis of which consent for the placing on the market of cut flowers of the genetically modified carnation (*Dianthus caryophyllus* L., line FLO-40685-2) for ornamental use should be withheld, if specific conditions are fulfilled.
- (5) The assessment report was submitted to the Commission and the competent authorities of the other Member States, some of which raised objections to the placing on the market of the product. One Member State maintained its objections.
- (6) In its opinion of 10 March 2016, the European Food Safety Authority ('the Authority'), concluded that there is no scientific reason to consider that the import, distribution and retailing in the Union of carnation FLO-40685-2 cut flowers for ornamental use will cause any adverse effect on human health or the environment ⁽²⁾. The Authority also found that the monitoring plan provided by the consent holder was acceptable in the light of the intended uses of the FLO-40685-2 carnation.
- (7) An examination of the opinion of the Authority, which took into consideration the full notification, the assessment report drafted by the competent authority of the Netherlands, the Member States' objections and the additional information provided by the notifier in order to answer to the Member States' objections, discloses no reason to believe that the placing on the market of cut flowers of the genetically modified carnation *Dianthus caryophyllus* L., line FLO-40685-2, will adversely affect human health or the environment in the context of its proposed ornamental use.

⁽¹⁾ OJ L 106, 17.4.2001, p. 1.

⁽²⁾ EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2016. Scientific opinion on a Part C notification (reference C/NL/13/02) from Suntory Holdings Limited for the import, distribution and retailing of carnation FLO-40685-2 cut flowers with modified petal colour for ornamental use. *EFSA Journal* 2016;14(4):4431, 18 pp. doi: 10.2903/j.efsa.2016.4431.

- (8) A unique identifier should be assigned to the genetically modified carnation *Dianthus caryophyllus* L., line FLO-40685-2, for the purposes of Regulation (EC) No 1830/2003 of the European Parliament and of the Council ⁽¹⁾ and Commission Regulation (EC) No 65/2004 ⁽²⁾.
- (9) In light of the opinion of the Authority, it is not necessary to establish specific conditions for the intended use with regard to the handling or packaging of the product and the protection of particular ecosystems, environments or geographical areas.
- (10) The labelling of the product should include information that cut flowers of the genetically modified carnation *Dianthus caryophyllus* L., line FLO-40685-2, may not be used for human or animal consumption nor for cultivation.
- (11) A detection method, as required in Annex III B.D.12 of Directive 2001/18/EC, was verified and tested for the genetically modified carnation *Dianthus caryophyllus* L., line FLO-40685-2, in December 2016.
- (12) The Committee set up under Article 30(1) of Directive 2001/18/EC 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 appeal committee did not deliver an opinion,

HAS ADOPTED THIS DECISION:

Article 1

Consent

1. Written consent shall be granted by the competent authority of the Netherlands to the placing on the market of the genetically modified carnation *Dianthus caryophyllus* L., line FLO-40685-2, notified by Suntory Holdings Limited, Osaka, Japan (Reference C/NL/13/02) and defined in Article 2.
2. The consent shall be given in writing and shall explicitly specify the requirements set out in Articles 3 and 4 and the unique identifier set out in Article 2(3).
3. The consent shall be limited to the placing on the market of cut flowers of the genetically modified carnation *Dianthus caryophyllus* L., line FLO-40685-2, as a product.
4. The consent shall cover progeny derived through vegetative reproduction of the genetically modified carnation *Dianthus caryophyllus* L., line FLO-40685-2.
5. The period of validity of the consent shall be 10 years starting from the date on which the consent is issued.

Article 2

Product

1. The genetically modified organism to be placed on the market is a carnation (*Dianthus caryophyllus* L.), with modified flower colour, derived from a *Dianthus caryophyllus* L. cell culture, and transformed with *Agrobacterium tumefaciens*, strain AGL0, using the vector pCGP1991, and resulting in line FLO-40685-2.

⁽¹⁾ Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (OJ L 268, 18.10.2003, p. 24).

⁽²⁾ Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms (OJ L 10, 16.1.2004, p. 5).

The genetically modified carnation contains the following DNA in three cassettes:

(a) Cassette 1

The petunia *df* gene encoding dihydroflavonol 4-reductase (DFR), a key enzyme in the anthocyanin biosynthetic pathway, including its own promoter and terminator.

(b) Cassette 2

The promoter sequence from snapdragon chalcone synthase gene, flavonoid 3'-5'-hydroxylase (*f3'5'h*) from *Viola hortensis* cDNA encoding F3'5'H, a key enzyme in the anthocyanin biosynthetic pathway, and the terminator from the *D8* petunia gene encoding a putative phospholipid transfer protein.

These two cassettes were inserted into the plant genome to obtain the desired flower colour.

(c) Cassette 3

The *Cauliflower mosaic virus* 35S promoter, the 5'-untranslated region from the petunia gene encoding chlorophyll a/b binding protein, the *SuRB (als)* gene coding for a mutant acetolactate synthase (ALS) derived from *Nicotiana tabacum*, which confers tolerance to sulfonylurea, including its own terminator. This trait was used as a marker in the selection of transformants.

2. The genetically modified carnation contains the insert, or part of it, in four loci:

- Locus 1: one copy of the T-DNA, containing the three cassettes and an incomplete copy of T-DNA containing only the *f3'5'h* cassette with the right T-DNA border. The two T-DNA copies are separated by a carnation genomic DNA region,
- Locus 2: one insert containing the *D8* terminator and the right T-DNA border,
- Locus 3: one complete and one incomplete copy of the *f3'5'h* cassette, both containing *D8* terminator sequences and the right T-DNA borders in a tail-to-tail orientation,
- Locus 4: an incomplete copy of the *als* cassette and the left T-DNA border.

3. The unique identifier of the genetically modified carnation shall be FLO-40685-2.

Article 3

Conditions for placing on the market

The genetically modified carnation *Dianthus caryophyllus* L., line FLO-40685-2, may be placed on the market subject to the following conditions:

- (a) the genetically modified carnation may only be used for ornamental purposes;
- (b) the cultivation of the genetically modified carnation is not allowed;
- (c) without prejudice to confidentiality requirements set out in Article 25 of Directive 2001/18/EC, the methodology for detecting and identifying the genetically modified carnation, including experimental data demonstrating the specificity of the methodology, as validated by the European Union Reference Laboratory is publicly available at <http://gmo-crl.jrc.ec.europa.eu/valid-2001-18.htm>;
- (d) without prejudice to confidentiality requirements set out in Article 25 of Directive 2001/18/EC, the consent holder, whenever requested to do so, makes positive and negative control samples of the product, or its genetic material, or reference materials available to the competent authorities and to inspection services of Member States as well as to Union control laboratories;
- (e) the words 'This product is a genetically modified organism' or 'This product is a genetically modified carnation', and the words 'not for human or animal consumption nor for cultivation' appear either on a label or, for non-pre-packaged products, in a document accompanying the genetically modified carnations.

*Article 4***Monitoring**

1. Throughout the period of validity of the consent, the consent holder shall ensure that the monitoring plan, contained in the notification and consisting of a general surveillance plan to check for any adverse effects on human health or the environment arising from handling or use of the genetically modified carnation *Dianthus caryophyllus* L., line FLO-40685-2, is put in place and implemented.

The monitoring plan is available at [Link: plan published on the internet].

2. The consent holder shall directly inform the operators and users concerning the safety and general characteristics of the genetically modified carnation and of the conditions as to monitoring, including the appropriate management measures to be taken in case of accidental propagation.

3. The consent holder shall submit to the Commission and to the competent authorities of the Member States annual reports on the results of the monitoring activities.

4. The consent holder shall be in the position to give evidence to the Commission and the competent authorities of the Member States:

- (a) that the existing monitoring networks, including national botanic survey networks and plant protection services, as specified in the monitoring plan contained in the notification, gather the information relevant for the monitoring of the genetically modified carnation; and
- (b) that these existing monitoring networks referred to in point (a) have agreed to make available that information to the consent holder before the date of submission of the monitoring reports to the Commission and competent authorities of the Member States in accordance with paragraph 3.

*Article 5***Addressee**

This Decision is addressed to the Kingdom of the Netherlands.

Done at Brussels, 26 July 2019.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

COMMISSION IMPLEMENTING DECISION (EU) 2019/1301**of 26 July 2019****amending Implementing Decision 2013/327/EU as regards the renewal of the authorisation to place on the market feed containing or consisting of genetically modified oilseed rapes Ms8, Rf3 and Ms8 × Rf3 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council***(notified under document C(2019) 5499)***(Only the German text is authentic)****(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 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed ⁽¹⁾, and in particular Articles 11(3) and 23(3) thereof,

Whereas:

- (1) Commission Implementing Decision 2013/327/EU ⁽²⁾ authorised the placing on the market of food containing or consisting of genetically modified oilseed rapes Ms8, Rf3 and Ms8 × Rf3 and of food and feed produced from those genetically modified oilseed rapes.
- (2) Previously, Commission Decision 2007/232/EC ⁽³⁾ authorised the placing on the market of feed containing or consisting of genetically modified oilseed rapes Ms8, Rf3 and Ms8 × Rf3. The scope of that authorisation also covered products containing or consisting of oilseed rapes Ms8, Rf3 and Ms8 × Rf3, for other uses than food or feed, with the exception of cultivation.
- (3) On 20 May 2016, Bayer CropScience AG submitted to the Commission an application, in accordance with Article 11 and Article 23 of Regulation (EC) No 1829/2003, for the renewal of the authorisation for the placing on the market of the products covered by Decision 2007/232/EC.
- (4) On 28 November 2017, the European Food Safety Authority ('the Authority') issued a favourable opinion ⁽⁴⁾ in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003. It concluded that the renewal application did not contain evidence for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on oilseed rapes Ms8, Rf3 and Ms8 × Rf3, adopted by EFSA in 2005 ⁽⁵⁾.
- (5) In its opinion, the Authority considered all the specific questions and concerns raised by the Member States in the context of the consultation of the national competent authorities as provided for by Article 6(4) and Article 18(4) of Regulation (EC) No 1829/2003.
- (6) The Authority also concluded that the monitoring plan for the environmental effects, consisting of a general surveillance plan, submitted by the applicant, is in line with the intended uses of the products.
- (7) Taking into account those considerations, the authorisation for the placing on the market of the products covered by Decision 2007/232/EC should be renewed.

⁽¹⁾ OJ L 268, 18.10.2003, p. 1.

⁽²⁾ Commission Implementing Decision 2013/327/EU of 25 June 2013 authorising the placing on the market of food containing or consisting of genetically modified oilseed rape Ms8, Rf3 and Ms8 × Rf3, or food and feed produced from those genetically modified organisms pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 175, 27.6.2013, p. 57).

⁽³⁾ Commission Decision 2007/232/EC of 26 March 2007 concerning the placing on the market, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of oilseed rape products (*Brassica napus* L., lines Ms8, Rf3 and Ms8 × Rf3) genetically modified for tolerance to the herbicide glufosinate-ammonium (OJ L 100, 17.4.2007, p. 20).

⁽⁴⁾ EFSA GMO Panel 2017. Scientific opinion on the assessment of genetically modified oilseed rape MS8, RF3 and MS8 × RF3 for renewal of authorisation under regulation (EC) No 1829/2003 (application EFSA-GMO-RX-004). *EFSA Journal* 2017;15(11):5067.

⁽⁵⁾ EFSA, 2005. Opinion of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to the application (Reference C/BE/96/01) for the placing on the market of glufosinate-tolerant hybrid oilseed rape Ms8 × Rf3, derived from genetically modified parental lines (Ms8, Rf3), for import and processing for feed and industrial uses, under Part C of Directive 2001/18/EC from Bayer CropScience. *EFSA Journal* 2005; 3(10):281, p. 23.

- (8) On 30 November 2017, the applicant Bayer CropScience asked the Commission to merge into a single authorisation the uses of oilseed rapes Ms8, Rf3 and Ms8 × Rf3 covered by the renewal application and the uses of those oilseed rapes covered by Implementing Decision 2013/327/EU. By a letter dated 5 December 2017, the Commission informed the applicant that the merger would take effect through the extension of the scope of Implementing Decision 2013/327/EU to the products concerned by the renewal application of 20 May 2016. The applicant has therefore been made aware that, as a result of the merger, the products covered by the renewal application would be subject to the conditions of authorisation set out in Implementing Decision 2013/327/EU.
- (9) The Commission considers that the request of the applicant is justified, in the interest of simplification. Therefore, Implementing Decision 2013/327/EU should be amended to incorporate into its scope the products currently covered by Decision 2007/232/EC.
- (10) By letter dated 1 August 2018, Bayer CropScience AG requested the Commission the transfer of its rights and obligations for all authorisations to BASF Agricultural Solutions Seed US LLC. By letter dated 6 August 2018, BASF SE confirmed the agreement to this transfer on behalf of BASF Agricultural Solutions Seed US LLC. This transfer affects Decision 2007/232/EC and Implementing Decision 2013/327/EU.
- (11) A unique identifier has been assigned to oilseed rapes Ms8, Rf3 and Ms8 × Rf3, in accordance with Commission Regulation (EC) No 65/2004 ⁽⁶⁾. That unique identifier should continue to be used.
- (12) On the basis of the opinion of the Authority, no specific labelling requirements, other than those provided for in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003 of the European Parliament and of the Council ⁽⁷⁾, appear to be necessary for the products covered by this Decision. However, in order to ensure that the use of those products remains within the limits of the authorisation granted by this Decision, the labelling of the products containing or consisting of oilseed rapes Ms8, Rf3 and Ms8 × Rf3, with the exception of food products, should contain a clear indication that the products in question are not intended for cultivation.
- (13) The monitoring plan for environmental effects set out in Implementing Decision 2013/327/EU does not need to be amended as it is substantially identical to the one assessed by the Authority in the framework of the renewal application.
- (14) All relevant information on the authorisation of the products should be entered in the Community register of genetically modified food and feed referred to in Article 28(1) of Regulation (EC) No 1829/2003.
- (15) Decision 2007/232/EC should be repealed.
- (16) This Decision is to be notified through the Biosafety Clearing-House to the Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, pursuant to Article 9(1) and Article 15(2)(c) of Regulation (EC) No 1946/2003 of the European Parliament and of the Council ⁽⁸⁾.
- (17) The Standing Committee on Plants, Animals, Food and Feed has not delivered an opinion within the time limit laid down by its Chairman. This implementing act was deemed to be necessary and the chair submitted it to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

HAS ADOPTED THIS DECISION:

Article 1

Amendments

1. Implementing Decision 2013/327/EU is amended as follows:

- (1) The title is replaced by the following:

‘Commission Implementing Decision 2013/327/EU of 25 June 2013 authorising the placing on the market of food and feed containing, consisting of or produced from genetically modified oilseed rapes Ms8, Rf3 and Ms8 × Rf3 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council’

⁽⁶⁾ Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms (OJ L 10, 16.1.2004, p. 5).

⁽⁷⁾ Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (OJ L 268, 18.10.2003, p. 24).

⁽⁸⁾ Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms (OJ L 287, 5.11.2003, p. 1).

- (2) Article 2 is replaced by the following:

'Article 2

Authorisation

The following products are authorised for the purposes of Article 4(2) and Article 16(2) of Regulation (EC) No 1829/2003 in accordance with the conditions set out in this Decision:

- (a) foods and food ingredients containing, consisting of or produced from ACS-BNØØ5-8, ACS-BNØØ3-6 and ACS-BNØØ5-8 × ACS-BNØØ3-6 oilseed rapes;
- (b) feed containing, consisting of or produced from ACS-BNØØ5-8, ACS-BNØØ3-6 and ACS-BNØØ5-8 × ACS-BNØØ3-6 oilseed rapes;
- (c) ACS-BNØØ5-8, ACS-BNØØ3-6 and ACS-BNØØ5-8 × ACS-BNØØ3-6 oilseed rapes in products containing them or consisting of them for uses other than those provided in points (a) and (b), with the exception of cultivation.'

- (3) In Article 3, a new second paragraph is added:

'The words "not for cultivation" shall appear on the label of and in the documents accompanying products containing or consisting of genetically modified oilseed rapes referred to in Article 2, with the exception of foods and food ingredients.'

- (4) A new Article 3a is added:

'Article 3a

Method of detection

The method set out in point (d) of the Annex shall apply for the detection of oilseed rapes ACS-BNØØ5-8, ACS-BNØØ3-6 and ACS-BNØØ5-8 × ACS-BNØØ3-6.'

- (5) Article 6 is replaced by the following:

'Article 6

Authorisation holder

The authorisation holder shall be BASF Agricultural Solutions Seed US LLC, United States, represented by BASF SE, Germany.'

- (6) Article 8 is replaced by the following:

'Article 8

Addressee

This Decision is addressed to BASF SE, Carl-Bosch-Str. 38, D-67063 Ludwigshafen, Germany.'

2. The Annex to Implementing Decision 2013/327/EU is amended as follows:

- (1) Point (a) is replaced by the following:

'(a) Applicant and Authorisation holder

Name: BASF Agricultural Solutions Seed US LLC

Address: 100 Park Avenue, Florham Park, New Jersey 07932, United States of America

Represented by BASF SE, Carl-Bosch-Str. 38, D-67063 Ludwigshafen, Germany.'

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

'(b) Designation and specification of the products

- (1) foods and food ingredients containing, consisting of, or produced from ACS-BNØØ5-8, ACS-BNØØ3-6 and ACS-BNØØ5-8 × ACS-BNØØ3-6 oilseed rapes;
- (2) feed containing, consisting of, or produced from ACS-BNØØ5-8, ACS-BNØØ3-6 and ACS-BNØØ5-8 × ACS-BNØØ3-6 oilseed rapes;

- (3) ACS-BNØØ5-8, ACS-BNØØ3-6 and ACS-BNØØ5-8 × ACS-BNØØ3-6 oilseed rapes in products containing them or consisting of them for uses other than those provided in points (1) and (2), with the exception of cultivation.

The genetically modified ACS-BNØØ5-8, ACS-BNØØ3-6 and ACS-BNØØ5-8 × ACS-BNØØ3-6 oilseed rapes, as described in the applications, express the phosphinothricin acetyl transferase (PAT) protein which confers tolerance to the herbicidal active ingredient glufosinate-ammonium and barnase (ACS-BNØØ5-8) and barstar (ACS-BNØØ3-6) proteins for male sterility and restorer of fertility.'

- (3) In point (c), a new second paragraph is added:

'The words "not for cultivation" shall appear on the label of and in the documents accompanying products containing or consisting of genetically modified oilseed rapes referred to in point (b), with the exception of foods and food ingredients.'

Article 2

Repeal

Decision 2007/232/EC is repealed.

Article 3

Addressee

This Decision is addressed to BASF SE, Carl-Bosch-Str. 38, D-67063 Ludwigshafen, Germany.

Done at Brussels, 26 July 2019.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

COMMISSION IMPLEMENTING DECISION (EU) 2019/1302**of 26 July 2019****authorising the placing on the market of products containing, consisting of or produced from genetically modified cotton GHB614 × LLCotton25 × MON 15985 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council***(notified under document C(2019) 5501)***(Only the German text is authentic)****(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 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed ⁽¹⁾, and in particular to Articles 7(3) and 19(3) thereof,

Whereas:

- (1) On 11 February 2011, Bayer CropScience AG ('the applicant') submitted an application, in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003, for the placing on the market of foods, food ingredients and feed containing, consisting of or produced from cotton GHB614 × LLCotton25 × MON 15985 and the subcombination LLCotton25 × MON 15985 ('the application') to the national competent authority of the Netherlands. The application also covered the placing on the market of genetically modified cotton GHB614 × LLCotton25 × MON 15985 and the subcombination LLCotton25 × MON 15985 in products consisting of it or containing it for uses other than food and feed, with the exception of cultivation.
- (2) By letter of 20 April 2011, the applicant was informed that, due to the reproductive characteristics of cotton GHB614 × LLCotton25 × MON 15985, the subcombination LLCotton25 × MON 15985 should be removed from the application in order to assess it separately. By letter of 15 June 2015, the applicant submitted an updated version of the application to the European Food Safety Authority ('the Authority'), limiting the scope of the application to the placing on the market of foods, food ingredients and feed containing, consisting of or produced from cotton GHB614 × LLCotton25 × MON 15985.
- (3) In accordance with Articles 5(5) and 17(5) of Regulation (EC) No 1829/2003, the application included information and conclusions about the risk assessment carried out in accordance with the principles set out in Annex II to Directive 2001/18/EC of the European Parliament and of the Council ⁽²⁾ and the information required by Annexes III and IV to that Directive. It also included a monitoring plan for environmental effects in accordance with Annex VII to Directive 2001/18/EC.
- (4) On 20 April 2018, the Authority issued a favourable opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003 ⁽³⁾. The Authority concluded that genetically modified cotton GHB614 × LLCotton25 × MON 15985 is as safe as and is expected to have the same nutritional impact as its non-genetically modified comparator in the context of the scope of the application.
- (5) In its opinion, the Authority considered all the specific questions and concerns raised by the Member States in the context of the consultation of the national competent authorities as provided for by Article 6(4) and Article 18(4) of Regulation (EC) No 1829/2003.
- (6) The Authority also concluded that the monitoring plan for environmental effects submitted by the applicant, consisting of a general surveillance plan, is in line with the intended uses of the products.

⁽¹⁾ OJ L 268, 18.10.2003, p. 1.⁽²⁾ Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).⁽³⁾ EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2018. Scientific opinion on the assessment of genetically modified cotton GHB614 × LLCotton25 × MON 15985 for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2011-94). EFSA Journal 2018;16(4):5213, 27 pp. doi: 10.2903/j.efsa.2018.5213

- (7) Taking those considerations into account, the placing on the market of products containing, consisting of or produced from genetically modified cotton GHB614 × LLCotton25 × MON 15985 should be authorised.
- (8) By letter dated 1 August 2018, Bayer CropScience AG requested that the Commission transfer the rights and obligations of Bayer CropScience AG pertaining to all authorisations and pending applications for genetically modified products, to BASF Agricultural Solutions Seed US LLC. By letter dated 6 August 2018, BASF SE confirmed consent to this transfer on behalf of BASF Agricultural Solutions Seed US LLC.
- (9) A unique identifier should be assigned to genetically modified cotton GHB614 × LLCotton25 × MON 15985 in accordance with Commission Regulation (EC) No 65/2004 ⁽⁴⁾.
- (10) On the basis of the Authority's opinion, no specific labelling requirements, other than those provided for in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003 of the European Parliament and of the Council ⁽⁵⁾, appear necessary for the products covered by this Decision. However, in order to ensure that the use of those products remains within the limits of the authorisation granted by this Decision, the labelling of products containing or consisting of genetically modified cotton GHB614 × LLCotton25 × MON 15985, with the exception of food products, should contain a clear indication that they are not intended for cultivation.
- (11) The authorisation holder should submit annual reports on the implementation and on the results of the activities set out in the monitoring plan for environmental effects. Those results should be presented in accordance with the standard reporting format requirements laid down in Commission Decision 2009/770/EC ⁽⁶⁾.
- (12) The opinion of the Authority does not justify the imposition of specific conditions or restrictions for the placing on the market, and/or specific conditions or restrictions for the use and handling, including post-market monitoring requirements regarding the consumption of the food and feed, or for the protection of particular ecosystems/environment or geographical areas, as provided for in Article 6(5)(e) and Article 18(5)(e) of Regulation (EC) No 1829/2003.
- (13) All relevant information on the authorisation of the products should be entered in the Community register of genetically modified food and feed referred to in Article 28(1) of Regulation (EC) No 1829/2003.
- (14) This Decision is to be notified through the Biosafety Clearing-House to the Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, pursuant to Article 9(1) and Article 15(2)(c) of Regulation (EC) No 1946/2003 of the European Parliament and of the Council ⁽⁷⁾.
- (15) The Standing Committee on Plants, Animals, Food and Feed has not delivered an opinion within the time limit laid down by its Chairman. This implementing act was deemed to be necessary and the chair submitted it to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

HAS ADOPTED THIS DECISION:

Article 1

Genetically modified organism and unique identifier

Genetically modified cotton (*Gossypium hirsutum*) GHB614 × LLCotton25 × MON 15985, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier BCS-GHØØ2-5 × ACS-GHØØ1-3 × MON-15985-7, in accordance with Regulation (EC) No 65/2004.

⁽⁴⁾ Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms (OJ L 10, 16.1.2004, p. 5).

⁽⁵⁾ Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (OJ L 268, 18.10.2003, p. 24).

⁽⁶⁾ Commission Decision 2009/770/EC of 13 October 2009 establishing standard reporting formats for presenting the monitoring results of the deliberate release into the environment of genetically modified organisms, as or in products, for the purpose of placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council (OJ L 275, 21.10.2009, p. 9).

⁽⁷⁾ Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms (OJ L 287, 5.11.2003, p. 1).

*Article 2***Authorisation**

The following products are authorised for the purposes of Article 4(2) and Article 16(2) of Regulation (EC) No 1829/2003 in accordance with the conditions set out in this Decision:

- (a) foods and food ingredients containing, consisting of or produced from GHB614 × LLCotton25 × MON 15985 cotton;
- (b) feed containing, consisting of or produced from GHB614 × LLCotton25 × MON 15985 cotton;
- (c) products containing or consisting of GHB614 × LLCotton25 × MON 15985 cotton for uses other than those provided for in points (a) and (b) of this Article, with the exception of cultivation.

*Article 3***Labelling**

- 1. For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'cotton'.
- 2. The words 'not for cultivation' shall appear on the label and in the documents accompanying products containing or consisting of genetically modified cotton referred to in Article 1, with the exception of food and food ingredients.

*Article 4***Method for detection**

The method set out in point (d) of the Annex shall apply for the detection of the genetically modified cotton referred to in Article 1.

*Article 5***Monitoring plan for environmental effects**

- 1. The authorisation holder shall ensure that the monitoring plan for environmental effects, as set out in point (h) of the Annex, is put in place and implemented.
- 2. The authorisation holder shall submit annual reports on the implementation and the results of the activities set out in the monitoring plan to the Commission in accordance with Decision 2009/770/EC.

*Article 6***Community register**

The information set out in the Annex to this Decision shall be entered in the Community register of genetically modified food and feed, as referred to in Article 28(1) of Regulation (EC) No 1829/2003.

*Article 7***Authorisation holder**

The authorisation holder shall be BASF Agricultural Solutions Seed US LLC, USA, represented by BASF SE, Germany.

*Article 8***Validity**

This Decision shall apply for a period of 10 years from the date of its notification.

*Article 9***Addressee**

This Decision is addressed to BASF SE, Carl-Bosch-Str. 38, D-67063 Ludwigshafen, Germany.

Done at Brussels, 26 July 2019.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

ANNEX

(a) Applicant and Authorisation holder:

Name: BASF Agricultural Solutions Seed US LLC

Address: 100 Park Avenue, Florham Park, New Jersey 07932, United States of America

Represented by BASF SE, Carl-Bosch-Str. 38, D-67063 Ludwigshafen, Germany.

(b) Designation and specification of the products:

- (1) foods and food ingredients containing, consisting of or produced from GHB614 × LLCotton25 × MON 15985 cotton;
- (2) feed containing, consisting of or produced from GHB614 × LLCotton25 × MON 15985 cotton;
- (3) products containing or consisting of GHB614 × LLCotton25 × MON 15985 cotton for uses other than those provided in points (1) and (2), with the exception of cultivation.

The genetically modified cotton GHB614 × LLCotton25 × MON 15985, as described in the application, expresses the 2mEPSPS protein which confers tolerance to glyphosate-containing herbicides, the PAT protein which confers tolerance to glufosinate-ammonium based herbicides, the Cry1Ac and the Cry1Ab2 proteins which confer protection against certain lepidopteran pests. In addition, *uidA* gene, coding for the GUS protein, *nptII* gene, conferring kanamycin and neomycin resistance, and *aadA* gene, conferring spectinomycin and streptomycin resistance, were used as selection markers in the genetic modification process.

(c) Labelling:

- (1) For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003, and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'cotton';
- (2) The words 'not for cultivation' shall appear on the label of and in the accompanying documents of the products containing or consisting of GHB614 × LLCotton25 × MON 15985 cotton specified in point (e), with the exception of foods and food ingredients.

(d) Method for detection:

- (1) The quantitative event-specific PCR detection methods for cotton GHB614 × LLCotton25 × MON 15985 are those validated for genetically modified cotton events BCS-GHØØ2-5, ACS-GHØØ1-3 and MON-15985-7. The detection methods have been validated on genomic DNA extracted from leaves BCS-GHØØ2-5, ACS-GHØØ1-3 and MON-15985-7 cotton.
- (2) Validated by the EU Reference Laboratory established under Regulation (EC) No 1829/2003, published at <http://gmo-crl.jrc.ec.europa.eu/statusofdossiers.aspx>;
- (3) Reference Material: AOCS 1108-A5 (for BCS-GHØØ2-5), AOCS 0306-E2 (for ACS-GHØØ1-3) and AOCS 0804-D (MON-15985-7) are accessible via the American Oil Chemists' Society (AOCS) at <https://www.aocs.org/crm>

(e) Unique identifier:

BCS-GHØØ2-5 × ACS-GHØØ1-3 × MON-15985-7

(f) Information required under Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity:

[Biosafety Clearing-House, Record ID number: *published in the Community register of genetically modified food and feed when notified*].

(g) Conditions or restrictions on the placing on the market, use or handling of the products:

Not required.

(h) Monitoring plan for environmental effects:

Monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.

[Link: *plan published in the Community register of genetically modified food and feed*]

(i) **Post market monitoring requirements for the use of the food for human consumption**

Not required.

Note: links to relevant documents may need to be modified over the time. Those modifications will be made available to the public via the updating of the Community register of genetically modified food and feed.

COMMISSION IMPLEMENTING DECISION (EU) 2019/1303**of 26 July 2019****authorising the placing on the market of products containing, consisting of or produced from genetically modified maize 5307 (SYN-Ø53Ø7-1), pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed***(notified under document C(2019) 5493)***(Only the Dutch and French texts are authentic)****(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 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed ⁽¹⁾, and in particular Article 7(3) and Article 19(3) thereof,

Whereas:

- (1) On 7 April 2011, Syngenta Crop Protection AG submitted, through its affiliated company Syngenta Crop Protection NV/SA, an application in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003, for the placing on the market of foods, food ingredients and feed containing, consisting of or produced from genetically modified maize 5307 ('the application') to the national competent authority of Germany. The application also covered the placing on the market of products containing or consisting of genetically modified maize 5307 for uses other than food and feed, with the exception of cultivation.
- (2) In accordance with Articles 5(5) and 17(5) of Regulation (EC) No 1829/2003, the application included information and conclusions about the risk assessment carried out in accordance with the principles set out in Annex II to Directive 2001/18/EC of the European Parliament and of the Council ⁽²⁾ and the information required by Annexes III and IV to that Directive. It also included a monitoring plan for environmental effects in accordance with Annex VII to Directive 2001/18/EC.
- (3) On 5 May 2015, the European Food Safety Authority ('the Authority') issued an opinion, in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003 ⁽³⁾. The Authority was not able to reach an overall conclusion on maize 5307 due to an inadequate 28-day toxicity study provided for protein eCry3.1Ab.
- (4) On 8 December 2016, the applicant provided a new 28-day toxicity study on protein eCry3.1Ab.
- (5) On 11 April 2018, the Authority published a statement complementing its scientific opinion ⁽⁴⁾, taking into consideration the supplementary toxicity study. The Authority concluded that maize 5307, as assessed in the initial opinion and in the supplementary toxicity study, is as safe and nutritious as its conventional counterpart in the scope of the application.
- (6) In its opinion, the Authority considered all the questions and concerns raised by the Member States in the context of the consultation of the national competent authorities provided for by Articles 6(4) and 18(4) of Regulation (EC) No 1829/2003.

⁽¹⁾ OJ L 268, 18.10.2003, p. 1.

⁽²⁾ Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).

⁽³⁾ EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2015. Scientific Opinion on application (EFSA-GMO-DE-2011-95) for the placing on the market of genetically modified maize 5307 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Syngenta Crop Protection AG. *EFSA Journal* 2015;13(5):4083, 29 pp. <https://doi.org/10.2903/j.efsa.2015.4083>

⁽⁴⁾ EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2018. Statement complementing the EFSA Scientific Opinion on application (EFSA-GMO-DE-2011-95) for the placing on the market of genetically modified maize 5307 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Syngenta Crop Protection AG taking into consideration an additional toxicological study. *EFSA Journal* 2018;16(4):5233, 9 pp. <https://doi.org/10.2903/j.efsa.2018.5233>

- (7) The Authority also concluded that the monitoring plan for environmental effects consisting of a general surveillance plan, submitted by the applicant, was in line with the intended uses of the products.
- (8) Taking into account those conclusions, the placing on the market of products containing, consisting of or produced from genetically modified maize 5307 should be authorised for the uses listed in the application.
- (9) A unique identifier should be assigned to genetically modified maize 5307 in accordance with Commission Regulation (EC) No 65/2004 ⁽⁵⁾.
- (10) On the basis of the Authority's opinion, no specific labelling requirements, other than those laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003 of the European Parliament and of the Council ⁽⁶⁾, appear to be necessary for the products covered by this Decision. However, in order to ensure the use of those products within the limits of the authorisation granted by this Decision, the labelling of the products containing or consisting of genetically modified maize 5307, with the exception of food products, should contain a clear indication that the products in question are not intended for cultivation.
- (11) In order to account for the implementation and the results of the activities set out in the monitoring plan for environmental effects, the authorisation holder should submit annual reports, presented in accordance with the standard reporting format requirements laid down in Commission Decision 2009/770/EC ⁽⁷⁾.
- (12) The opinion of the Authority does not justify the imposition of specific conditions or restrictions for the placing on the market, for the use and handling, including post-market monitoring requirements regarding the consumption of the food and feed, or for the protection of particular ecosystems/environment or geographical areas, as provided for in Article 6(5)(e) and Article 18(5)(e) of Regulation (EC) No 1829/2003.
- (13) All relevant information on the authorisation of the products should be entered in the Community register of genetically modified food and feed referred to in Article 28(1) of Regulation (EC) No 1829/2003.
- (14) This Decision is to be notified through the Biosafety Clearing-House to the Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, pursuant to Articles 9(1) and 15(2)(c) of Regulation (EC) No 1946/2003 of the European Parliament and of the Council ⁽⁸⁾.
- (15) The Standing Committee on Plants, Animals, Food and Feed has not delivered an opinion within the time limit laid down by its Chairman. This implementing act was deemed to be necessary and the chair submitted it to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

HAS ADOPTED THIS DECISION:

Article 1

Genetically modified organism and unique identifier

Genetically modified maize (*Zea mays* L.) 5307, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier SYN-Ø53Ø7-1, in accordance with Regulation (EC) No 65/2004.

⁽⁵⁾ Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms (OJ L 10, 16.1.2004, p. 5).

⁽⁶⁾ Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (OJ L 268, 18.10.2003, p. 24).

⁽⁷⁾ Commission Decision 2009/770/EC of 13 October 2009 establishing standard reporting formats for presenting the monitoring results of the deliberate release into the environment of genetically modified organisms, as or in products, for the purpose of placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council (OJ L 275, 21.10.2009, p. 9).

⁽⁸⁾ Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms (OJ L 287, 5.11.2003, p. 1).

*Article 2***Authorisation**

The following products are authorised for the purposes of Articles 4(2) and 16(2) of Regulation (EC) No 1829/2003 in accordance with the conditions set out in this Decision:

- (a) foods and food ingredients containing, consisting of or produced from SYN-Ø53Ø7-1 maize;
- (b) feed containing, consisting of or produced from SYN-Ø53Ø7-1 maize;
- (c) products containing or consisting of SYN-Ø53Ø7-1 maize for uses other than those provided for in points (a) and (b) of this Article, with the exception of cultivation.

*Article 3***Labelling**

- 1. For the purposes of the labelling requirements laid down in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'maize'.
- 2. The words 'not for cultivation' shall appear on the label of and in the documents accompanying products containing or consisting of SYN-Ø53Ø7-1 maize, with the exception of products referred to in point (a) of Article 2.

*Article 4***Method for detection**

The method set out in point (d) of the Annex shall apply for the detection of SYN-Ø53Ø7-1 maize.

*Article 5***Monitoring for environmental effects**

- 1. The authorisation holder shall ensure that the monitoring plan for environmental effects, as set out in point (h) of the Annex, is put in place and implemented.
- 2. The authorisation holder shall submit to the Commission annual reports on the implementation and the results of the activities set out in the monitoring plan in accordance with Decision 2009/770/EC.

*Article 6***Community register**

The information set out in the Annex to this Decision shall be entered in the Community register of genetically modified food and feed, as referred to in Article 28(1) of Regulation (EC) No 1829/2003.

*Article 7***Authorisation holder**

The authorisation holder shall be Syngenta Crop Protection AG, Switzerland, represented by Syngenta Crop Protection NV/SA, Belgium.

*Article 8***Validity**

This Decision shall apply for a period of 10 years from the date of its notification.

*Article 9***Addressee**

This Decision is addressed to Syngenta Crop Protection NV/SA, Avenue Louise 489, 1050 Brussels, Belgium.

Done at Brussels, 26 July 2019.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

ANNEX

(a) Applicant and Authorisation holder:

Name: Syngenta Crop Protection AG

Address: Schwarzwaldallee 215, CH-4058 Basel, Switzerland

Represented by Syngenta Crop Protection NV/SA, Avenue Louise 489, 1050 Brussels, Belgium.

(b) Designation and specification of the products:

(1) food containing, consisting of or produced from SYN-Ø53Ø7-1 maize;

(2) feed containing, consisting of or produced from SYN-Ø53Ø7-1 maize;

(3) products containing or consisting of SYN-Ø53Ø7-1 maize for uses other than those provided for in points (1) and (2), with the exception of cultivation.

The genetically modified SYN-Ø53Ø7-1 maize, as described in the application, expresses the protein eCry3.1Ab, which confers resistance to certain coleopteran pests, and the protein PMI, which was used as a selection marker.

(c) Labelling:

(1) For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003, and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'maize'.

(2) The words 'not for cultivation' shall appear on the label of and in documents accompanying the products containing or consisting of SYN-Ø53Ø7-1 maize, with the exception of products referred to in point (a) of Article 2.

(d) Method for detection:

(1) Event specific real-time quantitative PCR based method for detection of the genetically modified maize SYN-Ø53Ø7-1.

(2) Validated by the EU reference laboratory established under Regulation (EC) No 1829/2003, published at <http://gmo-crl.jrc.ec.europa.eu/StatusOfDossiers.aspx>

(3) Reference Material: AOCS 0411-C and AOCS 0411-D are accessible via the American Oil Chemists Society (AOCS) at <https://www.aocs.org/crm>

(e) Unique identifier:

SYN-Ø53Ø7-1

(f) Information required under Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity:

[Biosafety Clearing-House, Record ID number: *published in the Community register of genetically modified food and feed when notified*].

(g) Conditions or restrictions on the placing on the market, use or handling of the products:

Not required.

(h) Monitoring plan for environmental effects:

Monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.

[Link: *plan published in the register of genetically modified food and feed*]

(i) Post-market monitoring requirements for the use of the food for human consumption:

Not required.

Note: links to relevant documents may need to be modified over the time. Those modifications will be made available to the public via the updating of the register of genetically modified food and feed.

COMMISSION IMPLEMENTING DECISION (EU) 2019/1304**of 26 July 2019****authorising the placing on the market of products containing, consisting of or produced from genetically modified maize 4114 (DP-ØØ4114-3), pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council***(notified under document C(2019) 5491)***(Only the Dutch and French texts are authentic)****(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 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed ⁽¹⁾, and in particular to Articles 7(3) and 19(3) thereof,

Whereas:

- (1) On 27 November 2014, Pioneer Overseas Corporation, on behalf of Pioneer Hi-Bred International Inc., United States, submitted to the national competent authority of the Netherlands an application in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003 ('the application'). The application covered the placing on the market of foods, food ingredients and feed containing, consisting of or produced from genetically modified maize 4114. The application also covered the placing on the market of products containing or consisting of genetically modified maize 4114 for uses other than food and feed, with the exception of cultivation.
- (2) In accordance with Articles 5(5) and 17(5) of Regulation (EC) No 1829/2003, the application included information and conclusions about the risk assessment carried out in accordance with the principles set out in Annex II to Directive 2001/18/EC of the European Parliament and of the Council ⁽²⁾. It also included the information required pursuant to Annexes III and IV to that Directive and a monitoring plan for environmental effects in accordance with Annex VII to that Directive.
- (3) On 24 May 2018, the European Food Safety Authority ('the Authority') issued a favourable opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003 ⁽³⁾. The Authority concluded that genetically modified maize 4114, as described in the application, is as safe as the non-GM comparator(s) and the tested non-genetically modified maize reference varieties with respect to potential effects on human and animal health and the environment.
- (4) In its opinion, the Authority considered all the questions and concerns raised by the Member States in the context of the consultation of the national competent authorities as provided for in Articles 6(4) and 18(4) of Regulation (EC) No 1829/2003.
- (5) The Authority also concluded that the monitoring plan for environmental effects consisting of a general surveillance plan, submitted by the applicant, is in line with the intended uses of the products.
- (6) Taking those considerations into account, the placing on the market of products containing, consisting of or produced from genetically modified maize 4114 should be authorised for the uses listed in the application.
- (7) A unique identifier should be assigned to genetically modified maize 4114 in accordance with Commission Regulation (EC) No 65/2004 ⁽⁴⁾.

⁽¹⁾ OJ L 268, 18.10.2003, p. 1.

⁽²⁾ Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).

⁽³⁾ EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2018. Scientific Opinion on the assessment of genetically modified maize 4114 for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2014-123). *EFSA Journal* 2018; 16(5):5280, 25 pp. <https://doi.org/10.2903/j.efsa.2018.5280>

⁽⁴⁾ Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms (OJ L 10, 16.1.2004, p. 5).

- (8) On the basis of the Authority's opinion, no specific labelling requirements, other than those provided for in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003 of the European Parliament and of the Council ⁽⁵⁾, appear to be necessary for the products covered by this Decision. However, in order to ensure that the use of those products remains within the limits of the authorisation granted by this Decision, the labelling of the products containing or consisting of genetically modified maize 4114, with the exception of foods and food ingredients, should contain a clear indication that they are not intended for cultivation.
- (9) In order to account for the implementation and the results of the activities set out in the monitoring plan for environmental effects, the authorisation holder should submit annual reports, presented in accordance with the standard reporting format requirements laid down in Commission Decision 2009/770/EC ⁽⁶⁾.
- (10) The opinion of the Authority does not justify the imposition of specific conditions or restrictions for the placing on the market, for the use and handling, including post-market monitoring requirements regarding the consumption of the food and feed, or for the protection of particular ecosystems/environment or geographical areas, as provided for in Article 6(5)(e) and Article 18(5)(e) of Regulation (EC) No 1829/2003.
- (11) All relevant information on the authorisation of the products should be entered in the Community register of genetically modified food and feed referred to in Article 28(1) of Regulation (EC) No 1829/2003.
- (12) This Decision is to be notified through the Biosafety Clearing-House to the Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, pursuant to Article 9(1) and Article 15(2)(c) of Regulation (EC) No 1946/2003 of the European Parliament and of the Council ⁽⁷⁾.
- (13) The Standing Committee on Plants, Animals, Food and Feed has not delivered an opinion within the time limit laid down by its Chairman. This implementing act was deemed to be necessary and the chair submitted it to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

HAS ADOPTED THIS DECISION:

Article 1

Genetically modified organism and unique identifier

Genetically modified maize (*Zea mays* L.) 4114, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier DP-ØØ4114-3, in accordance with Regulation (EC) No 65/2004.

Article 2

Authorisation

The following products are authorised for the purposes of Articles 4(2) and 16(2) of Regulation (EC) No 1829/2003 in accordance with the conditions set out in this Decision:

- (a) foods and food ingredients containing, consisting of or produced from genetically modified maize 4114;
- (b) feed containing, consisting of or produced from genetically modified maize 4114;
- (c) products containing or consisting of genetically modified maize 4114 for uses other than those provided for in points (a) and (b), with the exception of cultivation.

⁽⁵⁾ Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (OJ L 268, 18.10.2003, p. 24).

⁽⁶⁾ Commission Decision 2009/770/EC of 13 October 2009 establishing standard reporting formats for presenting the monitoring results of the deliberate release into the environment of genetically modified organisms, as or in products, for the purpose of placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council (OJ L 275, 21.10.2009, p. 9).

⁽⁷⁾ Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms (OJ L 287, 5.11.2003, p. 1).

*Article 3***Labelling**

1. For the purposes of the labelling requirements laid down in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'maize'.
2. The words 'not for cultivation' shall appear on the label of and in the documents accompanying products containing or consisting of genetically modified maize 4114, with the exception of foods and food ingredients.

*Article 4***Method for detection**

The method set out in point (d) of the Annex shall apply for the detection of genetically modified maize 4114.

*Article 5***Monitoring for environmental effects**

1. The authorisation holder shall ensure that the monitoring plan for environmental effects, as set out in point (h) of the Annex, is put in place and implemented.
2. The authorisation holder shall submit to the Commission annual reports on the implementation and the results of the activities set out in the monitoring plan in accordance with Decision 2009/770/EC.

*Article 6***Community register**

The information set out in the Annex to this Decision shall be entered in the Community register of genetically modified food and feed referred to in Article 28(1) of Regulation (EC) No 1829/2003.

*Article 7***Authorisation holder**

The authorisation holder shall be Pioneer Hi-Bred International, Inc., United States, represented by Pioneer Overseas Corporation, Belgium.

*Article 8***Validity**

This Decision shall apply for a period of 10 years from the date of its notification.

*Article 9***Addressee**

This Decision is addressed to Pioneer Overseas Corporation, Avenue des Arts 44, 1040 Brussels, Belgium.

Done at Brussels, 26 July 2019.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

ANNEX

(a) Applicant and authorisation holder:

Name: Pioneer Hi-Bred International, Inc.

Address: 7100 NW 62nd Avenue, P.O. Box 1014, Johnston, IA 50131-1014, U.S.A.

Represented by: Pioneer Overseas Corporation, Avenue des Arts, 44, 1040 Brussels, Belgium.

(b) Designation and specification of the products:

- (1) foods and food ingredients containing, consisting of or produced from genetically modified maize 4114;
- (2) feed containing, consisting of or produced from genetically modified maize 4114;
- (3) products containing or consisting of genetically modified maize 4114 for uses other than those provided for in points (1) and (2), with the exception of cultivation.

The genetically modified maize 4114 expresses the Cry1F (truncated version), Cry34Ab1 and Cry35Ab1 proteins providing protection against specific lepidopteran and coleopteran pests, and the PAT protein conferring tolerance to glufosinate-ammonium based herbicides.

(c) Labelling:

- (1) For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003, and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'maize'.
- (2) The words 'not for cultivation' shall appear on the label of and in documents accompanying the products containing or consisting of genetically modified maize 4114, with the exception of products referred to in point (b)(1) of this Annex.

(d) Method for detection:

- (1) Event-specific real-time quantitative PCR based method for detection of the genetically modified maize DP-ØØ4114-3.
- (2) Validated by the EU reference laboratory established under Regulation (EC) No 1829/2003, published at <http://gmo-crl.jrc.ec.europa.eu/StatusOfDossiers.aspx>
- (3) Reference Material: ERM®-BF439 is accessible via the Joint Research Centre (JRC) of the European Commission at <https://ec.europa.eu/jrc/en/reference-materials/catalogue/>

(e) Unique identifier:

DP-ØØ4114-3

(f) Information required under Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity:

[Biosafety Clearing-House, Record ID number: *published in the register of genetically modified food and feed when notified*].

(g) Conditions or restrictions on the placing on the market, use or handling of the products:

Not required.

(h) Monitoring plan for environmental effects:

Monitoring plan for environmental effects in accordance with Annex VII to Directive 2001/18/EC.

[Link: *plan published in the register of genetically modified food and feed*]

(i) Post-market monitoring requirements for the use of the food for human consumption:

Not required.

Note: links to relevant documents may need to be modified over the time. Those modifications will be made available to the public via the updating of the register of genetically modified food and feed.

COMMISSION IMPLEMENTING DECISION (EU) 2019/1305**of 26 July 2019**

authorising the placing on the market of products containing, consisting of or produced from genetically modified maize Bt11 × MIR162 × 1507 × GA21 and sub-combinations Bt11 × MIR162 × 1507, MIR162 × 1507 × GA21 and MIR162 × 1507 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

(notified under document C(2019) 5502)

(Only the Dutch and French texts are authentic)

(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 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed ⁽¹⁾, and in particular Article 7(3) and Article 19(3) thereof,

Whereas:

- (1) On 10 August 2010, Syngenta Crop Protection AG submitted, through its affiliated company Syngenta Crop Protection NV/SA, an application, in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003, for the placing on the market of foods, food ingredients and feed containing, consisting of or produced from genetically modified maize Bt11 × MIR162 × 1507 × GA21 ('the application') to the national competent authority of Germany. The application also covered the placing on the market of products containing or consisting of genetically modified maize Bt11 × MIR162 × 1507 × GA21 for uses other than food and feed, with the exception of cultivation.
- (2) In accordance with Article 5(5) and Article 17(5) of Regulation (EC) No 1829/2003, the application included information and conclusions about the risk assessment carried out in accordance with the principles set out in Annex II to Directive 2001/18/EC of the European Parliament and of the Council ⁽²⁾ and the information required by Annexes III and IV to that Directive. It also included a monitoring plan for environmental effects in accordance with Annex VII to Directive 2001/18/EC.
- (3) On 30 July 2013, Syngenta extended the scope of the application to all ten sub-combinations of the single transformation events constituting maize Bt11 × MIR162 × 1507 × GA21.
- (4) On 31 March 2016, Syngenta updated the scope of the application by excluding the sub-combinations that were in the scope of other applications: Bt11 × MIR162 × GA21, Bt11 × MIR162, Bt11 × GA21 and MIR162 × GA21, authorised by Commission Implementing Decision (EU) 2016/1685 ⁽³⁾ and sub-combinations Bt11 × 1507 × GA21, Bt11 × 1507 and 1507 × GA21, authorised by Commission Implementing Decision (EU) 2017/1209 ⁽⁴⁾. The scope of the application therefore covers sub-combinations Bt11 × MIR162 × 1507, MIR162 × 1507 × GA21 and MIR162 × 1507.
- (5) On 11 July 2018, the European Food Safety Authority ('the Authority') issued a favourable opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003 ⁽⁵⁾. The Authority concluded that genetically modified

⁽¹⁾ OJ L 268, 18.10.2003, p. 1.

⁽²⁾ Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).

⁽³⁾ Commission Implementing Decision (EU) 2016/1685 of 16 September 2016 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize Bt11 × MIR162 × MIR604 × GA21, and genetically modified maize combining two or three of the events Bt11, MIR162, MIR604 and GA21, and repealing Decisions 2010/426/EU, 2011/892/EU, 2011/893/EU and 2011/894/EU (OJ L 254, 20.9.2016, p. 22).

⁽⁴⁾ Commission Implementing Decision (EU) 2017/1209 of 4 July 2017 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize Bt11 × 59122 × MIR604 × 1507 × GA21, and genetically modified maize combining two, three or four of the events Bt11, 59122, MIR604, 1507 and GA21 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed (OJ L 173, 6.7.2017, p. 28).

⁽⁵⁾ EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2018. Scientific Opinion on the assessment of genetically modified maize Bt11 × MIR162 × 1507 × GA21 and three subcombinations independently of their origin, for food and feed uses under Regulation (EC) No 1829/2003 (application EFSA-GMO-DE-2010-86). *EFSA Journal* 2018;16(7):5309.

maize Bt11 × MIR162 × 1507 × GA21, as described in the application, is as safe as and nutritionally equivalent to its non-genetically modified comparator in the context of the scope of the application. As regards the three sub-combinations in the scope of the application, the Authority concluded that they are expected to be as safe as the single events Bt11, MIR162, 1507 and GA21, the previously assessed sub-combinations and the four-event stack maize Bt11 × MIR162 × 1507 × GA21.

- (6) In its opinion, the Authority considered the questions and concerns raised by the Member States in the context of the consultation of the national competent authorities as provided for in Articles 6(4) and 18(4) of Regulation (EC) No 1829/2003.
- (7) The Authority also concluded that the monitoring plan for environmental effects submitted by the applicant, consisting of a general surveillance plan, is in line with the intended uses of the products.
- (8) Taking into account those conclusions, the placing on the market of products containing, consisting of or produced from genetically modified maize Bt11 × MIR162 × 1507 × GA21 and of the three maize sub-combinations Bt11 × MIR162 × 1507, MIR162 × 1507 × GA21 and MIR162 × 1507 should be authorised for the uses listed in the application.
- (9) A unique identifier should be assigned to each genetically modified organism covered by this Decision, in accordance with Commission Regulation (EC) No 65/2004 ⁽⁶⁾.
- (10) On the basis of the Authority's opinion, no specific labelling requirements, other than those provided for in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003 of the European Parliament and of the Council ⁽⁷⁾, appear to be necessary for the products covered by this Decision. However, in order to ensure the use of those products within the limits of the authorisation granted by this Decision, the labelling of such products, with the exception of food products, should contain a clear indication that they are not intended for cultivation.
- (11) In order to account for the implementation and the results of the activities set out in the monitoring plan for environmental effects, the authorisation holder should submit annual reports, presented in accordance with the standard reporting format requirements laid down in Commission Decision 2009/770/EC ⁽⁸⁾.
- (12) The opinion of the Authority does not justify the imposition of specific conditions or restrictions for the placing on the market, for the use and handling, including post-market monitoring requirements regarding the consumption of the food and feed, or for the protection of particular ecosystems/environment or geographical areas, as provided for in Article 6(5)(e) and Article 18(5)(e) of Regulation (EC) No 1829/2003.
- (13) All relevant information on the authorisation of the products should be entered in the Community register of genetically modified food and feed referred to in Article 28(1) of Regulation (EC) No 1829/2003.
- (14) This Decision is to be notified through the Biosafety Clearing-House to the Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, pursuant to Article 9(1) and Article 15(2)(c) of Regulation (EC) No 1946/2003 of the European Parliament and of the Council ⁽⁹⁾.
- (15) The Standing Committee on Plants, Animals, Food and Feed has not delivered an opinion within the time limit laid down by its Chairman. This implementing act was deemed to be necessary and the chair submitted it to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

⁽⁶⁾ Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms (OJ L 10, 16.1.2004, p. 5).

⁽⁷⁾ Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (OJ L 268, 18.10.2003, p. 24).

⁽⁸⁾ Commission Decision 2009/770/EC of 13 October 2009 establishing standard reporting formats for presenting the monitoring results of the deliberate release into the environment of genetically modified organisms, as or in products, for the purpose of placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council (OJ L 275, 21.10.2009, p. 9).

⁽⁹⁾ Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms (OJ L 287, 5.11.2003, p. 1).

HAS ADOPTED THIS DECISION:

Article 1

Genetically modified organisms and unique identifiers

Genetically modified maize, as specified in point (b) of the Annex to this Decision, are assigned the following unique identifiers, in accordance with Regulation (EC) No 65/2004:

- (a) the unique identifier SYN-BTØ11-1 × SYN-IR162-4 × DAS-Ø15Ø7-1 × MON-ØØØ21-9 for genetically modified maize (*Zea mays* L.) Bt11 × MIR162 × 1507 × GA21;
- (b) the unique identifier SYN-BTØ11-1 × SYN-IR162-4 × DAS-Ø15Ø7-1 for genetically modified maize (*Zea mays* L.) Bt11 × MIR162 × 1507;
- (c) the unique identifier SYN-IR162-4 × DAS-Ø15Ø7-1 × MON-ØØØ21-9 for genetically modified maize (*Zea mays* L.) MIR162 × 1507 × GA21;
- (d) the unique identifier SYN-IR162-4 × DAS-Ø15Ø7-1 for genetically modified maize (*Zea mays* L.) MIR162 × 1507.

Article 2

Authorisation

The following products are authorised for the purposes of Article 4(2) and Article 16(2) of Regulation (EC) No 1829/2003 in accordance with the conditions set out in this Decision:

- (a) foods and food ingredients containing, consisting of or produced from genetically modified maize as referred to in Article 1;
- (b) feed containing, consisting of or produced from genetically modified maize as referred to in Article 1;
- (c) products containing or consisting of genetically modified maize as referred to in Article 1 for uses other than those provided for in points (a) and (b), with the exception of cultivation.

Article 3

Labelling

1. For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'maize'.
2. The words 'not for cultivation' shall appear on the label of and in the documents accompanying products containing or consisting of genetically modified maize as referred to in Article 1, with the exception of products referred to in point (a) of Article 2.

Article 4

Method for detection

The method set out in point (d) of the Annex shall apply for the detection of genetically modified maize as referred to in Article 1.

Article 5

Monitoring for environmental effects

1. The authorisation holder shall ensure that the monitoring plan for environmental effects, as set out in point (h) of the Annex, is put in place and implemented.
2. The authorisation holder shall submit to the Commission annual reports on the implementation and the results of the activities set out in the monitoring plan in accordance with Decision 2009/770/EC.

*Article 6***Community register**

The information set out in the Annex to this Decision shall be entered in the Community register of genetically modified food and feed, as referred to in Article 28(1) of Regulation (EC) No 1829/2003.

*Article 7***Authorisation holder**

The authorisation holder shall be Syngenta Crop Protection AG, Switzerland, represented by Syngenta Crop Protection NV/SA, Belgium.

*Article 8***Validity**

This Decision shall apply for a period of 10 years from the date of its notification.

*Article 9***Addressee**

This Decision is addressed to Syngenta Crop Protection NV/SA, Avenue Louise, 489, 1050 Brussels, Belgium.

Done at Brussels, 26 July 2019.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

ANNEX

(a) Applicant and Authorisation holder:

Name: Syngenta Crop Protection AG

Address: Schwarzwaldallee 215, CH-4058 Basel, Switzerland

Represented by Syngenta Crop Protection NV/SA, 489, Avenue Louise, 1050 Brussels, Belgium.

(b) Designation and specification of the products:

(1) foods and food ingredients containing, consisting of or produced from genetically modified maize (*Zea mays* L.) as referred to in point (e);

(2) feed containing, consisting of or produced from genetically modified maize (*Zea mays* L.) as referred to in point (e);

(3) products containing or consisting of genetically modified maize as referred to in point (e) for uses other than those provided for in points (1) and (2), with the exception of cultivation.

The genetically modified SYN-BTØ11-1 maize expresses the Cry1Ab protein, which confers protection against certain lepidopteran pests, and the PAT protein, which confers tolerance to glufosinate-ammonium-based herbicides.

The genetically modified SYN-IR162-4 maize expresses the Vip3Aa20 protein, which confers protection against certain lepidopteran pests, and the PMI protein, which was used as a selectable marker.

The genetically modified DAS-Ø15Ø7-1 maize expresses the Cry1F protein, which confers protection against certain lepidopteran pests, and the PAT protein, which confers tolerance to glufosinate-ammonium-based herbicides.

The genetically modified MON-ØØØ21-9 maize expresses the mEPSPS protein, which confers tolerance to glyphosate-based herbicides.

(c) Labelling:

(1) For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003, and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'maize';

(2) The words 'not for cultivation' shall appear on the label of and in the accompanying documents of the products containing or consisting of the maize specified in point (e), with the exception of products referred to in point (b)(1) of this Annex.

(d) Method for detection:

(1) The quantitative event-specific PCR detection methods for maize Bt11 × MIR162 × 1507 × GA21 are those validated for genetically modified maize events SYN-BTØ11-1, SYN-IR162-4, DAS-Ø15Ø7-1 and MON-ØØØ21-9.

(2) Validated by the EU Reference Laboratory established under Regulation (EC) No 1829/2003, published at <http://gmo-crl.jrc.ec.europa.eu/statusofdossiers.aspx>;

(3) Reference Material: ERM®-BF412 (for SYN-BTØ11-1) and ERM®-BF418 (for DAS-Ø15Ø7-1) are accessible via the Joint Research Centre (JRC) of the European Commission at <https://ec.europa.eu/jrc/en/reference-materials/catalogue/>, and AOCS 1208-A and AOCS 0407-A (for SYN-IR162-4), AOCS 0407-A and AOCS 0407-B (for MON-ØØØ21-9) are accessible via the American Oil Chemists Society at <https://www.aocs.org/crm#maize>.

(e) Unique identifiers:

SYN-BTØ11-1 × SYN-IR162-4 × DAS-Ø15Ø7-1 × MON-ØØØ21-9;

SYN-BTØ11-1 × SYN-IR162-4 × DAS-Ø15Ø7-1;

SYN-IR162-4 × DAS-Ø15Ø7-1 × MON-ØØØ21-9;

SYN-IR162-4 × DAS-Ø15Ø7-1.

(f) **Information required under Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity:**

[Biosafety Clearing-House, Record ID number: *published in the Community register of genetically modified food and feed when notified*].

(g) **Conditions or restrictions on the placing on the market, use or handling of the products:**

Not required.

(h) **Monitoring plan for environmental effects:**

Monitoring plan for environmental effects in accordance with Annex VII to Directive 2001/18/EC.

[Link: *plan published in the Community register of genetically modified food and feed*]

(i) **Post-market monitoring requirements for the use of the food for human consumption**

Not required.

Note: links to relevant documents may need to be modified over the time. Those modifications will be made available to the public via the updating of the Community register of genetically modified food and feed.

COMMISSION IMPLEMENTING DECISION (EU) 2019/1306**of 26 July 2019****renewing the authorisation for the placing on the market of products containing, consisting of or produced from genetically modified maize 1507 × NK603 (DAS-Ø15Ø7-1 × MON-ØØ6Ø3-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council***(notified under document C(2019) 5503)***(Only the Dutch and French texts are authentic)****(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 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed ⁽¹⁾, and in particular to Articles 11(3) and 23(3) thereof,

Whereas:

- (1) Commission Decision 2007/703/EC ⁽²⁾ authorised the placing on the market of food and feed containing, consisting of, or produced from genetically modified maize 1507 × NK603 (hereinafter ‘maize 1507 × NK603’). The scope of that authorisation also covers the placing on the market of products, other than food and feed, containing or consisting of maize 1507 × NK603 for the same uses as any other maize with the exception of cultivation.
- (2) On 20 October 2016, Pioneer Overseas Corporation, on behalf of Pioneer Hi-Bred International, Inc., and Dow AgroSciences Europe, on behalf of Dow AgroSciences LLC, jointly submitted to the Commission an application, in accordance with Articles 11 and 23 of Regulation (EC) No 1829/2003, for the renewal of that authorisation.
- (3) On 25 July 2018, the European Food Safety Authority (‘the Authority’) issued a favourable opinion ⁽³⁾ in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003. It concluded that the renewal application did not contain evidence for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on maize 1507 × NK603, adopted by the Authority in 2006 ⁽⁴⁾.
- (4) In its opinion of 25 July 2018, the Authority considered all the questions and concerns raised by the Member States in the context of the consultation of the national competent authorities as provided for in Articles 6(4) and 18(4) of Regulation (EC) No 1829/2003.
- (5) The Authority also concluded that the monitoring plan for the environmental effects, consisting of a general surveillance plan, submitted by the applicants, is in line with the intended uses of the products.
- (6) Taking into account those conclusions, the authorisation for the placing on the market of food and feed containing, consisting of or produced from genetically modified maize 1507 × NK603 and of products consisting of it or containing it for other uses than food or feed, with the exception of cultivation, should be renewed.

⁽¹⁾ OJ L 268, 18.10.2003, p. 1.

⁽²⁾ Commission Decision 2007/703/EC of 24 October 2007 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize 1507×NK603 (DAS-Ø15Ø7-1×MON-ØØ6Ø3-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 285, 31.10.2007, p. 47).

⁽³⁾ EFSA GMO Panel 2018. Scientific Opinion on the assessment of genetically modified maize 1507 × NK603 for renewal of authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-008). *EFSA Journal* 2018;16(7): 5347.

⁽⁴⁾ Opinion of the Scientific Panel on Genetically Modified Organisms on an application (Reference EFSA-GMO-UK-2004-05) for the placing on the market of insect-protected and glufosinate and glyphosate-tolerant genetically modified maize 1507 × NK603, for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Pioneer Hi-Bred and Mycogen Seeds. *The EFSA Journal* 2006;4(5): 355.

- (7) By letter dated 13 September 2018, Dow AgroSciences Europe requested the Commission, in the context of the withdrawal of the United Kingdom from the European Union, that the representative in the Union of Dow AgroSciences LLC, United States, should be Dow AgroSciences Distribution S.A.S., based in France. By letter dated 7 September 2018, Dow AgroSciences Distribution S.A.S confirmed its agreement.
- (8) By letter dated 12 October 2018, Dow AgroSciences LLC also confirmed its agreement to be represented by Dow AgroSciences Distribution S.A.S. and clarified that Mycogen Seeds is a subsidiary of Dow AgroSciences LLC.
- (9) A unique identifier has been assigned to genetically modified maize 1507 × NK603, in accordance with Commission Regulation (EC) No 65/2004 ⁽⁵⁾, in the context of its initial authorisation. That unique identifier should continue to be used.
- (10) On the basis of the opinion of the Authority, no specific labelling requirements, other than those provided for in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003 of the European Parliament and of the Council ⁽⁶⁾, appear to be necessary for the products covered by this Decision. However, in order to ensure that the use of products containing or consisting of maize 1507 × NK603 remains within the limits of the authorisation granted by this Decision, the labelling of such products, with the exception of food products, should contain a clear indication that they are not intended for cultivation.
- (11) The authorisation holders should submit joint annual reports on the implementation and on the results of the activities set out in the monitoring plan. Those results should be presented in accordance with the requirements laid down in Commission Decision 2009/770/EC ⁽⁷⁾.
- (12) The opinion of the Authority does not justify the imposition of specific conditions or restrictions for the placing on the market, for the use and handling, including post-market monitoring requirements regarding the consumption of the food and feed, or for the protection of particular ecosystems/environment or geographical areas, as provided for in Articles 6(5)(e) and 18(5)(e) of Regulation (EC) No 1829/2003.
- (13) All relevant information on the authorisation of the products should be entered in the Community register of genetically modified food and feed referred to in Article 28(1) of Regulation (EC) No 1829/2003.
- (14) This Decision is to be notified through the Biosafety Clearing-House to the Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, pursuant to Articles 9(1) and 15(2)(c) of Regulation (EC) No 1946/2003 of the European Parliament and of the Council ⁽⁸⁾.
- (15) The Standing Committee on Plants, Animals, Food and Feed has not delivered an opinion within the time limit laid down by its Chairman. This implementing act was deemed to be necessary and the chair submitted it to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

HAS ADOPTED THIS DECISION:

Article 1

Genetically modified organism and unique identifier

Genetically modified maize (*Zea mays* L.) 1507 × NK603, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier DAS-Ø15Ø7-1 × MON-ØØ6Ø3-6, in accordance with Regulation (EC) No 65/2004.

⁽⁵⁾ Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms (OJ L 10, 16.1.2004, p. 5).

⁽⁶⁾ Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (OJ L 268, 18.10.2003, p. 24).

⁽⁷⁾ Commission Decision 2009/770/EC of 13 October 2009 establishing standard reporting formats for presenting the monitoring results of the deliberate release into the environment of genetically modified organisms, as or in products, for the purpose of placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council (OJ L 275, 21.10.2009, p. 9).

⁽⁸⁾ Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms (OJ L 287, 5.11.2003, p. 1).

*Article 2***Renewal of the authorisation**

The authorisation for the placing on the market of the following products is renewed in accordance with the conditions set out in this Decision:

- (a) foods and food ingredients containing, consisting of, or produced from genetically modified maize 1507 × NK603;
- (b) feed containing, consisting of, or produced from genetically modified maize 1507 × NK603;
- (c) products containing or consisting of genetically modified maize 1507 × NK603 for uses other than those provided for in points (a) and (b) of this Article, with the exception of cultivation.

*Article 3***Labelling**

1. For the purposes of the labelling requirements laid down in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'maize'.
2. The words 'not for cultivation' shall appear on the label of and in the documents accompanying the products containing or consisting of genetically modified maize 1507 × NK603, with the exception of products referred to in point (a) of Article 2.

*Article 4***Method for detection**

The method set out in point (d) of the Annex shall apply for the detection of genetically modified maize 1507 × NK603.

*Article 5***Monitoring plan for environmental effects**

1. The authorisation holders shall ensure that the monitoring plan for environmental effects, as set out in point (h) of the Annex, is put in place and implemented.
2. The authorisation holders shall submit to the Commission joint annual reports on the implementation and the results of the activities set out in the monitoring plan in accordance with the format set out in Decision 2009/770/EC.

*Article 6***Community register**

The information set out in the Annex to this Decision shall be entered in the Community register of genetically modified food and feed, as referred to in Article 28(1) of Regulation (EC) No 1829/2003.

*Article 7***Authorisation holders**

1. The authorisation holders shall be:
 - (a) Pioneer Hi-Bred International, Inc., United States, represented by Pioneer Overseas Corporation, Belgium; and
 - (b) Dow AgroSciences LLC, United States, represented by Dow AgroSciences Distribution S.A.S., France.
2. Both authorisation holders shall be responsible for fulfilling the duties imposed on authorisation holders by this Decision and Regulation (EC) No 1829/2003.

*Article 8***Validity**

This Decision shall apply for a period of 10 years from the date of its notification.

*Article 9***Addressees**

This Decision is addressed to:

- (a) Pioneer Overseas Corporation, Avenue des Arts 44, 1040 Brussels, Belgium; and
- (b) Dow AgroSciences Distribution S.A.S., 6, rue Jean Pierre Timbaud, 78180 Montigny le Bretonneux, France.

Done at Brussels, 26 July 2019.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

ANNEX

(a) Applicants and authorisation holders:

Name: Pioneer Hi-Bred International, Inc.

Address: 7100 NW 62nd Avenue, P.O. Box 1014, Johnston, IA 50131-1014, United States

Represented by: Pioneer Overseas Corporation, Avenue des Arts, 44, 1040 Brussels, Belgium;

and

Name: Dow AgroSciences LLC

Address: 9330 Zionsville Road, Indianapolis, IN 46268-1054, United States

Represented by: Dow AgroSciences Distribution S.A.S., 6, rue Jean Pierre Timbaud, 78180 Montigny le Bretonneux, France.

(b) Designation and specification of the products:

- (1) foods and food ingredients containing, consisting of or produced from genetically modified maize 1507 × NK603;
- (2) feed containing, consisting of or produced from genetically modified maize 1507 × NK603;
- (3) products containing or consisting of genetically modified maize 1507 × NK603 for uses other than those provided for in points (1) and (2), with the exception of cultivation.

The genetically modified maize 1507 × NK603 expresses the *cry1F* gene, which confers protection against certain lepidopteran pests, the *pat* gene, which confers tolerance to glufosinate-ammonium based herbicides, and the *cp4 epsps* gene, which confers tolerance to glyphosate based herbicides.

(c) Labelling:

- (1) For the purposes of the labelling requirements laid down in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003, and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'maize'.
- (2) The words 'not for cultivation' shall appear on the label of and in the documents accompanying the products containing or consisting of genetically modified maize 1507 × NK603, with the exception of products referred to in point (b)(1) of this Annex.

(d) Method for detection:

- (1) Event specific real-time quantitative PCR based methods for genetically modified maize DAS-Ø15Ø7-1 and maize MON-ØØ6Ø3-6 validated on maize DAS-Ø15Ø7-1 × MON-ØØ6Ø3-6.
- (2) Validated by the EU reference laboratory established under Regulation (EC) No 1829/2003, published at <http://gmo-crl.jrc.ec.europa.eu/StatusOfDossiers.aspx>
- (3) Reference Material: ERM®-BF418 (for DAS-Ø15Ø7-1) and ERM®-BF415 (for MON-ØØ6Ø3-6) accessible via the Joint Research Centre (JRC) of the European Commission at <https://ec.europa.eu/jrc/en/reference-materials/catalogue/>

(e) Unique identifier:

DAS-Ø15Ø7-1 × MON-ØØ6Ø3-6

(f) Information required under Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity:

[Biosafety Clearing-House, Record ID number: *published in the register of genetically modified food and feed when notified*].

(g) Conditions or restrictions on the placing on the market, use or handling of the products:

Not required.

(h) **Monitoring plan for environmental effects:**

Monitoring plan for environmental effects in accordance with Annex VII to Directive 2001/18/EC of the European Parliament and of the Council ⁽¹⁾.

[Link: *plan published in the register of genetically modified food and feed*]

(i) **Post-market monitoring requirements for the use of the food for human consumption:**

Not required.

Note: links to relevant documents may need to be modified over time. Those modifications will be made available to the public via the updating of the register of genetically modified food and feed.

⁽¹⁾ Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).

COMMISSION IMPLEMENTING DECISION (EU) 2019/1307**of 26 July 2019****authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MON 87403 (MON-87403-1), pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council***(notified under document C(2019) 5481)***(Only the Dutch and French texts are authentic)****(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 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed ⁽¹⁾, and in particular Articles 7(3) and 19(3) thereof,

Whereas:

- (1) On 26 June 2015, Monsanto Europe S.A./N.V. submitted, on behalf of Monsanto company, United States, an application, in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003, for the placing on the market of foods, food ingredients and feed containing, consisting of or produced from genetically modified maize MON 87403 ('the application') to the national competent authority of Belgium. The application also covered the placing on the market of products containing or consisting of genetically modified maize MON 87403 for uses other than food and feed, with the exception of cultivation.
- (2) In accordance with Articles 5(5) and 17(5) of Regulation (EC) No 1829/2003, the application included information and conclusions about the risk assessment carried out in accordance with the principles set out in Annex II to Directive 2001/18/EC of the European Parliament and of the Council ⁽²⁾ and the information required by Annexes III and IV to that Directive. It also included a monitoring plan for environmental effects in accordance with Annex VII to Directive 2001/18/EC.
- (3) On 26 April 2018, the European Food Safety Authority ('the Authority') issued a favourable opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003 ⁽³⁾. The Authority concluded that genetically modified maize MON 87403, as described in the application, is as safe as its conventional counterpart and the tested non-genetically modified maize reference varieties, with respect to the potential effects on human and animal health and the environment.
- (4) In its opinion, the Authority considered all the questions and concerns raised by the Member States in the context of the consultation of the national competent authorities as provided for by Articles 6(4) and 18(4) of Regulation (EC) No 1829/2003.
- (5) The Authority also concluded that the monitoring plan for environmental effects consisting of a general surveillance plan, submitted by the applicant, was in line with the intended uses of the products.
- (6) Taking into account those conclusions, the placing on the market of products containing, consisting of or produced from genetically modified maize MON 87403 should be authorised for the uses listed in the application.
- (7) By letter dated 27 August 2018, Monsanto Europe N.V. informed the Commission that Monsanto Europe N.V. converted its legal form and changed its name to Bayer Agriculture BVBA, Belgium.
- (8) A unique identifier should be assigned to genetically modified maize MON 87403 in accordance with Commission Regulation (EC) No 65/2004 ⁽⁴⁾.

⁽¹⁾ OJ L 268, 18.10.2003, p. 1.

⁽²⁾ Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).

⁽³⁾ EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2018. Scientific Opinion on the assessment of genetically modified maize MON 87403 for food and feed uses, import and processing, under Regulation (EC) No 1829/2003 (application EFSA-GMO-BE-2015-125). *EFSA Journal* 2018;16(3):5225, 28 pp. <https://doi.org/10.2903/j.efsa.2018.5225>

⁽⁴⁾ Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms (OJ L 10, 16.1.2004, p. 5).

- (9) On the basis of the Authority's opinion, no specific labelling requirements, other than those provided for in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003 of the European Parliament and of the Council ⁽⁵⁾, appear to be necessary for the products covered by this Decision. However, in order to ensure that the use of those products remains within the limits of the authorisation granted by this Decision, the labelling of the products containing or consisting of genetically modified maize MON 87403, with the exception of food products, should contain a clear indication that they are not intended for cultivation.
- (10) In order to account for the implementation and the results of the activities set out in the monitoring plan for environmental effects, the authorisation holder should submit annual reports, presented in accordance with the standard reporting format requirements laid down in Commission Decision 2009/770/EC ⁽⁶⁾.
- (11) The opinion of the Authority does not justify the imposition of specific conditions or restrictions for the placing on the market, for the use and handling, including post-market monitoring requirements regarding the consumption of the food and feed, or for the protection of particular ecosystems/environment or geographical areas, as provided for in Articles 6(5)(e) and 18(5)(e) of Regulation (EC) No 1829/2003.
- (12) All relevant information on the authorisation of the products should be entered in the Community register of genetically modified food and feed referred to in Article 28(1) of Regulation (EC) No 1829/2003.
- (13) This Decision is to be notified through the Biosafety Clearing-House to the Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, pursuant to Articles 9(1) and 15(2)(c) of Regulation (EC) No 1946/2003 of the European Parliament and of the Council ⁽⁷⁾.
- (14) The Standing Committee on Plants, Animals, Food and Feed has not delivered an opinion within the time limit laid down by its Chairman. This implementing act was deemed to be necessary and the chair submitted it to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

HAS ADOPTED THIS DECISION:

Article 1

Genetically modified organism and unique identifier

Genetically modified maize (*Zea mays* L.) MON 87403, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier MON-874Ø3-1, in accordance with Regulation (EC) No 65/2004.

Article 2

Authorisation

The following products are authorised for the purposes of Articles 4(2) and 16(2) of Regulation (EC) No 1829/2003 in accordance with the conditions set out in this Decision:

- (a) foods and food ingredients containing, consisting of or produced from MON-874Ø3-1 maize;
- (b) feed containing, consisting of or produced from MON-874Ø3-1 maize;
- (c) products containing or consisting of MON-874Ø3-1 maize for uses other than those provided for in points (a) and (b) of this Article, with the exception of cultivation.

⁽⁵⁾ Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (OJ L 268, 18.10.2003, p. 24).

⁽⁶⁾ Commission Decision 2009/770/EC of 13 October 2009 establishing standard reporting formats for presenting the monitoring results of the deliberate release into the environment of genetically modified organisms, as or in products, for the purpose of placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council (OJ L 275, 21.10.2009, p. 9).

⁽⁷⁾ Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms (OJ L 287, 5.11.2003, p. 1).

*Article 3***Labelling**

1. For the purposes of the labelling requirements laid down in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'maize'.
2. The words 'not for cultivation' shall appear on the label of and in the documents accompanying products containing or consisting of MON-874Ø3-1 maize, with the exception of products referred to in point (a) of Article 2.

*Article 4***Method for detection**

The method set out in point (d) of the Annex shall apply for the detection of MON-874Ø3-1 maize.

*Article 5***Monitoring for environmental effects**

1. The authorisation holder shall ensure that the monitoring plan for environmental effects, as set out in point (h) of the Annex, is put in place and implemented.
2. The authorisation holder shall submit to the Commission annual reports on the implementation and the results of the activities set out in the monitoring plan in accordance with Decision 2009/770/EC.

*Article 6***Community register**

The information set out in the Annex to this Decision shall be entered in the Community register of genetically modified food and feed, as referred to in Article 28(1) of Regulation (EC) No 1829/2003.

*Article 7***Authorisation holder**

The authorisation holder shall be Monsanto Company, United States, represented by Bayer Agriculture BVBA, Belgium.

*Article 8***Validity**

This Decision shall apply for a period of 10 years from the date of its notification.

*Article 9***Addressee**

This Decision is addressed to Bayer Agriculture BVBA, Scheldelaan 460, 2040 Antwerp, Belgium.

Done at Brussels, 26 July 2019.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

ANNEX

(a) Applicant and Authorisation holder:

Name: Monsanto Company

Address: 800 N. Lindbergh Boulevard, St. Louis, Missouri 63167, United States of America

Represented by Bayer Agriculture BVBA, Scheldelaan 460, 2040 Antwerp, Belgium.

(b) Designation and specification of the products:

(1) foods and food ingredients containing, consisting of or produced from MON-874Ø3-1 maize;

(2) feed containing, consisting of or produced from MON-874Ø3-1 maize;

(3) products containing or consisting of MON-874Ø3-1 maize for uses other than those provided for in points (1) and (2), with the exception of cultivation.

The genetically modified MON-874Ø3-1 maize was developed to increase ear biomass at early reproductive phase through the expression of the AtHB17Δ113 protein (encoded by a gene from *Arabidopsis thaliana*).

(c) Labelling:

(1) For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003, and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'maize'.

(2) The words 'not for cultivation' shall appear on the label of and in documents accompanying the products containing or consisting of MON-874Ø3-1 maize, with the exception of products referred to in point (a) of Article 2.

(d) Method for detection:

(1) Event specific real-time quantitative PCR based method for detection of the genetically modified maize MON-874Ø3-1.

(2) Validated by the EU reference laboratory established under Regulation (EC) No 1829/2003, published at <http://gmo-crl.jrc.ec.europa.eu/StatusOfDossiers.aspx>

(3) Reference Material: AOCS 0216-A is accessible via the American Oil Chemists Society (AOCS) at <https://www.aocs.org/crm>

(e) Unique identifier:

MON-874Ø3-1

(f) Information required under Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity:

[Biosafety Clearing-House, Record ID number: *published in the Community register of genetically modified food and feed when notified*].

(g) Conditions or restrictions on the placing on the market, use or handling of the products:

Not required.

(h) Monitoring plan for environmental effects:

Monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.

[Link: *plan published in the register of genetically modified food and feed*]

(i) Post-market monitoring requirements for the use of the food for human consumption:

Not required.

Note: links to relevant documents may need to be modified over the time. Those modifications will be made available to the public via the updating of the register of genetically modified food and feed.

COMMISSION IMPLEMENTING DECISION (EU) 2019/1308**of 26 July 2019****authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MON 87411 (MON-87411-9), pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council***(notified under document C(2019) 5487)***(Only the Dutch and French texts are authentic)****(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 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed ⁽¹⁾, and in particular to Articles 7(3) and 19(3) thereof,

Whereas:

- (1) On 5 February 2015, Monsanto Europe N.V. submitted, on behalf of the Monsanto Company, United States, an application, in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003, for the placing on the market of foods, food ingredients and feed containing, consisting of or produced from maize MON 87411 ('the application') to the national competent authority of the Netherlands. The application also covered the placing on the market of products consisting of genetically modified maize MON 87411 for uses other than food and feed as any other maize, with the exception of cultivation.
- (2) In accordance with Articles 5(5) and 17(5) of Regulation (EC) No 1829/2003, the application included information and conclusions about the risk assessment carried out in accordance with the principles set out in Annex II to Directive 2001/18/EC of the European Parliament and of the Council ⁽²⁾ and the information required by Annexes III and IV to that Directive. It also included a monitoring plan for environmental effects set out in Annex VII to Directive 2001/18/EC.
- (3) On 02 July 2018, the European Food Safety Authority ('the Authority') issued a favourable opinion in accordance with Article 6 and Article 18 of Regulation (EC) No 1829/2003 ⁽³⁾. The Authority concluded that genetically modified maize MON 87411, as described in the application, is as safe as and nutritionally equivalent to its conventional counterpart and the tested non-genetically modified maize reference varieties with respect to the potential effects on human and animal health and the environment.
- (4) In its opinion, the Authority considered all the questions and concerns raised by the Member States in the context of the consultation of the national competent authorities as provided for by Articles 6(4) and 18(4) of Regulation (EC) No 1829/2003.
- (5) The Authority also concluded that the monitoring plan for environmental effects submitted by the applicant, consisting of a general surveillance plan, is in line with the intended uses of the products.
- (6) Taking into account those conclusions, the placing on the market of products containing, consisting of or produced from genetically modified maize MON 87411 should be authorised for the uses listed in the application.

⁽¹⁾ OJ L 268, 18.10.2003, p. 1.⁽²⁾ Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).⁽³⁾ EFSA GMO Panel (EFSA Panel on genetically Modified Organisms), 2018. Scientific opinion on the assessment of genetically modified maize MON 87411 for food and feed uses, import and processing, under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2015-124). *EFSA Journal* 2018; 16(6):5310, 29 pp. doi: 10.2903/j.efsa.2018.5310

- (7) By letter dated 27 August 2018, Monsanto Europe N.V. informed the Commission that Monsanto Europe N.V. converted its legal form and changed its name to Bayer Agriculture BVBA, Belgium.
- (8) A unique identifier should be assigned to genetically modified maize MON 87411 in accordance with Commission Regulation (EC) No 65/2004 ⁽⁴⁾.
- (9) On the basis of the Authority's opinion, no specific labelling requirements, other than those provided for in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003 of the European Parliament and of the Council ⁽⁵⁾, appear necessary for the products covered by this Decision. However, in order to ensure that the use of those products remains within the limits of the authorisation granted by this Decision, the labelling of the products containing or consisting of genetically modified maize MON 87411, with the exception of food products, should contain a clear indication that they are not intended for cultivation.
- (10) In order to account for the implementation and the results of the activities set out in the monitoring plan for environmental effects, the authorisation holder should submit annual reports, presented in accordance with the standard reporting format requirements laid down in Commission Decision 2009/770/EC ⁽⁶⁾.
- (11) The opinion of the Authority does not justify the imposition of specific conditions or restrictions for the placing on the market, for the use and handling, including post-market monitoring requirements regarding the consumption of the food and feed, or for the protection of particular ecosystems/environment or geographical areas, as provided for in Articles 6(5)(e) and 18(5)(e) of Regulation (EC) No 1829/2003.
- (12) All relevant information on the authorisation of the products should be entered in the Community register of genetically modified food and feed referred to in Article 28(1) of Regulation (EC) No 1829/2003.
- (13) This Decision is to be notified through the Biosafety Clearing-House to the Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, pursuant to Articles 9(1) and 15(2)(c) of Regulation (EC) No 1946/2003 of the European Parliament and of the Council ⁽⁷⁾.
- (14) The Standing Committee on Plants, Animals, Food and Feed has not delivered an opinion within the time limit laid down by its Chairman. This implementing act was deemed to be necessary and the chair submitted it to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

HAS ADOPTED THIS DECISION:

Article 1

Genetically modified organism and unique identifier

Genetically modified maize (*Zea mays* L.) MON 87411, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier MON-87411-9, as provided for in Regulation (EC) No 65/2004.

⁽⁴⁾ Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms (OJ L 10, 16.1.2004, p. 5).

⁽⁵⁾ Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (OJ L 268, 18.10.2003, p. 24).

⁽⁶⁾ Commission Decision 2009/770/EC of 13 October 2009 establishing standard reporting formats for presenting the monitoring results of the deliberate release into the environment of genetically modified organisms, as or in products, for the purpose of placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council (OJ L 275, 21.10.2009, p. 9).

⁽⁷⁾ Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms (OJ L 287, 5.11.2003, p. 1).

*Article 2***Authorisation**

The following products are authorised for the purposes of Article 4(2) and Article 16(2) of Regulation (EC) No 1829/2003 in accordance with the conditions set out in this Decision:

- (a) foods and food ingredients containing, consisting of or produced from MON-87411-9 maize;
- (b) feed containing, consisting of or produced from MON-87411-9 maize;
- (c) products containing or consisting of MON-87411-9 maize for uses other than those provided for in points (a) and (b) of this Article, with the exception of cultivation.

*Article 3***Labelling**

- 1. For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'maize'.
- 2. The words 'not for cultivation' shall appear on the label of and in the documents accompanying products containing or consisting of MON-87411-9 maize, with the exception of products referred to in point (a) of Article 2.

*Article 4***Method for detection**

The method set out in point (d) of the Annex shall apply for the detection of MON-87411-9 maize.

*Article 5***Monitoring for environmental effects**

- 1. The authorisation holder shall ensure that the monitoring plan for environmental effects, as set out in point (h) of the Annex, is put in place and implemented.
- 2. The authorisation holder shall submit to the Commission annual reports on the implementation and the results of the activities set out in the monitoring plan in accordance with Decision 2009/770/EC.

*Article 6***Community register**

The information set out in the Annex to this Decision shall be entered in the Community register of genetically modified food and feed, as referred to in Article 28(1) of Regulation (EC) No 1829/2003.

*Article 7***Authorisation holder**

The authorisation holder shall be Monsanto Company, United States, represented by Bayer Agriculture BVBA, Belgium.

*Article 8***Validity**

This Decision shall apply for a period of 10 years from the date of its notification.

*Article 9***Addressee**

This Decision is addressed to Bayer Agriculture BVBA, Scheldelaan 460, 2040 Antwerp, Belgium.

Done at Brussels, 26 July 2019.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

ANNEX

(a) Applicant and Authorisation holder:

Name: Monsanto Company

Address: 800 N. Lindbergh Boulevard, St. Louis, Missouri 63167, United States of America

Represented by Bayer Agriculture BVBA, Scheldelaan 460, 2040 Antwerp, Belgium.

(b) Designation and specification of the products:

(1) foods and food ingredients containing, consisting of or produced from MON-87411-9 maize;

(2) feed containing, consisting of or produced from MON-87411-9 maize;

(3) products containing or consisting of MON-87411-9 maize for uses other than those provided in points (1) and (2), with the exception of cultivation.

The genetically modified MON-87411-9 maize expresses the CP4 EPSPS protein, which confers tolerance to glyphosate-containing herbicides, the Cry3Bb1 protein and the DvSnf7 dsRNA, which confer resistance to corn rootworm (*Diabrotica* spp.).

(c) Labelling:

(1) For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003, and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'maize';

(2) The words 'not for cultivation' shall appear on the label of and in documents accompanying the products containing or consisting of MON-87411-9 maize, with the exception of products referred to in point (b)(1) of this Annex.

(d) Method for detection:

(1) Event-specific real-time quantitative PCR based method for detection of the genetically modified maize MON 87411.

(2) Validated by the EU reference laboratory established under Regulation (EC) No 1829/2003, published at <http://gmo-crl.jrc.ec.europa.eu/statusofdossiers.aspx>;

(3) Reference Material: AOCS 0215-B is accessible via the American Oil Chemists' Society (AOCS) at <https://www.aocs.org/crm>

(e) Unique identifier:

MON-87411-9

(f) Information required under Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity:

[Biosafety Clearing-House, Record ID number: *published in the Community register of genetically modified food and feed when notified*].

(g) Conditions or restrictions on the placing on the market, use or handling of the products:

Not required.

(h) Monitoring plan for environmental effects:

Monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.

[Link: *plan published in the Community register of genetically modified food and feed*]

(i) Post market monitoring requirements for the use of the food for human consumption

Not required.

Note: links to relevant documents may need to be modified over the time. Those modifications will be made available to the public via the updating of the Community register of genetically modified food and feed.

COMMISSION IMPLEMENTING DECISION (EU) 2019/1309**of 26 July 2019****authorising the placing on the market of products containing, consisting of or produced from genetically modified soybean MON 87751 (MON-87751-7), pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council***(notified under document C(2019) 5489)***(Only the Dutch and French texts are authentic)****(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 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed ⁽¹⁾, and in particular Articles 7(3) and 19(3) thereof,

Whereas:

- (1) On 26 September 2014, Monsanto Europe S.A./N.V. submitted on behalf of Monsanto company, United States, an application, in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003, for the placing on the market of foods, food ingredients and feed containing, consisting of or produced from genetically modified soybean MON 87751 ('the application') to the national competent authority of the Netherlands. The application also covered the placing on the market of products containing or consisting of genetically modified soybean MON 87751 for uses other than food and feed, with the exception of cultivation.
- (2) In accordance with Articles 5(5) and 17(5) of Regulation (EC) No 1829/2003, the application included information and conclusions about the risk assessment carried out in accordance with the principles set out in Annex II to Directive 2001/18/EC of the European Parliament and of the Council ⁽²⁾ and the information required by Annexes III and IV to that Directive. It also included a monitoring plan for environmental effects in accordance with Annex VII to Directive 2001/18/EC.
- (3) On 2 August 2018, the European Food Safety Authority ('the Authority') issued a favourable opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003 ⁽³⁾. The Authority concluded that genetically modified soybean MON 87751, as described in the application, is as safe as and nutritionally equivalent to its conventional counterpart and the tested non-genetically modified soybean reference varieties, with respect to the potential effects on human and animal health and the environment.
- (4) In its opinion, the Authority considered all the questions and concerns raised by the Member States in the context of the consultation of the national competent authorities as provided for by Articles 6(4) and 18(4) of Regulation (EC) No 1829/2003.
- (5) The Authority also concluded that the monitoring plan for environmental effects consisting of a general surveillance plan, submitted by the applicant, was in line with the intended uses of the products.
- (6) Taking those conclusions into account, the placing on the market of products containing, consisting of or produced from genetically modified soybean MON 87751 should be authorised for the uses listed in the application.
- (7) By letter dated 27 August 2018, Monsanto Europe N.V. informed the Commission that Monsanto Europe N.V. converted its legal form and changed its name to Bayer Agriculture BVBA, Belgium.
- (8) A unique identifier should be assigned to genetically modified soybean MON 87751 in accordance with Commission Regulation (EC) No 65/2004 ⁽⁴⁾.

⁽¹⁾ OJ L 268, 18.10.2003, p. 1.

⁽²⁾ Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).

⁽³⁾ EFSA GMO Panel (EFSA Panel on genetically Modified Organisms), 2018. Scientific opinion on the assessment of genetically modified soybean MON 87751 for food and feed uses under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2014-121). *EFSA Journal* 2018; 16(8):5346, 32 pp. doi: 10.2903/j.efsa.2018.5346

⁽⁴⁾ Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms (OJ L 10, 16.1.2004, p. 5).

- (9) On the basis of the Authority's opinion, no specific labelling requirements, other than those provided for in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003 of the European Parliament and of the Council ⁽⁵⁾, appear to be necessary for the products covered by this Decision. However, in order to ensure that the use of those products remains within the limits of the authorisation granted by this Decision, the labelling of the products containing or consisting of genetically modified soybean MON 87751, with the exception of food products, should contain a clear indication that they are not intended for cultivation.
- (10) In order to account for the implementation and the results of the activities set out in the monitoring plan for environmental effects, the authorisation holder should submit annual reports, presented in accordance with the standard reporting format requirements laid down in Commission Decision 2009/770/EC ⁽⁶⁾.
- (11) The opinion of the Authority does not justify the imposition of specific conditions or restrictions for the placing on the market, for the use and handling, including post-market monitoring requirements regarding the consumption of the food and feed, or for the protection of particular ecosystems/environment or geographical areas, as provided for in Articles 6(5)(e) and 18(5)(e) of Regulation (EC) No 1829/2003.
- (12) All relevant information on the authorisation of the products should be entered in the Community register of genetically modified food and feed referred to in Article 28(1) of Regulation (EC) No 1829/2003.
- (13) This Decision is to be notified through the Biosafety Clearing-House to the Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, pursuant to Articles 9(1) and 15(2)(c) of Regulation (EC) No 1946/2003 of the European Parliament and of the Council ⁽⁷⁾.
- (14) The Standing Committee on Plants, Animals, Food and Feed has not delivered an opinion within the time limit laid down by its Chairman. This implementing act was deemed to be necessary and the chair submitted it to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

HAS ADOPTED THIS DECISION:

Article 1

Genetically modified organism and unique identifier

Genetically modified soybean (*Glycine max* (L.) Merr.) MON 87751, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier MON-87751-7, in accordance with Regulation (EC) No 65/2004.

Article 2

Authorisation

The following products are authorised for the purposes of Articles 4(2) and 16(2) of Regulation (EC) No 1829/2003 in accordance with the conditions set out in this Decision:

- (a) foods and food ingredients containing, consisting of or produced from genetically modified soybean MON-87751-7;
- (b) feed containing, consisting of or produced from genetically modified soybean MON-87751-7;
- (c) products containing or consisting of genetically modified soybean MON-87751-7 for uses other than those provided for in points (a) and (b), with the exception of cultivation.

⁽⁵⁾ Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (OJ L 268, 18.10.2003, p. 24).

⁽⁶⁾ Commission Decision 2009/770/EC of 13 October 2009 establishing standard reporting formats for presenting the monitoring results of the deliberate release into the environment of genetically modified organisms, as or in products, for the purpose of placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council (OJ L 275, 21.10.2009, p. 9).

⁽⁷⁾ Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms (OJ L 287, 5.11.2003, p. 1).

*Article 3***Labelling**

1. For the purposes of the labelling requirements laid down in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'soybean'.
2. The words 'not for cultivation' shall appear on the label of and in the documents accompanying products containing or consisting of genetically modified soybean MON-87751-7, with the exception of products referred to in point (a) of Article 2.

*Article 4***Method for detection**

The method set out in point (d) of the Annex shall apply for the detection of genetically modified soybean MON-87751-7.

*Article 5***Monitoring for environmental effects**

1. The authorisation holder shall ensure that the monitoring plan for environmental effects, as set out in point (h) of the Annex, is put in place and implemented.
2. The authorisation holder shall submit to the Commission annual reports on the implementation and the results of the activities set out in the monitoring plan in accordance with Decision 2009/770/EC.

*Article 6***Community register**

The information set out in the Annex shall be entered in the Community register of genetically modified food and feed, as referred to in Article 28(1) of Regulation (EC) No 1829/2003.

*Article 7***Authorisation holder**

The authorisation holder shall be Monsanto Company, United States, represented by Bayer Agriculture BVBA, Belgium.

*Article 8***Validity**

This Decision shall apply for a period of 10 years from the date of its notification.

*Article 9***Addressee**

This Decision is addressed to Bayer Agriculture BVBA, Scheldelaan 460, 2040 Antwerp, Belgium.

Done at Brussels, 26 July 2019.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

ANNEX

(a) Applicant and authorisation holder:

Name: Monsanto Company

Address: 800 N. Lindbergh Boulevard, St. Louis, Missouri 63167, United States of America

Represented by Bayer Agriculture BVBA, Scheldelaan 460, 2040 Antwerp, Belgium.

(b) Designation and specification of the products:

(1) foods and food ingredients containing, consisting of or produced from genetically modified soybean MON-87751-7;

(2) feed containing, consisting of or produced from genetically modified soybean MON-87751-7;

(3) products containing or consisting of genetically modified soybean MON-87751-7 for uses other than those provided in points (1) and (2), with the exception of cultivation.

The genetically modified soybean MON-87751-7 was developed to confer protection against certain lepidopteran pests through the expression of *cry1A.105* and *cry2Ab2* genes.

(c) Labelling:

(1) For the purposes of the labelling requirements laid down in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003, and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'soybean';

(2) The words 'not for cultivation' shall appear on the label of and in documents accompanying the products containing or consisting of genetically modified soybean MON-87751-7, with the exception of products referred to in point (b)(1) of this Annex.

(d) Method for detection:

(1) Event-specific real time quantitative PCR detection methods for genetically modified soybean MON-87751-7.

(2) Validated by the EU Reference Laboratory established under Regulation (EC) No 1829/2003, published at <http://gmo-crl.jrc.ec.europa.eu/statusofdossiers.aspx>;

(3) Reference Material: AOCS 0215-A is accessible via the American Oil Chemists' Society (AOCS) at <https://www.aocs.org/crm>.

(e) Unique identifier:

MON-87751-7

(f) Information required under Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity:

[Biosafety Clearing-House, Record ID number: *published in the Community register of genetically modified food and feed when notified*].

(g) Conditions or restrictions on the placing on the market, use or handling of the products:

Not required.

(h) Monitoring plan for environmental effects:

Monitoring plan for environmental effects in accordance with Annex VII to Directive 2001/18/EC.

[Link: *plan published in the Community register of genetically modified food and feed*]

(i) Post market monitoring requirements for the use of the food for human consumption

Not required.

Note: links to relevant documents may need to be modified over time. Those modifications will be made available to the public via the updating of the Community register of genetically modified food and feed.

COMMISSION IMPLEMENTING DECISION (EU) 2019/1310**of 31 July 2019****laying down rules on the operation of the European Civil Protection Pool and rescEU***(notified under document C(2019) 5614)***(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Decision No 1313/2013/EU of the European Parliament and of the Council of 17 December 2013 on a Union Civil Protection Mechanism ⁽¹⁾, and in particular Article 32(1)(g) thereof,

Whereas:

- (1) Whilst respecting the primary responsibility of Member States for preventing, preparing for and responding to natural and man-made disasters, the Union Mechanism promotes solidarity and cooperation between Member States in accordance with Article 3(3) of the Treaty on European Union (TEU) and Article 196 of the Treaty on the Functioning of the European Union (TFEU), respectively.
- (2) With the adoption of Decision (EU) 2019/420 of the European Parliament and of the Council ⁽²⁾, the Union Mechanism was reinforced by increasing Union financial support for the European Civil Protection Pool and with the establishment of rescEU.
- (3) In accordance with point (c) of Article 21(2) of Decision No 1313/2013/EU, response capacities benefiting from Union financial support for adaptation costs are to be made available as part of the European Civil Protection Pool for a minimum period linked to the funding received and ranging between 3 and 10 years starting from their effective availability date. The exact periods of commitment should be specified with a view to guaranteeing legal certainty.
- (4) rescEU should provide assistance in overwhelming situations where overall existing capacities at national level and those committed by Member States to the European Civil Protection Pool are not sufficient in order to respond effectively to disasters. Rules for the establishment, management and maintenance of rescEU capacities should be adopted in order to ensure the effective implementation of rescEU.
- (5) rescEU capacities are made available for response operations under the Union Mechanism. Following a request for assistance through the *Emergency Response Coordination Centre* (ERCC), the Commission, in close coordination with the requesting Member State and the Member State owning, renting or leasing the rescEU capacity, is to decide on the deployment of that capacity. Criteria for deployment decisions as well as relevant operating procedures should be laid down in order to ensure an effective and transparent decision-making process. Criteria should also be laid down for decision-making on deployment in the event of conflicting requests for the use of rescEU capacities.
- (6) rescEU capacities can be used for national purposes when not used or needed for response operations under the Union Mechanism. In order to guarantee that rescEU capacities are on stand-by and ready for deployment under the Union Mechanism within the timeframe laid out by the quality requirements for each type of rescEU capacity, appropriate rules for their national use should be established.
- (7) When rescEU capacities are used for national purposes, Member States should notify the Commission. The notification system in case of national use of rescEU capacities should be simple and effective.
- (8) In order to ensure operational efficiency, clear rules should be established for the demobilisation and disengagement of rescEU capacities.

⁽¹⁾ OJ L 347, 20.12.2013, p. 924.

⁽²⁾ Decision (EU) 2019/420 of the European Parliament and of the Council of 13 March 2019 amending Decision No 1313/2013/EU on a Union Civil Protection Mechanism (OJ L 77I, 20.3.2019, p. 1).

- (9) In accordance with Article 12(10) of Decision No 1313/2013/EU, Member States can in specific cases refuse to deploy personnel operating rescEU capacities outside the Union. Rules should be laid down governing those specific cases.
- (10) With the adoption of Commission Implementing Decision (EU) 2019/570 ⁽³⁾, aerial forest firefighting capacities were defined as rescEU capacities. In order to provide Union financial assistance for developing such capacities in accordance with Article 21(3) of Decision No 1313/2013/EU, their total estimated costs should be defined. Total estimated costs should be calculated taking into account the categories of eligible costs laid down in Annex IA of Decision No 1313/2013/EU.
- (11) In order to reduce deployment times and improve legal certainty, the terms and conditions relating to the hosting and operating of rescEU capacities should be clarified. Such conditions should form the basis of operational contracts between the Commission and the Member States.
- (12) In order to ensure prominence to the Union and when rescEU capacities are deployed and to ensure uniform conditions when Article 20a of Decision No 1313/2013/EU is implemented, this Decision should lay down rules on appropriate visibility arrangements.
- (13) rescEU capacities should be registered, certified and adequately maintained by Member States in accordance with existing national and international regulations. The Union Mechanism certification process should also be completed.
- (14) With the entry into force on 21 March 2019 of Decision (EU) 2019/420, the Union can from now on provide financial assistance for operational costs. It is therefore necessary to lay down rules and procedures for the Member States to request such assistance.
- (15) The measures provided for in this Decision are in accordance with the opinion of the committee referred to in Article 33(1) of Decision No 1313/2013/EU,

HAS ADOPTED THIS DECISION:

Article 1

Subject matter

This Decision lays down rules for the implementation of Decision No 1313/2013/EU as regards:

- (a) the commitment to the European Civil Protection Pool of capacities receiving funding for adaptation costs;
- (b) criteria for deployment decisions on rescEU capacities, including in the event of conflicting requests;
- (c) criteria for demobilisation and disengagement decisions;
- (d) national use of rescEU capacities;
- (e) refusal to deploy personnel outside the Union
- (f) the general content of operational contracts;
- (g) visibility requirements for the use of rescEU capacities;
- (h) certification and registration of rescEU capacities;
- (i) total estimated costs of aerial forest firefighting rescEU capacities; and
- (j) arrangements for requesting financial assistance for operational costs.

⁽³⁾ Commission Implementing Decision (EU) 2019/570 of 8 April 2019 laying down rules for the implementation of Decision No 1313/2013/EU of the European Parliament and of the Council as regards rescEU capacities and amending Commission Implementing Decision 2014/762/EU (OJ L 99, 10.4.2019, p. 41).

*Article 2***Commitment to the European Civil Protection Pool of capacities receiving funding for adaptation costs**

1. Member States receiving Union financial support for adaptation costs of capacities in accordance with point (c) of Article 21(2) of Decision No 1313/2013/EU shall commit said capacities to the European Civil Protection Pool for different minimum periods based on the total amount of funding received.

Minimum periods shall be determined as follows:

- (a) a minimum period of 3 years for capacities receiving up to EUR 300 000 of Union financial support;
- (b) a minimum period of 5 years for capacities receiving from EUR 300 001 up to EUR 1 000 000 of Union financial support;
- (c) a minimum period of 7 years for capacities receiving from EUR 1 000 001 up to EUR 2 000 000 of Union financial support;
- (d) a minimum period of 10 years for capacities receiving more than EUR 2 000 000 of Union financial support.

2. Where the economic life span of a capacity is shorter than the minimum period referred to in paragraph 1, the minimum period shall be determined by the length of the economic life span.

3. The Commission through the ERCC may agree to terminate the minimum period referred to in paragraph 1 in relation to a specific capacity where this is duly justified by a Member State.

*Article 3***Criteria for deployment decisions on rescEU capacities**

1. Upon receiving a request for assistance, the ERCC shall assess whether existing capacities offered by Member States through the Union Mechanism and those pre-committed to the European Civil Protection Pool are sufficient to ensure an effective response to that request. Where an effective response cannot be ensured, the Commission through the ERCC shall decide on the deployment of rescEU capacities in accordance with the procedure laid down in Article 12(6) of Decision No 1313/2013/EU.

2. The decision to deploy rescEU capacities shall take the following specific criteria into account:

- (a) the operational situation across Member States as well as potential disaster risks;
- (b) appropriateness and adequateness of the rescEU capacities to respond to the disaster;
- (c) geographic location of the rescEU capacities, including estimated transport times to the affected area;
- (d) other relevant criteria, including the terms and conditions of rescEU capacities as stipulated in operational contracts.

3. In the event of conflicting requests for assistance, the following additional criteria shall be taken into account when deciding where to deploy rescEU capacities:

- (a) the projected risks to human lives;
- (b) the projected risks to critical infrastructure as referred to in Article 2(a) of Council Directive 2008/114/EC ⁽⁴⁾, irrespective of whether it is located inside or outside the Union;
- (c) the projected impact of the disasters, including environmental impact;
- (d) needs identified by the ERCC as well as any existing deployment plans;
- (e) the potential risk of the disasters spreading;
- (f) socioeconomic effects;
- (g) the triggering of the solidarity clause pursuant to Article 222 of the Treaty on the Functioning of the European Union;
- (h) other relevant operational factors.

⁽⁴⁾ Council Directive 2008/114/EC of 8 December 2008 on the identification and designation of European critical infrastructures and the assessment of the need to improve their protection (OJ L 345, 23.12.2008, p. 75).

*Article 4***Criteria for demobilisation and disengagement decisions**

1. rescEU capacities shall be demobilised in the following cases:
 - (a) upon receipt of a pre-closure notification in CECIS; or
 - (b) when a decision to disengage is taken in accordance with paragraph 2.
2. A decision to disengage a rescEU capacity shall be taken by the Commission through the ERCC when there is a greater operational need for the capacity elsewhere or the needs on the ground no longer justify its use. The decision shall be taken in close coordination with the Member State hosting the rescEU capacity and the Member State(s) requesting assistance as well as, where appropriate, with third countries or international organisations.
3. For the purposes of taking the decision referred to in paragraph 2, the Commission shall, inter alia, consider the criteria listed in paragraphs 2 and 3 of Article 3.

*Article 5***National use of rescEU capacities**

1. Member States using rescEU capacities for national purposes shall ensure:
 - (a) availability and readiness for operations under the Union Mechanism within the timeframe provided for in the relevant quality requirements, unless otherwise agreed with the Commission;
 - (b) equal treatment of rescEU capacities and other national capacities with regard to adequate maintenance, storage, insurance, staffing, and other relevant management and maintenance activities;
 - (c) rapid repair in case of damage.
2. Member States shall, through the ERCC, notify the Commission of the national use of rescEU capacities and submit a report following their use.
3. Where national use of rescEU capacities impacts availability as provided in subparagraph 1(a) of this Article, Member States shall obtain the consent of the Commission, through the ERCC, prior to deployment.

Member States shall ensure availability in the shortest time possible, where the rescEU capacities in question are needed for response operations under the Union Mechanism.

*Article 6***Refusal to deploy personnel outside the Union**

1. Where a decision to deploy rescEU capacities outside the Union has been taken in accordance with Article 12(10) of Decision No 1313/2013/EU, Member States may refuse to deploy their personnel in the following cases:
 - (a) where diplomatic relations between the Member State and the requesting third country have been severed;
 - (b) where armed conflict, the threat thereof, or other equally serious grounds would result in the safety and security of the personnel being put at risk and prevent the relevant Member State from fulfilling its duty of care.
2. The Member State refusing deployment of its personnel shall immediately inform the Commission and provide it with a reasoned justification.

*Article 7***General content of operational contracts**

The operational contracts referred to in Article 12(5) of Decision No 1313/2013/EU shall, inter alia:

- (a) specify the nature of the entity hosting the rescEU capacity;
- (b) specify the locations of hosted rescEU capacities;

- (c) provide information on relevant logistics and insurance;
- (d) outline the national decision-making process for ensuring availability and readiness of rescEU capacities for operations under the Union Mechanism within the timeframe provided for in the relevant quality requirements;
- (e) contain up-to-date information on personnel, including the terms and conditions of their employment, insurance contracts, training as well as a description of the measures that have been taken to guarantee their international deployment;
- (f) include a maintenance work plan;
- (g) lay down specific reporting requirements;
- (h) stipulate visibility requirements for the Union as referred to in Article 20a of Decision No 1313/2013/EU.

Article 8

Visibility arrangements for the use of rescEU capacities

Where rescEU capacities are used for response operations under the Union Mechanism, appropriate visibility to the Union shall be provided in accordance with Article 20a of Decision No 1313/2013/EU by the Member State hosting the rescEU capacity and the Member State requesting assistance.

Article 9

Liability and compensation for damage

Member States shall refrain from bringing any claim against the Commission for damages resulting from assistance interventions provided under the Union Mechanism or for consequences resulting from non-deployment, demobilisation or disengagement of rescEU capacities provided under the Union Mechanism, and this Decision, unless they are proven to be the result of fraud or serious misconduct.

Article 10

Certification and registration rules

1. Member States shall ensure certification and registration of rescEU capacities in accordance with applicable national and international rules and regulations.
2. Where rescEU capacities are multi-purpose, certification and registration shall be completed accordingly.
3. Member States shall certify rescEU capacities under the Union Mechanism certification process as soon as possible and in accordance with Article 11(4) of Decision No 1313/2013/EU and Chapter 5 of Commission Implementing Decision 2014/762/EU ⁽⁵⁾. rescEU capacities that are in the process of completing the Union certification process may be deployed in accordance with Article 3.

Article 11

Total estimated costs of rescEU aerial forest firefighting capacities

1. The cost categories referred to in points 1 to 6 and point 8 of Annex IA of Decision No 1313/2013/EU shall be taken into account when calculating the total estimated cost of rescEU aerial forest firefighting capacities.
2. The costs of the equipment cost category referred to in point 1 of Annex IA of Decision No 1313/2013/EU for aerial forest firefighting capacities using airplanes shall be calculated based on market prices applicable when the capacities are acquired, rented or leased in accordance with Article 12(3) of Decision No 1313/2013/EU. Where Member States acquire, rent or lease rescEU capacities, they shall provide the Commission with documented evidence of the actual applicable market prices.

⁽⁵⁾ Commission Implementing Decision 2014/762/EU of 16 October 2014 laying down rules for the implementation of Decision No 1313/2013/EU of the European Parliament and of the Council on a Union Civil Protection Mechanism and repealing Commission Decisions 2004/277/EC, Euratom and 2007/606/EC, Euratom (OJ L 320, 6.11.2014, p. 1).

The costs of the equipment cost category referred to in point 1 of Annex IA of Decision No 1313/2013/EU for aerial forest firefighting capacities using helicopters shall be calculated based on the market prices applicable when the capacities are acquired, rented or leased in accordance with Article 12(3) of Decision No 1313/2013/EU. Where Member States acquire, rent or lease rescEU capacities, they shall provide the Commission with documented evidence of the actual applicable market prices.

3. The cost of the cost categories referred to in points 2 to 6 and point 8 of Annex IA of Decision No 1313/2013/EU for aerial forest firefighting capacities using airplanes shall be calculated at least once during the period of each *multiannual financial framework starting from the period 2014-2020*, taking into account information available to the Commission, including inflation and the cost calculations undertaken for the purposes of financing national capacities in accordance with Article 35 of Decision No 1313/2013/EU. This cost shall be used by the Commission for the purpose of providing annual financial assistance.

The cost of the cost categories referred to in points 2 to 6 and point 8 of Annex IA of Decision No 1313/2013/EU for aerial forest firefighting capacities using helicopters shall be calculated at least once during the period of each *multiannual financial framework starting from the period 2014-2020*, taking into account information available to the Commission, including inflation and the cost calculations undertaken for the purposes of financing national capacities in accordance with Article 35 of Decision No 1313/2013/EU. This cost shall be used by the Commission for the purpose of providing annual financial assistance.

Article 12

Eligible operational costs

1. The operational costs referred to in Article 23(2), 23(4b) and 23(4c) of Decision No 1313/2013/EU shall include all the costs of running a capacity during an operation that are necessary to make it operationally effective. Such costs may encompass, as appropriate, costs related to personnel, international and local transport, logistics, consumables and supplies, maintenance, as well as other costs necessary to ensure the effective use of such capacities.
2. The costs referred to in paragraph 1 shall not be eligible for financing where covered by means of Host Nation Support, by virtue of Article 39 of Implementing Decision 2014/762/EU or in accordance with Article 3(2) of Implementing Decision (EU) 2019/570, or where they are financed via other Union financial instruments.
3. The procedures for requesting transport support provided for in Article 48, paragraphs 1 and 3 of Article 49, Article 51, Article 53 and Annex VIII of Implementing Decision 2014/762/EU shall apply *mutatis mutandis* to requests for financial assistance for operational costs until they are replaced as appropriate.

Article 13

Addresses

This Decision is addressed to the Member States.

Done at Brussels, 31 July 2019.

For the Commission
Christos STYLIANIDES
Member of the Commission

DECISION (EU) 2019/1311 OF THE EUROPEAN CENTRAL BANK
of 22 July 2019
on a third series of targeted longer-term refinancing operations (ECB/2019/21)

THE GOVERNING COUNCIL OF THE EUROPEAN CENTRAL BANK,

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

Having regard to the Statute of the European System of Central Banks and of the European Central Bank, and in particular the first indent of Article 3.1, Article 12.1, the second indent of Article 18.1 and the second indent of Article 34.1 thereof,

Whereas:

- (1) Decision ECB/2014/34 ⁽¹⁾ provides for a series of targeted longer-term refinancing operations (TLTROs) to be conducted over a period of two years from 2014 to 2016 (TLTROs-I) and Decision (EU) 2016/810 of the European Central Bank (ECB/2016/10) ⁽²⁾ provides for a second series of TLTROs to be conducted from June 2016 to March 2017 (TLTROs-II).
- (2) On 7 March 2019, in pursuing its price stability mandate, the Governing Council decided to launch a new series of seven targeted longer-term refinancing operations (TLTROs-III), to be conducted from September 2019 to March 2021, each with a maturity of two years. The TLTROs-III are intended to assist in preserving favourable bank lending conditions and support the accommodative stance of monetary policy in Member States whose currency is the euro. Eligible lending in the context of this measure includes loans to the non-financial private sector with the exception of loans to households for the purposes of house purchases. In conjunction with other non-standard measures in place, TLTROs-III aim to contribute to a return of inflation rates to levels below, but close to, 2 % over the medium term.
- (3) As with the first and second series of TLTROs, in order to facilitate the participation of institutions that, for organisational reasons, borrow from the Eurosystem by means of a group structure, participation in TLTROs-III should be possible on a group basis subject to certain conditions. Group participation should be conducted through one specific group member and where prescribed conditions have been fulfilled. Moreover, in order to address the issues related to intra-group liquidity distribution, in the case of groups that are established on the basis of close links between members, all group members should formally confirm in writing their participation in the group. A TLTRO group that was recognised for the purposes of TLTROs-II pursuant to Decision (EU) 2016/810 (ECB/2016/10) should be able to participate in TLTROs-III as a TLTRO-III group subject to certain procedures concerning notification and recognition.
- (4) The overall amount that may be borrowed under all TLTROs-III should be determined on the basis of a participant's outstanding amount of eligible loans to the non-financial private sector as at 28 February 2019, and taking into account any amounts previously borrowed by the TLTRO-III participant under TLTROs-II pursuant to Decision (EU) 2016/810 (ECB/2016/10) and still outstanding. In addition, eligible loans to the non-financial private sector that have been self-securitised (i.e. where the asset-backed securities resulting from the securitisation are fully retained) may, subject to certain conditions, also be taken into account for the purpose of calculating the participant's borrowing allowance. This will improve the relationship between the borrowing allowance and the loan provision to the economy.
- (5) A maximum bid limit should apply to each TLTRO-III. Limiting the size of the bids aims to avoid an excessive concentration of bids in a few operations.
- (6) The interest rate applicable to each TLTRO-III should be determined based on the lending history of the participant in the period 1 April 2019 to 31 March 2021 in accordance with the principles set out in this Decision.

⁽¹⁾ Decision ECB/2014/34 of 29 July 2014 on measures relating to targeted longer-term refinancing operations (OJ L 258, 29.8.2014, p. 11).

⁽²⁾ Decision (EU) 2016/810 of the European Central Bank of 28 April 2016 on a second series of targeted longer-term refinancing operations (ECB/2016/10) (OJ L 132, 21.5.2016, p. 107).

- (7) Each TLTRO-III will have a maturity of two years. In the light of the shorter maturity term, compared with the first TLTROs and TLTROs-II, participants should not have the option of voluntarily repaying any amounts that have been allotted under TLTROs-III before their maturity.
- (8) Institutions that wish to participate in TLTROs-III should be subject to certain reporting requirements. The reported data will be used: (a) in determining the borrowing allowance; (b) in calculating the applicable benchmark; (c) to assess participants' performance against their benchmarks; and (d) for other analytical purposes as required for performing Eurosystem tasks. It is further envisaged that the national central banks of Member States whose currency is the euro (hereinafter the 'NCBs') in receipt of reported data may exchange such data within the Eurosystem to the extent and to the level necessary for the proper implementation of the TLTRO-III framework, as well as an analysis of its effectiveness and for other Eurosystem analytical purposes. Reported data may be shared within the Eurosystem for the purpose of validating the data provided.
- (9) In order to allow credit institutions sufficient time to make operational preparations for the first TLTRO-III, this Decision should enter into force without undue delay,

HAS ADOPTED THIS DECISION:

Article 1

Definitions

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

- (1) 'benchmark net lending' means the amount of eligible net lending that a participant needs to exceed in the period 1 April 2019 to 31 March 2021 in order to qualify for an interest rate on the participant's TLTRO-III borrowing that is lower than the initial rate applied and which is calculated in accordance with the principles and the detailed provisions set out in Article 4 and Annex I, respectively;
- (2) 'benchmark outstanding amount' means the sum of a participant's outstanding amounts of eligible loans as at 31 March 2019 and the participant's benchmark net lending which is calculated in accordance with the principles and the detailed provisions set out in Article 4 and Annex I, respectively;
- (3) 'bid limit' means the maximum amount that may be borrowed by a participant in any TLTRO-III calculated in accordance with the principles and the detailed provisions set out in Article 4 and Annex I, respectively;
- (4) 'borrowing allowance' means the overall amount that may be borrowed by a participant in all TLTROs-III and calculated in accordance with the principles and the detailed provisions set out in Article 4 and Annex I, respectively;
- (5) 'credit institution' means a credit institution as defined in point (14) of Article 2 of Guideline (EU) 2015/510 of the European Central Bank (ECB/2014/60) ⁽³⁾;
- (6) 'deviation from the benchmark outstanding amount' means the percentage points by which a participant's eligible loans granted in the period 1 April 2019 to 31 March 2021 have increased or decreased with respect to its benchmark outstanding amount, as calculated in accordance with the detailed provisions set out in Article 4 and Annex I;
- (7) 'eligible loans' means loans to non-financial corporations and households (including non-profit institutions serving households) resident, as defined in point (4) of Article 1 of Council Regulation (EC) No 2533/98 ⁽⁴⁾, in Member States whose currency is the euro, except loans to households for house purchases, as further detailed in Annex II;
- (8) 'eligible net lending' means gross lending in the form of eligible loans net of repayments of outstanding amounts of eligible loans during a specific period, as further detailed in Annex II;

⁽³⁾ Guideline (EU) 2015/510 of the European Central Bank of 19 December 2014 on the implementation of the Eurosystem monetary policy framework (ECB/2014/60) (OJ L 91, 2.4.2015, p. 3).

⁽⁴⁾ 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).

- (9) 'financial vehicle corporation' (FVC) means a financial vehicle corporation as defined in Article 1(1) of Regulation (EU) No 1075/2013 of the European Central Bank (ECB/2013/40) ⁽⁵⁾;
- (10) 'first reference period' means the period 1 April 2018 to 31 March 2019;
- (11) 'FVC code' means a unique identification code for an FVC on the list of FVCs maintained and published by the European Central Bank (ECB) for statistical purposes in accordance with Article 3 of Regulation (EU) No 1075/2013 (ECB/2013/40);
- (12) 'interest rate incentive adjustment' means the reduction, if any, in the interest rate to be applied to amounts borrowed under TLTROs-III, expressed as a fraction of the average difference between the maximum possible interest rate and the minimum possible interest rate, as calculated in accordance with the detailed provisions set out in Annex I;
- (13) 'Legal Entity Identifier' (LEI) means an alphanumeric reference code in line with ISO 17442 that is assigned to a legal entity;
- (14) 'monetary financial institution' (MFI) means a monetary financial institution as defined in point (a) of Article 1 of Regulation (EU) No 1071/2013 of the European Central Bank (ECB/2013/33) ⁽⁶⁾;
- (15) 'MFI code' means a unique identification code for an MFI in the list of MFIs maintained and published by the European Central Bank (ECB) for statistical purposes in accordance with Article 4 of Regulation (EU) No 1071/2013 (ECB/2013/33);
- (16) 'outstanding amounts of eligible loans' means outstanding eligible loans on the balance sheet, excluding eligible loans securitised or otherwise transferred without derecognition from the balance sheet as further detailed in Annex II;
- (17) 'participant' means a counterparty eligible for Eurosystem monetary policy open market operations in accordance with Guideline (EU) 2015/510 (ECB/2014/60), which submits bids in TLTRO-III tender procedures either on an individual basis or on a group basis as lead institution, and which is subject to all rights and obligations associated with its participation in the TLTRO-III tender procedures;
- (18) 'reference outstanding amount' means the sum of outstanding amounts of eligible loans and, upon exercise of the option in Article 6(3), outstanding amounts of self-securitised eligible loans as at 28 February 2019;
- (19) 'relevant NCB' means, with reference to a particular participant, the NCB of the Member State in which the participant is established;
- (20) 'second reference period' means the period 1 April 2019 to 31 March 2021;
- (21) 'securitisation' means a transaction that is either: (a) a traditional securitisation as defined in Article 2(9) of Regulation (EU) No 2017/2402 of the European Parliament and of the Council ⁽⁷⁾; and/or (b) a securitisation as defined in Article 1(2) of Regulation (EU) No 1075/2013 (ECB/2013/40) and which involves the transfer of the loans being securitised to an FVC;
- (22) 'self-securitised eligible loans' means eligible loans originated and securitised by a participant or a TLTRO-III group member whereby the asset-backed securities resulting from the securitisation are 100 % retained by that participant or TLTRO-III group member.

Article 2

The third series of targeted longer-term refinancing operations

1. The Eurosystem shall conduct seven TLTROs-III in accordance with the indicative calendar for TLTROs-III published on the ECB's website.

⁽⁵⁾ Regulation (EU) No 1075/2013 of the European Central Bank of 18 October 2013 concerning statistics on the assets and liabilities of financial vehicle corporations engaged in securitisation transactions (ECB/2013/40) (OJ L 297, 7.11.2013, p. 107).

⁽⁶⁾ 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).

⁽⁷⁾ Regulation (EU) 2017/2402 of the European Parliament and of the Council of 12 December 2017 laying down a general framework for securitisation and creating a specific framework for simple, transparent and standardised securitisation, and amending Directives 2009/65/EC, 2009/138/EC and 2011/61/EU and Regulations (EC) No 1060/2009 and (EU) No 648/2012 (OJ L 347, 28.12.2017, p. 35).

2. Each TLTRO-III shall mature, without there being an option for voluntary early repayment, two years after the respective settlement date, on a day that coincides with the settlement date of a Eurosystem main refinancing operation, in accordance with the indicative calendar for TLTROs-III published on the ECB's website.

3. TLTROs-III shall be:

- (a) liquidity-providing reverse transactions;
- (b) executed in a decentralised manner by the NCBs;
- (c) executed through standard tenders; and
- (d) executed in the form of fixed-rate tender procedures.

4. The standard conditions under which the NCBs are prepared to conduct credit operations shall apply in respect of TLTROs-III, unless otherwise specified in this Decision. These conditions shall include the procedures for conducting open market operations, the criteria for determining the eligibility of counterparties and collateral for the purposes of Eurosystem credit operations and the sanctions applicable in the event of non-compliance with counterparty obligations. Each of these conditions is laid down in the general and temporary legal frameworks applicable to refinancing operations and as implemented in NCBs' contractual and/or regulatory national frameworks.

5. In the event of a conflict between this Decision and Guideline (EU) 2015/510 (ECB/2014/60) or any other ECB legal act laying down the legal framework applicable to longer-term refinancing operations and/or any national measures implementing it at national level, this Decision shall prevail.

Article 3

Participation

1. Institutions may participate in TLTROs-III on an individual basis if they are eligible counterparties for Eurosystem monetary policy open market operations.

2. Institutions may participate in TLTROs-III on a group basis by forming a TLTRO-III group. Participation on a group basis is relevant for the purposes of calculating the applicable borrowing allowance and the benchmarks as laid down in Article 4 and the associated reporting obligations as laid down in Article 6. Participation on a group basis shall be subject to the following restrictions:

- (a) an institution shall not be a member of more than one TLTRO-III group;
- (b) an institution participating in TLTROs-III on a group basis may not participate on an individual basis;
- (c) the institution appointed as lead institution shall be the only member of the TLTRO-III group that may participate in TLTRO-III tender procedures; and
- (d) the composition and the lead institution of a TLTRO-III group shall remain unchanged for all TLTROs-III, subject to paragraphs 5 and 6 of this Article.

3. In order to participate in TLTROs-III through a TLTRO-III group, the following conditions shall be fulfilled.

- (a) With effect from the last day of the month preceding the application referred to in point (d) of this paragraph, each member of a given group shall:
 - (i) have a close link to another member of the group within the meaning of 'close link' as defined in Article 138 of Guideline (EU) 2015/510 (ECB/2014/60) and references therein to 'counterparty', 'guarantor', 'issuer' or 'debtor' shall be understood as referring to a group member; or
 - (ii) hold required reserves with the Eurosystem in accordance with Regulation (EC) No 1745/2003 of the European Central Bank (ECB/2003/9) (*) indirectly through another member of the group or be used by another member of the group in order to indirectly hold required reserves with the Eurosystem.

(*) Regulation (EC) No 1745/2003 of the European Central Bank of 12 September 2003 on the application of minimum reserves (ECB/2003/9) (OJ L 250, 2.10.2003, p. 10).

- (b) The group shall appoint one member as the lead institution for the group. The lead institution shall be an eligible counterparty for Eurosystem monetary policy open market operations.
- (c) Each member of the TLTRO-III group shall be a credit institution established in a Member State whose currency is the euro, and shall fulfil the criteria laid down in points (a), (b) and (c) of Article 55 of Guideline (EU) 2015/510 (ECB/2014/60).
- (d) Subject to point (e), the lead institution shall apply for group participation to its NCB in accordance with the indicative calendar for TLTROs-III published on the ECB's website. The application shall include:
 - (i) the name of the lead institution;
 - (ii) a list of the MFI codes and names of all the institutions to be included in the TLTRO-III group;
 - (iii) an explanation of the basis for a group application, including a list of the close links and/or indirect reserve holding relationships between the members of the group, identifying each member by its MFI code;
 - (iv) in the case of group members which meet the conditions stipulated in point (ii) of point (a): written confirmation from the lead institution certifying that each member of its TLTRO-III group has formally decided to be a member of the TLTRO-III group in question and agrees not to participate in TLTROs-III as an individual counterparty or as a member of any other TLTRO-III group, together with appropriate evidence that the written confirmation from the lead institution was executed by duly authorised signatories. A lead institution may make the necessary confirmation in respect of its TLTRO-III group members where there are agreements in place, such as those for the indirect holding of minimum reserves pursuant to Article 10(2) of Regulation (EC) No 1745/2003 (ECB/2003/9), which expressly state that the relevant group members participate in Eurosystem open market operations exclusively through the lead institution. The relevant NCB, in cooperation with the NCBs of the relevant group members, may check the validity of the written confirmation concerned; and
 - (v) in the case of a group member to which point (i) of point (a) applies: (1) written confirmation from the relevant group member of its formal decision to be a member of the TLTRO-III group in question and not to participate in TLTROs-III as an individual counterparty or as a member of any other TLTRO-III group; and (2) appropriate evidence, confirmed by the NCB of the relevant group member, that this formal decision was taken at the highest decision-making level of the member's corporate structure, such as the Board of Directors or equivalent in accordance with any applicable law.
- (e) A TLTRO-II group recognised for the purposes of TLTROs-II pursuant to Decision (EU) 2016/810 (ECB/2016/10) may participate in TLTROs-III as a TLTRO-III group provided that its lead institution submits a written notification to that effect to the relevant NCB in accordance with the indicative calendar for TLTROs-III published on the ECB's website. The notification shall include:
 - (i) a list of members of the TLTRO-II group who have formally decided to be members of the TLTRO-III group in question and not to participate in TLTRO-III as individual counterparties or as members of any other TLTRO-III group. In the case of group members which meet the conditions stipulated in point (ii) of point (a), the lead institution may provide the necessary notification where there are agreements in place, as referred to in point (iv) of point (d), which expressly state that the relevant group members participate in Eurosystem open market operations exclusively through the lead institution. The relevant NCB, in cooperation with the NCBs of the relevant group members, may check the validity of that list; and
 - (ii) appropriate evidence, as may be requested by the lead institution's NCB, that it was executed by duly authorised signatories.
- (f) The lead institution shall obtain confirmation from its NCB that the TLTRO-III group has been recognised. Prior to issuing its confirmation, the relevant NCB may request any additional information relevant for its assessment of the potential TLTRO-III group from the lead institution. In its assessment of a group application, the relevant NCB shall also take into account any assessments by the NCBs of group members that may be necessary, such as the verification of documentation provided in accordance with points (d) or (e) as applicable.

For the purposes of this Decision, credit institutions subject to consolidated supervision, including branches of the same credit institution, shall also be regarded as suitable applicants for TLTRO-III group recognition, and shall be required to meet the conditions laid down in this Article *mutatis mutandis*. This facilitates the formation of TLTRO-III groups among such institutions, where they are part of the same legal entity. For the purpose of confirming the formation, or a change in the composition, of a TLTRO-III group of this nature, paragraph 3(d)(v) and paragraph 6(b)(ii)(5) shall apply respectively.

4. If one or more of the institutions included in the application for TLTRO-III group recognition do not fulfil the conditions of paragraph 3, the relevant NCB may partially reject the application of the proposed group. In such a case, the institutions submitting the application may decide to act as a TLTRO-III group with the composition limited to those group members that fulfil the necessary conditions or to withdraw the application for TLTRO-III group recognition.

5. In exceptional cases, where there are objective reasons, the Governing Council may decide to deviate from the conditions set out in paragraphs 2 and 3.

6. Without prejudice to paragraph 5, the composition of a group recognised in accordance with paragraph 3 may change in the following circumstances:

- (a) A member shall be excluded from the TLTRO-III group if it no longer meets the requirements of point (a) or (c) of paragraph 3. The relevant group member's NCB shall inform the lead institution of the group member's failure to meet those requirements.

In such cases, the lead institution concerned shall notify the relevant NCB of the change in status of its group member.

- (b) If, in relation to the TLTRO-III group, additional close links or indirect holdings of required reserves with the Eurosystem are established after the last day of the month preceding the application referred to in point (d) of paragraph 3, the TLTRO-III group composition may change to reflect the addition of a new member provided that:

- (i) the lead institution applies to its NCB for recognition of the change in the TLTRO-III group's composition in accordance with the indicative calendar for TLTROs-III published on the ECB's website;

- (ii) the application referred to in point (i) includes:

- (1) the name of the lead institution;

- (2) the list of MFI codes and names of all the institutions that are intended to be included in the new composition of the TLTRO-III group;

- (3) an explanation of the basis for the application, including details of the changes to the close links and/or indirect reserve holding relationships between the members of the group, identifying each member by its MFI code;

- (4) in the case of group members to which point (ii) of paragraph 3(a) applies: written confirmation from the lead institution certifying that each member of its TLTRO-III group has formally decided to be a member of the TLTRO-III group in question and not to participate in TLTROs-III as an individual counterparty or as a member of any other TLTRO-III group. A lead institution may make the necessary certification in respect of its TLTRO-III group members where there are agreements in place, such as those for the indirect holding of minimum reserves pursuant to Article 10(2) of Regulation (EC) No 1745/2003 (ECB/2003/9), which expressly state that the relevant group members participate in Eurosystem open market operations exclusively through the lead institution. The relevant NCB, in cooperation with the NCBs of the relevant group members, may check the validity of that written confirmation; and

- (5) in the case of group members to which point (i) of paragraph 3(a) applies, written confirmation from each additional member of its formal decision to be a member of the TLTRO-III group in question and not to participate in TLTROs-III as an individual counterparty or as a member of any other TLTRO-III group, and written confirmation from each member of the TLTRO-III group, included in both the old and the new composition, of its formal decision to agree to the new composition of the TLTRO-III group, together with appropriate evidence, confirmed by the NCB of the relevant group member, as detailed in point (v) of paragraph 3(d); and

- (iii) the lead institution has obtained confirmation from its NCB that the changed TLTRO-III group has been recognised. Prior to issuing its confirmation, the relevant NCB may request any additional information relevant for its assessment of the new TLTRO-III group composition from the lead institution. In its assessment of a group application, the relevant NCB must also take into account any necessary assessment of the NCBs of group members, such as the verification of documentation provided in accordance with point (ii).

- (c) If, in relation to the TLTRO-III group, a merger, acquisition or division involving the TLTRO-III group members takes place after the last day of the month preceding the application referred to in point (d) of paragraph 3 and that operation does not result in any change in the set of eligible loans, the TLTRO-III group composition may change to reflect the merger, acquisition or division, as applicable, provided that the conditions listed in point (b) are met.

7. Where changes in the composition of a TLTRO-III group have been accepted by the Governing Council in accordance with paragraph 5, or changes in the composition of TLTRO-III groups have taken place in accordance with paragraph 6, unless otherwise decided by the Governing Council, the following shall apply:

- (a) in respect of the changes to which paragraph 5, paragraph 6(b) or paragraph 6(c) applies, the lead institution may participate in a TLTRO-III on the basis of the new composition of its TLTRO-III group only after it has obtained confirmation from its NCB that the new composition of the TLTRO-III group has been recognised; and
- (b) an institution that is no longer a member of a TLTRO-III group shall not participate in any further TLTRO-III either individually or as member of another TLTRO-III group, unless it submits a new application to participate in accordance with paragraphs 1, 3 or 6.

8. If a lead institution loses its eligibility as a counterparty for Eurosystem monetary policy open market operations, its TLTRO-III group shall no longer be recognised and such lead institution shall be obliged to repay all amounts borrowed under TLTROs-III.

Article 4

Borrowing allowance, bid limit and benchmarks

1. The borrowing allowance applicable to an individual participant shall be calculated on the basis of the loan data in respect of the reference outstanding amount of the individual participant. The borrowing allowance applicable to a participant which is the lead institution of a TLTRO-III group shall be calculated on the basis of the aggregated loan data in respect of the reference outstanding amount for all members of the TLTRO-III group.

2. Each participant's borrowing allowance shall equal 30 % of its total reference outstanding amount, less any amount previously borrowed by that TLTRO-III participant under TLTROs-II pursuant to Decision (EU) 2016/810 (ECB/2016/10) and still outstanding on the settlement date of a TLTRO-III having regard to any legally binding notification for early repayment submitted by the participant in accordance with Article 6 of Decision (EU) 2016/810 (ECB/2016/10). The relevant technical calculations are outlined in Annex I.

3. If a member of a TLTRO group recognised for the purposes of TLTROs-II pursuant to Decision (EU) 2016/810 (ECB/2016/10) is not willing to be a member of the respective TLTRO-III group, for the purposes of calculating the TLTRO-III borrowing allowance for that credit institution as an individual participant, that institution shall be deemed to have borrowed under TLTROs-II an amount equal to the amount borrowed by the lead institution of the TLTRO-II group under TLTROs-II and still outstanding on the settlement date of a TLTRO-III multiplied by the share of eligible loans of the member to those of the TLTRO-II group as at 31 January 2016. This latter amount will be subtracted from the amount that the respective TLTRO-III group is deemed to have borrowed under TLTROs-II for the purpose of calculating the TLTRO-III borrowing allowance of the lead institution.

4. Each participant's bid limit for each TLTRO-III shall be equal to either: (i) its borrowing allowance reduced by the amounts borrowed under previous TLTROs-III; or (ii) one tenth of the total reference outstanding amount, whichever is lower. This amount shall be considered to represent a maximum bid limit for each participant and the rules applicable to bids exceeding the maximum bid limit, as laid down in Article 36 of Guideline (EU) 2015/510 (ECB/2014/60), shall apply. The relevant technical calculations are outlined in Annex I.

5. A participant's benchmark net lending shall be determined on the basis of eligible net lending in the first reference period, as follows:

- (a) for participants who report positive or zero eligible net lending in the first reference period, the benchmark net lending shall be zero;
- (b) for participants who report negative eligible net lending in the first reference period, the benchmark net lending shall be equal to the eligible net lending for the first reference period.

The relevant technical calculations are outlined in Annex I. The benchmark net lending for participants that have been granted banking licences after 28 February 2019 shall be zero unless the Governing Council, in circumstances where it is objectively justified, decides otherwise.

6. A participant's benchmark outstanding amount shall be determined as the sum of the outstanding amounts of eligible loans as at 31 March 2019 and the benchmark net lending. The relevant technical calculations are outlined in Annex I.

*Article 5***Interest**

1. Subject to paragraph 2, the interest rate applicable to the amount borrowed under each TLTRO-III shall be set at 10 basis points above the average rate on the main refinancing operation over the life of the respective TLTRO-III.
2. The interest rate applicable to the amounts borrowed by participants whose eligible net lending in the second reference period exceeds their benchmark net lending shall be lower than the rate specified in paragraph 1 and may be as low as 10 basis points above the average rate on the deposit facility over the life of the respective TLTRO-III, depending on the deviation from the benchmark outstanding amount. The detailed provisions and calculations are outlined in Annex I.
3. The deviation from the benchmark outstanding amount, the resulting interest rate incentive adjustment, if any, and the final interest rates shall be communicated to participants in accordance with the indicative calendar for TLTROs-III published on the ECB's website.
4. Interest shall be settled in arrears on the maturity of each TLTRO-III.
5. If, due to the exercise of remedies available to an NCB in accordance with its contractual or regulatory arrangements, a participant is required to repay the TLTRO-III outstanding amounts before the deviation from the benchmark outstanding amount and the resulting interest rate incentive adjustment, if any, are communicated to that participant, the interest rate applicable to the amounts borrowed by that participant under each TLTRO-III shall be set at 10 basis points above the average rate on the main refinancing operation over the life of the relevant TLTRO-III up to the date on which the repayment was required to be made by the NCB. If such repayment is required after the deviation from the benchmark outstanding amount and the resulting interest rate incentive adjustment, if any, have been communicated to the participant, the interest rate applicable to the amounts borrowed by that participant under each TLTRO-III shall be set taking into account the deviation from the benchmark outstanding amount.

*Article 6***Reporting requirements**

1. Each participant in TLTROs-III shall submit to the relevant NCB the data identified in the reporting templates set out in Annex II as follows:
 - (a) the reference outstanding amount for the purposes of establishing the participant's borrowing allowance and bid limits, and data relating to the first reference period for the purposes of establishing the participant's benchmarks (hereinafter referred to as the 'first report'); and
 - (b) data relating to the second reference period for the purposes of determining the applicable interest rates (hereinafter referred to as the 'second report').
2. The data shall be provided in accordance with:
 - (a) the indicative calendar for TLTROs-III published on the ECB's website;
 - (b) the guidelines set out in Annex II; and
 - (c) the minimum standards for accuracy and compliance with concepts specified in Annex IV to Regulation (EU) No 1071/2013 (ECB/2013/33).
3. Participants intending to include self-securitised eligible loans for the purposes of calculating their borrowing allowance shall exercise this option by providing the supplementary items relating to all self-securitised eligible loans, as detailed in Annex II, together with the auditor's evaluation of these supplementary items, in accordance with the following rules:
 - (a) Participants who participate in the first or second TLTRO-III operation may participate on the basis of a first report which omits the supplementary items. However, in order for self-securitised loans to be included in the calculations of their borrowing allowance and bid limits as of the second or third operation, the supplementary items and the respective auditor's evaluation of the supplementary items shall be made available to the relevant NCB before the deadline for the first report for either of these operations specified in the indicative calendar for TLTROs-III published on the ECB's website

- (b) Participants who first participate in the third or subsequent TLTRO-III operations shall make available, by the relevant deadline specified in the indicative calendar for TLTROs-III published on the ECB's website, to the relevant NCB both the first report including the supplementary items, and the respective auditor's evaluation of the supplementary items.

4. Terms used in the report submitted by participants shall be interpreted in accordance with the definitions of those terms in Regulation (EU) No 1071/2013 (ECB/2013/33).

5. Lead institutions of TLTRO-III groups shall submit reports reflecting aggregated data in respect of all members of the TLTRO-III group. In addition, the lead institution's NCB, or the NCB of a member of a TLTRO-III group may, in coordination with the lead institution's NCB, require the lead institution to submit disaggregated data for each individual group member.

6. Each participant shall ensure that the quality of the data submitted pursuant to paragraphs 1 to 3 is evaluated by an external auditor in accordance with the following rules:

- (a) the auditor's evaluation of the first report shall be made available to the relevant NCB by the relevant deadline specified in the indicative calendar for TLTROs-III published on the ECB's website;
- (b) the results of the auditor's evaluation in respect of the second report shall be made available to the relevant NCB by the relevant deadline specified in the indicative calendar for TLTROs-III published on the ECB's website;
- (c) the auditor's evaluations shall focus on the requirements set out in paragraphs 2 and 4. In particular, the auditor shall:
 - (i) evaluate the accuracy of the data provided by verifying that the set of the participant's eligible loans including, in the case of a lead institution the eligible loans of its TLTRO-III group members, satisfies the eligibility criteria;
 - (ii) check that the data reported complies with the guidelines detailed in Annex II and with the concepts introduced by Regulation (EU) No 1071/2013 (ECB/2013/33);
 - (iii) check that the data reported are consistent with data compiled pursuant to Regulation (EU) No 1071/2013 (ECB/2013/33);
 - (iv) check whether controls and procedures are in place to validate the integrity, accuracy and consistency of the data; and
 - (v) with respect to the supplementary items, ensure, by means of a positive assurance engagement procedure, i.e. a procedure that certifies that the data reported are accurate and relevant, that self-securitised eligible loans included for the purpose of calculating a participant's reference outstanding amount correspond to the relevant asset-backed securities 100 % retained by the respective participant or TLTRO-III group member that originated the self-securitised eligible loans.

In the case of participation on a group basis, the results of the auditor's evaluations shall be shared with the NCBs of the other TLTRO-III group members. At the request of the participant's NCB, detailed results of the evaluations conducted pursuant to this paragraph shall be provided to that NCB and, in the case of group participation, subsequently shared with the NCBs of the group members.

- (d) the auditor's evaluations shall contain, at least the following elements:
 - (i) the type of auditing procedure applied;
 - (ii) the period covered by the audit;
 - (iii) the documentation analysed;
 - (iv) a description of the methods followed by the auditors to perform the tasks described in Article 6(6)(c);
 - (v) where applicable, the identifiers (FVC codes and/or LEIs, as applicable) of each securitisation vehicle holding the self-securitised eligible loans referred to in paragraph (c)(v), and the MFI code of the participant or TLTRO-III group member that originated the self-securitised eligible loans;
 - (vi) corrections performed, if any, after applying the methods described in point (iv);
 - (vii) confirmation that the data included in the reporting templates are in line with the information contained in the participants' internal systems; and
 - (viii) final observations or assessment as a result of the external audit.

The Eurosystem may provide further guidance on the manner in which the auditor's evaluation is to be conducted in which case the participants shall ensure that such guidance is applied by the auditors in their evaluation.

7. Subject to paragraph 8, following a change in the TLTRO-III group composition or a corporate reorganisation, such as a merger, acquisition or division (including one that results from a participant's resolution or liquidation), that affects the set of the participant's eligible loans, a revised first report shall be submitted in accordance with the instructions received from the participant's NCB. The relevant NCB shall assess the impact of the revision and undertake appropriate action. Such action may include a requirement to repay amounts borrowed which, taking into account the change to the TLTRO-III group composition or the corporate reorganisation, exceed the relevant borrowing allowance. The participant concerned, which may include a newly-established entity following the corporate reorganisation, shall provide any additional information requested by the relevant NCB to assist in the assessment of the impact of the revision.

8. By way of exception from paragraph 7, revision of the first report is not required, but the relevant impact on eligible loans may instead be recorded as an adjustment in the second report in cases where:

- (a) the corporate reorganisation involves institutions which prior to the corporate reorganisation were subject to supervisory or resolution measures and these measures, as confirmed by the relevant NCB, actually hampered their ability to lend during at least half of the second reference period;
- (b) the corporate reorganisation involves an acquisition by a participant that was completed in the last six months of the second reference period; or
- (c) the relevant NCB assesses the impact of the change in the group composition or corporate reorganisation as not requiring a revised report.

For cases (b) and (c), participants may still choose to revise the first report to take into account the corporate reorganisations.

9. The data provided by the participants pursuant to this Article may be used by the Eurosystem for the implementation of the TLTRO-III framework, as well as for the analysis of the framework's effectiveness and other Eurosystem analytical purposes. For these purposes NCBs that receive data reported pursuant to this Article may exchange such data within the Eurosystem. Data reported pursuant to this Article may be also shared within the Eurosystem for the purpose of validating the data provided.

Article 7

Non-compliance with reporting requirements

1. Where a participant fails to submit a report or comply with audit requirements, or where errors are identified in the data reported, the following shall apply:

- (a) If a participant fails to make the first report available to the relevant NCB by the relevant deadline, its borrowing allowance shall be set at zero.
- (b) If a participant fails to make the results of the auditor's evaluation of the first report available to the relevant NCB by the relevant deadline specified in the indicative calendar for TLTROs-III published on the ECB website, the participant shall repay all the outstanding amounts borrowed under TLTRO-III on the settlement day of the next main refinancing operation at the interest rate of 10 basis points above the average rate on the main refinancing operation over the life of each respective TLTRO-III.
- (c) If a participant fails to make the second report available to the relevant NCB by the relevant deadline, the interest rate of 10 basis points above the average rate on the main refinancing operation over the life of each respective TLTRO-III shall apply to the amounts borrowed by that participant under TLTROs-III together with an additional daily penalty of EUR 500 until the second report is submitted but up to a maximum of EUR 15 000. The penalty shall be accumulated and charged upon receipt by the relevant NCB of the second report or when the maximum penalty has been reached if the second report has still not been received by then.
- (d) If a participant fails to make the results of the auditor's evaluation of the second report available to the relevant NCB by the relevant deadline, the interest rate of 10 basis points above the average rate on the main refinancing operation over the life of each respective TLTRO-III shall apply to the amounts borrowed by that participant under TLTROs-III.

- (e) If a participant fails to otherwise comply with the obligations set out in Article 6(6) or (7), the interest rate of 10 basis points above the average rate on the main refinancing operation over the life of each respective TLTRO-III shall apply to the amounts borrowed by that participant under TLTROs-III.
 - (f) If a participant, either in connection with the audit referred to in Article 6(6) or by any other means, identifies errors in the data submitted in the reports, including inaccuracies or incompleteness, it shall notify the relevant NCB thereof within the shortest timeframe possible. Where the relevant NCB has been notified of such errors, inaccuracies or omissions, or where such errors, inaccuracies or omissions come to its attention by other means:
 - (i) the participant shall provide any additional information requested by the relevant NCB within the shortest timeframe possible to assist in assessing the impact of the errors, inaccuracies or omissions concerned; and
 - (ii) the relevant NCB may take appropriate action, which may include a recalculation of the relevant values that in turn may affect the interest rate applied to the participant's borrowing under TLTROs-III and a requirement to repay the amounts borrowed which, due to the error, inaccuracy or omission exceed the participant's borrowing allowance.
2. Paragraph 1 shall be without prejudice to any sanction that may be imposed pursuant to Decision ECB/2010/10 ⁽⁹⁾ in respect of the reporting obligations laid down in Regulation (EU) No 1071/2013 (ECB/2013/33).

Article 8

Entry into force

This Decision shall enter into force on 3 August 2019.

Done at Frankfurt am Main, 22 July 2019.

The President of the ECB
Mario DRAGHI

⁽⁹⁾ Decision ECB/2010/10 of 19 August 2010 on non-compliance with statistical reporting requirements (OJ L 226, 28.8.2010, p. 48).

ANNEX I

CONDUCT OF THE THIRD SERIES OF TARGETED LONGER-TERM REFINANCING OPERATIONS

1. Calculation of the borrowing allowance and bid limit

Participants in one of the third series of targeted longer-term refinancing operations (TLTRO-III), acting either individually or as the lead institution of a TLTRO-III group, are subject to a borrowing allowance. The borrowing allowance calculated will be rounded up to the next multiple of EUR 10 000.

The borrowing allowance applicable to an individual participant in the TLTROs-III is calculated on the basis of the reference outstanding amount which comprises the outstanding amount of eligible loans and, upon exercise of the option in Article 6(3), self-securitised eligible loans as at 28 February 2019. The borrowing allowance applicable to the lead institution of a TLTRO-III group is calculated on the basis of the reference outstanding amount in relation to all members of that TLTRO-III group.

The borrowing allowance equals 30 % of the reference outstanding amount relating to the participant ⁽¹⁾ minus the amounts borrowed by the participant in the targeted longer-term refinancing operations pursuant to Decision (EU) 2016/810 (ECB/2016/10) (TLTROs-II) and still outstanding at the settlement date of the respective TLTRO-III, or zero if such amount is negative, i.e.:

$$BA_k = \max(0, 3 \times OR_{Feb2019} - OB_k, 0) \text{ for } k = 1, \dots, 7.$$

Where BA_k is the borrowing allowance in TLTRO-III k (with $k = 1, \dots, 7$), $OR_{Feb2019}$ is the reference outstanding amount as at 28 February 2019 and OB_k is the amount borrowed by the participant in TLTROs-II and still outstanding on the settlement date of the TLTRO-III k .

The bid limit applicable to each participant in each TLTRO-III is either: a) its borrowing allowance BA_k less the amounts borrowed under previous TLTROs-III; or b) one tenth of the total reference outstanding amount, whichever is lower. Let $C_k \geq 0$ be the borrowing of a participant in TLTRO-III k , then $C_k \leq BL_k$ where BL_k is the bid limit for this participant in operation k that is defined as follows:

$$BL_1 = \min(BA_1, 0,1 \times OR_{Feb2019})$$

and

$$BL_k = \min\left(BA_k - \sum_{j=1}^{k-1} C_j, 0,1 \times OR_{Feb2019}\right)$$

for $k = 2, \dots, 7$.

2. Calculation of benchmarks

Let NL_m be the eligible net lending of a participant in calendar month m , calculated as the participant's gross flow of new eligible loans in that month less repayments of eligible loans, as defined in Annex II.

Denote NLB by the benchmark net lending for this participant. This is defined as follows:

$$NLB = \min(NL_{Apr2018} + NL_{May2018} + \dots + NL_{Mar2019}, 0)$$

This implies that if the participant has positive or zero eligible net lending in the first reference period, then $NLB = 0$. If, however, the participant has negative eligible net lending in the first reference period, then $NLB = NL_{Apr2018} + NL_{May2018} + \dots + NL_{Mar2019}$.

Denote by OAB a participant's benchmark outstanding amount. This is defined as follows:

$$OAB = \max(OL_{Mar2019} + NLB, 0)$$

where $OL_{Mar2019}$ is the outstanding amount of eligible loans at the end of March 2019.

⁽¹⁾ References to a 'participant' should be understood as applying to individual participants or TLTRO-III groups.

3. Calculation of the interest rate

Let $NS_{Mar2021}$ denote the amount obtained by summing the eligible net lending over the period 1 April 2019 to 31 March 2021 and the outstanding amount of eligible loans as at 31 March 2019; this is calculated as $NS_{Mar2021} = OL_{Mar2019} + NL_{Apr2019} + \dots + NL_{Mar2021}$.

Denote now by EX the percentage deviation of $NS_{Mar2021}$ from the benchmark outstanding amount, that is,

$$EX = \frac{(NS_{Mar2021} - OAB)}{OAB} \times 100$$

EX will be expressed as a percentage rounded to 15 decimal positions. Where OAB is equal to zero, EX is deemed to equal 2,5.

Let $\overline{MRO}_k$ be the average of the main refinancing operation (MRO) rate prevailing over the life of TLTRO-III k and expressed as an annual percentage rate and let $\overline{DF}_k$ be the average of the deposit facility rate prevailing over the life of TLTRO-III k and expressed as an annual percentage rate, i.e.:

$$\overline{MRO}_k = \frac{1}{n_k} \sum_{t=1}^{n_k} MRO_{k,t}$$

$$\overline{DF}_k = \frac{1}{n_k} \sum_{t=1}^{n_k} DF_{k,t}$$

In the above equations n_k (for $k = 1, \dots, 7$) denotes the number of days of the TLTRO-III k , $MRO_{k,t}$ denotes the rate applied to the MRO on the t -th day of the TLTRO-III k , if this MRO is conducted under a fixed-rate full allotment regime, or $MRO_{k,t}$ denotes the minimum bid rate applied to the MRO on the t -th day of the TLTRO-III k , if this MRO is conducted under a variable-rate tender procedure, and expressed as an annual percentage rate. In the above equations $DF_{k,t}$ denotes the rate applied to the deposit facility on the t -th day of the TLTRO-III k , and expressed as an annual percentage rate.

Let the interest rate incentive adjustment, measured as a fraction of the average corridor between the maximum possible interest rate ($\overline{MRO}_k + 0,1$) and the minimum possible interest rate ($\overline{DF}_k + 0,1$), be denoted iri ; let the interest rate to be applied for TLTRO-III k , expressed as an annual percentage rate, be denoted r_k ; iri and r_k are determined as follows:

- (a) If a participant does not exceed its benchmark outstanding amount of eligible loans as at 31 March 2021, the interest rate to be applied to all amounts borrowed by the participant under TLTROs-III is set at 10 basis points above the average MRO rate over the life of the respective TLTRO-III, that is:

$$\text{if } EX \leq 0, \text{ then } iri = 0 \% \text{ and } r_k = \overline{MRO}_k + 0,1$$

- (b) If a participant exceeds its benchmark outstanding amount of eligible loans by at least 2,5 % as at 31 March 2021, the interest rate to be applied to all amounts borrowed by the participant under TLTROs-III equals 10 basis points above the average interest rate on the deposit facility prevailing over the life of the respective TLTRO-III, that is:

$$\text{if } EX \geq 2,5, \text{ then } iri = 100 \% \text{ and } r_k = \overline{DF}_k + 0,1$$

- (c) If a participant exceeds its benchmark outstanding amount of eligible loans but by less than 2,5 % as at 31 March 2021, the interest rate to be applied to all amounts borrowed by the participant under TLTROs-III is graduated linearly depending on the percentage by which the participant exceeds its benchmark outstanding amounts of eligible loans, that is,

$$\text{if } 0 < EX < 2,5, \text{ then } iri = \frac{EX}{2,5} \text{ and } r_k = \overline{MRO}_k + 0,1 - (\overline{MRO}_k - \overline{DF}_k) \times iri$$

The interest rate incentive adjustment (iri) will be expressed by rounding to 15 decimal positions.

The interest rate (r_k) will be expressed as an annual percentage rate, rounded down to the fourth decimal position.

ANNEX II

THE THIRD SERIES OF TARGETED LONGER-TERM REFINANCING OPERATIONS - GUIDELINES FOR COMPILING DATA REQUIRED BY THE REPORTING TEMPLATES**1. Introduction ⁽¹⁾**

These guidelines provide instructions for compiling the data reports that participants in the TLTROs-III must submit in accordance with Article 6. The reporting requirements are presented in the reporting templates at the end of this Annex. These guidelines also specify the reporting requirements of lead institutions of TLTRO-III groups participating in the operations.

Section 2 and 3 provide general information relating to the compilation and transmission of the data and section 4 explains the indicators to be reported.

2. General information

The measures to be used in the calculation of the borrowing allowance relate to monetary financial institution (MFI) loans to euro area non-financial corporations and MFI loans to euro area households ⁽²⁾, excluding loans for house purchases, in all currencies. In accordance with Article 6, two data reports must be submitted: the first report covers data on the reference outstanding amount and data relating to the first reference period, and the second report covers data relating to the second reference period. Amounts must be reported separately for non-financial corporations and for households. Outstanding amounts of eligible loans are adjusted to account for loans which are securitised or otherwise transferred and not derecognised, however participants may exercise the option under Article 6(3) to add self-securitised eligible loans for the purpose of calculating their borrowing allowance, regardless of their recognition status on the balance sheet. Detailed information is also required on the relevant sub-components of these items, as well as on effects that result in changes to outstanding amounts of eligible loans but that are not related to eligible net lending (hereinafter 'adjustments to the outstanding amounts'), also covering loan sales and purchases and other loan transfers.

As regards the use of the collected information, data on the reference outstanding amount will be used to determine the borrowing allowance. In addition, data on eligible net lending during the first reference period will be used for the calculation of the benchmark net lending and the benchmark outstanding amount. Meanwhile data on eligible net lending during the second reference period will be used to assess the lending developments and, consequently, the interest rates applicable. All other indicators are necessary to verify the internal consistency of the information and its consistency with the statistical data collected within the Eurosystem, as well as for in-depth monitoring of the impact of the TLTRO-III programme.

The general framework underlying the completion of the data reports is provided by the reporting requirements of euro area MFIs in the context of MFI balance sheet items (BSI) statistics, as specified in Regulation (EU) No 1071/2013 (ECB/2013/33). In particular, as regards loans, Article 8(2) of Regulation (EU) No 1071/2013 (ECB/2013/33) requires that they 'shall be reported at their principal amount outstanding at the end of the month. Write-offs and write-downs as determined by the relevant accounting practices shall be excluded from this amount. [...] loans shall not be netted against any other assets or liabilities'. However, as an exception to the rules laid down in Article 8(2), which also imply that loans are to be reported gross of provisions, Article 8(4) states that 'NCBs may allow the reporting of provisioned loans net of provisions and the reporting of purchased loans at the price agreed at the time of their acquisition [i.e. their transaction value], provided that such reporting practices are applied by all resident reporting agents'. Self-securitised eligible loans may not be reported net of provisions if they are derecognised from the balance sheet. The implications that this deviation from the general BSI guidance has for the compilation of the data reports are reviewed in more detail below.

Regulation (EU) No 1071/2013 (ECB/2013/33) should also be used as the reference document as regards the definitions to be applied in the compilation of the data reports. See, in particular, Article 1 for general definitions, and Parts 2 and 3 of Annex II for a definition of the categories of instruments to be covered under 'loans' and of the sectors of participants respectively. Importantly, in the BSI framework accrued interest receivable on loans is, as a rule, subject to

⁽¹⁾ The conceptual framework underlying the reporting requirements remains unchanged in comparison to that specified in Decisions ECB/2014/34 and (EU) 2016/810 (ECB/2016/10), with the exception of the changes relating to the inclusion of self-securitised eligible loans for the purpose of calculating the borrowing allowance.

⁽²⁾ For the purposes of the data reports, 'households' includes non-profit institutions serving households.

on-balance-sheet recording as it accrues (i.e. on an accrual basis rather than when it is actually received), but should be excluded from the data on outstanding amounts of loans. However, capitalised interest should be recorded as part of the outstanding amounts.

While much of the data to be reported are already compiled by MFIs in accordance with the requirements of Regulation (EU) No 1071/2013 (ECB/2013/33), some additional information must be compiled by participants bidding in TLTRO-III. The methodological framework for BSI statistics, as laid down in the Manual on MFI balance sheet statistics ⁽³⁾, provides all the background information required in order to compile these additional data; further details are provided in point 4 regarding the definitions of the individual indicators.

3. General reporting instructions

(a) Structure of the reporting templates

The templates include an indication of the reference dates to which the data refer and groups the indicators into two blocks: MFI loans to euro area non-financial corporations and MFI loans to euro area households, excluding loans for house purchases. The data in all cells highlighted in yellow are calculated from the data entered in the other cells, based on the formulas provided. The templates also incorporate validation rules that verify the internal consistency of the data.

There are two reports in the TLTRO-III:

- The first report requires the completed data template A relating to the reference outstanding amount for the purpose of calculating the borrowing allowance and bid limits. Participants exercising the option pursuant to Article 6(3) must provide the supplementary items relating to self-securitised eligible loans, and the auditor's evaluation of those items, in accordance with Article 6(6)(c)(v). The first report also requires the completed template B for the 'first reference period', i.e. 1 April 2018 to 31 March 2019, for the purposes of calculating the eligible net lending and benchmarks.
- The second report requires the completed data template B for the 'second reference period', i.e. 1 April 2019 to 31 March 2021, for the purposes of calculating the eligible net lending and the comparisons against benchmarks on which the applicable interest rates are based.

In Template B, indicators relating to outstanding amounts must be reported as at the end of the month preceding the start of the reporting period and as at the end of the reporting period; therefore, for the first reference period outstanding amounts must be reported as at 31 March 2018 and 31 March 2019, and for the second reference period outstanding amounts must be reported as at 31 March 2019 and as at 31 March 2021. In turn, data on transactions and adjustments must cover all relevant effects that take place during the reporting period.

(b) Reporting in respect of TLTRO-III groups

In respect of group participation in the TLTROs-III, data should be reported, as a rule, on an aggregated basis. However, national central banks of Member States whose currency is the euro (NCBs) have the option of collecting the information on an individual institution basis, if deemed appropriate.

(c) Transmission of the data reports

The completed data reports should be transmitted to the relevant NCB as specified in Article 6 and in accordance with the indicative calendar for TLTROs-III published on the ECB's website, which also stipulates the reference periods to be covered in each transmission and which data vintages should be used for the compilation of the data.

(d) Unit of the data

Data must be reported in terms of thousands of euro.

⁽³⁾ See the 'Manual on MFI balance sheet statistics', ECB, January 2019, available on the ECB's website at www.ecb.europa.eu. In particular, Section 4.3, p. 40, deals with the statistical reporting of loans.

4. Definitions

This section provides definitions of the items to be reported; the numbering used in the reporting templates is indicated in brackets.

(a) Outstanding amounts of eligible loans (1 and 4)

The data in these cells are calculated on the basis of the figures reported in respect of the following balance sheet items: 'Outstanding amounts on the balance sheet' (1.1 and 4.1), minus 'Outstanding amounts of loans that are securitised or otherwise transferred but not derecognised from the balance sheet' (1.2 and 4.2), plus 'Outstanding provisions' (1.3 and 4.3). The latter sub-term is relevant only in cases where, contrary to the general BSI practice, loans are reported net of provisions.

The underlying items of the outstanding amounts of eligible loans are as follows:

(i) Outstanding amounts on the balance sheet (1.1 and 4.1)

This item comprises outstanding amounts of loans granted to euro area non-financial corporations and households, excluding loans for house purchase. Accrued interest, as opposed to capitalised interest, is excluded from the indicators.

These cells are directly linked to the requirements of Part 2 of Annex I to Regulation (EU) No 1071/2013 (ECB/2013/33) (Block 2 of Table 1 on monthly stocks).

For a more detailed definition of the items to be included in the data reports, see Part 2 of Annex II to Regulation (EU) No 1071/2013 (ECB/2013/33) and Section 4.3 of the Manual on MFI balance sheet statistics.

(ii) Outstanding amounts of loans securitised or otherwise transferred but not derecognised from the balance sheet (1.2 and 4.2)

This item comprises the outstanding amounts of loans that are securitised or otherwise transferred but which have not been derecognised from the balance sheet. All securitisation activities must be reported, regardless of where the financial vehicle corporations involved are resident. Loans provided as collateral to the Eurosystem for monetary policy credit operations in the form of credit claims, which result in a transfer without derecognition from the balance sheet are excluded from this item.

Part 5 of Annex I to Regulation (EU) No 1071/2013 (ECB/2013/33) (Block 5.1 of Table 5a on monthly data) covers the required information on securitised loans to non-financial corporations and households that have not been derecognised, but does not require the latter to be broken down by purpose. In addition, outstanding amounts of loans which have been otherwise transferred (i.e. not through a securitisation) but are not derecognised, are not covered by Regulation (EU) No 1071/2013 (ECB/2013/33). For the purposes of compiling the data reports, separate data extractions from the MFIs' internal databases are thus required.

For additional details of the items to be included in the data reports, see Part 5 of Annex I to Regulation (EU) No 1071/2013 (ECB/2013/33) and Section 4.3.11 of the Manual on MFI balance sheet statistics.

(iii) Outstanding provisions (1.3 and 4.3)

These data are relevant only for those institutions that, contrary to the general BSI practice, report loans net of provisions. In the case of institutions bidding as a TLTRO-III group, this requirement only applies to those institutions in the group that record loans net of provisions.

This item includes individual and collective allowances for impairment and loan losses (before write-offs and write-downs take place). The data must refer to 'Outstanding amounts of loans on the balance sheet' (1.1 and 4.1), excluding 'Outstanding amounts of loans securitised or otherwise transferred but not derecognised from the balance sheet' (1.2 and 4.2).

As stated in the third subparagraph of point 2, in BSI statistics loans should be reported, as a rule, at the principal outstanding amount, with the corresponding provisions being allocated to 'Capital and reserves'. In such cases, no separate information on provisions should be reported. At the same time, in cases where loans are reported net of provisions, this additional information must be reported in order to gather fully comparable data across MFIs.

Where it is the practice to report outstanding amounts of loans net of provisions, NCBs have the option of making the reporting of this information non-mandatory. However, in such cases the calculations under the TLTRO-III framework will be based on amounts of outstanding loans on the balance sheet net of provisions ⁽⁴⁾.

For additional details, see the reference to provisions in the definition of '*Capital and reserves*' provided in Part 2 of Annex II to Regulation (EU) No 1071/2013 (ECB/2013/33).

(b) Eligible net lending (2)

These cells record the net lending (transactions) granted during the reporting period. The data are calculated on the basis of the figures reported for the sub-items, namely 'Gross lending' (2.1) minus 'Repayments' (2.2).

Loans which are renegotiated during the reporting period should be reported both as 'Repayments' and as 'Gross lending' at the time when the renegotiation takes place. Adjustment data must include effects relating to loan renegotiation.

Reversed transactions during the period (i.e. loans granted and repaid during the period) should in principle be reported both as 'Gross lending' and as 'Repayments'. However, it is also permissible for bidding MFIs to exclude these operations when compiling the data reports, to the extent that this would alleviate their reporting burden. In this case, they should inform the relevant NCB and the data on adjustments to the outstanding amounts must also exclude effects relating to these reversed operations. This exception does not apply to loans granted during the period which are securitised or otherwise transferred.

Credit card debt, revolving loans and overdrafts should also be considered. For these instruments, changes in balances owing to amounts used or withdrawn during the reporting periods should be used as proxies for net lending. Positive amounts should be reported as 'Gross lending' (2.1), whereas negative amounts should be reported (with the positive sign) as 'Repayments' (2.2).

(i) Gross lending (2.1)

This item comprises the flow of gross new loans in the reporting period, excluding any loan acquisitions. Credit granted that relates to credit card debt, revolving loans and overdrafts should also be reported, as explained above.

Amounts added during the period to customer balances due, for instance, to interest capitalisation (as opposed to interest accruals) and fees, should also be included.

(ii) Repayments (2.2)

This item comprises the flow of repayments of principal during the reporting period, excluding those relating to securitised or otherwise transferred loans which are not derecognised from the balance sheet. Repayments relating to credit card debt, revolving loans and overdrafts should also be reported, as explained above.

Interest payments relating to accrued interest not yet capitalised, loan disposals and other adjustments to the outstanding amounts (including write-offs and write-downs) should not be reported.

Regulation (EU) No 1071/2013 (ECB/2013/33) requires debt-to-equity conversions to be treated as transactions. However for the purposes of compiling the TLTRO-III data reports, debt-to-equity conversions, whereby loans granted by a participant to non-financial corporations are replaced by equity held by that participant in these non-financial corporations, may be reported as a reclassification rather than a repayment of the loans provided that the amount of funding provided by the participant to the real economy is not thereby reduced, as determined by the relevant NCB. The participant will provide all necessary information to the NCB in order for it to decide how the conversion should be treated.

(c) Adjustments to the outstanding amounts (3)

These cells are for reporting changes in outstanding amounts of eligible loans (reductions (–) and increases (+)) occurring during the reporting period which are not related to eligible net lending. Such changes arise from operations such as loan securitisations and other loan transfers during the reporting period, and from other adjustments related to revaluations owing to changes in exchange rates, loan write-offs and write-downs and reclassifications.

⁽⁴⁾ This exception also has implications for the reporting of data on write-offs and write-downs, as clarified below.

The items relating to adjustments of outstanding amounts are calculated on the basis of the figures reported under the sub-items, namely 'Loan sales and purchases and other loan transfers during the reporting period' (3.1) plus 'Other adjustments' (3.2).

(i) Loan sales and purchases and other loan transfers during the reporting period (3.1)

— Net flows of loans that are securitised with an impact on loan stocks (3.1A)

This item comprises the net amount of loans that are securitised during the reporting period with an impact on reported loan stocks, calculated as acquisitions minus disposals ⁽⁵⁾. All securitisation activities must be reported, regardless of where the financial vehicle corporations involved are resident. Loan transfers should be recorded at the nominal amount net of write-offs and write-downs at the time of the sale. These write-offs and write-downs should be reported, where identifiable, under item 3.2B (see below). In the case of MFIs that report loans net of provisions, the transfers should be recorded at the balance sheet value (i.e. the nominal amount net of outstanding provisions) ⁽⁶⁾.

The requirements of Part 5 of Annex I to Regulation (EU) No 1071/2013 (ECB/2013/33) (Block 1.1 of Table 5a on monthly data and Table 5b on quarterly data) cover these elements.

For a more detailed definition of the items to be reported, see Part 5 of Annex I to Regulation (EU) No 1071/2013 (ECB/2013/33) and Section 4.3.11 of the Manual on MFI balance sheet statistics.

— Net flows of loans that are otherwise transferred with an impact on loan stocks (3.1B)

This item comprises the net amount of loans disposed of or acquired during the period with an impact on reported loan stocks in operations not related to securitisation activities, and is calculated as acquisitions minus disposals. The transfers should be recorded at the nominal amount net of write-offs and write-downs at the time of the sale. These write-offs and write-downs should be reported, where identifiable, under item 3.2B. In the case of MFIs that report loans net of provisions, the transfers should be recorded at the balance sheet value (i.e. the nominal amount net of outstanding provisions).

The requirements of Part 5 of Annex I to Regulation (EU) No 1071/2013 (ECB/2013/33) partly cover these elements. Blocks 1.2 of Table 5a on monthly data and Table 5b on quarterly data cover data on net flows of loans that are otherwise transferred with an impact on loan stocks, but exclude:

- (1) loans disposed of to, or acquired from, another domestic MFI, including intra-group transfers owing to corporate business restructuring (e.g. the transfer of a pool of loans by a domestic MFI subsidiary to the parent MFI);
- (2) loan transfers in the context of intra-group reorganisations owing to mergers, acquisitions and divisions.

For the purposes of compiling the data reports, all of these effects must be reported. For additional details on the items to be reported, see Part 5 of Annex I to Regulation (EU) No 1071/2013 (ECB/2013/33) and Section 4.3.11 of the Manual on MFI balance sheet statistics. With regard to 'Changes in the structure of the MFI sector', Section 5.6 of the Manual on MFI balance sheet statistics provides a detailed description of intra-group transfers, distinguishing between cases where transfers take place between separate institutional units (e.g. before one or more of the units cease to exist in a merger or acquisition) and those that take place at the moment when some units cease to exist, in which case a statistical reclassification should be carried out. For the purposes of compiling the data reports, in both cases the implications are the same and the data should be reported under item 3.1C (and not under item 3.2C).

⁽⁵⁾ This sign convention, which is the opposite of the requirements of Regulation (EU) No 1071/2013 (ECB/2013/33), is consistent with the general requirement regarding adjustment data, as specified above – i.e. effects leading to increases or decreases in outstanding amounts are to be reported, respectively, with a positive or negative symbol.

⁽⁶⁾ Regulation (EU) No 1071/2013 (ECB/2013/33) allows MFIs to report purchased loans at their transaction value as long as this is a national practice applied by all MFIs resident in the country. In such cases, revaluation components that may arise must be reported under item 3.2B.

— Net flows of loans that are securitised or otherwise transferred without an impact on loan stocks (3.1C)

This item comprises the net amount of loans that are securitised or otherwise transferred during the reporting period without any impact on the reported loan stocks, and is calculated as acquisitions minus disposals. The transfers should be recorded at the nominal amount net of write-offs and write-downs at the time of the sale. These write-offs and write-downs should be reported, where identifiable, under item 3.2B. In the case of MFIs that report loans net of provisions, the transfers should be recorded at the balance sheet value (i.e. the nominal amount net of outstanding provisions). Net flows relating to the provision of loans as collateral to the Eurosystem for monetary policy credit operations in the form of credit claims which result in a transfer without derecognition from the balance sheet are excluded from this item.

The requirements of Part 5 of Annex I to Regulation (EU) No 1071/2013 (ECB/2013/33) partly cover these elements. Blocks 2.1 of Table 5a on monthly data and Table 5b on quarterly data cover data on net flows of loans that are securitised or otherwise transferred without any impact on loan stocks, but loans to households for house purchase are not separately identified and should thus be extracted from the MFIs' internal databases separately. In addition, as specified above, the requirements exclude:

- (1) Loans disposed of to, or acquired from, another domestic MFI, including intra-group transfers owing to corporate business restructuring (e.g. when a domestic MFI subsidiary transfers a pool of loans to the parent MFI);
- (2) Loan transfers in the context of intra-group reorganisations owing to mergers, acquisitions and divisions.

For the purposes of compiling the data reports, all of these effects must be reported.

For additional details on the items to be included, see Part 5 of Annex I to Regulation (EU) No 1071/2013 (ECB/2013/33) and Section 4.3.11 of the Manual on MFI balance sheet statistics.

(ii) Other adjustments (3.2)

The following items relating to other adjustments must be reported for outstanding loans on the balance sheet, excluding securitised or otherwise transferred loans which are not derecognised.

— Revaluations owing to changes in exchange rates (3.2A)

Movements in exchange rates against the euro give rise to changes in the value of loans denominated in foreign currencies when they are expressed in euro. Data on these effects should be reported with a negative (positive) sign when in net terms they give rise to a reduction (increase) in outstanding amounts, and are necessary to allow a full reconciliation between net lending and changes in outstanding amounts.

These adjustments are not covered under the requirements laid down by Regulation (EU) No 1071/2013 (ECB/2013/33). For the purposes of the data reports, if the data (or even an approximation) are not readily available to MFIs, they can be calculated in accordance with the guidance provided in Section 7.2.2 of the Manual on MFI balance sheet statistics. The suggested estimation procedure limits the scope of the calculations to major currencies and is based on the following steps:

- (1) the outstanding amounts of eligible loans at the end of the month preceding the start of the period and at the end of the period (items 1 and 4) are broken down by currency of denomination, focusing on the pools of loans denominated in GBP, USD, CHF and JPY. If these data are not readily available, data on total outstanding amounts on the balance sheet, including securitised or otherwise transferred loans which are not derecognised – items 1.1 and 4.1 – may be used;
- (2) each pool of loans is treated as follows. The relevant equation numbers in the Manual on MFI balance sheet statistics are provided in brackets:
 - outstanding amounts at the end of the month preceding the start of the reporting period and at the end of the period are converted into the original currency of denomination, using the corresponding nominal exchange rates ⁽⁷⁾ (equations [7.2.2] and [7.2.3]);

⁽⁷⁾ ECB reference exchange rates should be used. See the press release of 8 July 1998 on the setting-up of common market standards which is available on the ECB's website www.ecb.europa.eu.

- the change in outstanding amounts during the reference period denominated in foreign currency is computed and converted back into euro using the average value of the daily exchange rates during the reporting period (equation [7.2.4]);
- the difference between the change in outstanding amounts converted into euro, as calculated in the previous step, and the change in outstanding amounts in euro is computed (equation [7.2.5], with the opposite sign);

(3) the final exchange rate adjustment is estimated as the sum of the adjustments for each currency.

For additional information, see Sections 5.8 and 7.2.2 of the Manual on MFI balance sheet statistics.

— Write-offs/write-downs (3.2B)

In accordance with point (g) of Article 1 of Regulation (EU) No 1071/2013 (ECB/2013/33), “write-down” means the direct reduction of the carrying amount of a loan on the statistical balance sheet owing to its impairment.’ Similarly, in accordance with point (h) Article 1 of the same Regulation “write-off” means a write-down of the full carrying amount of a loan leading to its removal from the balance sheet.’ The effects of write-downs and write-offs should be reported with a negative or positive sign when in net terms they result in a reduction or increase, as applicable, in outstanding amounts. These data are necessary to allow a full reconciliation between net lending and changes in outstanding amounts.

As regards write-offs and write-downs relating to outstanding loans on the balance sheet, data compiled to comply with the minimum requirements of Part 4 of Annex I to Regulation (EU) No 1071/2013 (ECB/2013/33) Table 1A on Monthly revaluation adjustments) can be used. However, disentangling the impact of loan write-offs and write-downs on securitised or otherwise transferred loans which are not derecognised requires a separate data extraction from the MFIs’ internal databases.

Data on outstanding amounts of eligible loans (items 1 and 4) are in principle corrected for the outstanding amounts of provisions in cases where loans are recorded net of provisions on the statistical balance sheet.

- In cases where participants report items 1.3 and 4.3, data on loan write-offs and write-downs should incorporate the cancellation of past provisions on loans that have become (partly or fully) unrecoverable and, in addition, should also include any losses in excess of the provisions, if applicable. Similarly, when a provisioned loan is securitised or otherwise transferred, a write-off or write-down needs to be recorded that is equal to the outstanding provisions, with the opposite sign, in order to match the change in the value on the balance sheet, corrected for the amounts of provisions and the value of the net flow. Provisions may change over time as a result of new allowances for impairment and loan losses (net of possible reversals, including those that take place when a loan is repaid by the borrower). Such changes should not be recorded in the data reports as part of write-offs/write-downs (as the data reports reconstruct values gross of provisions) ⁽⁸⁾.

Disentangling the impact of loan write-offs and write-downs on securitised or otherwise transferred loans which are not derecognised may be omitted if separate data on provisions cannot be extracted from the MFIs’ internal databases.

- Where it is the practice that outstanding amounts of loans are reported net of provisions, but the relevant items (1.3 and 4.3) relating to provisions are not reported, see point 4(a), write-offs/write-downs must include new allowances for impairment and loan losses on the loan portfolio (net of possible reversals, including those that take place when a loan is repaid by the borrower) ⁽⁹⁾.

It is not necessary to disentangle the impact of write-offs and write-downs on securitised or otherwise transferred loans which are not derecognised if separate data on provisions cannot be extracted from the MFIs’ internal databases.

In principle, these items also cover revaluations arising when loans are securitised or otherwise transferred and the transaction value differs from the nominal amount outstanding when the transfer takes place. These revaluations must be reported, where identifiable, and should be calculated as the difference between the transaction value and the nominal amount outstanding at the time of the sale.

⁽⁸⁾ This requirement differs from the reporting requirements under Regulation (EU) No 1071/2013 (ECB/2013/33).

⁽⁹⁾ This requirement is the same as the information to be reported under Regulation (EU) No 1071/2013 (ECB/2013/33) by MFIs recording loans net of provisions.

For additional information, see Part 4 of Annex I to Regulation (EU) No 1071/2013 (ECB/2013/33) and Section 5.4 of the Manual on MFI balance sheet statistics.

— Reclassifications (3.2C)

Reclassifications record all other effects that are not related to net lending, as defined in point 4(b), but result in changes in the outstanding amounts of loans on the balance sheet, excluding securitised or otherwise transferred loans which are not derecognised.

These effects are not covered under the requirements laid down by Regulation (EU) No 1071/2013 (ECB/2013/33) and their impact is normally estimated on an aggregated basis when compiling macro-economic statistics. However, they are important at the level of individual institutions (or TLTRO-III groups) in order to reconcile net lending and changes in outstanding amounts.

The following effects must be reported, in respect of the outstanding amounts of loans on the balance sheet, excluding securitised or otherwise transferred loans which are not derecognised and the usual convention of recording effects leading to reductions (increases) in outstanding amounts with a negative (positive) sign applies to:

- (1) Changes in the sector classification or area of residence of borrowers that result in changes in the reported outstanding positions which are not due to net lending and thus need to be recorded;
- (2) Changes in the classification of instruments. These may also affect the indicators if the outstanding amounts of loans increase or decrease owing, for instance, to the reclassification of a debt security as a loan or a loan as a debt security;
- (3) Adjustments that result from the correction of reporting errors, in accordance with instructions received from the relevant NCB pursuant to point (f) of Article 7(1);
- (4) Adjustments relating to corporate reorganisations and changes in the composition of TLTRO-III groups for which resubmissions of the first report reflecting the new corporate structure and TLTRO-III group composition are not required, in accordance with Article 6(8).

For additional information, see Section 5.6 of the Manual on MFI balance sheet statistics. However, the conceptual differences highlighted above should be taken into account for the purposes of deriving reclassification data at the level of individual institutions.

(d) Supplementary amounts relating to self-securitised eligible loans (S.1)

Participants exercising the option pursuant to Article 6(3) must also provide the following supplementary items relating to outstanding amounts of self-securitised eligible loans in template A:

(i) 'Outstanding amounts of self-securitised eligible loans not derecognised from the balance sheet' (S.1.1)

These data refer to loans that have been self-securitised and are included in the amounts reported under item 1.2.

(ii) 'Outstanding amounts of self-securitised eligible loans derecognised from the balance sheet' (S.1.2)

These data refer to loans that have been self-securitised and are no longer recorded on the balance sheet because they have been derecognised. In so far as the loans continue to be serviced by the participant, they will still be subject to reporting under Part 5 of Annex I to Regulation (EU) No 1071/2013 (ECB/2013/33) (Block 3.1 of Tables 5a and 5b).

(iii) 'Outstanding amounts of provisions against self-securitised eligible loans not derecognised from the balance sheet' (S.1.3)

These data refer to loans not derecognised from the balance sheet – i.e. reported under S.1.1. These items are only to be reported in cases where, contrary to the general BSI practice, loans are reported net of provisions. However, where this is the case, participants may decide not to provide this information, in which case the relevant amounts will not be included in the calculation of the outstanding amounts of eligible loans.

TLTRO-III reporting

TLTRO-III reporting template A

Reporting period: 28 February 2019

Loans to non-financial corporations and households, excluding loans to households for house purchase (EUR thousands)

		Loans to non-financial corporations	Loans to households (including non-profit institutions serving households), excluding loans for house purchase	item	formula	validation
Main aggregates for the reference outstanding amount						
1	Outstanding amounts of eligible loans	0	0	1	1 = 1.1 – 1.2 (+ 1.3)	
S.1	Supplementary amounts relating to self-securitised eligible loans	0	0	S.1	S.1 = S.1.1 + S.1.2 (+ S.1.3)	
Underlying items						
Outstanding amounts of eligible loans on the balance sheet						
1.1	Outstanding amounts on the balance sheet			1.1		
1.2	Outstanding amounts of loans securitised or otherwise transferred but not derecognised from the balance sheet			1.2		
1.3	Outstanding provisions against loans reported in item 1.1 excluding 1.2 (*)			1.3		
Supplementary items relating to self-securitised eligible loans						
S.1.1	Outstanding amounts of self-securitised eligible loans not derecognised from the balance sheet			S.1.1		S.1.1 <= 1.2
S.1.2	Outstanding amounts of self-securitised eligible loans derecognised from the balance sheet			S.1.2		
S.1.3	Outstanding amounts of provisions against self-securitised eligible loans not derecognised from the balance sheet (*)			S.1.3		

(*) Only applicable in those cases where loans are reported net of provisions; see the reporting instructions for more details.

TLTRO-III reporting template B

Reporting period: 1 April 2018 to 31 March 2019 (first reference period) / 1 April 2019 to 31 March 2021 (second reference period)

Loans to non-financial corporations and households, excluding loans to households for house purchase (EUR thousands)

		Loans to non-financial corporations	Loans to households (including non-profit institutions serving households), excluding loans for house purchase	item	formula	validation
Main aggregates						
1	Outstanding amounts of eligible loans at the end of the month preceding the start of the reporting period	0	0	1	$1 = 1.1 - 1.2 (+ 1.3)$	
2	Eligible net lending in the reporting period	0	0	2	$2 = 2.1 - 2.2$	
3	Adjustments to the outstanding amounts: reductions (-) and increases (+)	0	0	3	$3 = 3.1 + 3.2$	
4	Outstanding amounts of eligible loans at the end of the reporting period	0	0	4	$4 = 4.1 - 4.2 (+ 4.3)$	$4 = 1 + 2 + 3$
Underlying items						
Outstanding amounts of eligible loans at the end of the month preceding the start of the reporting period						
1.1	Outstanding amounts on the balance sheet			1.1		
1.2	Outstanding amounts of loans securitised or otherwise transferred but not derecognised from the balance sheet			1.2		
1.3	Outstanding provisions against loans reported in item 1.1 excluding 1.2 (*)			1.3		
Eligible net lending in the reporting period						
2.1	Gross lending			2.1		
2.2	Repayments			2.2		
Adjustments to the outstanding amounts: reductions (-) and increases (+)						
3.1	Loan sales and purchases and other loan transfers during the reporting period	0	0	3.1	$3.1 = 3.1A + 3.1B + 3.1C$	
3.1A	Net flows of loans that are securitised with an impact on loan stocks			3.1A		
3.1B	Net flows of loans that are otherwise transferred with an impact on loan stocks			3.1B		
3.1C	Net flows of loans that are securitised or otherwise transferred without an impact on loan stocks			3.1C		
3.2	Other adjustments	0	0	3.2	$3.2 = 3.2A + 3.2B + 3.2C$	
3.2A	Revaluations owing to changes in exchange rates			3.2A		
3.2B	Write-offs/write-downs			3.2B		
3.2C	Reclassifications			3.2C		
Outstanding amounts of eligible loans at the end of the reporting period						
4.1	Outstanding amounts on the balance sheet			4.1		
4.2	Outstanding amounts of loans securitised or otherwise transferred but not derecognised from the balance sheet			4.2		
4.3	Outstanding provisions against loans reported in item 4.1 excluding 4.2 (*)			4.3		

(*) Only applicable in those cases where loans are reported net of provisions; see the reporting instructions for more details.

DECISION (EU) 2019/1312 OF THE EUROPEAN CENTRAL BANK**of 22 July 2019****amending Decision (EU) 2016/810 (ECB/2016/10) on a second series of targeted longer-term refinancing operations (ECB/2019/22)**

THE GOVERNING COUNCIL OF THE EUROPEAN CENTRAL BANK,

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

Having regard to the Statute of the European System of Central Banks and of the European Central Bank, and in particular the first indent of Article 3.1, Article 12.1, the second indent of Article 18.1 and the second indent of Article 34.1 thereof,

Having regard to Guideline (EU) 2015/510 of the European Central Bank of 19 December 2014 on the implementation of the Eurosystem monetary policy framework (ECB/2014/60) ⁽¹⁾,

Whereas:

- (1) Pursuant to Article 1(4) of Guideline (EU) 2015/510 (ECB/2014/60), the Governing Council may, at any time, change the tools, instruments, requirements, criteria and procedures for the implementation of Eurosystem monetary policy operations.
- (2) On 28 April 2016, in pursuing its price stability mandate and to strengthen the transmission of monetary policy by further incentivising bank lending to the non-financial private sector, the Governing Council adopted Decision (EU) 2016/810 of the European Central Bank (ECB/2016/10) ⁽²⁾. This Decision provided for a second series of targeted longer-term refinancing operations (TLTROs-II) to be conducted over the period from June 2016 to March 2017.
- (3) On 7 March 2019, to assist in preserving favourable bank lending conditions and support the accommodative stance of monetary policy in Member States whose currency is the euro, the Governing Council decided to conduct a new series of seven targeted longer-term refinancing operations (TLTROs-III). The provisions regarding the TLTROs-III will be set out in a separate decision.
- (4) In order to facilitate the calculation of the bid limits for the TLTROs-III, and taking into account any eventual voluntary early repayments of amounts borrowed under TLTROs-II, it is necessary to amend the notification period for such early repayment.
- (5) In order to allow credit institutions sufficient time to make operational preparations for the first TLTRO-III, this Decision should enter into force without undue delay.
- (6) Therefore, Decision (EU) 2016/810 (ECB/2016/10) should be amended accordingly,

HAS ADOPTED THIS DECISION:

*Article 1***Amendments**

In Article 6 of Decision (EU) 2016/810 (ECB/2016/10) paragraphs 3 and 4 are replaced by the following:

‘3. In order to benefit from the early repayment procedure, a participant shall notify the relevant NCB that it intends to repay under the early repayment procedure on the early repayment date, at least two weeks in advance of that early repayment date.

⁽¹⁾ Guideline (EU) 2015/510 of the European Central Bank of 19 December 2014 on the implementation of the Eurosystem monetary policy framework (ECB/2014/60) (General Documentation Guideline) (OJ L 91, 2.4.2015, p. 3).

⁽²⁾ Decision (EU) 2016/810 of the European Central Bank of 28 April 2016 on a second series of targeted longer-term refinancing operations (ECB/2016/10) (OJ L 132, 21.5.2016, p. 107).

4. The notification referred to in paragraph 3 shall become binding on the participant concerned two weeks before the early repayment date to which it refers. Failure by the participant to settle, in full or in part, the amount due under the early repayment procedure by the repayment date may result in the imposition of a financial penalty. The applicable financial penalty shall be calculated in accordance with Annex VII to Guideline (EU) 2015/510 (ECB/2014/60) and shall correspond to the financial penalty applied for failures to comply with the obligations to adequately collateralise and settle the amount the counterparty has been allotted as regards reverse transactions for monetary policy purposes. The imposition of a financial penalty shall be without prejudice to the NCB's right to exercise the remedies provided for on the occurrence of an event of default as set out in Article 166 of Guideline (EU) 2015/510 (ECB/2014/60).'

Article 2

Entry into force

This Decision shall enter into force on 3 August 2019.

Done at Frankfurt am Main, 22 July 2019.

For the Governing Council of the ECB

The President of the ECB

Mario DRAGHI

