

Official Journal of the European Union

L 316



English edition

Legislation

Volume 62

6 December 2019

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⁽¹⁾ Text with EEA relevance.

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⁽¹⁾ Text with EEA relevance.

II

(Non-legislative acts)

INTERNATIONAL AGREEMENTS

COUNCIL DECISION (EU) 2019/2073

of 5 December 2019

on the conclusion of the Agreement between the United States of America and the European Union on the Allocation to the United States of a Share in the Tariff Rate Quota for High Quality Beef referred to in the Revised Memorandum of Understanding Regarding the Importation of Beef from Animals Not Treated with Certain Growth-Promoting Hormones and Increased Duties Applied by the United States to Certain Products of the European Union (2014)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular the first subparagraph of Article 207(4), in conjunction with point (a)(v) of the second subparagraph of Article 218(6) thereof,

Having regard to the proposal from the European Commission,

Having regard to the consent of the European Parliament ⁽¹⁾,

Whereas:

- (1) In accordance with Council Decision (EU) 2019/1316 ⁽²⁾, the Agreement between the United States of America and the European Union on the Allocation to the United States of a Share in the Tariff Rate Quota for High Quality Beef referred to in the Revised Memorandum of Understanding Regarding the Importation of Beef from Animals Not Treated with Certain Growth-Promoting Hormones and Increased Duties Applied by the United States to Certain Products of the European Union (2014) was signed on 2 August 2019, subject to its conclusion at a later date.
- (2) The Agreement should be approved,

HAS ADOPTED THIS DECISION:

Article 1

The Agreement between the United States of America and the European Union on the Allocation to the United States of a Share in the Tariff Rate Quota for High Quality Beef referred to in the Revised Memorandum of Understanding Regarding the Importation of Beef from Animals Not Treated with Certain Growth-Promoting Hormones and Increased Duties Applied by the United States to Certain Products of the European Union (2014) is hereby approved on behalf of the Union.

The text of the Agreement is attached to this Decision.

⁽¹⁾ Consent of 28 November 2019 (not yet published in the Official Journal).

⁽²⁾ Council Decision (EU) 2019/1316 of 15 July 2019 on the signing, on behalf of the European Union, of the Agreement between the United States of America and the European Union on the Allocation to the United States of a Share in the Tariff Rate Quota for High Quality Beef referred to in the Revised Memorandum of Understanding Regarding the Importation of Beef from Animals Not Treated with Certain Growth-Promoting Hormones and Increased Duties Applied by the United States to Certain Products of the European Union (2014) (OJ L 205, 5.8.2019, p. 10).

Article 2

The President of the Council shall, on behalf of the Union, give the notification provided for in Article 6(5) of the Agreement ⁽³⁾.

Article 3

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

Done at Brussels, 5 December 2019.

For the Council
The President
M. LINTILÄ

⁽³⁾ The date of entry into force of the Agreement will be published in the *Official Journal of the European Union* by the General Secretariat of the Council.

AGREEMENT

between the United States of America and the European Union on the Allocation to the United States of a Share in the Tariff Rate Quota for High Quality Beef referred to in the Revised Memorandum of Understanding Regarding the Importation of Beef from Animals Not Treated with Certain Growth-Promoting Hormones and Increased Duties Applied by the United States to Certain Products of the European Union (2014)

The United States of America and the European Union, the Parties to the Revised Memorandum of Understanding between the United States of America and the European Union Regarding the Importation of Beef from Animals Not Treated with Certain Growth-Promoting Hormones and Increased Duties Applied by the United States to Certain Products of the European Union of 21 October 2013 (hereinafter 'the 2014 MoU'), have agreed as follows:

Article 1

Objectives

The objectives of this Agreement are to:

1. allocate to the United States a share of the autonomous tariff rate quota ("TRQ") for High Quality Beef of 45 000 metric tonnes product weight referred to in Article II.4, Article II.5 and Article VI of the 2014 MoU; and
2. complement or modify certain rights and obligations of the Parties referred to in Articles III, IV, V, VII and VIII of the 2014 MoU.

Article 2

Allocations within the quota

1. The European Union shall allocate to the United States 35 000 metric tonnes of the 45 000 metric tonnes tariff rate quota referred to in Article 1. The remaining quantity of 10 000 metric tonnes shall be made available to all other countries. The allocations shall be phased in over a period of seven years ('the implementation period') as follows:

	United States	All others
Year 1	18 500 metric tonnes	26 500 metric tonnes
Year 2	23 000 metric tonnes	22 000 metric tonnes
Year 3	25 400 metric tonnes	19 600 metric tonnes
Year 4	27 800 metric tonnes	17 200 metric tonnes
Year 5	30 200 metric tonnes	14 800 metric tonnes
Year 6	32 600 metric tonnes	12 400 metric tonnes
Year 7 and subsequent years	35 000 metric tonnes	10 000 metric tonnes

2. For certainty, the core obligations in Article II(1) of the 2014 MOU, including the in-quota tariff rate of zero (0) %, apply to the portion of the TRQ allocated to the United States.
3. The annual volume of the TRQ shall be evenly divided among four quarterly sub-periods. The quota year shall begin on 1 July and end on 30 June.

Should this Agreement enter into force on a date other than 1 July, Year 1 of the implementation period shall start on the first day of the next sub-period of the quota year and shall last for four consecutive sub-periods ⁽¹⁾. Any unused quantities from the sub-periods preceding, in that quota year, the first day of Year 1 shall be added to the quantities available in the first sub-period of Year 1 of the implementation period. These quantities shall be added to the quantities allocated to the United States and to all others in proportion to their shares in the overall volume of the TRQ.

Article 3

Quota management

The share of the TRQ for High Quality Beef allocated to the United States shall be administered by the European Union on a first-come, first-served basis. The European Union shall make every effort to administer the share of the TRQ allocated to the United States in a manner that allows importers to fully utilize it. This Article replaces Article III of the 2014 MoU.

Article 4

EC-Hormones dispute

1. The United States Trade Representative shall conclude the proceeding initiated in December 2016, pursuant to Section 306(c) of the Trade Act of 1974, as amended, with a determination not to reinstate action to exercise the authorization in WT/DS26/21. The United States shall publish its determination no later than on the date of the entry into effect of the country-specific quota allocation specified for Year 1 in Article 2.
2. During the implementation period referred to in Article 2(1), the review period referred to in Article 4(3), and until such time a mutually agreed solution referred to in Article 4(3) is notified:
 - (a) the Parties shall not request the establishment of a panel under Article 21.5 of the WTO Understanding on Rules and Procedures Governing the Settlement of Disputes ('DSU') in '*European Communities – Measures concerning meat and meat products (Hormones)*' (WT/DS26) ('EC — Hormones');
 - (b) the United States shall not suspend the application to the European Union of tariff concessions and related obligations as authorized by the Dispute Settlement Body of the World Trade Organization in EC — Hormones, Recourse by the United States to Article 22.7 of the Dispute Settlement Understanding WT/DS26/21.
3. No later than ten (10) years following the entry into force of this Agreement, the United States and the EU shall meet to review the operation of the TRQ with a view to reaching a mutually agreed solution to be notified to the WTO Dispute Settlement Body in accordance with Article 3.6 of DSU by the end of the review. The review shall be completed no later than 11 years following entry into force of this Agreement. This provision replaces Article IV of the 2014 MoU.
4. Should the Parties fail to jointly notify such a mutually agreed solution to the WTO Dispute Settlement Body within 11 years following the entry into force of this Agreement, either Party may terminate the Agreement in accordance with Article 6.1.

Article 5

On-the-spot checks

The Commission may request the Government of the United States to authorize representatives of the Commission to carry out on-the-spot checks in the United States provided such on-the-spot checks are conducted on a non-discriminatory basis with respect to other country suppliers. Those checks shall be performed jointly with the competent authorities of the United States.

⁽¹⁾ For greater clarity, if this Agreement enters into force at the beginning of sub-period n of a quota year, the volume for Year 1 shall be made available in four consecutive sub-periods, divided evenly between those sub-periods, starting from sub-period n of that quota year, and ending in sub-period n-1 of the subsequent quota year. The volumes from Year 2 onwards shall be made available in four consecutive sub-periods, divided evenly between those sub-periods, starting from sub-period n of the subsequent quota year.

Article 6

Withdrawal and Effects

1. Either Party may withdraw from this Agreement by providing written notice to the other Party. This Agreement shall be terminated six months from the date of receipt of that notice by the other Party. Withdrawal from this Agreement shall not constitute withdrawal from the 2014 MoU unless the Parties expressly declare such an intention.
2. Withdrawal from the 2014 MoU pursuant to its Article V.4 shall entail withdrawal from this Agreement. The Parties shall respect the core obligations listed in Article II of the 2014 MoU during the six-month period from the date when the withdrawal notice referred to in Article V.4 therein was provided.
3. Absent notification to the WTO Dispute Settlement Body of a mutually agreed solution pursuant to Article 4(3), nothing in this Agreement shall be construed as changing the respective rights or obligations of either party under the DSU with respect to EC — *Hormones*.
4. Nothing in this Agreement shall be construed as conferring rights or imposing obligations on persons other than those established between the Parties themselves, nor as permitting that this Agreement be directly invoked before the courts and in the domestic legal systems of the Parties.
5. This Agreement shall enter into force on the first day after the date on which both Parties notified each other of the completion of the internal procedures that are necessary to ensure compliance with obligations of the Parties under Article 2 and Article 4(1).

IN WITNESS WHEREOF the undersigned, being duly authorized by their respective authorities, have signed this Agreement.

DONE at Washington this second day of August in the year two thousand and nineteen, in duplicate in the English language, which is the authentic text of the Agreement.

For the European Union



For the United States of America



REGULATIONS

COMMISSION DELEGATED REGULATION (EU) 2019/2074

of 23 September 2019

supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council as regards rules on specific official controls on consignments of certain animals and goods originating from, and returning to the Union following a refusal of entry by a third country

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) ⁽¹⁾, and in particular Article 77(1)(h) thereof,

WHEREAS:

- (1) In accordance with Regulation (EU) 2017/625, the Commission is required to adopt rules for the performance of specific official controls on consignments of animals and goods referred to in Article 47(1)(a), (b) and (c) thereof, originating from, and returning to the Union following a refusal of entry by a third country.
- (2) Animals and goods originating from, and returning to the Union following a refusal of entry by a third country should be subject to documentary, identity and where appropriate physical checks at the border control post of arrival into the Union to ensure that they fulfil the requirements of Union law. In particular, those checks should ensure that the animals are fit for further transportation to their place of destination and that animal welfare requirements are respected.
- (3) Article 15 of Council Directive 97/78/EC ⁽²⁾ lays down rules concerning the veterinary checks to be conducted for the purposes of authorising the re-importation of consignments of products of Union origin returning to the Union following a refusal of entry by a third country. Regulation (EU) 2017/625 repeals and replaces Directive 97/78/EC with effect from 14 December 2019.
- (4) In order to ensure a high level of protection of animal and public health, the requirements set out in Article 15 of Directive 97/78/EC should be maintained with certain adaptations taking into account the experience gained in the application of the requirements laid down in that Article, and the new legal framework established by Regulation (EU) 2017/625.
- (5) In particular, in order to ensure that there is no risk for the introduction and spread into the Union of animal diseases or pests of plants, the competent authorities of the Member States should ensure that consignments of Union origin returning to the Union comply with the relevant requirements for the re-entry into the Union of such consignments, as laid down in the rules on animal health, on animal by-products, or on plant health, as appropriate.

⁽¹⁾ OJ L 095 7.4.2017, p. 1.

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

- (6) Consignments of products of animal origin and of composite products originating from, and returning to the Union, following a refusal of entry by a third country, may pose a risk to public health. In order to ensure that those consignments comply with the food and food safety rules referred to in Article 1(2)(a) of Regulation (EU) 2017/625, it is appropriate to require that the competent authorities of the border control posts of arrival into the Union should authorise the re-entry of products of animal origin listed in Commission Implementing Regulation (EU) 2019/2007 ⁽³⁾ and of composite products subject to veterinary checks at border control posts pursuant to Commission Decision 2007/275/EC ⁽⁴⁾, provided that those products comply with additional specific requirements.
- (7) It is necessary to ensure that consignments of products of animal origin and composite products originating from, and returning to, the Union following a refusal of entry by a third country arrive at their place of destination. Therefore, the procedural requirements laid down in Commission Delegated Regulation (EU) 2019/1666 ⁽⁵⁾ should apply to monitoring the transport and arrival of consignments of goods, from the border control post of arrival into the Union to the establishment at the place of destination.
- (8) Regulation (EU) 2017/625 applies from 14 December 2019. Accordingly, the rules laid down in this Regulation should also apply from that date,

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter and scope

This Regulation lays down rules for the performance of specific official controls at border control posts on consignments of the categories of animals and goods referred to in Article 47(1)(a), (b) and (c) of Regulation (EU) 2017/625 originating from and returning to the Union following a refusal of entry by a third country.

Article 2

Specific official controls on consignments of animals and goods originating from and returning to the Union following a refusal of entry by a third country

1. The competent authority at the border control post of arrival into the Union shall perform documentary and identity checks on consignments of animals and goods referred to in Article 47(1)(a), (b) and (c) of Regulation (EU) 2017/625 originating from and returning to the Union following a refusal of entry by a third country.
2. The competent authority at the border control post of arrival into the Union shall perform physical checks on the following consignments originating from and returning to the Union following a refusal of entry by a third country:
 - (a) consignments of animals referred to in Article 47(1)(a) of Regulation (EU) 2017/625;
 - (b) consignments of goods referred to in Article 47(1)(b) and (c) of Regulation (EU) 2017/625 where non-compliance of those goods with the rules referred to in Article 1(2) of Regulation (EU) 2017/625 is suspected in order to confirm or eliminate that suspicion.

⁽³⁾ Commission Implementing Regulation (EU) 2019/2007 of 18 November 2019 laying down rules for the application of Regulation (EU) 2017/625 of the European Parliament and of the Council as regards the lists of animals, products of animal origin, germinal products, animal by-products and derived products and hay and straw subject to official controls at border control posts and amending Decision 2007/275/EC (OJ L 312, 3.12.2019, p. 1).

⁽⁴⁾ Commission Decision 2007/275/EC of 17 April 2007 concerning lists of animals and products to be subject to controls at border inspection posts under Council Directives 91/496/EEC and 97/78/EC (OJ L 116, 4.5.2007, p. 9).

⁽⁵⁾ Commission Delegated Regulation (EU) 2019/1666 of 24 June 2019 supplementing Regulation (EU) 2017/625 of European Parliament and the Council as regards conditions for monitoring the transport and arrival of consignments of certain goods from the border control post of arrival to the establishment at the place of the destination in the Union (OJ L 255, 4.10.2019, p. 1).

3. The competent authority at the border control post of arrival into the Union shall verify compliance of consignments of animals and goods with the following requirements:

- (a) for animals referred to in Article 47(1)(a) of Regulation (EU) 2017/625 and for germinal products referred to in Article 47(1)(b) of Regulation (EU) 2017/625, the animal health and welfare requirements, as appropriate, set out in the rules referred to in Article 1(2)(d) and (f) of Regulation (EU) 2017/625;
- (b) for products of animal origin and composite products referred to in Article 47(1)(b) of Regulation (EU) 2017/625:
 - (i) the animal health requirements set out in the rules referred to in Article 1(2)(d) of Regulation (EU) 2017/625;
 - (ii) the additional rules laid down in Article 3 of this Regulation;
- (c) for animal by-products referred to in Article 47(1)(b) of Regulation (EU) 2017/625 and for derived products, the requirements set out in the rules referred to in Article 1(2)(e) of Regulation (EU) 2017/625;
- (d) for plants, plant products, and other objects referred to in Article 47(1)(c) of Regulation (EU) 2017/625, the plant health requirements set out in the rules referred to in Article 1(2)(g) of Regulation (EU) 2017/625.

4. The competent authority at the border control post of arrival into the Union shall inform the competent authority at the place of destination via the information management system for official controls referred to in Article 131 of Regulation (EU) 2017/625 ('IMSOC') of the fact that the consignment has been accepted to enter the Union with a specified place of destination indicated in the Common Health Entry Document (CHED).

Article 3

Additional rules on specific official controls on consignments of products of animal origin and composite products

1. The competent authority at the border control post of arrival into the Union shall authorise the entry into the Union of the following consignments of products originating from and returning to the Union following a refusal of entry by a third country provided that they comply with the requirements set out in paragraph 2:

- (a) products of animal origin listed in the Annex to Implementing Regulation (EU) 2019/2007;
- (b) composite products listed in Chapters 16 to 22 of Annex I to Decision 2007/275/EC that are subject to veterinary checks at border control posts of arrival into the Union in accordance with Article 4 of that Decision.

2. The consignments of products referred to in paragraph 1 shall be accompanied by the following documents:

- (a) the original official certificate issued by the competent authority of the Member State from which the goods originate and were dispatched to a third country ('Member State of origin'), or its electronic equivalent submitted in IMSOC, or an authenticated copy thereof;
- (b) the official declaration of the competent authority or of other public authorities of the third country indicating the reason for the refusal of entry, the place and date of unloading and re-loading in the third country and confirming that:
 - (i) the consignment did not undergo any other handling than unloading, storage and re-loading;
 - (ii) the unloading and re-loading of the products of animal origin and composite products was handled hygienically to avoid cross contamination;
 - (iii) the products of animal origin and composite products were stored under hygienic conditions and at the required temperature for the relevant types of goods;
- (c) the declaration of the competent authority of the place of destination in the Union that they agree to receive the consignment; however, that declaration shall not be required where the consignment returns to the establishment of origin of the consignment which is located in the same Member State as the border control post of arrival into the Union.

3. By way of derogation from paragraph 2(a), where it is not possible to provide the documents referred to in that provision, the origin of the consignment may be authenticated in another way on the basis of documented evidence presented by the operator responsible for the consignment.
4. The competent authority at the border control post of arrival into the Union may grant exemptions from the requirements laid down in paragraph 2(b) for sealed consignments, with an intact origin seal, provided that the operator responsible for the consignment submits a declaration stating the reason for the refusal of entry by the third country and confirming that transport has taken place under conditions appropriate for the relevant type of products of animal origin and composite products.
5. The competent authority at the border control post of arrival shall monitor the transport and arrival at the place of destination of the consignment in accordance with Delegated Regulation (EU) 2019/1666, where the competent authority of the place of destination has issued the declaration referred to in paragraph 2(c).

Article 4

Entry into force and date of application

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 14 December 2019.

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

Done at Brussels, 23 September 2019.

For the Commission
The President
Jean-Claude JUNCKER

COMMISSION REGULATION (EU) 2019/2075

of 29 November 2019

amending Regulation (EC) No 1126/2008 adopting certain international accounting standards in accordance with Regulation (EC) No 1606/2002 of the European Parliament and of the Council as regards International Accounting Standards 1, 8, 34, 37 and 38, International Financial Reporting Standards 2, 3 and 6, Interpretations 12, 19, 20 and 22 of the International Financial Reporting Interpretations Committee and Interpretation 32 of the Standing Interpretations Committee

(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 1606/2002 of the European Parliament and of the Council of 19 July 2002 on the application of international accounting standards ⁽¹⁾, and in particular Article 3(1) thereof,

Whereas:

- (1) By Commission Regulation (EC) No 1126/2008 ⁽²⁾ certain international standards and interpretations that were in existence at 15 October 2008 were adopted.
- (2) On 29 March 2018, the International Accounting Standards Board issued amendments to references in the conceptual framework in International Financial Reporting Standards. The objective of the amendments is to update existing references in several standards and interpretations to previous frameworks with references to the revised conceptual framework.
- (3) The consultations with the European Financial Reporting Advisory Group, confirm that the amendments to International Accounting Standard (IAS) 1 *Presentation of financial statements*, IAS 8 *Accounting policies, changes in accounting estimates and errors*, IAS 34 *Interim financial reporting*, IAS 37 *Provisions, contingent liabilities and contingent assets* and IAS 38 *Intangible assets*, and International Financial Reporting Standard (IFRS) 2 *Share-based payment*, IFRS 3 *Business Combinations* and IFRS 6 *Exploration for and evaluation of mineral resources*, and Interpretation 12 of the International Financial Reporting Interpretations Committee (IFRIC) *Service Concession Arrangements*, IFRIC 19 *Extinguishing Financial Liabilities with Equity Instruments*, IFRIC 20 *Stripping Costs in the Production Phase of a Surface Mine* and IFRIC 22 *Foreign Currency Transactions and Advance Consideration*, and Interpretation 32 of the Standing Interpretations Committee (SIC) *Intangible assets — website costs* meet the criteria for adoption set out in Article 3(2) of Regulation (EC) No 1606/2002.
- (4) Regulation (EC) No 1126/2008 should therefore be amended accordingly.
- (5) The measures provided for in this Regulation are in accordance with the opinion of the Accounting Regulatory Committee,

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Regulation (EC) No 1126/2008 is amended as follows:

- (a) International Accounting Standard (IAS) 1 *Presentation of financial statements* is amended as set out in the Annex to this Regulation;

⁽¹⁾ OJ L 243, 11.9.2002, p. 1.

⁽²⁾ Commission Regulation (EC) No 1126/2008 of 3 November 2008 adopting certain international accounting standards in accordance with Regulation (EC) No 1606/2002 of the European Parliament and of the Council (OJ L 320, 29.11.2008, p. 1).

- (b) IAS 8 *Accounting policies, changes in accounting estimates and errors* is amended as set out in the Annex to this Regulation;
- (c) IAS 34 *Interim financial reporting* is amended as set out in the Annex to this Regulation;
- (d) IAS 37 *Provisions, contingent liabilities and contingent assets* is amended as set out in the Annex to this Regulation;
- (e) IAS 38 *Intangible assets* is amended as set out in the Annex to this Regulation;
- (f) International Financial Reporting Standard (IFRS) 2 *Share-based payment* is amended as set out in the Annex to this Regulation;
- (g) IFRS 3 *Business Combinations* is amended as set out in the Annex to this Regulation;
- (h) IFRS 6 *Exploration for and evaluation of mineral resources* is amended as set out in the Annex to this Regulation;
- (i) Interpretation 12 of the International Financial Reporting Interpretations Committee (IFRIC 12) *Service Concession Arrangements* is amended as set out in the Annex to this Regulation;
- (j) IFRIC 19 *Extinguishing Financial Liabilities with Equity Instruments* is amended as set out in the Annex to this Regulation;
- (k) IFRIC 20 *Stripping Costs in the Production Phase of a Surface Mine* is amended as set out in the Annex to this Regulation;
- (l) IFRIC 22 *Foreign Currency Transactions and Advance Consideration* is amended as set out in the Annex to this Regulation;
- (m) Interpretation 32 of the Standing Interpretations Committee (SIC-32) *Intangible assets — website costs* is amended as set out in the Annex to this Regulation.

Article 2

Each company shall apply the amendments referred to in Article 1, at the latest, as from the commencement date of its first financial year starting on or after 1 January 2020.

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*.

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

Done at Brussels, 29 November 2019.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Amendments to References to the Conceptual Framework in IFRS Standards

Amendments to IFRS Standards

**Amendments to
IFRS 2 *Share-based Payment***

Paragraph 63E is added.

EFFECTIVE DATE

...

63E *Amendments to References to the Conceptual Framework in IFRS Standards*, issued 21 in 2018, amended the footnote to the definition of an equity instrument in Appendix A. An entity shall apply that amendment for annual periods beginning on or after 1 January 2020. Earlier application is permitted if at the same time an entity also applies all other amendments made by *Amendments to References to the Conceptual Framework in IFRS Standards*. An entity shall apply the amendment to IFRS 2 retrospectively, subject to the transitional provisions in paragraphs 53–59 of this Standard, in accordance with IAS 8 *Accounting Policies, Changes in Accounting Estimates and Errors*. However, if an entity determines that retrospective application would be impracticable or would involve undue cost or effort, it shall apply the amendment to IFRS 2 by reference to paragraphs 23–28, 50–53 and 54F of IAS 8.

In Appendix A, the footnote to the definition of an equity instrument is amended.

* The *Conceptual Framework for Financial Reporting* issued in 2018 defines a liability as a present obligation of the entity to transfer an economic resource as a result of past events

**Amendment to
IFRS 3 *Business Combinations***

In paragraph 11, the footnote to 'Framework' is deleted and a footnote to 'Framework for the Preparation and Presentation of Financial Statements' is added. Paragraph 11 has not been otherwise amended but is included for ease of reference.

Recognition conditions

11. To qualify for recognition as part of applying the acquisition method, the identifiable assets acquired and liabilities assumed must meet the definitions of assets and liabilities in the *Framework for the Preparation and Presentation of Financial Statements*[†] at the acquisition date. For example, costs the acquirer expects but is not obliged to incur in the future to effect its plan to exit an activity of an acquiree or to terminate the employment of or relocate an acquiree's employees are not liabilities at the acquisition date. Therefore, the acquirer does not recognise those costs as part of applying the acquisition method. Instead, the acquirer recognises those costs in its post-combination financial statements in accordance with other IFRSs.

† For this Standard, acquirers are required to apply the definitions of an asset and a liability and supporting guidance in the IASC's Framework for the Preparation and Presentation of Financial Statements adopted by the IASB in 2001 rather than the Conceptual Framework for Financial Reporting issued in 2018.

**Amendments to
IFRS 6 *Exploration for and Evaluation of Mineral Resources***

Paragraph 10 is amended, the footnote to 'Framework' in paragraph 10 is deleted and paragraph 26A is added.

Elements of cost of exploration and evaluation assets

...

10. Expenditures related to the development of mineral resources shall not be recognised as exploration and evaluation assets. The *Conceptual Framework for Financial Reporting* and IAS 38 *Intangible Assets* provide guidance on the recognition of assets arising from development.

...

EFFECTIVE DATE

...

- 26A *Amendments to References to the Conceptual Framework in IFRS Standards*, issued in 2018, amended paragraph 10. An entity shall apply that amendment for annual periods beginning on or after 1 January 2020. Earlier application is permitted if at the same time an entity also applies all other amendments made by *Amendments to References to the Conceptual Framework in IFRS Standards*. An entity shall apply the amendment to IFRS 6 retrospectively in accordance with IAS 8 *Accounting Policies, Changes in Accounting Estimates and Errors*. However, if an entity determines that retrospective application would be impracticable or would involve undue cost or effort, it shall apply the amendment to IFRS 6 by reference to paragraphs 23–28, 50–53 and 54F of IAS 8.

Amendments to IAS 1 *Presentation of Financial Statements*

Paragraphs 7, 15, 19–20, 23–24, 28 and 89 are amended and paragraph 139S is added. Four footnotes are deleted—the footnotes to ‘paragraph 25’ in paragraph 7, to the second sentence in paragraph 15, to paragraph 28 and to ‘Framework’s’ in paragraph 89.

DEFINITIONS

7. **The following terms are used in this Standard with the meanings specified:**

...

Material Omissions or misstatements of items are material if they could, individually or collectively, influence the economic decisions that users make on the basis of the financial statements. Materiality depends on the size and nature of the omission or misstatement judged in the surrounding circumstances. The size or nature of the item, or a combination of both, could be the determining factor.

Assessing whether an omission or misstatement could influence economic decisions of users, and so be material, requires consideration of the characteristics of those users. Users are assumed to have a reasonable knowledge of business and economic activities and accounting and a willingness to study the information with reasonable diligence. Therefore, the assessment needs to take into account how users with such attributes could reasonably be expected to be influenced in making economic decisions.

...

Fair presentation and compliance with IFRSs

15. **Financial statements shall present fairly the financial position, financial performance and cash flows of an entity. Fair presentation requires the faithful representation of the effects of transactions, other events and conditions in accordance with the definitions and recognition criteria for assets, liabilities, income and expenses set out in the *Conceptual Framework for Financial Reporting (Conceptual Framework)*. The application of IFRSs, with additional disclosure when necessary, is presumed to result in financial statements that achieve a fair presentation.**
- ...
19. **In the extremely rare circumstances in which management concludes that compliance with a requirement in an IFRS would be so misleading that it would conflict with the objective of financial statements set out in the *Conceptual Framework*, the entity shall depart from that requirement in the manner set out in paragraph 20 if the relevant regulatory framework requires, or otherwise does not prohibit, such a departure.**
20. **When an entity departs from a requirement of an IFRS in accordance with paragraph 19, it shall disclose:**
- (a) **that management has concluded that the financial statements present fairly the entity’s financial position, financial performance and cash flows;**

- (b) **that it has complied with applicable IFRSs, except that it has departed from a particular requirement to achieve a fair presentation;**
- (c) **the title of the IFRS from which the entity has departed, the nature of the departure, including the treatment that the IFRS would require, the reason why that treatment would be so misleading in the circumstances that it would conflict with the objective of financial statements set out in the *Conceptual Framework*, and the treatment adopted; and**
- (d) **for each period presented, the financial effect of the departure on each item in the financial statements that would have been reported in complying with the requirement.**

...

23. **In the extremely rare circumstances in which management concludes that compliance with a requirement in an IFRS would be so misleading that it would conflict with the objective of financial statements set out in the *Conceptual Framework*, but the relevant regulatory framework prohibits departure from the requirement, the entity shall, to the maximum extent possible, reduce the perceived misleading aspects of compliance by disclosing:**

- (a) **the title of the IFRS in question, the nature of the requirement, and the reason why management has concluded that complying with that requirement is so misleading in the circumstances that it conflicts with the objective of financial statements set out in the *Conceptual Framework*; and**
- (b) **for each period presented, the adjustments to each item in the financial statements that management has concluded would be necessary to achieve a fair presentation.**

24. For the purpose of paragraphs 19–23, an item of information would conflict with the objective of financial statements when it does not represent faithfully the transactions, other events and conditions that it either purports to represent or could reasonably be expected to represent and, consequently, it would be likely to influence economic decisions made by users of financial statements. When assessing whether complying with a specific requirement in an IFRS would be so misleading that it would conflict with the objective of financial statements set out in the *Conceptual Framework*, management considers:

- (a) why the objective of financial statements is not achieved in the particular circumstances; and
- (b) how the entity's circumstances differ from those of other entities that comply with the requirement. If other entities in similar circumstances comply with the requirement, there is a rebuttable presumption that the entity's compliance with the requirement would not be so misleading that it would conflict with the objective of financial statements set out in the *Conceptual Framework*.

...

Accrual basis of accounting

...

28. When the accrual basis of accounting is used, an entity recognises items as assets, liabilities, equity, income and expenses (the elements of financial statements) when they satisfy the definitions and recognition criteria for those elements in the *Conceptual Framework*.

...

Profit or loss for the period

...

89. Some IFRSs specify circumstances when an entity recognises particular items outside profit or loss in the current period. IAS 8 specifies two such circumstances: the correction of errors and the effect of changes in accounting policies. Other IFRSs require or permit components of other comprehensive income that meet the *Conceptual Framework's* definition of income or expense to be excluded from profit or loss (see paragraph 7).

...

TRANSITION AND EFFECTIVE DATE

...

- 139S *Amendments to References to the Conceptual Framework in IFRS Standards*, issued in 2018, amended paragraphs 7, 15, 19–20, 23–24, 28 and 89. An entity shall apply those amendments for annual periods beginning on or after 1 January 2020. Earlier application is permitted if at the same time an entity also applies all other amendments made by *Amendments to References to the Conceptual Framework in IFRS Standards*. An entity shall apply the amendments to IAS 1 retrospectively in accordance with IAS 8 *Accounting Policies, Changes in Accounting Estimates and Errors*. However, if an entity determines that retrospective application would be impracticable or would involve undue cost or effort, it shall apply the amendments to IAS 1 by reference to paragraphs 23–28, 50–53 and 54F of IAS 8.

**Amendments to
IAS 8 *Accounting Policies, Changes in Accounting Estimates and Errors***

Paragraphs 6 and 11(b) are amended. The footnotes to ‘paragraph 25’ in paragraph 6 and to paragraph 11(b) are deleted and a new footnote to paragraph 11(b) is added. The heading before paragraph 54 is amended and paragraphs 54F–54G are added.

DEFINITIONS

...

6. Assessing whether an omission or misstatement could influence economic decisions of users, and so be material, requires consideration of the characteristics of those users. Users are assumed to have a reasonable knowledge of business and economic activities and accounting and a willingness to study the information with reasonable diligence. Therefore, the assessment needs to take into account how users with such attributes could reasonably be expected to be influenced in making economic decisions.

...

Selection and application of accounting policies

...

11. **In making the judgement described in paragraph 10, management shall refer to, and consider the applicability of, the following sources in descending order:**
- (a) **the requirements in IFRSs dealing with similar and related issues; and**
 - (b) **the definitions, recognition criteria and measurement concepts for assets, liabilities, income and expenses in the *Conceptual Framework for Financial Reporting (Conceptual Framework)*.**

† Paragraph 54G explains how this requirement is amended for regulatory account balances.

...

EFFECTIVE DATE AND TRANSITION

...

- 54F *Amendments to References to the Conceptual Framework in IFRS Standards*, issued in 2018, amended paragraphs 6 and 11 (b). An entity shall apply those amendments for annual periods beginning on or after 1 January 2020. Earlier application is permitted if at the same time an entity also applies all other amendments made by *Amendments to References to the Conceptual Framework in IFRS Standards*. An entity shall apply the amendments to paragraphs 6 and 11(b) retrospectively in accordance with this Standard. However, if an entity determines that retrospective application would be impracticable or would involve undue cost or effort, it shall apply the amendments to paragraphs 6 and 11(b) by reference to paragraphs 23–28 of this Standard. If retrospective application of any amendment in *Amendments to References to the Conceptual Framework in IFRS Standards* would involve undue cost or effort, an entity shall, in applying paragraphs 23–28 of this Standard, read any reference except in the last sentence of paragraph 27 to ‘is impracticable’ as ‘involves undue cost or effort’ and any reference to ‘practicable’ as ‘possible without undue cost or effort’.

54G If an entity does not apply IFRS 14 *Regulatory Deferral Accounts*, the entity shall, in applying paragraph 11(b) to regulatory account balances, continue to refer to, and consider the applicability of, the definitions, recognition criteria, and measurement concepts in the *Framework for the Preparation and Presentation of Financial Statements** instead of those in the *Conceptual Framework*. A regulatory account balance is the balance of any expense (or income) account that is not recognised as an asset or a liability in accordance with other applicable IFRS Standards but is included, or is expected to be included, by the rate regulator in establishing the rate(s) that can be charged to customers. A rate regulator is an authorised body that is empowered by statute or regulation to establish the rate or a range of rates that bind an entity. The rate regulator may be a third-party body or a related party of the entity, including the entity's own governing board, if that body is required by statute or regulation to set rates both in the interest of the customers and to ensure the overall financial viability of the entity.

* The reference is to the IASC's *Framework for the Preparation and Presentation of Financial Statements* adopted by the Board in 2001.

Amendments to IAS 34 *Interim Financial Reporting*

Paragraphs 31 and 33 are amended and paragraph 58 is added. The footnote to '(the *Framework*),' in paragraph 31 is deleted.

Same accounting policies as annual

...

31. Under the *Conceptual Framework for Financial Reporting* (*Conceptual Framework*), recognition is the process of capturing, for inclusion in the statement of financial position or the statement(s) of financial performance, an item that meets the definition of one of the elements of the financial statements. The definitions of assets, liabilities, income, and expenses are fundamental to recognition, at the end of both annual and interim financial reporting periods.

...

33. An essential characteristic of income (revenue) and expenses is that the related inflows and outflows of assets and liabilities have already taken place. If those inflows or outflows have taken place, the related revenue and expense are recognized; otherwise they are not recognized. The *Conceptual Framework* does not allow the recognition of items in the statement of financial position which do not meet the definition of assets or liabilities.

...

EFFECTIVE DATE

...

58. *Amendments to References to the Conceptual Framework in IFRS Standards*, issued in 2018, amended paragraphs 31 and 33. An entity shall apply those amendments for annual periods beginning on or after 1 January 2020. Earlier application is permitted if at the same time an entity also applies all other amendments made by *Amendments to References to the Conceptual Framework in IFRS Standards*. An entity shall apply the amendments to IAS 34 retrospectively in accordance with IAS 8 *Accounting Policies, Changes in Accounting Estimates and Errors*. However, if an entity determines that retrospective application would be impracticable or would involve undue cost or effort, it shall apply the amendments to IAS 34 by reference to paragraphs 43–45 of this Standard and paragraphs 23–28, 50–53 and 54F of IAS 8.

Amendment to IAS 37 *Provisions, Contingent Liabilities and Contingent Assets*

A footnote is added to the definition of a liability in paragraph 10.

* The definition of a liability in this Standard was not revised following the revision of the definition of a liability in the *Conceptual Framework for Financial Reporting* issued in 2018.

**Amendment to
IAS 38 *Intangible Assets***

A footnote is added to the definition of an asset in paragraph 8.

- * The definition of an asset in this Standard was not revised following the revision of the definition of an asset in the *Conceptual Framework for Financial Reporting* issued in 2018.

**Amendment to
IFRIC 12 *Service Concession Arrangements***

The footnote to 'Framework for the Preparation and Presentation of Financial Statements' in the References section is amended.

- * The reference is to the IASC's *Framework for the Preparation and Presentation of Financial Statements*, adopted by the Board in 2001 and in effect when the Interpretation was developed.

**Amendment to
IFRIC 19 *Extinguishing Financial Liabilities with Equity Instruments***

The footnote to 'Framework for the Preparation and Presentation of Financial Statements' in the References section is amended.

- * The reference is to the IASC's *Framework for the Preparation and Presentation of Financial Statements*, adopted by the Board in 2001 and in effect when the Interpretation was developed.

**Amendment to
IFRIC 20 *Stripping Costs in the Production Phase of a Surface Mine***

A footnote is added to 'Conceptual Framework for Financial Reporting' in the References section.

- * The reference is to the *Conceptual Framework for Financial Reporting*, issued in 2010 and in effect when the Interpretation was developed.

**Amendment to
IFRIC 22 *Foreign Currency Transactions and Advance Consideration***

A footnote is added to 'Conceptual Framework for Financial Reporting' in the References section.

- * The reference is to the *Conceptual Framework for Financial Reporting*, issued in 2010 and in effect when the Interpretation was developed.

**Amendments to
SIC-32 *Intangible Assets—Web Site Costs***

Paragraph 5 is amended and the footnote to the 'Framework' in paragraph 5 is deleted. A new paragraph is added at the end of the section under the heading 'Effective date'.

ISSUE

...

5. This Interpretation does not apply to expenditure on purchasing, developing, and operating hardware (eg web servers, staging servers, production servers and internet connections) of a web site. Such expenditure is accounted for under IAS 16. Additionally, when an entity incurs expenditure on an internet service provider hosting the entity's web site, the expenditure is recognised as an expense under IAS 1.88 and the *Conceptual Framework for Financial Reporting* when the services are received.

...

EFFECTIVE DATE

...

Amendments to References to the Conceptual Framework in IFRS Standards, issued in 2018, amended paragraph 5. An entity shall apply that amendment for annual periods beginning on or after 1 January 2020. Earlier application is permitted if at the same time an entity also applies all other amendments made by *Amendments to References to the Conceptual Framework in IFRS Standards*. An entity shall apply the amendment to SIC-32 retrospectively in accordance with IAS 8 *Accounting Policies, Changes in Accounting Estimates and Errors*. However, if an entity determines that retrospective application would be impracticable or would involve undue cost or effort, it shall apply the amendment to SIC-32 by reference to paragraphs 23–28, 50–53 and 54F of IAS 8.

COMMISSION IMPLEMENTING REGULATION (EU) 2019/2076
of 29 November 2019
granting a Union authorisation for the biocidal product family ‘Contec IPA Product Family’
(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ⁽¹⁾, and in particular the first subparagraph of Article 44(5) thereof,

Whereas:

- (1) On 29 June 2016, Contec Europe, submitted an application in accordance with Article 43(1) of Regulation (EU) No 528/2012 for authorisation of a biocidal product family named ‘Contec IPA Product Family’ of product-types 2 and 4, as described in Annex V to that Regulation, providing written confirmation that the competent authority of United Kingdom had agreed to evaluate the application. The application was recorded under the case number BC-LA025582-58 in the Register for Biocidal Products.
- (2) ‘Contec IPA Product Family’ contains propan-2-ol, as the active substance, which is included in the Union list of approved active substances referred to in Article 9(2) of Regulation (EU) No 528/2012.
- (3) On 22 August 2018, the evaluating competent authority submitted, in accordance with Article 44(1) of Regulation (EU) No 528/2012, an assessment report and the conclusions of its evaluation to the European Chemicals Agency (‘the Agency’).
- (4) On 25 March 2019, the Agency submitted to the Commission an opinion ⁽²⁾, including the proposed terms and conditions of the authorisation, the draft summary of the biocidal product characteristics (‘SPC’) of ‘Contec IPA Product Family’ and the final assessment report on the biocidal product family in accordance with Article 44(3) of Regulation (EU) No 528/2012.
- (5) The opinion concludes that ‘Contec IPA Product Family’ is a ‘biocidal product family’ within the meaning of Article 3 (1)(s) of Regulation (EU) No 528/2012, that it is eligible for Union authorisation in accordance with Article 42(1) of that Regulation and that subject to compliance with the proposed terms and conditions and the draft SPC, it meets the conditions laid down in Article 19(1) and (6) of that Regulation.
- (6) On 28 May 2019, the Agency transmitted to the Commission the draft SPC in all the official languages of the Union in accordance with Article 44(4) of Regulation (EU) No 528/2012.
- (7) The Commission concurs with the opinion of the Agency and considers it therefore appropriate to grant a Union authorisation for ‘Contec IPA Product Family’.
- (8) In the opinion the Agency also recommends that a long-term storage test at ambient temperature for wipes in their commercial packaging be conducted by the authorisation holder as a condition in the authorisation. The Commission agrees with that recommendation and considers that the submission of this test should be a condition relating to the making available on the market and use of the biocidal product family pursuant to Article 22(1) of Regulation (EU) No 528/2012. The Commission also considers that the fact that data is to be provided after the authorisation is granted does not affect the conclusion on the fulfilment of the condition under Article 19(1)(d) of that Regulation on the basis of the existing data.
- (9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

⁽²⁾ ECHA opinion of 28 February 2019 on the Union authorisation of ‘Contec IPA Product Family’ (ECHA/BPC/221/2019).

HAS ADOPTED THIS REGULATION:

Article 1

A Union authorisation with authorisation number EU-0020460-0000 is granted to Contec Europe for the making available on the market and use of the biocidal product family 'Contec IPA Product Family', subject to compliance with the terms and conditions set out in Annex I and in accordance with the summary of the biocidal product characteristics set out in Annex II.

The Union authorisation is valid from 26 December 2019 until 30 November 2029.

Article 2

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

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

Done at Brussels, 29 November 2019.

For the Commission
The President
Jean-Claude JUNCKER

*ANNEX I***TERMS AND CONDITIONS (EU-0020460-0000)**

The authorisation holder shall conduct a long-term storage test at ambient temperature for wipes in their commercial packaging.

By 31 July 2021 the authorisation holder shall submit the results of the test to the Agency.

ANNEX II

Summary of product characteristics for a biocidal product family

Contec IPA Product Family

Product type 2 — Disinfectants and algacides not intended for direct application to humans or animals (Disinfectants)

Product type 4 — Food and feed area (Disinfectants)

Authorisation number: EU-0020460-0000

R4BP asset number: EU-0020460-0000

PART I

FIRST INFORMATION LEVEL

1. ADMINISTRATIVE INFORMATION

1.1. **Family name**

Name	Contec IPA Product Family
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1.2. **Product type(s)**

Product type(s)	PT02 — Disinfectants and algacides not intended for direct application to humans or animals (Disinfectants) PT04 — Food and feed area (Disinfectants)
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1.3. **Authorisation holder**

Name and address of the authorisation holder	Name	Contec Europe
	Address	Zl Du Prat, Avenue Paul Duplaix, 56000, Vannes, France
Authorisation number	EU-0020460-0000	
R4BP asset number	EU-0020460-0000	
Date of the authorisation	26 December 2019	
Expiry date of the authorisation	30 November 2029	

1.4. **Manufacturer(s) of the biocidal products**

Name of manufacturer	Contec Inc.
Address of manufacturer	525 Locust Grove, SC 29303 Spartanburg United States
Location of manufacturing sites	525 Locust Grove, SC 29303 Spartanburg United States
Name of manufacturer	Contec Cleanroom Technology (Suzhou) Co., Ltd. China
Address of manufacturer	17 Longyun Road, Suzhou Industrial Park, 215024 Suzhou China
Location of manufacturing sites	17 Longyun Road, Suzhou Industrial Park, 215024 Suzhou China

Name of manufacturer	Contec Cleanroom (UK) Ltd
Address of manufacturer	Unit 6A, Wansbeck Business Park, Rotary Parkway, NE6 3 8QW Ashington, Northumberland United Kingdom
Location of manufacturing sites	Unit 6A, Wansbeck Business Park, Rotary Parkway, NE6 3 8QW Ashington, Northumberland United Kingdom

Name of manufacturer	Flexible Medical Packaging
Address of manufacturer	Unit 8 Hightown, White Cross Industrial Estate, LA1 4XS Lancaster, Lancashire United Kingdom
Location of manufacturing sites	Unit 8 Hightown, White Cross Industrial Estate, LA1 4XS Lancaster, Lancashire United Kingdom

1.5. Manufacturer(s) of the active substance(s)

Active substance	Propan-2-ol
Name of manufacturer	Brenntag GmbH
Address of manufacturer	Messeallee 11, 45131 Essen, Germany
Location of manufacturing sites	Haven 3222, Vondelingenweg 601, 3196 KK Vondelingenplaat Netherlands

2. PRODUCT FAMILY COMPOSITION AND FORMULATION

2.1. Qualitative and quantitative information on the composition of the family

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Propan-2-ol		Active Sub-stance	67-63-0	200-661-7	62,9	62,9

2.2. Type(s) of formulation

Formulation(s)	AL (any other liquid) - RTU solution/trigger spray AL (any other liquid) – RTU wipe
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PART II

SECOND INFORMATION LEVEL — META SPC(S)

META SPC 1

1. META SPC 1 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 1 identifier

Identifier	Contec IPA Liquid Products
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1.2. Suffix to the authorisation number

Number	1-1
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1.3. **Product type(s)**

Product type(s)	PT02 — Disinfectants and algacides not intended for direct application to humans or animals (Disinfectants) PT04 — Food and feed area (Disinfectants)
-----------------	--

2. META SPC 1 COMPOSITION

2.1. **Qualitative and quantitative information on the composition of the meta SPC 1**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Propan-2-ol		Active Sub-stance	67-63-0	200-661-7	62,9	62,9

2.2. **Type(s) of formulation of the meta SPC 1**

Formulation(s)	AL (any other liquid) - RTU solution/trigger spray
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 1

Hazard statements	Highly flammable liquid and vapour. Causes serious eye irritation. May cause drowsiness or dizziness. Repeated exposure may cause skin dryness or cracking.
Precautionary statements	If medical advice is needed, have product container or label at hand. Keep out of reach of children. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Keep container tightly closed. Avoid breathing vapours. Wash hands thoroughly after handling. Use only outdoors or in a well-ventilated area. Wear eye protection. IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water. IF INHALED: Remove person to fresh air and keep comfortable for breathing. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Call a Poison centre if you feel unwell. If eye irritation persists: Get medical advice. In case of fire: Use alcohol resistant foam to extinguish. Store in a well-ventilated place. Keep cool. Store locked up. Dispose of contents/container in accordance with local regulations.

4. AUTHORISED USE(S) OF THE META SPC 1

4.1. Use description

Table 1

Use # 1 – Professional use

Product type	PT02 — Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants) PT04 — Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	
Target organism(s) (including development stage)	Bacteria Mycobacteria Yeasts
Field(s) of use	Indoor Disinfectant for use against bacteria, mycobacteria and yeast on hard, non-porous surfaces in cleanrooms for biotechnology, pharmaceutical, manufacture of medical devices, healthcare industries and other critical life science applications, and in industrial food and feed preparation areas. Acceptable use temperature: room temperature (20 ± 2 °C)
Application method(s)	Spraying and wiping
Application rate(s) and frequency	50 ml product per m ² of surface. Wiping: 1 minute contact time for bacteria and mycobacteria 3 minutes contact time for yeast
Category(ies) of users	Professional
Pack sizes and packaging material	High-density polyethylene (HDPE) trigger spray bottle – 0,5 L – 1 L HDPE capped refill bottle – 5 L

4.1.1. Use-specific instructions for use

See general directions for use

4.1.2. Use-specific risk mitigation measures

See general directions for use

4.1.3. Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See general directions for use

4.1.4. Where specific to the use, the instructions for safe disposal of the product and its packaging

See general directions for use

4.1.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See general directions for use

5. GENERAL DIRECTIONS FOR USE ⁽¹⁾ OF THE META SPC 1

5.1. **Instructions for use**

Use at room temperature. For visibly soiled surfaces, cleaning prior to disinfection is required.

Wiping: Apply/Spray product to a suitable quality cleanroom wipe. Ensure the wipe is sufficiently and uniformly saturated before wiping the surface to be disinfected.

Ensure the surface is uniformly covered with the product then wipe to dry with a sterile cleanroom wipe.

Contact times: Wiping 1 minute for bacteria and mycobacteria 3 minutes for yeast.

Used wipes must be disposed of in a closed container.

5.2. **Risk mitigation measures**

Wash hands and exposed skin before meals and after use.

Avoid contact with eyes

'For use in cleanrooms, adequate technical/engineering controls to remove airborne residues is mandatory e.g. room ventilation or LEV'

5.3. **Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment**

Likely direct or indirect adverse effects:

Headache, vertigo, hallucinations, respiratory depression, CNS depression or coma.

Severe irritation of the eyes and or ocular damage.

Nausea, vomiting, diarrhoea and haemorrhagic gastritis.

Pulmonary aspiration hazard may induce pneumonitis, hypotension and hypoglycemia.

First aid measures:

Relocate the individual from the exposure source and remove any contaminated/spattered clothing articles.

Eye contact: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention

Skin contact; wash affected area with plenty of water and soap. No scrubbing.

In case of ingestion: Do NOT induce vomiting and never give anything by mouth to an impaired or unconscious individual; if the individual is unconscious place individual in left sideways (recovery) position with the head lowered and the knees bent.

Keep the individual calm and at rest, conserve body temperature and control breathing. If necessary check for pulse and initiate artificial respiration.

Take the individual to a healthcare centre and bring packaging or label whenever possible.

NEVER LEAVE THE AFFECTED INDIVIDUAL UNATTENDED!

Advice for medical and healthcare personnel:

Monitor vital signs and provide symptomatic and supportive treatment.

Evaluate endoscopic procedure in case of ingestion.

Monitor glycaemia and ketones.

Ipecac use is contraindicated.

WHEN ASKING FOR MEDICAL ADVICE KEEP PACKAGING OR LABEL AT HAND AND CALL YOUR LOCAL POISON CONTROL CENTRE [INSERT LOCAL NUMBER HERE].

5.4. **Instructions for safe disposal of the product and its packaging**

Dispose of contents/container in accordance with local regulations.

Do not re-use empty container for any other purpose.

⁽¹⁾ Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 1.

5.5. Conditions of storage and shelf-life of the product under normal conditions of storage

Store in a cool, dry, well-ventilated place in original container.

Keep away from sources of ignition.

Keep away from direct sunlight.

Keep container tightly closed.

Shelf-life: 2 years

6. OTHER INFORMATION

The product contains propan-2-ol (CAS No: 67-63-0), for which an European reference value of 129,28 mg/m³ for the professional user was agreed and used for the risk assessment of the product.

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 1

7.1. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	Contec 70 % IPA FBC570I Contec Sterile 70 % IPA SBT170IW Contec Sterile 70 % IPA SBT0570IW Contec 70 % IPA FBT170I				
Authorisation number	EU-0020460-0001 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Sub-stance	67-63-0	200-661-7	62,9

META SPC 2

1. META SPC 2 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 2 identifier

Identifier	Contec IPA Wipes
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1.2. Suffix to the authorisation number

Number	1-2
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1.3. Product type(s)

Product type(s)	PT02 — Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants) PT04 — Food and feed area (Disinfectants)
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2. META SPC 2 COMPOSITION

2.1. Qualitative and quantitative information on the composition of the meta SPC 2

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Propan-2-ol		Active Substance	67-63-0	200-661-7	62,9	62,9

2.2. **Type(s) of formulation of the meta SPC 2**

Formulation(s)	AL (any other liquid) – RTU wipe
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 2

Hazard statements	Highly flammable liquid and vapour. Causes serious eye irritation. May cause drowsiness or dizziness. Repeated exposure may cause skin dryness or cracking.
Precautionary statements	If medical advice is needed, have product container or label at hand. Keep out of reach of children. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Keep container tightly closed. Avoid breathing vapours. Wash hands thoroughly after handling. Use only outdoors or in a well-ventilated area. Wear eye protection. IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water. IF INHALED: Remove person to fresh air and keep comfortable for breathing. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Call a POISON CENTRE if you feel unwell. If eye irritation persists: Get medical advice. In case of fire: Use alcohol resistant foam to extinguish. Store in a well-ventilated place. Keep cool. Store locked up. Dispose of contents/container in accordance with local regulations.

4. AUTHORISED USE(S) OF THE META SPC 2

4.1. **Use description**

Table 2

Use # 1 – Professional use

Product type	PT02 — Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants) PT04 — Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Bacteria Mycobacteria Yeasts
Field(s) of use	Indoor Disinfectant for use against bacteria, mycobacteria and yeast on hard, non-porous surfaces in cleanrooms for biotechnology, pharmaceutical, manufacture of medical devices, healthcare industries and other critical life science applications, and in industrial food and feed preparation areas.

	Acceptable use temperature: room temperature (20±2 °C)
Application method(s)	Wiping
Application rate(s) and frequency	1 minute contact time for bacteria and mycobacteria 3 minutes contact time for yeast
Category(ies) of users	Professional
Pack sizes and packaging material	Impregnated 100 % polypropylene wipes in: — HDPE canister with HDPE cap – 1 50 wipes (1,7 L or 2,15 L) — Polyethylene terephthalate (PET)/polyethylene (PE) packet sealed with PET/PE flow wrap – 30, 40 or 50 wipes Impregnated 100 % polyester wipes in: — HDPE canister with HDPE cap – 100 wipes (2,25 L) — PET/PE packet sealed with PET/PE flow wrap – 20 wipes Impregnated 100 % knitted polyester wipes in: — PET/PE packet sealed with PET/PE flow wrap – 8, 10, 20, 30 or 50 wipes Impregnated 55 % cellulose/45 % polyester wipes in: — HDPE canister with HDPE cap – 100 wipes (2,25 L) — PET/PE packet sealed with PET/PE flow wrap – 24, 30, 50 or 75 wipes Impregnated 50 % rayon/50 % polyester wipes in: — HDPE canister with HDPE cap – 700 wipes (11,4 L)

4.1.1. *Use-specific instructions for use*

See general directions for use

4.1.2. *Use-specific risk mitigation measures*

See general directions for use

4.1.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use

4.1.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use

4.1.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use

5. GENERAL DIRECTIONS FOR USE ^(*) OF THE META SPC 2

5.1. **Instructions for use**

For soiled surfaces, cleaning prior to disinfection is required.

Ensure the surface is uniformly covered with the product, allow to act for a contact time of 1 minute for bactericidal and mycobactericidal action and 3 minutes for yeasticidal action

5.2. **Risk mitigation measures**

Wash hands and exposed skin before meals and after use.

Avoid contact with eyes

'For use in cleanrooms, adequate technical/engineering controls to remove airborne residues is mandatory e.g. room ventilation or LEV'

^(*) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 2.

5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

Likely direct or indirect adverse effects:

Headache, vertigo, hallucinations, respiratory depression, CNS depression or coma.

Severe irritation of the eyes and or ocular damage.

Nausea, vomiting, diarrhoea and haemorrhagic gastritis.

Pulmonary aspiration hazard may induce pneumonitis, hypotension and hypoglycemia.

First aid measures:

Relocate the individual from the exposure source and remove any contaminated/spattered clothing articles.

Eye contact: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention

Skin contact; wash affected area with plenty of water and soap, No scrubbing.

In case of ingestion; Do NOT induce vomiting and never give anything by mouth to an impaired or unconscious individual; if the individual is unconscious place individual in left sideways (recovery) position with the head lowered and the knees bent.

Keep the individual calm and at rest, conserve body temperature and control breathing. If necessary check for pulse and initiate artificial respiration.

Take the individual to a healthcare centre and bring packaging or label whenever possible.

NEVER LEAVE THE AFFECTED INDIVIDUAL UNATTENDED!

Advice for medical and healthcare personnel:

Monitor vital signs and provide symptomatic and supportive treatment.

Evaluate endoscopic procedure in case of ingestion.

Monitor glycaemia and ketones.

Ipecac use is contraindicated.

WHEN ASKING FOR MEDICAL ADVICE KEEP PACKAGING OR LABEL AT HAND AND CALL YOUR LOCAL POISON CONTROL CENTRE [INSERT LOCAL NUMBER HERE].

5.4. Instructions for safe disposal of the product and its packaging

Dispose of contents/container in accordance with local regulations.

Do not re-use empty container for any other purpose.

Used wipes must be disposed in a closed container

Dispose of used wipes by dry waste to landfill

5.5. Conditions of storage and shelf-life of the product under normal conditions of storage

Store in a cool, dry, well-ventilated place in original container.

Keep away from sources of ignition.

Keep away from direct sunlight.

Keep container tightly closed.

Shelf-life: 2 years

6. OTHER INFORMATION

Polypropylene, polyester, kitted polyester, 55 % cellulose/45 % polyester or 50 % rayon/50 % polyester wipes, 34-240 gsm, containing 5 - 38 ml product (2,75 – 20,9 g propan-2-ol)

The product contains propan-2-ol (CAS No: 67-63-0), for which an European reference value of 129,28 mg/m³ for the professional user was agreed and used for the risk assessment of the product.

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 2

7.1. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	PROSAT MBPP PS-840IR PROSAT MBPP PS-911 PROSAT MBPP PS-911EB PROSAT MBPP PS-LPP-7030 PROSAT MBPP PS-LPP-7030IR PROSAT MBPP PSPP0039 PROSAT MBPP PSPP0043 SATWipes MBPP SWPP0003 PROSAT Delta PS-7030IR SATWipes nonwoven polyester SAT-C3-7030 Spec-Wipe 4 115-0039 PROSAT Polynit Heatseal PS-HS9-7030 PROSAT EasyReach PSME0001 PROSAT Polynit Heatseal PPS0047 PROSAT Polynit Heatseal PPS0076 PROSAT Polynit Heatseal PPS0091 PROSAT Polynit Heatseal PSWE0001 PROSAT Polynit Heatseal PSWE0002 PROSAT Polynit Heatseal PSWE0003 Spec-Wipe 3 115-0034 PROSAT Sigma PSC20001 PROSAT Sigma PSC20002 PROSAT Theta PSC20005 PROSAT Theta PSC20006 PROSAT Theta PSC20009 PROSAT Theta PSC20010 PROSAT Theta PSCP0001 PROSAT Theta PSCS1010 PROSAT Theta PSCS1010IR SATWipes polyester/cellulose SAT-C1-7030 SATWipes presaturated wipes SWNW0013				
Authorisation number	EU-0020460-0002 1-2				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Sub-stance	67-63-0	200-661-7	62,9

DECISIONS

POLITICAL AND SECURITY COMMITTEE DECISION (CFSP) 2019/2077

of 28 November 2019

extending the mandate of the Head of Mission of the European Union Integrated Border Management Assistance Mission in Libya (EUBAM Libya) (EUBAM Libya/1/2019)

THE POLITICAL AND SECURITY COMMITTEE,

Having regard to the Treaty on European Union, and in particular the third paragraph of Article 38 thereof,

Having regard to the Council Decision 2013/233/CFSP of 22 May 2013 on the European Union Integrated Border Management Assistance Mission in Libya (EUBAM Libya) ⁽¹⁾, and in particular Article 9(1) thereof,

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

Whereas:

- (1) Pursuant to Article 9(1) of Decision 2013/233/CFSP, the Political and Security Committee (PSC) is authorised, in accordance with Article 38 of the Treaty, to take the relevant decisions for the purpose of exercising political control and strategic direction of EUBAM Libya, including the decision to appoint a Head of Mission.
- (2) On 30 August 2016, the PSC adopted Decision (CFSP) 2016/1634 ⁽²⁾, appointing Mr Vincenzo TAGLIAFERRI as Head of Mission of EUBAM Libya from 1 September 2016 to 21 August 2017.
- (3) The mandate of Mr Vincenzo TAGLIAFERRI as Head of Mission of EUBAM Libya has been regularly extended, most recently by the adoption by the PSC of Decision (CFSP) 2018/2061 ⁽³⁾, extending the mandate of Mr Vincenzo TAGLIAFERRI as Head of Mission of EUBAM Libya until 31 December 2019.
- (4) On 17 December 2018, the Council adopted Decision (CFSP) 2018/2009 ⁽⁴⁾, amending and extending Decision 2013/233/CFSP until 30 June 2020.
- (5) The High Representative of the Union for Foreign Affairs and Security Policy has proposed to extend the mandate of Mr Vincenzo TAGLIAFERRI as Head of Mission of EUBAM Libya from 1 January 2020 to 30 June 2020,

HAS ADOPTED THIS DECISION:

Article 1

The mandate of Mr Vincenzo TAGLIAFERRI as Head of Mission of EUBAM Libya is hereby extended until 30 June 2020.

⁽¹⁾ OJ L 138, 24.5.2013, p. 15.

⁽²⁾ Political and Security Committee Decision (CFSP) 2016/1634 of 30 August 2016 on the appointment of the Head of Mission of the European Union Integrated Border Management Assistance Mission in Libya (EUBAM Libya) (EUBAM Libya/1/2016) (OJ L 243, 10.9.2016, p. 10).

⁽³⁾ Political and Security Committee Decision (CFSP) 2018/2061 of 18 December 2018 extending the mandate of the Head of Mission of the European Union Integrated Border Management Assistance Mission in Libya (EUBAM Libya) (EUBAM Libya/2/2018) (OJ L 329, 27.12.2018, p. 22).

⁽⁴⁾ Council Decision (CFSP) 2018/2009 of 17 December 2018 amending and extending Decision 2013/233/CFSP on the European Union Integrated Border Assistance Mission in Libya (EUBAM Libya) (OJ L 322, 18.12.2018, p. 25).

Article 2

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

It shall apply from 1 January 2020.

Done at Brussels, 28 November 2019.

For the Political and Security Committee
The Chairperson
S. FROM-EMMESBERGER

COUNCIL DECISION (EU, Euratom) 2019/2078**of 2 December 2019****appointing a member, proposed by the Federal Republic of Germany, of the European Economic and Social Committee**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 302 thereof,

Having regard to the Treaty establishing the European Atomic Energy Community, and in particular Article 106a thereof,

Having regard to the proposal of the German Government,

Having regard to the opinion of the European Commission,

Whereas:

- (1) On 18 September 2015 and 1 October 2015, the Council adopted Decisions (EU, Euratom) 2015/1600 ⁽¹⁾ and (EU, Euratom) 2015/1790 ⁽²⁾ appointing the members of the European Economic and Social Committee for the period from 21 September 2015 to 20 September 2020.
- (2) A member's seat on the European Economic and Social Committee has become vacant following the end of the term of office of Mr Günter LAMBERTZ,

HAS ADOPTED THIS DECISION:

Article 1

Ms Freya LEMCKE, *Managing Director DIHK Brussels*, is hereby appointed as a member of the European Economic and Social Committee for the remainder of the current term of office, which runs until 20 September 2020.

Article 2

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

Done at Brussels, 2 December 2019.

For the Council
The President
M. OHISALO

⁽¹⁾ Council Decision (EU, Euratom) 2015/1600 of 18 September 2015 appointing the members of the European Economic and Social Committee for the period from 21 September 2015 to 20 September 2020 (OJ L 248, 24.9.2015, p. 53).

⁽²⁾ Council Decision (EU, Euratom) 2015/1790 of 1 October 2015 appointing the members of the European Economic and Social Committee for the period from 21 September 2015 to 20 September 2020 (OJ L 260, 7.10.2015, p. 23).

COMMISSION IMPLEMENTING DECISION (EU) 2019/2079**of 27 November 2019****determining quantitative limits and allocating quotas for substances controlled under Regulation (EC) No 1005/2009 of the European Parliament and of the Council on substances that deplete the ozone layer, for the period 1 January to 31 December 2020***(notified under document C(2019) 8535)***(Only the Croatian, Czech, Dutch, English, French, German, Greek, Hungarian, Italian, Latvian, Maltese, Polish, Portuguese and Spanish texts are authentic)**

THE EUROPEAN COMMISSION,

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

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

Whereas:

- (1) The release for free circulation in the Union of imported controlled substances is subject to quantitative limits.
- (2) The Commission is required to determine those limits and allocate quotas to undertakings.
- (3) Furthermore, the Commission is required to determine the quantities of controlled substances other than hydrochlorofluorocarbons that may be used for essential laboratory and analytical uses, and the undertakings that may use them.
- (4) The determination of the allocated quotas for essential laboratory and analytical uses has to ensure that the quantitative limits set out in Article 10(6) of Regulation (EC) No 1005/2009 are respected, applying Commission Regulation (EU) No 537/2011 ⁽²⁾. As those quantitative limits include quantities of hydrochlorofluorocarbons licensed for laboratory and analytical uses, the production and import of hydrochlorofluorocarbons for those uses should also be covered by that allocation.
- (5) The Commission has published a notice to undertakings intending to import or export controlled substances that deplete the ozone layer to or from the European Union in 2020 and to undertakings intending to produce or import these substances for laboratory and analytical uses in 2020 ⁽³⁾, and has thereby received declarations on intended imports in 2020.
- (6) The quantitative limits and quotas should be determined for the period 1 January to 31 December 2020, in line with the annual reporting cycle under the Montreal Protocol on Substances that Deplete the Ozone Layer.
- (7) The measures provided for in this Decision are in accordance with the opinion of the Committee established by Article 25(1) of Regulation (EC) No 1005/2009,

⁽¹⁾ OJ L 286, 31.10.2009, p. 1.

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

⁽³⁾ OJ C 143, 24.4.2019, p. 4.

HAS ADOPTED THIS DECISION:

Article 1

Quantitative limits for release for free circulation

The quantities of controlled substances subject to Regulation (EC) No 1005/2009 which may be released for free circulation in the Union in 2020 from sources outside the Union shall be the followings:

Controlled substances	Quantity (in ozone depleting potential (ODP) kilograms)
Group I (chlorofluorocarbons 11, 12, 113, 114 and 115) and group II (other fully halogenated chlorofluorocarbons)	1 910 550,00
Group III (halons)	23 800 100,00
Group IV (carbon tetrachloride)	22 330 671,00
Group V (1,1,1-trichloroethane)	2 500 000,00
Group VI (methyl bromide)	510 912,00
Group VII (hydrobromofluorocarbons)	4 852,40
Group VIII (hydrochlorofluorocarbons)	5 358 037,25
Group IX (bromochloromethane)	324 024,00

Article 2

Allocation of quotas for release for free circulation

1. The allocation of quotas for chlorofluorocarbons 11, 12, 113, 114 and 115 and other fully halogenated chlorofluorocarbons during the period 1 January to 31 December 2020 shall be for the purposes and to the undertakings indicated in Annex I.
2. The allocation of quotas for halons during the period 1 January to 31 December 2020 shall be for the purposes and to the undertakings indicated in Annex II.
3. The allocation of quotas for carbon tetrachloride during the period 1 January to 31 December 2020 shall be for the purposes and to the undertakings indicated in Annex III.
4. The allocation of quotas for 1,1,1-trichloroethane during the period 1 January to 31 December 2020 shall be for the purposes and to the undertakings indicated in Annex IV.
5. The allocation of quotas for methyl bromide during the period 1 January to 31 December 2020 shall be for the purposes and to the undertakings indicated in Annex V.
6. The allocation of quotas for hydrobromofluorocarbons during the period 1 January to 31 December 2020 shall be for the purposes and to the undertakings indicated in Annex VI.
7. The allocation of quotas for hydrochlorofluorocarbons during the period 1 January to 31 December 2020 shall be for the purposes and to the undertakings indicated in Annex VII.
8. The allocation of quotas for bromochloromethane during the period 1 January to 31 December 2020 shall be for the purposes and to the undertakings indicated in Annex VIII.
9. The individual quotas for undertakings shall be as set out in Annex IX.

Article 3

Quotas for laboratory and analytical uses

The quotas for importing and producing controlled substances for laboratory and analytical uses in the year 2020 shall be allocated to the undertakings listed in Annex X.

The maximum quantities that may be produced or imported in 2020 for laboratory and analytical uses allocated to those undertakings are set out in Annex XI.

Article 4

Period of validity

This Decision shall apply from 1 January 2020 and shall expire on 31 December 2020.

Article 5

Addressees

This Decision is addressed to the following undertakings:

1	A-Gas (UK) Ltd Banyard road BS20 7XH Bristol United Kingdom	2	Abcr GmbH Im Schleht 10 76187 Karlsruhe Germany
3	AGC Chemicals Europe, Ltd. York House, Hillhouse International FY5 4QD Thornton Cleveleys United Kingdom	4	Albemarle Europe SPRL Parc Scientifique Einstein, Rue du Bosquet 9 1348 Louvain-la-Neuve Belgium
5	Arkema France Rue Estienne d'Orves 420 92705 COLOMBES Cedex France	6	Ateliers Bigata SASU Rue Jean-Baptiste Perrin 10 33320 Eysines France
7	Avocado Research Chemicals Limited Shore Road LA3 2XY Lancaster United Kingdom	8	BASF Agri-Production S.A.S. Rue de Verdun 32 76410 Saint-Aubin Les Elbeuf France
9	Bayer AG Alfred-Nobel-Str. 50 40789 Monheim Germany	10	BDL Czech Republic s.r.o. Náměstí Českého ráje 2 51101 Turnov Czech Republic
11	Biovit d.o.o. Varazdinska ulica — Odvojak II 15 HR-42000 Varazdin Croatia	12	Blue Cube Germany Assets GmbH & Co. KG Buetzflether Sand 2 21683 Stade Germany
13	Butterworth Laboratories Ltd Waldegrave Road 54-56 TW118NY LONDON United Kingdom	14	Ceram Optec SIA Skanstes street 7 K-1 LV-1013 Riga Latvia
15	Chemours Netherlands B.V. Baanhoekweg 22 3313LA Dordrecht Netherlands	16	Daikin Refrigerants Europe GmbH Industriepark Höchst 65926 Frankfurt am Main Germany
17	Dyneon GmbH Industrieparkstr. 1 84508 Burgkirchen Germany	18	EAF protect s.r.o. Karlovarská 131/50 35002 Cheb 2 Czech Republic

19	ESTO Cheb s.r.o. Palackého 2087/8A 35002 Cheb Czech Republic	20	Fire Fighting Enterprises Ltd Hunting Gate 9 SG4 0TJ Hitchin United Kingdom
21	Gedeon Richter Plc. Gyömrői út 19-21. H-1103 Budapest Hungary	22	GHC Gerling, Holz & Co. Handels GmbH Ruhrstr. 113 22761 Hamburg Germany
23	Gielle Industries di Luigi Galantucci Via Ferri ROCCO 32 70022 ALTAMURA Italy	24	GlaxoSmithKline Cobden Street DD10 8EA Montrose United Kingdom
25	Halon & Refrigerant Services Ltd J Reid Trading Estate, Factory Road CH5 2QJ Sandycroft United Kingdom	26	Honeywell Speciality Chemicals Seelze GmbH Wunstorfer Str. 40 30926 Seelze Germany
27	Hovione FarmaCiencia SA Quinta de S. Pedro — Sete Casas 2674-506 Loures Portugal	28	Hudson Technologies Europe S.r.l. Via degli Olmetti 39/E 00060 Formello Italy
29	ICL Europe Cooperatief U.A. Koningin Wilhelminaplein 30 1062 KR Amsterdam Netherlands	30	Intergeo LTD Industrial Park of Thermi 57001 Thessaloniki Greece
31	Labmix24 GmbH Industriestr. 18A 46499 Hamminkeln Germany	32	Laboratorios Miret S.A. Geminis 4 08228 Terrassa Spain
33	LGC Standards GmbH Mercatorstr. 51 46485 Wesel Germany	34	Ludwig-Maximilians-University Butenadtstr. 5-13 (Haus D) DE-81377 Munich Germany
35	Mebrom NV Antwerpsesteenweg 45 2830 Willebroek Belgium	36	Merck KGaA Frankfurter Strasse 250 64293 Darmstadt Germany
37	Meridian Technical Services Limited Hailey Road 14 DA18 4AP Erith United Kingdom	38	Mexichem UK Limited The Heath Business and Technical Park WA7 4QX Runcorn, Cheshire United Kingdom
39	Neochema GmbH Am Kümmerling 37A 55294 Bodenheim Germany	40	P.U. Poz-Pliszka Sp. z o.o. Mialki Szlak 52 80-717 Gdansk Poland
41	Philipps-Universität Marburg Biegenstrasse 10 35032 Marburg Germany	42	R.P. Chem s.r.l. Via San Michele 47 31032 Casale sul Sile (TV) Italy
43	Restek GmbH Schaberweg 23 D-61348 Bad Homburg Germany	44	Safety Hi-Tech srl Via Bellini 22 00198 Roma Italy
45	Sanofi Chimie Le Bourg 63480 Vertolaye France	46	Savi Technologie sp. z o.o. sp. k. Psary Wolnosci 20 51-180 Wrocław Poland

47	Sigma Aldrich Chimie sarl Rue de Luzais 80 38070 Saint Quentin Fallavier France	48	Sigma-Aldrich Chemie GmbH Riedstraße 2 89555 Steinheim Germany
49	Sigma-Aldrich Company LTD The Old Brickyard, New Road SP8 4XT Gillingham, Dorset United Kingdom	50	Solvay Fluor GmbH Hans-Boeckler-Allee 20 30173 Hannover Germany
51	Solvay Specialty Polymers France SAS Avenue de la Republique 39501 Tavaux Cedex France	52	Solvay Specialty Polymers Italy SpA Viale Lombardia 20 20021 Bollate Italy
53	SPEX CertiPrep LTD Dalston Gardens 2 HA7 1BQ Stanmore United Kingdom	54	Sterling Chemical Malta Limited Hal Far Industrial Estate HF 51 1504 Floriana Malta
55	Sterling SpA Via della Carboneria 30 06073 Solomeo — Corciano (PG) Italy	56	Syngenta Limited Priestley Road Surrey Research Park 30 GU2 7YH Guildford United Kingdom
57	Tazzetti SAU Calle Roma 2 28813 Torres de la Alameda Spain	58	Tazzetti SpA Corso Europa 600/A 10088 Volpiano Italy
59	Techlab SARL La tannerie 4C 57072 METZ Cedex 3 France	60	TEGA — Technische Gase und Gasetechnik GmbH Werner-von-Siemens-Str. 18 D-97076 Würzburg Germany
61	Thomas Swan & Co. Ltd. Rotary Way DH8 7ND Consett County Durham United Kingdom	62	Ultra Scientific Italia srl Via emilia 51/D 40011 Anzola emilia Italy
63	Valliscor Europa Limited 24-26 City Quay D02 NY19 Dublin 2 Ireland	64	Valvitalia SPA — Eusebi Division Piazza Sigmund Freud 1 20154 Milano Italy
65	Vatro-Servis d.o.o. Dravska 61 42202 Trnovec Bartolovecki Croatia		

Done at Brussels, 27 November 2019.

For the Commission
Miguel ARIAS CAÑETE
Member of the Commission

ANNEX I

GROUPS I AND II

Import quotas for chlorofluorocarbons 11, 12, 113, 114 and 115 and other fully halogenated chlorofluorocarbons allocated to importers in accordance with Regulation (EC) No 1005/2009 for feedstock uses and process agent uses during the period 1 January to 31 December 2020.

Company

Abcr GmbH (DE)

Solvay Specialty Polymers Italy SpA (IT)

Syngenta Limited (UK)

Tazzetti SAU (ES)

Tazzetti SpA (IT)

TEGA - Technische Gase und Gasetechnik GmbH (DE)

ANNEX II

GROUP III

Import quotas for halons allocated to importers in accordance with Regulation (EC) No 1005/2009 for feedstock uses and critical uses during the period 1 January to 31 December 2020.

Company

A-Gas (UK) Ltd (UK)

Abcr GmbH (DE)

Arkema France (FR)

Ateliers Bigata SASU (FR)

BASF Agri-Production S.A.S. (FR)

EAF protect s.r.o. (CZ)

ESTO Cheb s.r.o. (CZ)

Fire Fighting Enterprises Ltd (UK)

Gielle Industries di Luigi Galantucci (IT)

Halon & Refrigerant Services Ltd (UK)

Intergeo LTD (EL)

Meridian Technical Services Limited (UK)

P.U. Poz-Pliszka Sp. z o.o. (PL)

Savi Technologie sp. z o.o. sp. k. (PL)

Valvitalia SPA - Eusebi Division (IT)

Vatro-Servis d.o.o. (HR)

ANNEX III

GROUP IV

Import quotas for carbon tetrachloride allocated to importers in accordance with Regulation (EC) No 1005/2009 for feedstock uses and process agent uses for the period 1 January to 31 December 2020.

Company

Abcr GmbH (DE)

Arkema France (FR)

Avocado Research Chemicals Limited (UK)

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

Ceram Optec SIA (LV)

ANNEX IV

GROUP V

Import quotas for 1,1,1-trichloroethane allocated to importers in accordance with Regulation (EC) No 1005/2009 for feedstock uses for the period 1 January to 31 December 2020.

Company

Arkema france (FR)

ANNEX V

GROUP VI

Import quotas for methyl bromide allocated to importers in accordance with Regulation (EC) No 1005/2009 for feedstock uses for the period 1 January to 31 December 2020.

Company

Abcr GmbH (DE)

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

ICL Europe Cooperatief U.A. (NL)

Mebrom NV (BE)

Sanofi Chimie (FR)

Sigma-Aldrich Chemie GmbH (DE)

ANNEX VI

GROUP VII

Import quotas for hydrobromofluorocarbons allocated to importers in accordance with Regulation (EC) No 1005/2009 for feedstock uses for the period 1 January to 31 December 2020.

Company

Abcr GmbH (DE)

GlaxoSmithKline (UK)

Hovione FarmaCiencia SA (PT)

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

Sanofi Chimie (FR)

Sterling Chemical Malta Limited (MT)

Sterling SpA (IT)

Valliscor Europa Limited (IE)

ANNEX VII

GROUP VIII

Import quotas for hydrochlorofluorocarbons allocated to importers in accordance with Regulation (EC) No 1005/2009 for feedstock uses for the period 1 January to 31 December 2020.

Company

Abcr GmbH (DE)

AGC Chemicals Europe, Ltd. (UK)

Arkema france (FR)

Bayer AG (DE)

Chemours Netherlands B.V. (NL)

Dyneon GmbH (DE)

Solvay Fluor GmbH (DE)

Solvay Specialty Polymers France SAS (FR)

Solvay Specialty Polymers Italy SpA (IT)

Tazzetti SAU (ES)

Tazzetti SpA (IT)

ANNEX VIII

GROUP IX

Import quotas for bromochloromethane allocated to importers in accordance with Regulation (EC) No 1005/2009 for feedstock uses for the period 1 January to 31 December 2020.

Company

Albemarle Europe SPRL (BE)

ICL Europe Cooperatief U.A. (NL)

Laboratorios Miret S.A. (ES)

Sigma-Aldrich Chemie GmbH (DE)

Thomas Swan & Co. Ltd. (UK)

Valliscor Europa limited (IE)

ANNEX IX

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

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ANNEX X

Undertakings entitled to produce or import for laboratory and analytical uses in 2020

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

Company
Abcr GmbH (DE)
Arkema France (FR)
Avocado Research Chemicals Limited (UK)
BDL Czech Republic s.r.o. (CZ)
Biovit d.o.o. (HR)
Butterworth Laboratories Ltd (UK)
Daikin Refrigerants Europe GmbH (DE)
Gedeon Richter Plc. (HU)
Honeywell Speciality Chemicals Seelze GmbH (DE)
Hudson Technologies Europe S.r.l. (IT)
Labmix24 GmbH (DE)
LGC Standards GmbH (DE)
Ludwig-Maximilians-University (DE)
Merck KGaA (DE)
Mexichem UK Limited (UK)
Neochema GmbH (DE)
Philipps-Universität Marburg (DE)
Restek GmbH (DE)
Safety Hi-Tech srl (IT)
Sanofi Chimie (FR)
Sigma Aldrich Chimie sarl (FR)
Sigma-Aldrich Chemie GmbH (DE)
Sigma-Aldrich Company LTD (UK)
Solvay Fluor GmbH (DE)
Solvay Specialty Polymers France SAS (FR)
SPEX CertiPrep LTD (UK)
Techlab SARL (FR)
Ultra Scientific Italia srl (IT)
Valliscor Europa Limited (IE)

ANNEX XI

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

COMMISSION IMPLEMENTING DECISION (EU) 2019/2080**of 28 November 2019****authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MZHG0JG (SYN-ØØØJG-2), pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council***(notified under document C(2019) 7477)***(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 1 September 2016, Syngenta Crop Protection NV/SA submitted, on behalf of Syngenta Crop Protection AG, 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 MZHG0JG ('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 MZHG0JG 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 14 November 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⁾. It concluded that genetically modified maize MZHG0JG, 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 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 into account those conclusions, the placing on the market of products containing, consisting of or produced from genetically modified maize MZHG0JG should be authorised for the uses listed in the application.
- (7) A unique identifier should be assigned to genetically modified maize MZHG0JG 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 MZHG0JG for food and feed uses, import and processing under Regulation (EC) No 1829/2003 (application EFSA-GMO-DE-2016-133). *EFSA Journal* 2018; 16(11):5469, 26 pp. <https://doi.org/10.2903/j.efsa.2018.5469>

⁽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 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 ⁽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 MZHG0JG, with the exception of food products, 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 Articles 6(5)(e) and 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 Articles 9(1) and 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.) MZHG0JG, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier SYN-ØØØJG-2 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 SYN-ØØØJG-2;

⁽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).

- (b) feed containing, consisting of or produced from genetically modified maize SYN-ØØØJG-2;
- (c) products containing or consisting of genetically modified maize SYN-ØØØJG-2 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 genetically modified maize SYN-ØØØJG-2, 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 SYN-ØØØJG-2.

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 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 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, 28 November 2019.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

ANNEX

(a) Applicant and authorisation holder:

Name: Syngenta Crop Protection AG

Address: Rosentalstrasse 67, 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) foods and food ingredients containing, consisting of or produced from genetically modified maize SYN-ØØØJG-2;
- (2) feed containing, consisting of or produced from genetically modified maize SYN-ØØØJG-2;
- (3) products containing or consisting of genetically modified maize SYN-ØØØJG-2 for uses other than those provided for in points (1) and (2), with the exception of cultivation.

The genetically modified maize SYN-ØØØJG-2 expresses the *pat* gene, which confers tolerance to glufosinate-ammonium based herbicides, and the *mepsps* 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 documents accompanying the products containing or consisting of SYN-ØØØJG-2 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 SYN-ØØØJG-2.
- (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 1114-C is accessible via the American Oil Chemists Society (AOCS) at <https://www.aocs.org/crm>

(e) Unique identifier:

SYN-ØØØJG-2

(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 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.

COMMISSION IMPLEMENTING DECISION (EU) 2019/2081**of 28 November 2019**

renewing the authorisation for the placing on the market of products containing or produced from genetically modified oilseed rape T45 (ACS-BNØØ8-2), resulting from the commercialisation of this oilseed rape in third countries until 2005, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

*(notified under document C(2019) 7480)***(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 11(3) and 23(3) thereof,

Whereas:

- (1) Commission Decision 2009/184/EC ⁽²⁾ authorised the placing on the market of food and feed containing or produced from genetically modified oilseed rape T45 ('T45 oilseed rape'). The scope of that authorisation also covered the placing on the market of products, other than food and feed, containing T45 oilseed rape for the same uses as any other oilseed rape with the exception of cultivation.
- (2) The applicant indicated in its applications and in communications to the Commission that the commercialisation of T45 oilseed rape seeds was stopped after the 2005 planting season.
- (3) Therefore, the only purpose of these applications was to cover the presence of T45 oilseed rape resulting from its past cultivation in third countries.
- (4) Following the monitoring requirements set in Decision 2009/184/EC, the applicant has shown that minute traces of T45 oilseed rape are still present in commodity rapeseed in third countries and being imported into the Union.
- (5) As a result, on 9 January 2018, the authorisation holder Bayer CropScience AG 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.
- (6) The applicant reconfirmed in its application that the purpose of the application was to cover the presence of T45 oilseed rape in food and feed, resulting from its cultivation in third countries until 2005.
- (7) On 14 February 2019, the European Food Safety Authority ('the Authority') published a comprehensive favourable opinion ⁽³⁾ on T45 oilseed rape 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 T45 oilseed rape, adopted by the Authority in 2008 ⁽⁴⁾.

⁽¹⁾ OJ L 268, 18.10.2003, p. 1.

⁽²⁾ Commission Decision 2009/184/EC of 10 March 2009 authorising the placing on the market of products containing or produced from genetically modified oilseed rape T45 (ACS-BNØØ8-2) resulting from the commercialisation of this oilseed rape in third countries until 2005 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 68, 13.3.2009, p. 28).

⁽³⁾ EFSA GMO Panel 2019. Scientific Opinion on the assessment of genetically modified oilseed rape T45 for renewal of authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-012). EFSA Journal 2019;17(2):5597.

⁽⁴⁾ Opinion of the Scientific Panel on Genetically Modified Organisms on an application (Reference EFSA-GMO-UK-2005-25) for the placing on the market of glufosinate-tolerant oilseed rape T45 for food and feed uses, import and processing and renewal of the authorisation of oilseed rape T45 as existing products, both under Regulation (EC) No 1829/2003 from Bayer CropScience, The EFSA Journal (2008) 635, 1-22.

- (8) In its opinion of 14 February 2019, 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.
- (9) The Authority also concluded that the monitoring plan for the environmental effects, consisting of a general surveillance plan, submitted by Bayer CropScience AG, is in line with the intended uses of the products.
- (10) Taking into account those conclusions, the authorisation for the placing on the market of food and feed containing or produced from T45 oilseed rape and of products other than food and feed, containing T45 oilseed rape for the same uses as any other oilseed rape, with the exception of cultivation, should be renewed.
- (11) On the basis of the opinion of the Authority, no specific labelling requirements appear to be necessary for the products covered by this Decision. Pursuant to Articles 12(2) and 24(2) of Regulation (EC) No 1829/2003 and to Article 4(7) of Regulation (EC) No 1830/2003 of the European Parliament and of the Council ⁽⁵⁾, general traceability and labelling requirements do not apply to the adventitious or technically unavoidable presence of genetically modified food or feed in a proportion not exceeding 0,9 %.
- (12) In order to continue monitoring the phasing out of T45 oilseed rape, its presence in imported products should continue to be regularly reported as provided in Decision 2009/184/EC.
- (13) By letter dated 1 August 2018, Bayer CropScience AG requested that the Commission transfers their rights and obligations pertaining to all authorisations and pending applications for genetically modified products, to BASF Agricultural Solutions Seed US LLC. By letter dated 19 October 2018, BASF Agricultural Solutions Seed US LLC confirmed this transfer and authorised BASF SE to act as its representative in the Union.
- (14) On 17 May 2019, the applicant requested the Commission to restrict the scope of the Decision of renewal to allow the presence of T45 oilseed rape in food and feed in a proportion not exceeding 0,9 %. Following this request, the scope of this decision is restricted to a maximal level of 0,9 % of presence of T45 oilseed rape in food and feed.
- (15) A unique identifier has been assigned to T45 oilseed rape, in accordance with Commission Regulation (EC) No 65/2004 ⁽⁶⁾, in the context of its initial authorisation by Decision 2009/184/EC. That unique identifier should continue to be used.
- (16) The authorisation holder should submit 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⁾.
- (17) 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 containing or produced from genetically modified oilseed rape T45, or for the protection of particular ecosystems/environment and/or geographical areas, as provided for in Articles 6(5)(e) and 18(5)(e) of Regulation (EC) No 1829/2003.

⁽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 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⁾ 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).

- (18) 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.
- (19) 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⁾.
- (20) 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 oilseed rape (*Brassica napus* L) T45, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier ACS-BNØØ8-2, in accordance with Regulation (EC) No 65/2004.

Article 2

Renewal of the authorisation

1. The purpose of this Decision is to renew an authorisation covering, for the products referred to in paragraph 2, the presence of ACS-BNØØ8-2 oilseed rape resulting directly or indirectly from the commercialisation, until 2005, of ACS-BNØØ8-2 oilseed rape seeds in third countries.
2. 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 or produced from genetically modified oilseed rape ACS-BNØØ8-2;
 - (b) feed containing or produced from genetically modified oilseed rape ACS-BNØØ8-2;
 - (c) products containing genetically modified oilseed rape ACS-BNØØ8-2 for uses other than those provided for in points (a) and (b), with the exception of cultivation.

Article 3

Maximum level

The presence of genetically modified oilseed rape ACS-BNØØ8-2 in products defined in Article 2 is authorised in a proportion not exceeding 0,9 %.

Article 4

Method for detection

The method set out in point (c) of the Annex shall apply for the detection of genetically modified oilseed rape ACS-BNØØ8-2.

⁽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 5***Monitoring plan for environmental effects**

1. The authorisation holder shall ensure that the monitoring plan for environmental effects, as set out in point (g) 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 the format set out in Decision 2009/770/EC.

*Article 6***Monitoring of the phasing out**

1. The authorisation holder shall ensure that shipments of oilseed rape imported into the Union from a third country in which genetically modified oilseed rape seeds ACS-BNØØ8-2 were commercialised until 2005 are sampled and tested appropriately for the presence of genetically modified oilseed rape ACS-BNØØ8-2.
2. The method used for the sampling of oilseed rape ACS-BNØØ8-2 shall be internationally recognised. The testing shall be made in an accredited laboratory and in accordance with the validated method of detection as set out in the Annex.
3. The authorisation holder shall submit to the Commission, together with the reports referred to in Article 5(2), annual reports on the monitoring activities for the presence of genetically modified oilseed rape ACS-BNØØ8-2.

*Article 7***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 8***Authorisation holder**

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

*Article 9***Validity**

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

*Article 10***Addressee**

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

Done at Brussels, 28 November 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 or produced from genetically modified oilseed rape ACS-BNØØ8-2;
- (2) feed containing or produced from genetically modified oilseed rape ACS-BNØØ8-2;
- (3) products containing genetically modified oilseed rape ACS-BNØØ8-2 for uses other than those provided in points (1) and (2), with the exception of cultivation.

The genetically modified oilseed rape ACS-BNØØ8-2 expresses the *pat* gene which confers tolerance to glufosinate-ammonium based herbicides.

(c) Method for detection:

- (1) Event specific real-time PCR based method for the detection of genetically modified oilseed rape ACS-BNØØ8-2.
- (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 0208-A accessible via the American Oil Chemists Society at <https://www.aocs.org/crm>

(d) Unique identifier:

ACS-BNØØ8-2

(e) 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*].

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

Not required.

(g) 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 Community register of genetically modified food and feed*]

(h) 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.

⁽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) 2019/2082**of 28 November 2019****renewing the authorisation for the placing on the market of products containing, consisting of or produced from genetically modified cotton LLCotton25 (ACS-GHØØ1-3) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council***(notified under document C(2019) 7481)***(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 11(3) and 23(3) thereof,

Whereas:

- (1) Commission Decision 2008/837/EC ⁽²⁾ authorised the placing on the market of food and feed containing, consisting of, or produced from genetically modified cotton LLCotton25 (hereinafter 'LLCotton25'). The scope of that authorisation also covers the placing on the market of products, other than food and feed, containing or consisting of LLCotton25 for the same uses as any other cotton with the exception of cultivation.
- (2) On 2 October 2017, the initial authorisation holder, Bayer CropScience AG 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 14 November 2018, the European Food Safety Authority ('the Authority') published 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 LLCotton25, adopted by the Authority in 2006 ⁽⁴⁾.
- (4) In its opinion of 14 November 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 Bayer CropScience AG, 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 LLCotton25 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 2008/837/EC of 29 October 2008 authorising the placing on the market of products containing, consisting of, or produced from genetically modified LLCotton25 (ACS-GHØØ1-3) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 299, 8.11.2008, p. 36).

⁽³⁾ EFSA GMO Panel 2018. Assessment of genetically modified LLCotton25 for renewal of authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-010), EFSA Journal 2018;16(11): 5473.

⁽⁴⁾ Opinion of the Scientific Panel on Genetically Modified Organisms on an application (Reference EFSA-GMONL-2005-13) for the placing on the market of glufosinate-tolerant genetically modified LLCotton25, for food and feed uses, and import and processing under Regulation (EC) No 1829/2003 from Bayer CropScience, The EFSA Journal (2006) 429, 1-19.

- (7) By letter dated 1 August 2018, Bayer CropScience AG requested that the Commission transfers their rights and obligations pertaining to all authorisations and pending applications for genetically modified products, to BASF Agricultural Solutions Seed US LLC. By letter dated 19 October 2018, BASF Agricultural Solutions Seed US LLC confirmed its agreement with this transfer and authorised BASF SE to act as its representative in the Union.
- (8) A unique identifier has been assigned to LLCotton25, in accordance with Commission Regulation (EC) No 65/2004 ⁽⁵⁾, in the context of its initial authorisation by Decision 2008/837/EC. That unique identifier should continue to be used.
- (9) 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 LLCotton25 remains within the limits of the authorisation, the labelling of such products, with the exception of food products, should contain a clear indication that they are not intended for cultivation.
- (10) The authorisation holder should submit 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⁾.
- (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 containing, consisting of, or produced from genetically modified cotton LLCotton25, or for the protection of particular ecosystems/environment and/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 ⁽⁸⁾.
- (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 cotton (*Gossypium hirsutum*) LLCotton25, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier ACS-GHØØ1-3, 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 cotton ACS-GHØØ1-3;
- (b) feed containing, consisting of, or produced from genetically modified cotton ACS-GHØØ1-3;
- (c) products containing or consisting of genetically modified cotton ACS-GHØØ1-3 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 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 'cotton'.
- 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 cotton LLCotton25, 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 cotton LLCotton25.

*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 to the Commission 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 holder**

The authorisation holder shall be BASF Agricultural Solutions Seed US LLC, United States, 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, 28 November 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 genetically modified cotton LLCotton25;
- (2) feed containing, consisting of or produced from genetically modified cotton LLCotton25;
- (3) products containing or consisting of genetically modified cotton LLCotton25 for uses other than those provided in points (1) and (2), with the exception of cultivation.

The genetically modified cotton LLCotton25 expresses the *bar* gene which confers tolerance to glufosinate-ammonium 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 'cotton'.
- (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 cotton LLCotton25, with the exception of products referred to in point (b)(1).

(d) Method for detection:

- (1) Event specific real-time PCR based method for the detection of genetically modified cotton LLCotton25.
- (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 0306-A3 and AOCS 0306-E2 accessible via the American Oil Chemists Society at <https://www.aocs.org/crm>

(e) Unique identifier:

ACS-GHØØ1-3

(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 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 of the European Parliament and of the Council ⁽¹⁾.

[Link: *plan published in the Community 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).

(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) 2019/2083**of 28 November 2019****renewing the authorisation for the placing on the market of products containing, consisting of or produced from genetically modified soybean MON 89788 (MON-89788-1) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council***(notified under document C(2019) 7482)***(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 2008/933/EC ⁽²⁾ authorised the placing on the market of food and feed containing, consisting of or produced from genetically modified soybean MON 89788. The scope of that authorisation also covers the placing on the market of products containing or consisting of genetically modified soybean MON 89788 for uses other than food and feed, with the exception of cultivation.
- (2) On 20 November 2017, the authorisation holder, Monsanto Europe S.A./N.V., on behalf of Monsanto Company, 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 19 November 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 soybean MON 89788, adopted by the Authority in 2008 ⁽⁴⁾.
- (4) In its opinion of 19 November 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 applicant, 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 soybean MON 89788 and of products containing or consisting of it for uses other than food and feed, with the exception of cultivation, should be renewed.
- (7) By letter dated 27 August 2018, Monsanto Europe S.A./N.V. informed the Commission that it converted its legal form and changed its name to Bayer Agriculture BVBA, Belgium. Monsanto Company confirmed the change of representative.

⁽¹⁾ OJ L 268, 18.10.2003, p. 1.

⁽²⁾ Commission Decision 2008/933/EC of 4 December 2008 authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean MON89788 (MON-89788-1) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 333, 11.12.2008, p. 7).

⁽³⁾ EFSA GMO Panel 2018. Scientific Opinion on the assessment of genetically modified soybean MON 89788 for renewal of authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-011). EFSA Journal 2018;16(11):5468.

⁽⁴⁾ Opinion of the Scientific Panel on Genetically Modified Organisms on an application (Reference EFSA-GMO-NL-2006-36) for the placing on the market of the glyphosate-tolerant genetically modified soybean MON 89788, for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Monsanto. EFSA Journal 2008;6(7):429.

- (8) A unique identifier has been assigned to genetically modified soybean MON 89788, in accordance with Commission Regulation (EC) No 65/2004 ⁽⁵⁾, in the context of its initial authorisation by Decision 2008/933/EC. That unique identifier should continue to be used.
- (9) 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 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 89788, with the exception of food products, should contain a clear indication that they are not intended for cultivation.
- (10) 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 requirements laid down in Commission Decision 2009/770/EC ⁽⁷⁾.
- (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 ⁽⁸⁾.
- (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 89788, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier MON-89788-1, 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***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 soybean MON-89788-1;
- (b) feed containing, consisting of or produced from genetically modified soybean MON-89788-1;
- (c) products containing or consisting of genetically modified soybean MON-89788-1 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 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 the products containing or consisting of genetically modified soybean MON-89788-1, 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 soybean MON-89788-1.

*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 to the Commission 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 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, 28 November 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-89788-1;
- (2) feed containing, consisting of or produced from genetically modified soybean MON-89788-1;
- (3) products containing or consisting of genetically modified soybean MON-89788-1 for uses other than those provided for in points (1) and (2), with the exception of cultivation.

The genetically modified soybean MON-89788-1 expresses 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 'soybean'.
- (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 soybean MON-89788-1, 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 soybean MON-89788-1.
- (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 0906-A and AOCS 0906-B accessible via the American Oil Chemists Society (AOCS) at <https://www.aocs.org/crm>

(e) Unique identifier:

MON-89788-1

(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 of the European Parliament and of the Council ⁽¹⁾.

[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.

⁽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) 2019/2084**of 28 November 2019****renewing the authorisation for the placing on the market of products containing, consisting of or produced from genetically modified soybean A2704-12 (ACS-GMØØ5-3) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council***(notified under document C(2019) 7483)***(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 11(3) and 23(3) thereof,

Whereas:

- (1) Commission Decision 2008/730/EC ⁽²⁾ authorised the placing on the market of food and feed containing, consisting of or produced from genetically modified soybean A2704-12 ('soybean A2704-12'). The scope of that authorisation also covers the placing on the market of products, other than food and feed, containing or consisting of soybean A2704-12 for the same uses as any other soybean, with the exception of cultivation.
- (2) On 29 August 2017, the authorisation holder, Bayer CropScience AG 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 14 January 2019, the European Food Safety Authority ('the Authority') published 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 soybean A2704-12, adopted by the Authority in 2007 ⁽⁴⁾.
- (4) In its opinion of 14 January 2019, 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 Bayer CropScience AG, is in line with the intended uses of the products.

⁽¹⁾ OJ L 268, 18.10.2003, p. 1.

⁽²⁾ Commission Decision 2008/730/EC of 8 September 2008 authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean A2704-12 (ACS-GMØØ5-3) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 247, 16.9.2008, p. 50).

⁽³⁾ EFSA GMO Panel 2019. Scientific Opinion on the assessment of genetically modified soybean A2704-12 for renewal of authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-009). EFSA Journal 2019;17(1):5523.

⁽⁴⁾ Opinion of the Scientific Panel on genetically modified organisms (GMO) on an application (Reference EFSA-GMO-NL-2005-18) for the placing on the market of the glufosinatetolerant soybean A2704-12, for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Bayer CropScience. EFSA Journal 2007;5(7):524.

- (6) Taking into account those conclusions, the authorisation for the placing on the market of food and feed containing, consisting of, or produced from soybean A2704-12 and of products consisting of it or containing it for other uses than food or feed, with the exception of cultivation, should be renewed.
- (7) By letter dated 1 August 2018, Bayer CropScience AG requested the Commission to transfer their rights and obligations pertaining to all authorisations and pending applications for genetically modified products, to BASF Agricultural Solutions Seed US LLC. By letter dated 19 October 2018, BASF Agricultural Solutions Seed US LLC confirmed this transfer and authorised BASF SE, Germany, to act as its representative in the Union.
- (8) A unique identifier has been assigned to soybean A2704-12, in accordance with Commission Regulation (EC) No 65/2004 ⁽⁵⁾, in the context of its initial authorisation by Decision 2008/730/EC. That unique identifier should continue to be used.
- (9) For the products covered by this Decision, 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. However, in order to ensure that the use of products containing or consisting of soybean A2704-12 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.
- (10) The authorisation holder should submit 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⁾.
- (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 containing, consisting of, or produced from genetically modified soybean A2704-12, or for the protection of particular ecosystems/environment and/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 ⁽⁸⁾.
- (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,

⁽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).

HAS ADOPTED THIS DECISION:

Article 1

Genetically modified organism and unique identifier

Genetically modified soybean (*Glycine max*) A2704-12, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier ACS-GMØØ5-3, in accordance with Regulation (EC) No 65/2004.

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 soybean ACS-GMØØ5-3;
- (b) feed containing, consisting of, or produced from genetically modified soybean ACS-GMØØ5-3;
- (c) products containing or consisting of genetically modified soybean ACS-GMØØ5-3 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 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 the products containing or consisting of genetically modified soybean ACS-GMØØ5-3, 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 ACS-GMØØ5-3.

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 to the Commission 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 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, United States, represented in the Union 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, 28 November 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 genetically modified soybean ACS-GMØØ5-3;
- (2) feed containing, consisting of or produced from genetically modified soybean ACS-GMØØ5-3;
- (3) products containing or consisting of genetically modified soybean ACS-GMØØ5-3 for uses other than those provided in points (1) and (2), with the exception of cultivation.

The genetically modified soybean ACS-GMØØ5-3 expresses the *pat* gene which confers tolerance to glufosinate-ammonium 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 'soybean'.
- (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 soybean ACS-GMØØ5-3, with the exception of products referred to in point (b)(1) of this Annex.

(d) Method for detection:

- (1) Event specific real-time PCR based method for the detection of genetically modified soybean ACS-GMØØ5-3.
- (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: AOCS 0707-A and AOCS 0707-B accessible via the American Oil Chemists Society at <https://www.aocs.org/crm>

(e) Unique identifier:

ACS-GMØØ5-3

(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 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 of the European Parliament and of the Council ⁽¹⁾.

[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.

⁽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).

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authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MON 89034 × 1507 × NK603 × DAS-40278-9 and sub-combinations MON 89034 × NK603 × DAS-40278-9, 1507 × NK603 × DAS-40278-9 and NK603 × DAS-40278-9 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

*(notified under document (C(2019) 8419)***(Only the French 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 Article 7(3) and Article 19(3) thereof,

Whereas:

- (1) On 11 January 2013, Dow AgroSciences Europe submitted, on behalf of Dow AgroSciences LLC, 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 89034 × 1507 × NK603 × DAS-40278-9 ('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 maize MON 89034 × 1507 × NK603 × DAS-40278-9 for uses other than food and feed, with the exception of cultivation.
- (2) In addition, the application covered the placing on the market of products containing, consisting of or produced from ten sub-combinations of the single transformation events constituting maize MON 89034 × 1507 × NK603 × DAS-40278-9. Seven of those sub-combinations are already authorised as follows: MON 89034 × 1507, authorised by Commission Implementing Decision 2013/650/EU ⁽²⁾; MON 89034 × NK603, authorised by Commission Implementing Decision (EU) 2018/1111 ⁽³⁾; 1507 × NK603, authorised by Commission Implementing Decision (EU) 2019/1306 ⁽⁴⁾; MON 89034 × 1507 × NK603, authorised by Commission Implementing Decision 2013/648/EU ⁽⁵⁾; and MON 89034 × 1507 × DAS-40278-9, MON 89034 × DAS-40278-9, 1507 × DAS-40278-9, authorised by Commission Implementing Decision C(2019)8425 ⁽⁶⁾.

⁽¹⁾ OJ L 268, 18.10.2003, p. 1.

⁽²⁾ Commission Implementing Decision 2013/650/EU of 6 November 2013 authorising the placing on the market of products containing, consisting of, or produced from genetically modified (GM) maize MON 89034 × 1507 × MON88017 × 59122 (MON-89034-3 × DAS-01507-1 × MON-88017-3 × DAS-59122-7), four related GM maizes combining three different single GM events (MON89034 × 1507 × MON88017 (MON-89034-3 × DAS-01507-1 × MON-88017-3), MON89034 × 1507 × 59122 (MON-89034-3 × DAS-01507-1 × DAS-59122-7), MON89034 × MON88017 × 59122 (MON-89034-3 × MON-88017-3 × DAS-59122-7)), 1507 × MON 88017 × 59122 (DAS-01507-1 × MON-88017-3 × DAS-59122-7)) and four related GM maizes combining two different single GM events (MON89034 × 1507 (MON-89034-3 × DAS-01507-1), MON89034 × 59122 (MON-89034-3 × DAS-59122-7), 1507 × MON88017 (DAS-01507-1 × MON-88017-3), MON 88017 × 59122 (MON-88017-3 × DAS-59122-7)) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 302, 13.11.2013, p. 47).

⁽³⁾ Commission Implementing Decision (EU) 2018/1111 of 3 August 2018 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON 87427 × MON 89034 × NK603 (MON-87427-7 × MON-89034-3 × MON-00603-6) and genetically modified maize combining two of the events MON 87427, MON 89034 and NK603, and repealing Decision 2010/420/EU (OJ L 203, 10.8.2018, p. 20).

⁽⁴⁾ 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-01507-1 × MON-00603-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 204, 2.8.2019, p. 75).

⁽⁵⁾ Commission Implementing Decision 2013/648/EU of 6 November 2013 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON89034 × 1507 × NK603 (MON-89034-3 × DAS-01507-1 × MON-00603-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 302, 13.11.2013, p. 38).

⁽⁶⁾ Commission Implementing Decision authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MON 89034 × 1507 × MON 88017 × 59122 × DAS-40278-9 and genetically modified maize combining two, three or four of the single events MON 89034, 1507, MON 88017, 59122 and DAS-40278-9 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council.

- (3) This Decision covers the three remaining sub-combinations in the application: MON 89034 × NK603 × DAS-40278-9; 1507 × NK603 × DAS-40278-9 and NK603 × DAS-40278-9.
- (4) 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 ⁽⁷⁾. 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.
- (5) On 16 January 2019, the European Food Safety Authority ('the Authority') issued a favourable opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003 ⁽⁸⁾. The Authority concluded that genetically modified maize MON 89034 × 1507 × NK603 × DAS-40278-9 and its sub-combinations, as described in the application, are as safe as its non-genetically modified comparator and the tested non- genetically modified reference varieties with respect to the potential effects on human and animal health and the environment.
- (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 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 MON 89034 × 1507 × NK603 × DAS-40278-9, and of the three sub-combinations indicated in recital 3 and listed in the application, should be authorised for the uses listed in the application.
- (9) By letter dated 13 September 2018, Dow AgroSciences Europe informed the Commission that the new representative in the Union of Dow AgroSciences LLC, United States, is Dow AgroSciences Distribution S.A.S., based in France. By letters, respectively dated 7 September 2018 and 12 October 2018, Dow AgroSciences Distribution S.A.S. and Dow AgroSciences LLC confirmed their agreement.
- (10) A unique identifier should be assigned to each genetically modified organism covered by this Decision, in accordance with Commission Regulation (EC) No 65/2004 ⁽⁹⁾.
- (11) 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 ⁽¹⁰⁾, 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 covered by it, with the exception of food products, should contain a clear indication that they are not intended for cultivation.

⁽⁷⁾ 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).

⁽⁸⁾ EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Scientific Opinion on the assessment of genetically modified maize MON 89034 × 1507 × NK603 × DAS-40278-9 and subcombinations independently of their origin for food and feed uses, import and processing, under Regulation (EC) No 1829-2003 (application EFSA-GMO-NL-2013-112). EFSA Journal 2019;17(1):5522.

⁽⁹⁾ 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).

⁽¹⁰⁾ 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).

- (12) 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 ⁽¹¹⁾.
- (13) 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.
- (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) 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 ⁽¹²⁾.
- (16) 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 organisms and unique identifiers

Genetically modified maize (*Zea mays* L.), 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 MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-ØØ6Ø3-6 × DAS-4Ø278-9 for genetically modified maize MON 89034 × 1507 × NK603 × DAS-40278-9;
- (b) the unique identifier MON-89Ø34-3 × MON-ØØ6Ø3-6 × DAS-4Ø278-9 for genetically modified maize MON 89034 × NK603 × DAS-40278-9;
- (c) the unique identifier DAS-Ø15Ø7-1 × MON-ØØ6Ø3-6 × DAS-4Ø278-9 for genetically modified maize 1507 × NK603 × DAS-40278-9;
- (d) the unique identifier MON-ØØ6Ø3-6 × DAS-4Ø278-9 for genetically modified maize NK603 × DAS-40278-9.

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;

⁽¹¹⁾ 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).

⁽¹²⁾ 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).

- (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 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 Dow AgroSciences LLC, United States, represented in the Union by Dow AgroSciences Distribution S.A.S., France.

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 Dow AgroSciences Distribution S.A.S., 1 bis, avenue du 8 mai 1945, 78280 Guyancourt, France.

Done at Brussels, 28 November 2019.

For the Commission

Vytenis ANDRIUKAITIS

Member of the Commission

ANNEX

(a) **Applicant and authorisation holder:**

Name: Dow AgroSciences LLC

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

Represented in the Union by: Dow AgroSciences Distribution S.A.S., 1 bis, avenue du 8 mai 1945, 78280 Guyancourt, France.

(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 (*Zea mays* L.) 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 maize MON-89Ø34-3 expresses the *cry1A.105* and *cry2Ab2* genes, which confer protection against certain lepidopteran pests.

The genetically modified maize DAS-Ø15Ø7-1 expresses the *cry1F* gene, which confers protection against certain lepidopteran pests and the *pat* gene, which confers tolerance to glufosinate-ammonium-based herbicides.

The genetically modified maize MON-ØØ6Ø3-6 expresses the *cp4 epsps* gene, which confers tolerance to glyphosate-based herbicides.

The genetically modified maize DAS-4Ø278-9 expresses the *aad-1* gene, which confers tolerance to 2,4-dichlorophenoxyacetic acid (2,4-D) and aryloxyphenoxypropionate (AOPP) 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 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 are those individually validated for genetically modified maize events MON-89Ø34-3, DAS-Ø15Ø7-1, MON-ØØ6Ø3-6 and DAS-4Ø278-9 and further verified on maize stack MON 89034 × 1507 × NK603 × DAS-40278-9.
- (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: AOCs 0906 (for MON-89Ø34-3) is accessible via the American Oil Chemists Society at <https://www.aocs.org/crm#maize>, and ERM®-BF418 (for DAS-Ø15Ø7-1), ERM®-BF415 (for MON-ØØ6Ø3-6) and ERM®-BF433 (for DAS-4Ø278-9) are accessible via the Joint Research Centre (JRC) of the European Commission at <https://ec.europa.eu/jrc/en/reference-materials/catalogue>.

(e) **Unique identifiers:**

MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-ØØ6Ø3-6 × DAS-4Ø278-9;

MON-89Ø34-3 × MON-ØØ6Ø3-6 × DAS-4Ø278-9;

DAS-Ø15Ø7-1 × MON-ØØ6Ø3-6 × DAS-4Ø278-9;

MON-ØØ6Ø3-6 × DAS-4Ø278-9.

(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 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.

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authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MON 89034 × 1507 × MON 88017 × 59122 × DAS-40278-9 and genetically modified maize combining two, three or four of the single events MON 89034, 1507, MON 88017, 59122 and DAS-40278-9 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

(notified under document C(2019) 8425)

(Only the French 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 Article 7(3) and Article 19(3) thereof,

Whereas:

- (1) On 6 February 2013, Dow AgroSciences Europe submitted, on behalf of Dow AgroSciences LLC, an application to the national competent authority of the Netherlands ('the application') for the placing on the market of foods, food ingredients and feed containing, consisting of or produced from genetically modified maize MON 89034 × 1507 × MON 88017 × 59122 × DAS-40278-9 in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003. The application also covered the placing on the market of products containing or consisting of genetically modified maize MON 89034 × 1507 × MON 88017 × 59122 × DAS-40278-9 for uses other than food and feed, with the exception of cultivation.
- (2) In addition, the application covered the placing on the market of products containing, consisting of or produced from twenty-five sub-combinations of the single transformation events constituting maize MON 89034 × 1507 × MON 88017 × 59122 × DAS-40278-9. Eleven of those sub-combinations were already authorised as follows: 1507 × 59122, authorised by Commission Implementing Decision (EU) 2018/1110 ⁽²⁾; MON 89034 × MON 88017, authorised by Commission Implementing Decision (EU) 2018/2046 ⁽³⁾; and MON 89034 × 1507 × MON 88017 × 59122, MON 89034 × 1507 × MON 88017, MON 89034 × 1507 × 59122, MON 89034 × MON 88017 × 59122, 1507 × MON 88017 × 59122, MON 89034 × 1507, MON 89034 × 59122, 1507 × MON 88017, MON 88017 × 59122, authorised by Commission Implementing Decision 2013/650/EU ⁽⁴⁾.

⁽¹⁾ OJ L 268, 18.10.2003, p. 1.

⁽²⁾ Commission Implementing Decision (EU) 2018/1110 of 3 August 2018 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize 1507 × 59122 × MON 810 × NK603, and genetically modified maize combining two or three of the single events 1507, 59122, MON 810 and NK603, and repealing Decisions 2009/815/EC, 2010/428/EU and 2010/432/EU (OJ L 203, 10.8.2018, p. 13).

⁽³⁾ Commission Implementing Decision (EU) 2018/2046 of 19 December 2018 authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MON 87427 × MON 89034 × 1507 × MON 88017 × 59122, and genetically modified maize combining two, three or four of the single events MON 87427, MON 89034, 1507, MON 88017 and 59122 and repealing Decision 2011/366/EU (OJ L 327, 21.12.2018, p. 70).

⁽⁴⁾ Commission Implementing Decision 2013/650/EU of 6 November 2013 authorising the placing on the market of products containing, consisting of, or produced from genetically modified (GM) maize MON 89034 × 1507 × MON 88017 × 59122 (MON-89034-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7), four related GM maizes combining three different single GM events (MON89034 × 1507 × MON88017 (MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3), MON89034 × 1507 × 59122 (MON-89Ø34-3 × DAS-Ø15Ø7-1 × DAS-59122-7), MON89034 × MON88017 × 59122 (MON-89Ø34-3 × MON-88Ø17-3 × DAS-59122-7), 1507 × MON 88017 × 59122 (DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7)) and four related GM maizes combining two different single GM events (MON89034 × 1507 (MON-89Ø34-3 × DAS-Ø15Ø7-1), MON89034 × 59122 (MON-89Ø34-3 × DAS-59122-7), 1507 × MON88017 (DAS-Ø15Ø7-1 × MON-88Ø17-3), MON 88017 × 59122 (MON-88Ø17-3 × DAS-59122-7)) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 302, 13.11.2013, p. 47).

- (3) This Decision covers the remaining fourteen sub-combinations: four sub-combinations of four events (MON 89034 × 1507 × MON 88017 × DAS-40278-9, MON 89034 × 1507 × 59122 × DAS-40278-9, MON 89034 × MON 88017 × 59122 × DAS-40278-9 and 1507 × MON 88017 × 59122 × DAS-40278-9); six sub-combinations of three events (MON 89034 × 1507 × DAS-40278-9, MON 89034 × MON 88017 × DAS-40278-9, MON 89034 × 59122 × DAS-40278-9, 1507 × MON 88017 × DAS-40278-9, 1507 × 59122 × DAS-40278-9 and MON 88017 × 59122 × DAS-40278-9); and four sub-combinations of two events (MON 89034 × DAS-40278-9, 1507 × DAS-40278-9, MON 88017 × DAS-40278-9 and 59122 × DAS-40278-9).
- (4) 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 ⁽⁵⁾. 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.
- (5) On 14 January 2019, the European Food Safety Authority ('the Authority') issued a favourable opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003 ⁽⁶⁾. The Authority concluded that genetically modified maize MON 89034 × 1507 × MON 88017 × 59122 × DAS-40278-9 and its sub-combinations, as described in the application, are as safe as its non-genetically modified comparator and the tested non-genetically modified reference varieties with respect to the potential effects on human and animal health and the environment.
- (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 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 MON 89034 × 1507 × MON 88017 × 59122 × DAS-40278-9, and of the fourteen sub-combinations indicated in recital 3 and listed in the application, should be authorised for the uses listed in the application.
- (9) By letter dated 13 September 2018, Dow AgroSciences Europe informed the Commission that the new representative in the Union of Dow AgroSciences LLC, United States, is Dow AgroSciences Distribution S.A.S., based in France. By letters, respectively dated 7 September 2018 and 12 October 2018, Dow AgroSciences Distribution S.A.S. and Dow AgroSciences LLC confirmed their agreement.
- (10) A unique identifier should be assigned to each genetically modified organism covered by this Decision, in accordance with Commission Regulation (EC) No 65/2004 ⁽⁷⁾.
- (11) 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 ⁽⁸⁾, 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 covered by it, with the exception of food products, should contain a clear indication that they are not intended for cultivation.

⁽⁵⁾ 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).

⁽⁶⁾ EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Scientific Opinion on the assessment of genetically modified maize MON 89034 × 1507 × MON 88017 × 59122 × DAS-40278-9 and subcombinations independently of their origin for food and feed uses, import and processing under Regulation (EC) No 1829/2003 (application EFSAGMO-NL-2013-113). EFSA Journal 2019;17(1):5521.

⁽⁷⁾ 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⁾ 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).

- (12) 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 ⁽⁹⁾.
- (13) 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.
- (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) 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 ⁽¹⁰⁾.
- (16) 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 organisms and unique identifiers

Genetically modified maize (*Zea mays* L.), 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 MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7 × DAS-4Ø278-9 for genetically modified maize MON 89034 × 1507 × MON 88017 × 59122 × DAS-40278-9;
- (b) the unique identifier MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-4Ø278-9 for genetically modified maize MON 89034 × 1507 × MON 88017 × DAS-40278-9;
- (c) the unique identifier MON-89Ø34-3 × DAS-Ø15Ø7-1 × DAS-59122-7 × DAS-4Ø278-9 for genetically modified maize MON 89034 × 1507 × 59122 × DAS-40278-9;
- (d) the unique identifier MON-89Ø34-3 × MON-88Ø17-3 × DAS-59122-7 × DAS-4Ø278-9 for genetically modified maize MON 89034 × MON 88017 × 59122 × DAS-40278-9;
- (e) the unique identifier DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7 × DAS-4Ø278-9 for genetically modified maize 1507 × MON 88017 × 59122 × DAS-40278-9;
- (f) the unique identifier MON-89Ø34-3 × DAS-Ø15Ø7-1 × DAS-4Ø278-9 for genetically modified maize MON 89034 × 1507 × DAS-40278-9;
- (g) the unique identifier MON-89Ø34-3 × MON-88Ø17-3 × DAS-4Ø278-9 for genetically modified maize MON 89034 × MON 88017 × DAS-40278-9;
- (h) the unique identifier MON-89Ø34-3 × DAS-59122-7 × DAS-4Ø278-9 for genetically modified maize MON 89034 × 59122 × DAS-40278-9;
- (i) the unique identifier DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-4Ø278-9 for genetically modified maize 1507 × MON 88017 × DAS-40278-9;

⁽⁹⁾ 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).

⁽¹⁰⁾ 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).

- (j) the unique identifier DAS-Ø15Ø7-1 × DAS-59122-7 × DAS-4Ø278-9 for genetically modified maize 1507 × 59122 × DAS-40278-9;
- (k) the unique identifier MON-88Ø17-3 × DAS-59122-7 × DAS-4Ø278-9 for genetically modified maize MON 88017 × 59122 × DAS-40278-9;
- (l) the unique identifier MON-89Ø34-3 × DAS-4Ø278-9 for genetically modified maize MON 89034 × DAS-40278-9;
- (m) the unique identifier DAS-Ø15Ø7-1 × DAS-4Ø278-9 for genetically modified maize 1507 × DAS-40278-9;
- (n) the unique identifier MON-88Ø17-3 × DAS-4Ø278-9 for genetically modified maize MON 88017 × DAS-40278-9;
- (o) the unique identifier DAS-59122-7 × DAS-4Ø278-9 for genetically modified maize 59122 × DAS-40278-9.

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 the format set out in 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 Dow AgroSciences LLC, United States, represented in the Union by Dow AgroSciences Distribution S.A.S., France.

*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 Dow AgroSciences Distribution S.A.S., 1 bis, avenue du 8 mai 1945, 78280 Guyancourt, France.

Done at Brussels, 28 November 2019.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

ANNEX

(a) Applicant and authorisation holder:

Name: Dow AgroSciences LLC

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

Represented in the Union by: Dow AgroSciences Distribution S.A.S., 1 bis, avenue du 8 mai 1945, 78280 Guyancourt, France.

(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 (*Zea mays* L.) 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 maize MON-89Ø34-3 expresses the *cry1A.105* and *cry2Ab2* genes, which confer protection against certain lepidopteran pests.

The genetically modified maize DAS-Ø15Ø7-1 expresses the *cry1F* gene, which confers protection against certain lepidopteran pests and the *pat* gene, which confers tolerance to glufosinate-ammonium-based herbicides.

The genetically modified maize MON-88Ø17-3 expresses a modified *cry3Bb1* gene, which provides protection to certain coleopteran pests and the *cp4 epsps* gene, which confers tolerance to glyphosate-based herbicides.

The genetically modified maize DAS-59122-7 expresses the *Cry34Ab1* and *Cry35Ab1* genes, which confer protection against certain coleopteran pests and the *pat* gene, which confers tolerance to glufosinate-ammonium-based herbicides.

The genetically modified maize DAS-4Ø278-9 expresses the *aad-1* gene, which confers tolerance to 2,4-dichlorophenoxyacetic acid (2,4-D) and aryloxyphenoxypropionate (AOPP) 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 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 are those individually validated for genetically modified maize events MON-89Ø34-3, DAS-Ø15Ø7-1, MON-88Ø17-3, DAS-59122-7 and DAS-4Ø278-9 and further verified on maize stack MON 89034 × 1507 × MON 88017 × 59122 × DAS-40278-9.
- (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: AOCs 0906 (for MON-89Ø34-3) and AOCs 0406 (for MON-88Ø17-3) are accessible via the American Oil Chemists Society at <https://www.aocs.org/crm#maize>, and ERM®-BF418 (for DAS-Ø15Ø7-1), ERM®-BF424 (for DAS-59122-7) and ERM®-BF433 (for DAS-4Ø278-9) are accessible via the Joint Research Centre (JRC) of the European Commission at <https://ec.europa.eu/jrc/en/reference-materials/catalogue>.

(e) **Unique identifiers:**

MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7 × DAS-4Ø278-9;
MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-4Ø278-9;
MON-89Ø34-3 × DAS-Ø15Ø7-1 × DAS-59122-7 × DAS-4Ø278-9;
MON-89Ø34-3 × MON-88Ø17-3 × DAS-59122-7 × DAS-4Ø278-9;
DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7 × DAS-4Ø278-9;
MON-89Ø34-3 × DAS-Ø15Ø7-1 × DAS-4Ø278-9;
MON-89Ø34-3 × MON-88Ø17-3 × DAS-4Ø278-9;
MON-89Ø34-3 × DAS-59122-7 × DAS-4Ø278-9;
DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-4Ø278-9;
DAS-Ø15Ø7-1 × DAS-59122-7 × DAS-4Ø278-9;
MON-88Ø17-3 × DAS-59122-7 × DAS-4Ø278-9;
MON-89Ø34-3 × DAS-4Ø278-9;
DAS-Ø15Ø7-1 × DAS-4Ø278-9;
MON-88Ø17-3 × DAS-4Ø278-9;
DAS-59122-7 × DAS-4Ø278-9.

(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 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) 2019/2087**of 28 November 2019**

authorising the placing on the market of products containing, consisting of or produced from genetically modified maize Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21 and genetically modified maize combining two, three, four or five of the single events Bt11, MIR162, MIR604, 1507, 5307 and GA21 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

(notified under document C(2019) 8428)

(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 16 December 2011, Syngenta Crop Protection AG submitted, through its affiliated company Syngenta Crop Protection NV/SA, an application to the national competent authority of Germany for the placing on the market of foods, food ingredients and feed containing, consisting of or produced from genetically modified maize Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21 ('the application'), in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003. The application also covered the placing on the market of products containing or consisting of genetically modified maize Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21 for uses other than food and feed, with the exception of cultivation.
- (2) In addition, the application covered the placing on the market of products containing, consisting of or produced from 56 sub-combinations of the single transformation events constituting maize Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21. 22 of those sub-combinations were already authorized as follows: Bt11 × MIR162 × MIR604 × GA21, Bt11 × MIR162 × MIR604, Bt11 × MIR162 × GA21, Bt11 × MIR604 × GA21, MIR162 × MIR604 × GA21, Bt11 × MIR162, Bt11 × MIR604, Bt11 × GA21, MIR162 × MIR604, MIR162 × GA21 and MIR604 × GA21, authorised by Commission Implementing Decision (EU) 2016/1685 ⁽²⁾; Bt11 × MIR604 × 1507 × GA21, Bt11 × MIR604 × 1507, Bt11 × 1507 × GA21, MIR604 × 1507 × GA21, Bt11 × 1507, MIR604 × 1507 and 1507 × GA21, authorised by Commission Implementing Decision (EU) 2017/1209 ⁽³⁾; and Bt11 × MIR162 × 1507 × GA21, Bt11 × MIR162 × 1507, MIR162 × 1507 × GA21 and MIR162 × 1507, authorised by Commission Implementing Decision (EU) 2019/1305 ⁽⁴⁾.

⁽¹⁾ OJ L 268, 18.10.2003, p. 1.

⁽²⁾ 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).

⁽³⁾ 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).

⁽⁴⁾ 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 (OJ L 204, 2.8.2019, p. 69).

- (3) This Decision covers the remaining 34 sub-combinations: six sub-combinations of five events (Bt11 × MIR162 × MIR604 × 1507 × 5307, Bt11 × MIR162 × MIR604 × 1507 × GA21, Bt11 × MIR162 × MIR604 × 5307 × GA21, Bt11 × MIR162 × 1507 × 5307 × GA21, Bt11 × MIR604 × 1507 × 5307 × GA21 and MIR162 × MIR604 × 1507 × 5307 × GA21); 12 sub-combinations of four events (Bt11 × MIR162 × MIR604 × 1507, Bt11 × MIR162 × MIR604 × 5307, Bt11 × MIR162 × 1507 × 5307, Bt11 × MIR162 × 5307 × GA21, Bt11 × MIR604 × 1507 × 5307, Bt11 × MIR604 × 5307 × GA21, Bt11 × 1507 × 5307 × GA21, MIR162 × MIR604 × 1507 × 5307, MIR162 × MIR604 × 1507 × GA21, MIR162 × MIR604 × 5307 × GA21, MIR162 × 1507 × 5307 × GA21 and MIR604 × 1507 × 5307 × GA21); 11 sub-combinations of three events (Bt11 × MIR162 × 5307, Bt11 × MIR604 × 5307, Bt11 × 1507 × 5307, Bt11 × 5307 × GA21, MIR162 × MIR604 × 1507, MIR162 × MIR604 × 5307, MIR162 × 1507 × 5307, MIR162 × 5307 × GA21, MIR604 × 1507 × 5307, MIR604 × 5307 × GA21 and 1507 × 5307 × GA21); and five sub-combinations of two events (Bt11 × 5307, MIR162 × 5307, MIR604 × 5307, 1507 × 5307 and 5307 × GA21).
- (4) 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 ⁽⁵⁾. 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.
- (5) On 5 April 2019, the European Food Safety Authority ('the Authority') issued a favourable opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003 ⁽⁶⁾. The Authority concluded that genetically modified maize Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21 and its sub-combinations, as described in the application, are as safe as its non-genetically modified comparator and the tested non-genetically modified reference varieties with respect to the potential effects on human and animal health and the environment.
- (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 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 × MIR604 × 1507 × 5307 × GA21, and of the 34 sub-combinations indicated in recital (3) and listed in the application, 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 ⁽⁷⁾.
- (10) 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 ⁽⁸⁾, 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 covered by it, with the exception of food products, should contain a clear indication that they are not intended for cultivation.

⁽⁵⁾ 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).

⁽⁶⁾ EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Scientific Opinion on assessment of genetically modified maize Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21 and subcombinations, for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA-GMO-DE-2011-103). EFSA Journal 2019;17(4):5635.

⁽⁷⁾ 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⁾ 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).

- (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 environment effects. Those results should be presented in accordance with the requirements laid down in Commission Decision 2009/770/EC ⁽⁹⁾.
- (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 ⁽¹⁰⁾.
- (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 organisms and unique identifiers

Genetically modified maize (*Zea mays* L.), 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 × SYN-IR6Ø4-5 × DAS-Ø15Ø7-1 × SYN-Ø53Ø7-1 × MON-ØØØ21-9 for genetically modified maize Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21;
- (b) the unique identifier SYN-BTØ11-1 × SYN-IR162-4 × SYN-IR6Ø4-5 × DAS-Ø15Ø7-1 × SYN-Ø53Ø7-1 for genetically modified maize Bt11 × MIR162 × MIR604 × 1507 × 5307;
- (c) the unique identifier SYN-BTØ11-1 × SYN-IR162-4 × SYN-IR6Ø4-5 × DAS-Ø15Ø7-1 × MON-ØØØ21-9 for genetically modified maize Bt11 × MIR162 × MIR604 × 1507 × GA21;
- (d) the unique identifier SYN-BTØ11-1 × SYN-IR162-4 × SYN-IR6Ø4-5 × SYN-Ø53Ø7-1 × MON-ØØØ21-9 for genetically modified maize Bt11 × MIR162 × MIR604 × 5307 × GA21;
- (e) the unique identifier SYN-BTØ11-1 × SYN-IR162-4 × DAS-Ø15Ø7-1 × SYN-Ø53Ø7-1 × MON-ØØØ21-9 for genetically modified maize Bt11 × MIR162 × 1507 × 5307 × GA21;
- (f) the unique identifier SYN-BTØ11-1 × SYN-IR6Ø4-5 × DAS-Ø15Ø7-1 × SYN-Ø53Ø7-1 × MON-ØØØ21-9 for genetically modified maize Bt11 × MIR604 × 1507 × 5307 × GA21;
- (g) the unique identifier SYN-IR162-4 × SYN-IR6Ø4-5 × DAS-Ø15Ø7-1 × SYN-Ø53Ø7-1 × MON-ØØØ21-9 for genetically modified maize MIR162 × MIR604 × 1507 × 5307 × GA21;
- (h) the unique identifier SYN-BTØ11-1 x SYN-IR162-4 x SYN-IR6Ø4-5 x DAS-Ø15Ø7-1 for genetically modified maize Bt11 × MIR162 × MIR604 × 1507;

⁽⁹⁾ 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).

⁽¹⁰⁾ 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).

- (i) the unique identifier SYN-BTØ11-1 × SYN-IR162-4 × SYN-IR6Ø4-5 × SYN-Ø53Ø7-1 for genetically modified maize Bt11 × MIR162 × MIR604 × 5307;
- (j) the unique identifier SYN-BTØ11-1 × SYN-IR162-4 × DAS-Ø15Ø7-1 × SYN-Ø53Ø7-1 for genetically modified maize Bt11 × MIR162 × 1507 × 5307;
- (k) the unique identifier SYN-BTØ11-1 × SYN-IR162-4 × SYN-Ø53Ø7-1 × MON-ØØØ21-9 for genetically modified maize Bt11 × MIR162 × 5307 × GA21;
- (l) the unique identifier SYN-BTØ11-1 × SYN-IR6Ø4-5 × DAS-Ø15Ø7-1 × SYN-Ø53Ø7-1 for genetically modified maize Bt11 × MIR604 × 1507 × 5307;
- (m) the unique identifier SYN-BTØ11-1 × SYN-IR6Ø4-5 × SYN-Ø53Ø7-1 × MON-ØØØ21-9 for genetically modified maize Bt11 × MIR604 × 5307 × GA21;
- (n) the unique identifier SYN-BTØ11-1 × DAS-Ø15Ø7-1 × SYN-Ø53Ø7-1 × MON-ØØØ21-9 for genetically modified maize Bt11 × 1507 × 5307 × GA21;
- (o) the unique identifier SYN-IR162-4 × SYN-IR6Ø4-5 × DAS-Ø15Ø7-1 × SYN-Ø53Ø7-1 for genetically modified maize MIR162 × MIR604 × 1507 × 5307;
- (p) the unique identifier SYN-IR162-4 × SYN-IR6Ø4-5 × DAS-Ø15Ø7-1 × MON-ØØØ21-9 for genetically modified maize MIR162 × MIR604 × 1507 × GA21;
- (q) the unique identifier SYN-IR162-4 × SYN-IR6Ø4-5 × SYN-Ø53Ø7-1 × MON-ØØØ21-9 for genetically modified maize MIR162 × MIR604 × 5307 × GA21;
- (r) the unique identifier SYN-IR162-4 × DAS-Ø15Ø7-1 × SYN-Ø53Ø7-1 × MON-ØØØ21-9 for genetically modified maize MIR162 × 1507 × 5307 × GA21;
- (s) the unique identifier SYN-IR6Ø4-5 × DAS-Ø15Ø7-1 × SYN-Ø53Ø7-1 × MON-ØØØ21-9 for genetically modified maize MIR604 × 1507 × 5307 × GA21;
- (t) the unique identifier SYN-BTØ11-1 × SYN-IR162-4 × SYN-Ø53Ø7-1 for genetically modified maize Bt11 × MIR162 × 5307;
- (u) the unique identifier SYN-BTØ11-1 × SYN-IR6Ø4-5 × SYN-Ø53Ø7-1 for genetically modified maize Bt11 × MIR604 × 5307;
- (v) the unique identifier SYN-BTØ11-1 × DAS-Ø15Ø7-1 × SYN-Ø53Ø7-1 for genetically modified maize Bt11 × 1507 × 5307;
- (w) the unique identifier SYN-BTØ11-1 × SYN-Ø53Ø7-1 × MON-ØØØ21-9 for genetically modified maize Bt11 × 5307 × GA21;
- (x) the unique identifier SYN-IR162-4 × SYN-IR6Ø4-5 × DAS-Ø15Ø7-1 for genetically modified maize MIR162 × MIR604 × 1507;
- (y) the unique identifier SYN-IR162-4 × SYN-IR6Ø4-5 × SYN-Ø53Ø7-1 for genetically modified maize MIR162 × MIR604 × 5307;
- (z) the unique identifier SYN-IR162-4 × DAS-Ø15Ø7-1 × SYN-Ø53Ø7-1 for genetically modified maize MIR162 × 1507 × 5307;
- (aa) the unique identifier SYN-IR162-4 × SYN-Ø53Ø7-1 × MON-ØØØ21-9 for genetically modified maize MIR162 × 5307 × GA21;
- (bb) the unique identifier SYN-IR6Ø4-5 × DAS-Ø15Ø7-1 × SYN-Ø53Ø7-1 for genetically modified maize MIR604 × 1507 × 5307;
- (cc) the unique identifier SYN-IR6Ø4-5 × SYN-Ø53Ø7-1 × MON-ØØØ21-9 for genetically modified maize MIR604 × 5307 × GA21;
- (dd) the unique identifier DAS-Ø15Ø7-1 × SYN-Ø53Ø7-1 × MON-ØØØ21-9 for genetically modified maize 1507 × 5307 × GA21;
- (ee) the unique identifier SYN-BTØ11-1 × SYN-Ø53Ø7-1 for genetically modified maize Bt11 × 5307;
- (ff) the unique identifier SYN-IR162-4 × SYN-Ø53Ø7-1 for genetically modified maize MIR162 × 5307;

- (gg) the unique identifier SYN-IR6Ø4-5 × SYN-Ø53Ø7-1 for genetically modified maize MIR604 × 5307;
- (hh) the unique identifier DAS-Ø15Ø7-1 × SYN-Ø53Ø7-1 for genetically modified maize 1507 × 5307;
- (ii) the unique identifier SYN-Ø53Ø7-1 × MON-ØØØ21-9 for genetically modified maize 5307 × GA21.

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 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 in the Union 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, 28 November 2019.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

ANNEX

(a) Applicant and Authorisation holder:

Name: Syngenta Crop Protection AG
Address: Rosentalstrasse 67, CH-4058 Basel, Switzerland

Represented in the Union by: Syngenta Crop Protection NV/SA, Avenue Louise, 489, 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 (*Zea mays* L.) 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 maize SYN-BTØ11-1 expresses the *cry1Ab* gene, which confers protection against certain lepidopteran pests, and the *pat* gene, which confers tolerance to glufosinate-ammonium-based herbicides.

The genetically modified maize SYN-IR162-4 expresses the *vip3Aa20* gene, which confers protection against certain lepidopteran pests, and the *pmi* gene, which was used as a selectable marker.

The genetically modified maize SYN-IR6Ø4-5 expresses a modified *cry3A* gene, which provides protection against certain coleopteran pests, and the *pmi* gene, which was used as a selectable marker.

The genetically modified maize DAS-Ø15Ø7-1 expresses the *cry1F* gene, which confers protection against certain lepidopteran pests and the *pat* gene, which confers tolerance to glufosinate-ammonium-based herbicides.

The genetically modified maize SYN-Ø53Ø7-1 expresses the *ecry3.1Ab* gene, which confers resistance to certain coleopteran pests, and the *pmi* gene, which was used as a selectable marker.

The genetically modified maize MON-ØØØ21-9 expresses the *mepsps* gene, 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 documents accompanying 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 are those individually validated for genetically modified maize events SYN-BTØ11-1, SYN-IR162-4, SYN-IR6Ø4-5, DAS-Ø15Ø7-1, SYN-Ø53Ø7-1 and MON-ØØØ21-9 and further verified on maize stack Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21.
- (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), ERM®-BF423 (for SYN-IR6Ø4-5) 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 0917-A and 1208-A (for SYN-IR162-4), AOCs 0411-C and 0411-D (for SYN-Ø53Ø7-1) and AOCs 0407-A and 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-BT011-1 × SYN-IR162-4 × SYN-IR604-5 × DAS-01507-1 × SYN-05307-1 × MON-00021-9;

SYN-BT011-1 × SYN-IR162-4 × SYN-IR604-5 × DAS-01507-1 × SYN-05307-1;

SYN-BT011-1 × SYN-IR162-4 × SYN-IR604-5 × DAS-01507-1 × MON-00021-9;

SYN-BT011-1 × SYN-IR162-4 × SYN-IR604-5 × SYN-05307-1 × MON-00021-9;

SYN-BT011-1 × SYN-IR162-4 × DAS-01507-1 × SYN-05307-1 × MON-00021-9;

SYN-BT011-1 × SYN-IR604-5 × DAS-01507-1 × SYN-05307-1 × MON-00021-9;

SYN-IR162-4 × SYN-IR604-5 × DAS-01507-1 × SYN-05307-1 × MON-00021-9;

SYN-BT011-1 x SYN-IR162-4 x SYN-IR604-5 x DAS-01507-1;

SYN-BT011-1 × SYN-IR162-4 × SYN-IR604-5 × SYN-05307-1;

SYN-BT011-1 × SYN-IR162-4 × DAS-01507-1 × SYN-05307-1;

SYN-BT011-1 × SYN-IR162-4 × SYN-05307-1 × MON-00021-9;

SYN-BT011-1 × SYN-IR604-5 × DAS-01507-1 × SYN-05307-1;

SYN-BT011-1 × SYN-IR604-5 × SYN-05307-1 × MON-00021-9;

SYN-BT011-1 × DAS-01507-1 × SYN-05307-1 × MON-00021-9;

SYN-IR162-4 × SYN-IR604-5 × DAS-01507-1 × SYN-05307-1;

SYN-IR162-4 × SYN-IR604-5 × DAS-01507-1 × MON-00021-9;

SYN-IR162-4 × SYN-IR604-5 × SYN-05307-1 × MON-00021-9;

SYN-IR162-4 × DAS-01507-1 × SYN-05307-1 × MON-00021-9;

SYN-IR604-5 × DAS-01507-1 × SYN-05307-1 × MON-00021-9;

SYN-BT011-1 × SYN-IR162-4 × SYN-05307-1;

SYN-BT011-1 × SYN-IR604-5 × SYN-05307-1;

SYN-BT011-1 × DAS-01507-1 × SYN-05307-1;

SYN-BT011-1 × SYN-05307-1 × MON-00021-9;

SYN-IR162-4 × SYN-IR604-5 × DAS-01507-1;

SYN-IR162-4 × SYN-IR604-5 × SYN-05307-1;

SYN-IR162-4 × DAS-01507-1 × SYN-05307-1;

SYN-IR162-4 × SYN-05307-1 × MON-00021-9;

SYN-IR604-5 × DAS-01507-1 × SYN-05307-1;

SYN-IR604-5 × SYN-05307-1 × MON-00021-9;

DAS-01507-1 × SYN-05307-1 × MON-00021-9;

SYN-BT011-1 × SYN-05307-1;

SYN-IR162-4 × SYN-05307-1;

SYN-IR604-5 × SYN-05307-1;

DAS-01507-1 × SYN-05307-1;

SYN-05307-1 × MON-00021-9.

(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 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.

RULES OF PROCEDURE

AMENDMENTS OF THE RULES OF PROCEDURE OF THE COURT OF JUSTICE

THE COURT OF JUSTICE,

Having regard to the Treaty on the Functioning of the European Union, and in particular the sixth paragraph of Article 253 thereof,

Having regard to the Treaty establishing the European Atomic Energy Community, and in particular Article 106a(1) thereof,

Having regard to the Protocol on the Statute of the Court of Justice of the European Union, and in particular Article 63 thereof,

Whereas experience gained from the implementation of the Rules of Procedure should be taken into account to clarify the scope of certain of their provisions or, as appropriate, to supplement or simplify them,

Whereas it is also necessary to amend the Rules of Procedure in order to take into account certain recent developments relating, in particular, to the method for designating the First Advocate General and the new regulatory framework for the protection of personal data in the European Union, which requires certain adjustments to be made to the standard rules for the service and publication of procedural documents,

With the approval of the Council given on 8 November 2019,

HAS ADOPTED THE FOLLOWING AMENDMENTS TO ITS RULES OF PROCEDURE:

Article 1

The Rules of Procedure of the Court of Justice of 25 September 2012 ⁽¹⁾ are hereby amended as follows:

1. The title of Chapter 2 of Title I is amended as follows:

‘PRESIDENCY OF THE COURT, CONSTITUTION OF THE CHAMBERS AND ELECTION OF THE FIRST ADVOCATE GENERAL’

2. Article 14 is replaced by the following:

Article 14

Election of the First Advocate General

1. The Advocates General shall, immediately after the partial replacement provided for in the second paragraph of Article 253 TFEU, elect one of their number as First Advocate General for a term of three years.
 2. If the office of the First Advocate General falls vacant before the normal date of expiry of the term thereof, he shall be replaced for the remainder of the term.
 3. The elections provided for in this Article shall be by secret ballot. The Advocate General obtaining the votes of more than half of the Advocates General of the Court shall be elected. If no Advocate General obtains that majority, further ballots shall be held until that majority is attained.
 4. The name of the First Advocate General elected in accordance with this Article shall be published in the *Official Journal of the European Union*.
3. Article 21(4) is replaced by the following:
 - ‘4. A notice shall be published in the *Official Journal of the European Union* indicating the date of registration of an application initiating proceedings, the names of the parties or, as the case may be, initials replacing a name, the form of order sought by the applicant and a summary of the pleas in law and of the main supporting arguments.

⁽¹⁾ OJ L 265, 29.9.2012, p. 1, as amended on 18 June 2013 (OJ L 173, 26.6.2013, p. 65), 19 July 2016 (OJ L 217, 12.8.2016, p. 69) and 9 April 2019 (OJ L 111, 25.4.2019, p. 73).

5. In the cases referred to in Title III of these Rules, the notice published in the *Official Journal of the European Union* shall indicate the date of lodging of a request for a preliminary ruling, the referring court or tribunal, the names of the parties to the main proceedings or, as the case may be, initials replacing a name, as well as the questions referred to the Court.'
4. Article 37(3) is replaced by the following:
- '3. In preliminary ruling proceedings, the language of the case shall be the language of the referring court or tribunal. At the duly substantiated request of one of the parties to the main proceedings, and after the other party to the main proceedings and the Advocate General have been heard, the use of another of the languages mentioned in Article 36 may be authorised for the oral part of the procedure. Where granted, the authorisation to use that other language shall apply in respect of all the interested persons referred to in Article 23 of the Statute.'
5. Article 38(5) is replaced by the following:
- '5. The States, other than the Member States, which are parties to the EEA Agreement, and also the EFTA Surveillance Authority, shall be entitled to use one of the languages mentioned in Article 36, other than the language of the case, when they take part in preliminary ruling proceedings or intervene in a case before the Court. This provision shall apply both to written documents and to oral statements. The Registrar shall arrange in each instance for translation into the language of the case.'
6. Article 38(6) is replaced by the following:
- '6. Non-Member States taking part in preliminary ruling proceedings pursuant to the fourth paragraph of Article 23 of the Statute shall be entitled to use one of the languages mentioned in Article 36 other than the language of the case. This provision shall apply both to written documents and to oral statements. The Registrar shall arrange in each instance for translation into the language of the case.'
7. Article 39 is replaced by the following:
- '1. The Registrar shall arrange for procedural documents lodged during the written part of the procedure to be translated into the language of the case and, as the case may be, into another language mentioned in Article 36.
2. The Registrar shall also ensure that what is said at the hearing is interpreted into the language of the case and into the other languages that are mentioned in Article 36 and are used by the parties present at the hearing or considered necessary for the efficient conduct of that hearing.'
8. The following sentence is added to Article 57(7):
- 'Article 51 of these Rules shall not apply to the latter time limit.'
9. In Article 89(1), point (h) is replaced by the following:
- '(h) a description of the parties or of the interested persons referred to in Article 23 of the Statute who participated in the proceedings,'
10. Article 95(2) is replaced by the following:
- '2. At the request of the referring court or tribunal, of a party to the main proceedings or of its own motion, the Court may also render anonymous one or more persons or entities concerned by the case.'
11. Article 119(4) is replaced by the following:
- '4. If those documents are not lodged, the Registrar shall prescribe a reasonable time limit within which the party concerned is to produce them. If the party concerned fails to produce the required documents within the time limit prescribed, the President shall, after hearing the Judge-Rapporteur and the Advocate General, decide whether the non-compliance with that procedural requirement renders the application or written pleading formally inadmissible. If he considers it necessary, the President may refer that question to the Court of Justice.'
12. Article 122(3) is replaced by the following:
- '3. If an application does not comply with the requirements set out in paragraphs 1 or 2 of this Article, the Registrar shall prescribe a reasonable time limit within which the applicant is to produce the abovementioned documents. If the applicant fails to put the application in order, the President shall, after hearing the Judge-Rapporteur and the Advocate General, decide whether the non-compliance with these conditions renders the application formally inadmissible. If he considers it necessary, the President may refer that question to the Court of Justice.'

13. Article 123 is replaced by the following:

‘The application shall be served on the defendant. In cases where Article 119(4) or Article 122(3) applies, service shall be effected as soon as the application has been put in order or the President or the Court has declared it admissible notwithstanding the failure to observe the requirements set out in those two Articles.’

14. Article 131 is replaced by the following:

‘1. The application to intervene shall be served on the parties in order to obtain any written or oral observations they may wish to make on that application.

2. Where the application is submitted pursuant to the first paragraph of Article 40 of the Statute, the intervention shall be allowed by decision of the President and the intervener shall receive a copy of every procedural document served on the parties, unless the parties have, within 10 days after the service referred to in paragraph 1 has been effected, identified secret or confidential items or documents which, if communicated to the intervener, the parties claim would be prejudicial to them. In that case, the President shall decide on the application to intervene by order, after hearing the Judge-Rapporteur and the Advocate General, and the intervener shall receive a copy of every procedural document served on the parties, save, where applicable, for the secret or confidential items or documents excluded from such communication.

3. Where the application is submitted pursuant to the second paragraph of Article 40 of the Statute, the President shall decide on the application to intervene by order, after hearing the Judge-Rapporteur and the Advocate General, or shall refer the application to the Court. If the application to intervene is granted, the intervener shall receive a copy of every procedural document served on the parties, save, where applicable, for the secret or confidential items or documents excluded from such communication.

4. Where the application is submitted pursuant to the third paragraph of Article 40 of the Statute, the intervention shall be allowed by decision of the President and the intervener shall receive a copy of every procedural document served on the parties unless those parties have, within 10 days after the service referred to in paragraph 1 has been effected, put forward observations on the application to intervene or identified secret or confidential items or documents which, if communicated to the intervener, the parties claim would be prejudicial to them. In such cases, the President shall decide on the application to intervene by order, after hearing the Judge-Rapporteur and the Advocate General, and the intervener shall receive a copy of every procedural document served on the parties, save, where applicable, for the secret or confidential items or documents excluded from such communication.’

15. The following Article is inserted after Article 159:

‘Article 159a

Manifestly inadmissible or manifestly unfounded requests and applications

Where a request or an application referred to in this Chapter is, in whole or in part, manifestly inadmissible or manifestly unfounded, the Court may, having heard the Judge-Rapporteur and the Advocate General, at any time decide to dismiss it, in whole or in part, by reasoned order.’

16. Article 167 is replaced by the following:

‘1. An appeal shall be brought by lodging an application at the Registry of the Court of Justice or of the General Court. When that application is lodged at the Registry of the General Court, it shall be transmitted forthwith to the Registry of the Court of Justice.

2. As soon as it is informed of the existence of an appeal, the Registry of the General Court shall forthwith transmit to the Registry of the Court of Justice the file in the case at first instance and any procedural file of the Board of Appeal transmitted to the General Court pursuant to the provisions of the Rules of Procedure of the General Court concerning proceedings relating to intellectual property rights.’

17. Article 168(4) is replaced by the following:

‘4. If an appeal does not comply with paragraphs 1 to 3 of this Article, the Registrar shall prescribe a reasonable time limit within which the appellant is to put the appeal in order. If the appellant fails to put the appeal in order within the time limit prescribed, the President shall, after hearing the Judge-Rapporteur and the Advocate General, decide whether the non-compliance with that formal requirement renders the appeal formally inadmissible. If he considers it necessary, the President may refer that question to the Court of Justice.’

18. Article 171(2) is replaced by the following:

‘2. In a case where Article 168(4) of these Rules applies, service shall be effected as soon as the appeal has been put in order or the President or the Court of Justice has declared it admissible notwithstanding the failure to observe the formal requirements laid down by that Article.’

19. Title VII shall be renamed as follows:

‘REQUESTS FOR OPINIONS’

20. Article 200 is replaced by the following:

‘1. The Opinion, signed by the President, the Judges who took part in the deliberations and the Registrar, shall be delivered in open court.

2. It shall be served on all the Member States and on the institutions referred to in Article 196(1).’

21. Article 205 is repealed.

22. Article 206(2) is replaced by the following:

‘2. The request and annexes thereto shall be served on the European Council or on the Council, as appropriate, each of which shall have a non-extendible time limit of 10 days from such service to submit its written observations. Article 51 shall not apply to that time limit.’

Article 2

These amendments to the Rules of Procedure, authentic in the languages referred to in Article 36 of those Rules, shall be published in the *Official Journal of the European Union* and shall enter into force on the first day of the month following that of their publication.

The amendment referred to in Article 1(2) shall apply from the next partial replacement of Judges and Advocates General, provided for in the second paragraph of Article 253 of the Treaty on the Functioning of the European Union.

Done at Luxembourg, on 26 November 2019.

CORRIGENDA**Corrigendum to Council Regulation (EU) 2019/1890 of 11 November 2019 concerning restrictive measures in view of Turkey's unauthorised drilling activities in the Eastern Mediterranean***(Official Journal of the European Union L 291 of 12 November 2019)*

On page 8, in Article 12(1):

for: 'Where the Council decides to subject a natural or legal person, entity or body to the measures referred to in Article 3, it shall amend Annex I accordingly.'

read: 'Where the Council decides to subject a natural or legal person, entity or body to the measures referred to in Article 2, it shall amend Annex I accordingly.'

ISSN 1977-0677 (electronic edition)
ISSN 1725-2555 (paper edition)



Publications Office of the European Union
2985 Luxembourg
LUXEMBOURG

