Official Journal of the European Union

L 300

Volume 64

English edition

Legislation

24 August 2021

Contents

[1] Text with EEA relevance.

EN

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

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

([1]) Text with EEA relevance.

II

(Non-legislative acts)

INTERNATIONAL AGREEMENTS

Information relating to the entry into force of the Agreement between the European Union and Antigua and Barbuda amending the Agreement between the European Community and Antigua and Barbuda on the short-stay visa waiver

The Agreement between the European Union and Antigua and Barbuda amending the Agreement between the European Community and Antigua and Barbuda on the short-stay visa waiver will enter into force on 1 November 2021, the procedure provided for in Article 2 of the Agreement having been completed on 10 May 2021.

DECISIONS

COMMISSION IMPLEMENTING DECISION (EU) 2021/1384

of 13 August 2021

on the request for registration of the European citizens' initiative entitled 'ReturnthePlastics: A Citizen's Initiative to implement an EU-wide deposit-system to recycle plastic bottles' pursuant to Regulation (EU) 2019/788 of the European Parliament and of the Council

(notified under document C(2021) 5953)

(Only the English text is authentic)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2019/788 of the European Parliament and of the Council of 17 April 2019 on the European citizens' initiative ([1]), and in particular Article 6(2) and (3) thereof,

Whereas:

(1) A request for registration of a European citizens' initiative entitled 'ReturnthePlastics: A Citizen's Initiative to implement an EU-wide deposit-system to recycle plastic bottles' was submitted to the Commission on 2 July 2021.

(2) The objectives of the initiative are expressed as follows: '(1) To implement an EU-wide deposit-system to recycle plastic bottles; (2) To incentivize all EU Member states that supermarkets (chains) which are selling plastic bottles to install reverse vending machines for recycling the plastic bottles after being purchased and used by the consumer; (3) To make the plastic bottle producing companies pay plastic taxes for the recycling and deposit-system of the plastic bottles (under the principle that the polluter should pay)'.

(3) An annex provides further details on the subject matter, objectives and background to the initiative. In particular, it explains that the initiative proposes an 'EU Directive for a deposit system to allow consumers to conveniently return their plastic bottles to the supermarkets where they were purchased', with a suggested deposit of EUR 0,15 per bottle. It claims that such a system is needed in view of the fact that plastic bottles, which are among the most commonly used plastic products, are not included in the single-use plastics ban. Finally, the annex states that the goal is to have the #ReturnthePlastics recycling system for plastic bottles implemented in five Member States by the time the Climate Conference COP26 is held on 1-12 November 2021, and later in the whole of the Union.

(4) Insofar as the initiative aims at preserving, protecting and improving the quality of the environment, protecting human health and prudent and rational utilisation of natural resources, the Commission has the power to present a proposal for a legal act on the basis of Article 192(1) of the Treaty.

(5) Insofar as there are differences between national rules that can create obstacles to trade and obstruct the fundamental freedoms and thus have a direct effect on the functioning of the internal market or cause significant distortions of competition, the Commission has the power to present a proposal for a legal act approximating the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market on the basis of Article 114 of the Treaty.

([1]) OJ L 130, 17.5.2019, p. 55.

(6) For those reasons, none of the parts of the initiative manifestly falls outside the framework of the Commission's powers to submit a proposal for a legal act of the Union for the purpose of implementing the Treaties.

(7) This conclusion is without prejudice to the assessment of whether the concrete factual and substantive conditions required for the Commission to act, including compliance with the principle of proportionality, would be met in this case.

(8) The group of organisers has provided appropriate evidence that it fulfils the requirements laid down in Article 5(1) and (2) of Regulation (EU) 2019/788 and has designated the contact persons in accordance with Article 5(3), first subparagraph, of that Regulation.

(9) The initiative is not manifestly abusive, frivolous or vexatious, nor is it manifestly contrary to the values of the Union as set out in Article 2 of the Treaty on European Union and rights enshrined in the Charter of Fundamental Rights of the European Union.

(10) The initiative entitled 'ReturnthePlastics: A Citizen's Initiative to implement an EU-wide deposit-system to recycle plastic bottles' should therefore be registered,

HAS ADOPTED THIS DECISION:

Article 1

The European citizens' initiative entitled 'ReturnthePlastics: A Citizen's Initiative to implement an EU-wide deposit-system to recycle plastic bottles' shall be registered.

Article 2

This Decision is addressed to the group of organisers of the European citizens' initiative entitled 'ReturnthePlastics: A Citizen's Initiative to implement an EU-wide deposit-system to recycle plastic bottles', represented by Ms Anouk STALLAERTS and Ms Marina KONSTANTINIDI, acting as contact persons.

Done at Brussels, 13 August 2021.

For the Commission
Věra JOUROVÁ
Vice-President

COMMISSION IMPLEMENTING DECISION (EU) 2021/1385

of 17 August 2021

renewing the authorisation for the placing on the market of feed and products other than food and feed containing or consisting of genetically modified oilseed rape GT73 (MON-ØØØ73-7) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

(notified under document C(2021) 5992)

(Only the Dutch text is authentic)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to 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 2005/635/EC ([2]) authorised the placing on the market of feed containing or consisting of genetically modified oilseed rape GT73. The scope of that authorisation also covers products containing or consisting of oilseed rape GT73 for uses other than food or feed, with the exception of cultivation.

(2) On 18 February 2016, Monsanto Europe N.V., based in Belgium, submitted on behalf of the authorisation holder Monsanto Company, based in the United States, an application to the Commission, in accordance with Articles 11 and 23 of Regulation (EC) No 1829/2003, for the renewal of the authorisation for the placing on the market of the products covered by Decision 2005/635/EC.

(3) By a letter dated 27 August 2018, Monsanto Europe N.V. informed the Commission that, as of 23 August 2018, it converted its legal form and changed its name to Bayer Agriculture BVBA.

(4) By a letter dated 28 July 2020, Bayer Agriculture BVBA, Belgium, informed the Commission that, as of 1 August 2020, it changed its name to Bayer Agriculture BV, Belgium.

(5) By a letter dated 28 July 2020, Bayer Agriculture BVBA, Belgium, representing Monsanto Company, United States, informed the Commission that, as of 1 August 2020, Monsanto Company, United States, converted its legal form and changed its name to Bayer CropScience LP, United States.

(6) On 29 July 2020, 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 any new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on genetically modified oilseed rape GT73, adopted by the Authority in 2004 ([4]).

([1]) OJ L 268, 18.10.2003, p. 1.

([2]) Commission Decision 2005/635/EC of 31 August 2005 concerning the placing on the market, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of an oilseed rape product (*Brassica napus* L., GT73 line) genetically modified for tolerance to the herbicide glyphosate (OJ L 228, 3.9.2005, p. 11).

([3]) EFSA Panel on Genetically Modified Organisms (GMO) 2020. Scientific Opinion on the assessment of genetically modified oilseed rape GT73 for renewal authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-002). EFSA Journal 2020;18 (7):6199. https://doi.org/10.2903/j.efsa.2020.6199.

([4]) Opinion of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to the Notification (Reference C/NL/98/11) for the placing on the market of glyphosate-tolerant oilseed rape event GT73, for import and processing, under Part C of Directive 2001/18/EC from Monsanto. EFSA Journal 2004;2(3):29. https://doi.org/10.2903/j.efsa.2004.29.

(7) 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.

(8) The Authority also concluded that the monitoring plan for the environmental effects submitted by the applicant, consisting of a general surveillance plan, is in line with the intended uses of the products.

(9) Taking into account those conclusions, the authorisation for the placing on the market of the products covered by Decision 2005/635/EC should be renewed.

(10) A unique identifier has been assigned to genetically modified oilseed rape GT73, in accordance with Commission Regulation (EC) No 65/2004 ([5]), in the context of its initial authorisation by Decision 2005/635/EC. That unique identifier should continue to be used.

(11) 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 genetically modified oilseed rape GT73 remains within the limits of the authorisation granted by this Decision, the labelling of such products should contain a clear indication that they are not intended for cultivation.

(12) 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]).

(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 feed containing or consisting of genetically modified oilseed rape GT73, 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.

(14) All relevant information on the authorisation of the products covered by this Decision 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 ([8]).

(16) The Standing Committee on Plants, Animals, Food and Feed has not delivered an opinion within the time limit laid down by its Chair. 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,

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([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 oilseed rape (*Brassica napus* L.) GT73, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier MON-ØØØ73-7, 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) feed containing or consisting of genetically modified oilseed rape MON-ØØØ73-7;

(b) products containing or consisting of genetically modified oilseed rape MON-ØØØ73-7 for uses other than those provided for in point (a) and other than food, 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 'oilseed rape'.

2. The words 'not for cultivation' shall appear on the label of and in the documents accompanying the products covered by this Decision.

Article 4

Method for detection

The method set out in point (d) of the Annex shall apply for the detection of genetically modified oilseed rape MON-ØØØ73-7.

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 Bayer CropScience LP, United States, represented in the Union by Bayer Agriculture BV, 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 CropScience LP represented in the Union by Bayer Agriculture BV, Scheldelaan 460, 2040 Antwerp, Belgium.

Done at Brussels, 17 August 2021.

For the Commission,
Stella KYRIAKIDES
Member of the Commission

ANNEX

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

Name: Bayer CropScience LP

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

Represented in the Union by: Bayer Agriculture BV, Scheldelaan 460, 2040 Antwerp, Belgium.

(b) **Designation and specification of the products:**

(1) feed containing or consisting of genetically modified oilseed rape MON-ØØØ73-7;

(2) products containing or consisting of genetically modified oilseed rape MON-ØØØ73-7 for uses other than those provided in point (1) and other than food, with the exception of cultivation.

The genetically modified oilseed rape MON-ØØØ73-7 expresses the *cp4 epsps* and *goxv247* genes, which confer 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 'oilseed rape'.

(2) The words 'not for cultivation' shall appear on the label of and in the documents accompanying the products referred to in points (b)(1) and (2).

(d) **Method for detection:**

(1) Event specific real-time quantitative PCR based method for the detection of genetically modified oilseed rape MON-ØØØ73-7.

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

(3) Reference Material: AOCS 0304-B accessible via the American Oil Chemists Society at https://www.aocs.org/crm

(e) **Unique identifier:**

MON-ØØØ73-7

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

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

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

Not required.

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

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

[Link: *plan published in the 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) 2021/1386

of 17 August 2021

authorising the placing on the market of products containing, consisting of or produced from genetically modified soybean DAS-81419-2 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

(notified under document C(2021) 5993)

(Only the Dutch text is authentic)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to 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 9 February 2012, Dow AgroSciences Ltd, based in United Kingdom, submitted, on behalf of Dow AgroSciences LLC, based in the United States of America, an application to the national competent authority of the Netherlands for the placing on the market of foods, food ingredients and feed containing, consisting of or produced from genetically modified soybean DAS-81419-2, in accordance with Article 5 and Article 17 of Regulation (EC) No 1829/2003 ('the application'). The application also concerned the placing on the market of products containing or consisting of genetically modified soybean DAS-81419-2 for uses other than food and feed, with the exception of cultivation.

(2) In accordance with Article 5(5) and Article 17(5) of Regulation (EC) No 1829/2003, the application included information and conclusions about the risk assessment carried out in accordance with the principles set out in Annex II to Directive 2001/18/EC of the European Parliament and of the Council ([2]). 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 5 December 2016, the European Food Safety Authority ('the Authority') issued a favourable scientific opinion in accordance with Article 6 and Article 18 of Regulation (EC) No 1829/2003 ([3]). The Authority concluded that genetically modified soybean DAS-81419-2, as described in the application, is as safe as and as nutritious as its conventional counterpart and the tested non-genetically modified soybean reference varieties with respect to the potential effects on human and animal health and the environment.

(4) In its opinion, the Authority considered all the questions and concerns raised by the Member States in the context of the consultation of the national competent authorities as provided for in Article 6(4) and Article 18(4) of Regulation (EC) No 1829/2003.

(5) The Authority also concluded that the monitoring plan for the environmental effects, submitted by the applicant, consisting of a general surveillance plan, is in line with the intended uses of the products.

([1]) OJ L 268, 18.10.2003, p. 1.

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

([3]) EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2016. Scientific Opinion on an application by Dow AgroSciences (EFSA-GMO-NL-2013-116) for placing on the market of genetically modified insect-resistant soybean DAS-81419-2 for food and feed uses, import and processing under Regulation (EC) No 1829/2003. *EFSA Journal* 2016;14(12):4642[, 23 pp.; https://doi.org/10.2903/j.efsa.2016.4642

(6) By a letter dated 10 July 2017, Dow AgroSciences Ltd, requested the Commission not to proceed with the authorisation of genetically modified soybean DAS-81419-2 until the scientific opinion of the Authority on genetically modified soybean DAS-81419-2 x DAS-44406-6 is published.

(7) By a letter dated 13 September 2018, Dow AgroSciences Ltd informed the Commission that the new representative in the Union of Dow AgroSciences LLC, United States, is Dow AgroSciences Distribution SAS, based in France. By letters, respectively dated 7 September 2018 and 12 October 2018, Dow AgroSciences Distribution SAS and Dow AgroSciences LLC confirmed their agreement with the requested change.

(8) By a letter dated 25 January 2021, following the publication on 20 November 2020 of the Authority's positive scientific opinion on genetically modified soybean DAS-81419-2 x DAS-44406-6 ([4]), Dow AgroSciences Distribution SAS requested the Commission to proceed with the authorisation of genetically modified soybean DAS-81419-2.

(9) Taking into account the conclusions expressed in the Authority's opinion, the placing on the market of products containing, consisting of or produced from genetically modified soybean DAS-81419-2 should be authorised for the uses listed in the application.

(10) By a letter of 22 March 2021, Corteva Agriscience Belgium BV informed the Commission that Dow AgroSciences LLC changed the name to Corteva Agriscience LLC, based in the United States, as of 1 January 2021.

(11) By a letter of 22 March 2021, Corteva Agriscience LLC informed the Commission that its representative in the Union is Corteva Agriscience Belgium B.V., based in Belgium, as of 22 March 2021.

(12) A unique identifier should be assigned to genetically modified soybean DAS-81419-2 in accordance with Commission Regulation (EC) No 65/2004 ([5]).

(13) For the products covered by this Decision, 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 ([6]), appear to be necessary. 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 DAS-81419-2, with the exception of foods and food ingredients, should contain a clear indication that they are not intended for cultivation.

(14) 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 ([7]).

(15) 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 DAS-81419-2, 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.

([4]) EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2020. Scientific Opinion on application EFSA-GMO-NL-2016-132 for authorisation of genetically modified of insect-resistant and herbicide-tolerant soybean DAS–81419–2 × DAS–44406–6 for food and feed uses, import and processing submitted in accordance with Regulation (EC) No 1829/2003 by Dow Agrosciences LCC. *EFSA Journal* 2020;18(11):6302, 37 pp.; https://doi.org/10.2903/j.efsa.2020.6302

([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).

(16) All relevant information on the authorisation of the products covered by this Decision 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.

(17) This Decision is to be notified through the Biosafety Clearing-House to the Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, pursuant to Article 9(1) and Article 15(2)(c) of Regulation (EC) No 1946/2003 of the European Parliament and of the Council ([8]).

(18) 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.) DAS-81419-2, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier DAS-81419-2, in accordance with Regulation (EC) No 65/2004.

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 soybean DAS-81419-2;

(b) feed containing, consisting of or produced from genetically modified soybean DAS-81419-2;

(c) products containing or consisting of genetically modified soybean DAS-81419-2 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 '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 DAS-81419-2 as referred to in Article 1, with the exception of products referred to in Article 2, point (a).

Article 4

Method for detection

The method set out in point (d) of the Annex shall apply for the detection of genetically modified soybean DAS-81419-2.

([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 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 Corteva Agriscience LLC represented in the Union by Corteva Agriscience Belgium B.V.

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 Corteva Agriscience LLC, 9330 Zionsville Road Indianapolis, Indiana 46268-1054, United States of America, represented by Corteva Agriscience Belgium B.V., Bedrijvenlaan 9, 2800 Mechelen, Belgium.

Done at Brussels, 17 August 2021.

For the Commission,
Stella KYRIAKIDES
Member of the Commission

ANNEX

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

Name: Corteva Agriscience LLC

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

Represented in the Union by: Corteva Agriscience Belgium B.V., Bedrijvenlaan 9, 2800 Mechelen, Belgium.

(b) **Designation and specification of the products:**

(1) foods and food ingredients containing, consisting of or produced from genetically modified soybean DAS-81419-2;

(2) feed containing, consisting of or produced from genetically modified soybean DAS-81419-2;

(3) products containing or consisting of genetically modified soybean DAS-81419-2 for uses other than those provided for in points (1) and (2), with the exception of cultivation.

The genetically modified soybean DAS-81419-2 expresses the synthetic *cry1Fv3* gene and the synthetic *cry1Ac* gene, which confer protection against certain lepidopteran pests. In addition, the *pat* gene, conferring tolerance to glufosinate-ammonium-based herbicide, was used as a selection marker in the genetic modification process.

(c) **Labelling:**

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

(2) The words 'not for cultivation' shall appear on the label of and in documents accompanying the products containing or consisting of soybean DAS-81419-2, with the exception of products referred to in point (b)(1).

(d) **Method for detection:**

(1) Event specific real-time quantitative PCR based method for detection of the genetically modified soybean DAS-81419-2;

(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: ERM®-BF437 is accessible via the Joint Research Centre (JRC) of the European Commission at https://ec.europa.eu/jrc/en/reference-materials/catalogue.

(e) **Unique identifier:**

DAS-81419-2

(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 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) 2021/1387

of 17 August 2021

authorising the placing on the market of products containing, consisting of or produced from genetically modified soybean DAS-81419-2 × DAS–44406–6, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

(notified under document C(2021)5994)

(Only the Dutch text is authentic)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to 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 2 March 2016, Dow AgroSciences Ltd, based in United Kingdom submitted, on behalf of Dow AgroSciences LLC, based in United States of America, an application to the national competent authority of the Netherlands for the placing on the market of foods, food ingredients and feed containing, consisting of or produced from genetically modified soybean DAS-81419-2 × DAS–44406–6, in accordance with Article 5 and Article 17 of Regulation (EC) No 1829/2003 ('the application'). The application also covered the placing on the market of products containing or consisting of genetically modified soybean DAS-81419-2 × DAS–44406–6 for uses other than food and feed, with the exception of cultivation.

(2) In accordance with Article 5(5) and Article 17(5) of Regulation (EC) No 1829/2003, the application included information and conclusions about the risk assessment carried out in accordance with the principles set out in Annex II to Directive 2001/18/EC of the European Parliament and of the Council ([2]). 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 20 November 2020, the European Food Safety Authority ('the Authority') issued a favourable scientific opinion in accordance with Article 6 and Article 18 of Regulation (EC) No 1829/2003 ([3]). The Authority concluded that genetically modified soybean DAS-81419-2 × DAS–44406–6, as described in the application, is as safe as its conventional counterpart and the tested non-genetically modified soybean reference varieties with respect to the potential effects on human and animal health and the environment. The Authority concluded that the consumption of food and feed from genetically modified soybean DAS-81419-2 × DAS–44406–6 does not represent any nutritional concern in humans and animals.

(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 Article 6(4) and Article 18(4) of Regulation (EC) No 1829/2003.

(5) The Authority also concluded that the monitoring plan for the environmental effects, submitted by the applicant, consisting of a general surveillance plan, is in line with the intended uses of the products.

([1]) OJ L 268, 18.10.2003, p. 1.

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

([3]) EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2020. Scientific Opinion on application EFSA-GMO-NL-2016-132 for authorisation of genetically modified of insect-resistant and herbicide-tolerant soybean DAS–81419–2 × DAS–44406–6 for food and feed uses, import and processing submitted in accordance with Regulation (EC) No 1829/2003 by Dow Agrosciences LLC. EFSA Journal 2020;18(11):6302, 37 pp.; https://doi.org/10.2903/j.efsa.2020.6302

(6) By a letter dated 13 September 2018, Dow AgroSciences Ltd informed the Commission that the new representative in the Union of Dow AgroSciences LLC, is Dow AgroSciences Distribution SAS, based in France. By letters, respectively dated 7 September 2018 and 12 October 2018, Dow AgroSciences Distribution SAS and Dow AgroSciences LLC confirmed their agreement with the requested change.

(7) By the letter of 22 March 2021, Corteva Agriscience Belgium B.V. informed the Commission that Dow AgroSciences LLC changed the name to Corteva Agriscience LLC, based in the United States of America, as of 1 January 2021.

(8) By the letter of 22 March 2021, Corteva AgriScience LLC informed the Commission that its representative in the Union is Corteva Agriscience Belgium B.V., based in Belgium, as of 22 March 2021.

(9) Taking into account the conclusions in the Authority's opinion, the placing on the market of products containing, consisting of or produced from genetically modified soybean DAS-81419-2 × DAS–44406–6 should be authorised for the uses listed in the application.

(10) A unique identifier should be assigned to genetically modified soybean DAS-81419-2 × DAS–44406–6 in accordance with Commission Regulation (EC) No 65/2004 ([4]).

(11) For the products covered by this Decision, 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 ([5]), appear to be necessary. 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 DAS-81419-2 × DAS–44406–6, with the exception of foods and food ingredients, should contain a clear indication that they are not intended for cultivation.

(12) 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 ([6]).

(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 containing, consisting of or produced from genetically modified soybean DAS-81419-2 × DAS–44406–6, 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 covered by this Decision 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 ([7]).

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

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

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

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

(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 organism and unique identifier

Genetically modified soybean (*Glycine max* (L.) Merr) DAS-81419-2 × DAS−44406−6, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier DAS-81419-2 × DAS-444Ø6-6, in accordance with Regulation (EC) No 65/2004.

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 soybean DAS-81419-2 × DAS-444Ø6-6;

(b) feed containing, consisting of or produced from genetically modified soybean DAS-81419-2 × DAS-444Ø6-6;

(c) products containing or consisting of genetically modified soybean DAS-81419-2 × DAS-444Ø6-6 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 'soybean'.

2. The words 'not for cultivation' shall appear on the label of and in the documents accompanying products containing or consisting of genetically modified soybean DAS-81419-2 × DAS-444Ø6-6, as referred to in Article 1, with the exception of products referred to in Article 2, point (a).

Article 4

Method for detection

The method set out in point (d) of the Annex shall apply for the detection of genetically modified soybean DAS-81419-2 × DAS-444Ø6-6.

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 Corteva Agriscience LLC represented by Corteva Agriscience Belgium B.V.

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 Corteva Agriscience LLC, 9330 Zionsville Road Indianapolis, Indiana,46268-1054, United States of America, represented by Corteva Agriscience Belgium B.V., Bedrijvenlaan 9, 2800 Mechelen, Belgium.

Done at Brussels, 17 August 2021.

For the Commission,
Stella KYRIAKIDES
Member of the Commission

ANNEX

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

Name: Corteva Agriscience LLC

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

Represented in the Union by: Corteva Agriscience Belgium B.V., Bedrijvenlaan 9, 2800 Mechelen, Belgium.

(b) **Designation and specification of the products:**

(1) foods and food ingredients containing, consisting of or produced from genetically modified soybean DAS-81419-2 × DAS-444Ø6-6;

(2) feed containing, consisting of or produced from genetically modified soybean DAS-81419-2 × DAS-444Ø6-6;

(3) products containing or consisting of genetically modified soybean DAS-81419-2 × DAS-444Ø6-6 for uses other than those provided for in points (1) and (2), with the exception of cultivation.

The genetically modified soybean DAS-81419-2 × DAS-444Ø6-6 expresses the *2mepsps* gene, which confers tolerance to glyphosate-based herbicides, the *aad-12* gene, which confers tolerance to 2,4-dichlorophenoxyacetic acid (2,4-D) and other related phenoxy herbicides, the *pat* gene, which confers tolerance to glufosinate-ammonium based herbicides and the synthetic *cry1F* and *cry1Ac* genes, which confer protection against certain lepidopteran pests.

(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 'soybean'.

(2) The words 'not for cultivation' shall appear on the label of and in documents accompanying the products containing or consisting of soybean DAS-81419-2 × DAS–444Ø6–6, with the exception of products referred to in point (b)(1).

(d) **Method for detection:**

(1) The quantitative event-specific PCR detection methods are those individually validated for genetically modified soybean events DAS-81419-2 and DAS-444Ø6-6 and further verified on soybean stack DAS-81419-2 × DAS-444Ø6-6;

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

(3) Reference Material: ERM®-BF437 (for DAS-81419-2) and ERM®-BF436 (for DAS-444Ø6-6) are accessible via the Joint Research Centre (JRC) of the European Commission at https://ec.europa.eu/jrc/en/reference-materials/catalogue.

(e) **Unique identifier:**

DAS-81419-2 × DAS-444Ø6-6

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

[Biosafety Clearing-House, Record ID number: *published in the 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) 2021/1388

of 17 August 2021

authorising the placing on the market of products containing, consisting of or produced from genetically modified maize 1507 × MIR162 × MON810 × NK603 and genetically modified maize combining two or three of the single events 1507, MIR162, MON810 and NK603, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

(notified under document C(2021)5995)

(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 8 December 2015, Pioneer Overseas Corporation based in Belgium submitted, on behalf of Pioneer Hi-Bred International Inc., based in United States of America, 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 1507 × MIR162 × MON810 × NK603 in accordance with Article 5 and Article 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 1507 × MIR162 × MON810 × NK603 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 10 sub-combinations of those single transformation events constituting maize 1507 × MIR162 × MON810 × NK603.

(3) Six sub-combinations included in the application were authorised as follows: 1507 × MON810 × NK603 and 1507 × MON810, authorised by Commission Implementing Decision (EU) 2018/1110 ([2]); MON810 × NK603, authorised by Commission Implementing Decision (EU) 2018/2045 ([3]); MIR162 × NK603, authorised by Commission Implementing Decision (EU) 2021/60 ([4]); 1507 × NK603, authorised by Commission Implementing Decision (EU) 2019/1306 ([5]); and 1507 × MIR162, authorised by Commission Implementing Decision (EU) 2019/1305 ([6]).

([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) 2018/2045 of 19 December 2018 renewing the authorisation for the placing on the market of products containing, consisting of or produced from genetically modified maize NK603 × MON 810 (MON-ØØ6Ø3-6 × MON-ØØ81Ø-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 327, 21.12.2018, p. 65).

([4]) Commission Implementing Decision (EU) 2021/60 of 22 January 2021 authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MON 87427 × MON 89034 × MIR162 × NK603 and genetically modified maize combining two or three of the single events MON 87427, MON 89034, MIR162 and NK603, and repealing Implementing Decision (EU) 2018/1111 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 26, 26.1.2021, p. 5).

([5]) Commission Implementing Decision (EU) 2019/1306 of 26 July 2019 renewing the authorisation for the placing on the market of products containing, consisting of or produced from genetically modified maize 1507 × NK603 (DAS-Ø15Ø7-1 × MON-ØØ6Ø3-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 204, 2.8.2019, p. 75).

([6]) 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).

(4) This Decision covers the four remaining sub-combinations in the application: MIR162 × MON810, 1507 × MIR162 × MON810, 1507 × MIR162 × NK603 and MIR162 × MON810 × NK603.

(5) 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.

(6) On 13 January 2021, the European Food Safety Authority ('the Authority') issued a favourable opinion in accordance with Article 6 and Article 18 of Regulation (EC) No 1829/2003 ([8]). The Authority concluded that genetically modified maize 1507 × MIR162 × MON810 × NK603, as described in the application, is as safe as and nutritionally equivalent to their 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.

(7) No new safety concerns were identified for the previously assessed sub-combinations and therefore previous conclusions on those sub-combinations remain valid. As regards the remaining sub-combinations, the Authority concluded that they are expected to be as safe as and nutritionally equivalent to the single transformation events 1507, MON810, MIR162 and NK603, the previously assessed sub-combinations and the four-event stack maize 1507 × MIR162 x MON810 × NK603.

(8) 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 Article 6(4) and Article 18(4) of Regulation (EC) No 1829/2003.

(9) 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.

(10) Taking into account those conclusions, the placing on the market of products containing, consisting of or produced from genetically modified maize 1507 × MIR162 × MON810 × NK603, and of the four sub-combinations referred to above and listed in the application, should be authorised for the uses listed in the application.

(11) 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]).

(12) For the products covered by this Decision 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. 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), 2021. Scientific Opinion on the assessment of genetically modified maize 1507 × MIR162 × MON810 × NK603 and subcombinations, for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2015-127). EFSA Journal 2021;19(1):6348, 40 pp, https://doi.org/10.2903/j.efsa.2021.6348

([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).

(13) 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 ([11]).

(14) 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 food and feed containing, consisting of or produced from genetically modified 1507 × MIR162 × MON810 × NK603, 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.

(15) 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.

(16) This Decision is to be notified through the Biosafety Clearing-House to the Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, pursuant to Article 9(1) and Article 15(2)(c) of Regulation (EC) No 1946/2003 of the European Parliament and of the Council ([12]).

(17) The Standing Committee on Plants, Animals, Food and Feed has not delivered an opinion within the time limit laid down by its Chairman. This implementing act was deemed to be necessary and the chair submitted it to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

HAS ADOPTED THIS DECISION:

Article 1

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 DAS-Ø15Ø7-1 × SYN-IR162-4 × MON-ØØ81Ø-6 × MON-ØØ6Ø3-6 for genetically modified maize 1507 × MIR162 × MON810 × NK603;

(b) the unique identifier DAS-Ø15Ø7-1 × SYN-IR162-4 × MON-ØØ81Ø-6 for genetically modified maize 1507 × MIR162 × MON810;

(c) the unique identifier DAS-Ø15Ø7-1 × SYN-IR162-4 × MON-ØØ6Ø3-6 for genetically modified maize 1507 × MIR162 × NK603;

(d) the unique identifier SYN-IR162-4 × MON-ØØ81Ø-6 × MON-ØØ6Ø3-6 for genetically modified maize MIR162 × MON810 × NK603;

(e) the unique identifier SYN-IR162-4 × MON-ØØ81Ø-6 for genetically modified maize MIR162 × MON810.

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 Article 2, point (a).

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 Pioneer Hi-Bred International, Inc., represented by Pioneer Overseas Corporation.

Article 8

Validity

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

Article 9

Addressee

This Decision is addressed to Pioneer Hi-Bred International, Inc., 7100 NW 62nd Avenue, P.O. Box 1014, Johnston, IA 50131-1014, United States of America represented by Pioneer Overseas Corporation, Rue Montoyer 25, B-1000 Brussels, Belgium.

Done at Brussels, 17 August 2021.

For the Commission
Stella KYRIAKIDES
Member of the Commission

ANNEX

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

Name: Pioneer Hi-Bred International, Inc.

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

Represented in the Union by: Pioneer Overseas Corporation, Rue Montoyer 25, 1000 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 DAS-Ø15Ø7-1 expresses the *pat* gene, which confers tolerance to glufosinate-ammonium based herbicides, and the *cry1F* gene, which confers protection against certain lepidopteran pests.

The genetically modified maize SYN-IR162-4 expresses a modified *vip3Aa20* gene, which provides protection against certain lepidopteran pests. In addition, the *pmi* gene, coding for the PMI protein, was used as a selection marker in the genetic modification process.

The genetically modified maize MON-ØØ81Ø-6 expresses the *cry1Ab* gene, which confer protection against certain lepidopteran pests.

The genetically modified maize MON-ØØ6Ø3-6 expresses the CP4 *epsps* and the CP4 *epsps* L214P genes, 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 genetically modified maize specified in point (e), with the exception of products referred to in point (b)(1).

(d) **Method for detection:**

(1) The quantitative event-specific PCR detection methods are those individually validated for genetically modified maize events AS-Ø15Ø7-1, SYN-IR162-4, MON-ØØ81Ø-6 and MON-ØØ6Ø3-6 and further verified on maize AS-Ø15Ø7-1 × SYN-IR162-4 × MON-ØØ81Ø-6 × MON-ØØ6Ø3-6;

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

(3) Reference Material: ERM®-BF418 (for AS-Ø15Ø7), ERM®-BF413 (for MON-ØØ81Ø-6) and ERM®-BF415 (for MON-ØØ6Ø3-6) is accessible via the Joint Research Centre (JRC) of the European Commission at https://crm.jrc.ec.europa.eu/ and AOCS 1208 (for SYN-IR162-4) is accessible via the American Oil Chemists Society at https://www.aocs.org/crm#maize.

(e) **Unique identifiers:**

DAS-Ø15Ø7-1 × SYN-IR162-4 × MON-ØØ81Ø-6 × MON-ØØ6Ø3-6;

DAS-Ø15Ø7-1 × SYN-IR162-4 × MON-ØØ81Ø-6;

DAS-Ø15Ø7-1 × SYN-IR162-4 × MON-ØØ6Ø3-6;

SYN-IR162-4 × MON-ØØ81Ø-6 × MON-ØØ6Ø3-6;

SYN-IR162-4 × MON-ØØ81Ø-6.

(f) **Information required pursuant to 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) 2021/1389

of 17 August 2021

authorising the placing on the market of products containing, consisting of or produced from genetically modified cotton GHB614 × T304-40 × GHB119 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

(notified under document C(2021)5996)

(Only the German text is authentic)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed ([1]), and in particular to Articles 7(3) and 19(3) thereof,

Whereas:

(1) On 30 September 2014, Bayer CropScience AG submitted an application to the national competent authority of the Netherlands in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003 ('the application'). The application covered the placing on the market of foods, food ingredients and feed containing, consisting of or produced from genetically modified cotton GHB614 × T304-40 × GHB119. The application also covered the placing on the market of products containing or consisting of genetically modified cotton GHB614 × T304-40 × GHB119 for uses other than food and feed, with the exception of cultivation.

(2) In accordance with Article 5(5) and Article 17(5) of Regulation (EC) No 1829/2003, the application included information and conclusions about the risk assessment carried out in accordance with the principles set out in Annex II to Directive 2001/18/EC of the European Parliament and of the Council ([2]). 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 25 July 2018, the European Food Safety Authority ('the Authority') issued a favourable opinion in accordance with Article 6 and Article 18 of Regulation (EC) No 1829/2003 ([3]). This opinion was invalidated for reasons of formal nature related to the application, which was further addressed by the applicant. On 31 July 2020, the Authority published a new favourable opinion. It concluded that genetically modified cotton GHB614 × T304-40 × GHB119, as described in the application, is as safe as, and nutritionally equivalent to, its conventional counterpart and the tested non-genetically modified cotton reference varieties with respect to the potential effects on human and animal health and the environment.

(4) In its opinion, the Authority considered all the questions and concerns raised by the Member States in the context of the consultation of the national competent authorities as provided for by Article 6(4) and Article 18(4) of Regulation (EC) No 1829/2003.

(5) The Authority also concluded that the monitoring plan for environmental effects submitted by the applicant, consisting of a general surveillance plan, is in line with the intended uses of the products.

([1]) OJ L 268, 18.10.2003, p. 1.

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

([3]) EFSA GMO Panel (EFSA Panel on genetically Modified Organisms), 2018. Scientific opinion on the assessment of genetically modified cotton GHB614 × T304-40 × GHB119 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2014-122). EFSA Journal 2018;16(7):5349; https://doi/10.2903/j.efsa.2018.5349.

(6) Taking into account those conclusions, the placing on the market of products containing, consisting of or produced from genetically modified cotton GHB614 × T304-40 × GHB119 should be authorised for the uses listed in the application.

(7) By letter dated 1 August 2018, Bayer CropScience AG requested that the Commission transfer its 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, based in Germany, to act as its representative in the Union.

(8) A unique identifier should be assigned to genetically modified cotton GHB614 × T304-40 × GHB119 in accordance with Commission Regulation (EC) No 65/2004 ([4]).

(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 ([5]), appear to be necessary. 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 cotton GHB614 × T304-40 × GHB119, with the exception of foods and food ingredients, 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 ([6]).

(11) The opinion of the Authority does not justify the imposition of specific conditions or restrictions for the placing on the market, for the use and handling, including post-market monitoring requirements regarding the consumption of the food and feed containing or consisting of genetically modified cotton GHB614 × T304-40 × GHB119, 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 covered by this Decision should be entered in the Community register of genetically modified food and feed referred to in Article 28(1) of Regulation (EC) No 1829/2003.

(13) This Decision is to be notified through the Biosafety Clearing-House to the Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, pursuant to Articles 9(1) and 15(2)(c) of Regulation (EC) No 1946/2003 of the European Parliament and of the Council ([7]).

(14) The Standing Committee on Plants, Animals, Food and Feed has not delivered an opinion within the time limit laid down by its Chairman. This implementing act was deemed to be necessary and the chair submitted it to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

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

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

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

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

HAS ADOPTED THIS DECISION:

Article 1

Genetically modified organism and unique identifier

Genetically modified cotton (*Gossypium hirsutum* and *Gossypium barbadense*) GHB614 × T304-40 × GHB119, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier BCS-GHØØ2-5 × BCS-GHØØ4-7 × BCS-GHØØ5-8, in accordance with Regulation (EC) No 65/2004.

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 cotton BCS-GHØØ2-5 × BCS-GHØØ4-7 × BCS-GHØØ5-8;

(b) feed containing, consisting of or produced from genetically modified cotton BCS-GHØØ2-5 × BCS-GHØØ4-7 × BCS-GHØØ5-8;

(c) products containing or consisting of genetically modified cotton BCS-GHØØ2-5 × BCS-GHØØ4-7 × BCS-GHØØ5-8 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 'cotton'.

2. The words 'not for cultivation' shall appear on the label of and in the documents accompanying products containing or consisting of genetically modified cotton BCS-GHØØ2-5 × BCS-GHØØ4-7 × BCS-GHØØ5-8, 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 BCS-GHØØ2-5 × BCS-GHØØ4-7 × BCS-GHØØ5-8.

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 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 provided for in Article 28(1) of Regulation (EC) No 1829/2003.

Article 7

Authorisation holder

The authorisation holder shall be BASF Agricultural Solutions Seed US LLC, USA, represented 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, 17 August 2021.

For the Commission,
Stella KYRIAKIDES
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 in the Union 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 BCS-GHØØ2-5 × BCS-GHØØ4-7 × BCS-GHØØ5-8;

(2) feed containing, consisting of or produced from genetically modified cotton BCS-GHØØ2-5 × BCS-GHØØ4-7 × BCS-GHØØ5-8;

(3) products containing or consisting of genetically modified cotton BCS-GHØØ2-5 × BCS-GHØØ4-7 × BCS-GHØØ5-8 for uses other than those provided for in points (1) and (2), with the exception of cultivation.

The genetically modified cotton BCS-GHØØ2-5 × BCS-GHØØ4-7 × BCS-GHØØ5-8 expresses the *2mepsps* gene, which confers tolerance to glyphosate based herbicides, the *bar* gene, which confers tolerance to glufosinate-ammonium based herbicides, the *cry1Ab*, and the *cry2Ae* genes, which confer resistance to certain lepidopteran pests.

(c) **Labelling:**

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

(2) The words 'not for cultivation' shall appear on the label of and in documents accompanying the products containing or consisting of cotton BCS-GHØØ2-5 × BCS-GHØØ4-7 × BCS-GHØØ5-8, with the exception of foods and food ingredients.

(d) **Method for detection:**

(1) The quantitative event-specific PCR detection methods for cotton GHB614 × T304-40 × GHB119 are those validated for genetically modified cotton events BCS-GHØØ2-5, BCS-GHØØ4-7 and BCS-GHØØ5-8. The detection methods have been validated on genomic DNA extracted from leaves of BCS-GHØØ2-5, BCS-GHØØ4-7, BCS-GHØØ5-8 and verified on genomic DNA extracted from leaves of BCS-GHØØ2-5 × BCS-GHØØ4-7 × BCS-GHØØ5-8.

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

(3) Reference Material: AOCS 1108-A5 (for BCS-GHØØ2-5) is accessible via the American Oil Chemists' Society (AOCS) at https://www.aocs.org/crm. ERM-BF429 (for BCS-GHØØ4-7) and ERM-BF428 (BCS-GHØØ5-8) are accessible via the Joint Research Centre (JRC) of the European Commission at https://crm.jrc.ec.europa.eu/

(e) **Unique identifier:**

BCS-GHØØ2-5 × BCS-GHØØ4-7 × BCS-GHØØ5-8

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

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

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

Not required.

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

Monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC 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 the 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) 2021/1390

of 17 August 2021

authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MZIR098 (SYN-ØØØ98-3), pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

(notified under document C(2021)5997)

(Only the French and Dutch texts are authentic)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed ([1]), and in particular to Articles 7(3) and 19(3) thereof,

Whereas:

(1) On 25 April 2017, Syngenta Crop Protection NV/SA submitted, on behalf of Syngenta Crop Protection AG, 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 MZIR098, in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003 ('the application'). The application also covered the placing on the market of products containing or consisting of genetically modified maize MZIR098 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 26 June 2020, the European Food Safety Authority ('the Authority') issued a favourable opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003 ([3]). The Authority concluded that genetically modified maize MZIR098, as described in the application, is as safe as its conventional counterpart and the tested non-genetically modified maize reference varieties with respect to the potential effects on human and animal health and the environment. The Authority concluded that the consumption of food and feed from genetically modified maize MZIR098 does not represent a nutritional concern in humans and animals.

(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 the environmental effects, submitted by the applicant, consisting of a general surveillance plan, is in line with the intended uses of the products.

([1]) OJ L 268, 18.10.2003, p. 1.

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

([3]) EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2018. Scientific Opinion on the assessment of genetically modified maize MZIR098 for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA-GMO-DE-2017-142). EFSA Journal 2020;1 8(6):6171, 28 pp.; https://doi.org/10.2903/j.efsa.2020.6171.

(6) Taking into account those conclusions, the placing on the market of products containing, consisting of or produced from genetically modified maize MZIR098 should be authorised for the uses listed in the application.

(7) A unique identifier should be assigned to genetically modified maize MZIR098 in accordance with Commission Regulation (EC) No 65/2004 ([4]).

(8) 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 ([5]), appear to be necessary. 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 MZIR098, with the exception of foods and food ingredients, should contain a clear indication that they are not intended for cultivation.

(9) 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 ([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 covered by this Decision should be entered in the Community register of genetically modified food and feed referred to in Article 28(1) of Regulation (EC) No 1829/2003.

(12) This Decision is to be notified through the Biosafety Clearing-House to the Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, pursuant to Article 9(1) and Article 15(2)(c) of Regulation (EC) No 1946/2003 of the European Parliament and of the Council ([7]).

(13) The Standing Committee on Plants, Animals, Food and Feed has not delivered an opinion within the time limit laid down by its Chairman. This implementing act was deemed to be necessary and the chair submitted it to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

HAS ADOPTED THIS DECISION:

Article 1

Genetically modified organism and unique identifier

Genetically modified maize (*Zea mays* L.) MZIR098, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier SYN-ØØØ98-3, in accordance with Regulation (EC) No 65/2004.

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

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

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

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

Article 2

Authorisation

The following products are authorised for the purposes of 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-ØØØ98-3;

(b) feed containing, consisting of or produced from genetically modified maize SYN-ØØØ98-3;

(c) products containing or consisting of genetically modified maize SYN-ØØØ98-3 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 '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-ØØØ98-3, 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 maize SYN-ØØØ98-3.

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 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, 17 August 2021.

For the Commission,
Stella KYRIAKIDES
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 SYN-ØØØ98-3;

(2) feed containing, consisting of or produced from genetically modified maize SYN-ØØØ98-3;

(3) products containing or consisting of genetically modified maize SYN-ØØØ98-3 for uses other than those provided for in points (1) and (2), with the exception of cultivation.

The genetically modified maize SYN-ØØØ98-3 expresses the *ecry3.1Ab* gene and the *mcry3A* gene, which confer protection against certain coleopteran pests and 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 'maize'.

(2) The words 'not for cultivation' shall appear on the label of and in documents accompanying the products containing or consisting of SYN-ØØØ98-3 maize, with the exception of products referred to in point (b)(1).

(d) **Method for detection:**

(1) Event specific real-time quantitative PCR based method for detection of the genetically modified maize SYN-ØØØ98-3;

(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 1114-B2 is accessible via the American Oil Chemists Society (AOCS) at https://www.aocs.org/crm.

(e) **Unique identifier:**

SYN-ØØØ98-3

(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).

COMMISSION IMPLEMENTING DECISION (EU) 2021/1391

of 17 August 2021

authorising the placing on the market of products containing, consisting of or produced from genetically modified oilseed rapes Ms8 × Rf3 × GT73, Ms8 × GT73 and Rf3 × GT73 pursuant to Regulation (EC) No 1829/2003 of the European parliament and of the Council

(notified under document C(2021)5998)

(Only the Dutch and German 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 20 October 2009, Monsanto Europe S.A/N.V., based in Belgium, submitted, on behalf of Monsanto Company, based in the United States, and Bayer CropScience AG, based in Germany, an application to the national competent authority of the Netherlands for the placing on the market of foods, food ingredients and feed containing, consisting of or produced from genetically modified oilseed rape Ms8 × Rf3 × GT73, in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003 ('the application'). The application also concerned the placing on the market of products containing or consisting of genetically modified oilseed rape Ms8 × Rf3 × GT73 for uses other than food and feed, with the exception of cultivation. In addition, the application concerned the placing on the market of products containing, consisting of or produced from all sub-combinations of the single transformation events constituting oilseed rape Ms8 × Rf3 × GT73.

(2) In accordance with Article 5(5) and Article 17(5) of Regulation (EC) No 1829/2003, the application included information and conclusions about the risk assessment carried out in accordance with the principles set out in Annex II to Directive 2001/18/EC of the European Parliament and of the Council ([2]). 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 9 September 2013, Monsanto Europe S.A./N.V. and Bayer CropScience AG updated the contents of the application, in order to exclude from its scope the specific use of Ms8 × Rf3 × GT73 oilseed rape for the production of isolated seed protein for food.

(4) On 12 August 2015, Monsanto Europe S.A./N.V. and Bayer CropScience AG updated further the contents of the application, in order to exclude from its scope the sub-combination Ms8 × Rf3, which was already authorised by Commission Decision 2007/232/EC ([3]) and Commission Implementing Decision 2013/327/EU ([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]) Commission Decision 2007/232/EC of 26 March 2007 concerning the placing on the market, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of oilseed rape products (*Brassica napus L.*, lines Ms8, Rf3 and Ms8 × Rf3) genetically modified for tolerance to the herbicide glufosinate-ammonium (OJ L 100, 17.4.2007, p. 20).

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

(5) This Decision concerns the remaining two sub-combinations, Ms8 × GT73 and Rf3 × GT73, and excludes the use, for food, of isolated seed protein products produced from oilseed rape Ms8 × Rf3 × GT73 and from the sub-combinations Ms8 × GT73 and Rf3 × GT73.

(6) On 20 May 2016, the European Food Safety Authority ('the Authority') issued an opinion, in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003 ([5]). The Authority was not able to reach a conclusion on the safety of Ms8 × Rf3 × GT73 oilseed rape products rich in protein, such as rapeseed protein isolates, in feed, because of a lack of a 28-day toxicity study with the GOXv247 protein. As the risk assessment of the three-event stack oilseed rape could not be completed for products rich in protein, the Authority was not in a position to complete the food and feed safety assessment of the sub-combinations Ms8 × GT73 and Rf3 × GT73 within the scope of the application.

(7) By a letter dated 1 August 2018, Bayer CropScience AG requested that the Commission transfer its rights and obligations pertaining to all authorisations and pending applications for genetically modified products to BASF Agricultural Solutions Seed US LLC. By a letter dated 19 October 2018, BASF Agricultural Solutions Seed US LLC confirmed its agreement with this transfer and authorised BASF SE, based in Germany, to act as its representative in the Union.

(8) By a letter dated 27 August 2018, Monsanto Europe S.A./N.V. informed the Commission that, as of 23 August, it converted its legal form and changed its name to Bayer Agriculture BVBA.

(9) On 23 October 2018, the co-applicants provided a new 28-day toxicity study on the GOXv247 protein.

(10) By a letter dated 28 July 2020, Bayer Agriculture BVBA informed the Commission that, as of 1 August 2020, it changed its name to Bayer Agriculture BV.

(11) By a letter dated 28 July 2020, Bayer Agriculture BVBA representing Monsanto Company, informed the Commission that, as of 1 August 2020, Monsanto Company converted its legal form and changed its name to Bayer CropScience LP.

(12) On 30 July 2020, the Authority published a statement complementing its scientific opinion ([6]), taking into consideration the supplementary toxicity study. The Authority concluded that oilseed rape Ms8 × Rf3 × GT73 and its sub-combinations Ms8 × GT73 and Rf3 × GT73, as defined in the application and as assessed in the initial opinion and in the supplementary toxicity study, are as safe as its conventional counterpart for the requested uses.

(13) In its opinion of 20 May 2016, 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.

(14) 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.

(15) Taking into account these conclusions, the placing on the market of products containing, consisting of or produced from genetically modified oilseed rapes Ms8 × Rf3 × GT73, Ms8 × GT73 and Rf3 × GT73 should be authorised for the uses listed in the application.

([5]) EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2016. Scientific Opinion on an application by Bayer CropScience and Monsanto (EFSA-GMO-NL-2009-75) for placing on the market of genetically modified glufosinate-ammonium- and glyphosate-tolerant oilseed rape MS8 × RF3 × GT73 and subcombinations, which have not been authorised previously (i.e. MS8 × GT73 and RF3 × GT73) independently of their origin, for food and feed uses, import and processing, with the exception of isolated seed protein for food, under Regulation (EC) No 1829/2003; EFSA Journal 2016;14(5):4466; https://doi.org/10.2903/j.efsa.2016.4466.

([6]) EFSA GMO Panel, 2020. Scientific Opinion on the statement complementing the EFSA Scientific Opinion on application (EFSA-GMO-NL-2009-75) for placing on the market of genetically modified oilseed rape Ms8 × Rf3 × GT73 and subcombinations, which have not been authorised previously (i.e. Ms8 × GT73 and Rf3 × GT73) independently of their origin, for food and feed uses, import and processing, with the exception of isolated seed protein for food, under Regulation (EC) No 1829/2003), taking into consideration additional information; EFSA Journal 2020;18(7):6200; https://doi.org/10.2903/j.efsa.2020.6200.

(16) 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]).

(17) For the products covered by this Decision, 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. 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.

(18) The authorisation holders 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]).

(19) 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 oilseed rapes Ms8 × Rf3 × GT73, Ms8 × GT73 and Rf3 × GT73, with the exception of isolated seed protein for food, 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.

(20) All relevant information on the authorisation of the products covered by this Decision 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.

(21) 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]).

(22) The Standing Committee on Plants, Animals, Food and Feed has not delivered an opinion within the time limit laid down by its Chair. 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 oilseed rapes (*Brassica napus* 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 ACS-BNØØ5-8 × ACS-BNØØ3-6 × MON-ØØØ73-7 for genetically modified oilseed rape Ms8 × Rf3 × GT73;

([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).

([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).

(b) the unique identifier ACS-BNØØ5-8 × MON-ØØØ73-7 for genetically modified oilseed rape Ms8 × GT73;

(c) the unique identifier ACS-BNØØ3-6 × MON-ØØØ73-7 for genetically modified oilseed rape Rf3 × GT73.

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 oilseed rapes as referred to in Article 1, with the exception of isolated seed protein;

(b) feed containing, consisting of or produced from genetically modified oilseed rapes as referred to in Article 1;

(c) products containing or consisting of genetically modified oilseed rapes 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 'oilseed rape'.

2. The words 'not for cultivation' shall appear on the label of and in the documents accompanying products containing or consisting of genetically modified oilseed rapes 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 methods set out in point (d) of the Annex shall apply for the detection of genetically modified oilseed rapes as referred to in Article 1.

Article 5

Monitoring for environmental effects

1. The authorisation holders shall ensure that the monitoring plan for environmental effects, as set out in point (h) of the Annex, is put in place and implemented.

2. The authorisation holders shall submit to the Commission joint annual reports on the implementation and the results of the activities set out in the monitoring plan in accordance with the format set out in Decision 2009/770/EC.

Article 6

Community register

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

Article 7

Authorisation holders

The authorisation holders shall be:

(a) Bayer CropScience LP represented in the Union by Bayer Agriculture BV

and

(b) BASF Agricultural Solutions Seed US LLC represented in the Union by BASF SE.

Article 8

Validity

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

Article 9

Addressees

This Decision is addressed to Bayer CropScience LP represented in the Union by Bayer Agriculture BV, Scheldelaan 460, BE-2040 Antwerp, Belgium and to BASF Agricultural Solutions Seed US LLC represented in the Union by BASF SE, Carl-Bosch-Str. 38, D-67063 Ludwigshafen, Germany.

Done at Brussels, 17 August 2021.

For the Commission
Stella KYRIAKIDES
Member of the Commission

ANNEX

(a) **Applicants and authorisation holders:**

(1) Name: Bayer CropScience LP

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

Represented in the Union by: Bayer Agriculture BV, Scheldelaan 460, BE-2040 Antwerp, Belgium.

and

(2) Name: BASF Agricultural Solutions Seed US LLC

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

Represented in the Union 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 oilseed rapes (*Brassica napus* L.) as referred to in point (e), with the exception of isolated seed protein;

(2) feed containing, consisting of or produced from genetically modified oilseed rapes (*Brassica napus* L.) as referred to in point (e);

(3) products containing or consisting of genetically modified oilseed rapes (*Brassica napus* 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 ACS-BNØØ5-8 oilseed rape expresses the *pat* gene, which confers tolerance to glufosinate-ammonium-based herbicides, and the *barnase* gene, which confers male sterility during anther development.

The genetically modified ACS-BNØØ3-6 oilseed rape expresses the *pat* gene, which confers tolerance to glufosinate-ammonium-based herbicides, and the *barstar* gene, which restores fertility after crossing with ACSBNØØ5-8.

The genetically modified oilseed rape MON-ØØØ73-7 expresses the *cp4 epsps* and *goxv247* genes, which confer 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 'oilseed rape';

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

(d) **Method for detection:**

(1) The quantitative event-specific PCR detection methods are those individually validated for genetically modified oilseed rape events ACS-BNØØ5-8, ACS-BNØØ3-6 and MON-ØØØ73-7 and further verified on oilseed rape stack ACSBNØØ5-8 × ACS-BNØØ3-6 × MON-ØØØ73-7;

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

(3) Reference Material: AOCS 0306-F (for ACSBNØØ5-8), AOCS 0306-G (for ACS-BNØØ3-6) and AOCS 0304-B (for MON-ØØØ73-7) are accessible via the American Oil Chemists Society at https://www.aocs.org/crm.

(e) **Unique identifiers:**

ACS-BNØØ5-8 × ACS-BNØØ3-6 × MON-ØØØ73-7;

ACS-BNØØ5-8 × MON-ØØØ73-7;

ACS-BNØØ3-6 × MON-ØØØ73-7.

(f) **Information required pursuant to 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) 2021/1392

of 17 August 2021

renewing the authorisation for the placing on the market of products containing, consisting of or produced from genetically modified maize Bt 11 (SYN-BTØ11-1) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

(notified under document C(2021)5999)

(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 11(3) and Article 23(3) thereof,

Whereas:

(1) Commission Decision 2010/419/EU ([2]) authorised the placing on the market of food and feed containing, consisting of or produced from genetically modified maize Bt11. The scope of that authorisation also covers the placing on the market of products containing or consisting of genetically modified maize Bt11 for uses other than food and feed, with the exception of cultivation.

(2) On 24 September 2018, Syngenta Crop Protection NV/SA, based in Belgium, on behalf of Syngenta Crop Protection AG, based in Switzerland, submitted to the Commission an application, in accordance with Article 11 and Article 23 of Regulation (EC) No 1829/2003, for the renewal of that authorisation.

(3) On 13 January 2021, the European Food Safety Authority ('the Authority') issued a favourable scientific opinion ([3]) in accordance with Article 6 and Article 18 of Regulation (EC) No 1829/2003. It concluded that the renewal application did not contain evidence for any new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on genetically modified maize Bt11, issued by the Authority in 2009 ([4]).

(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 Article 6(4) and Article 18(4) of Regulation (EC) No 1829/2003.

(5) The Authority also concluded that the monitoring plan for the environmental effects, submitted by the applicant, consisting of a general surveillance plan, is in line with the intended uses of the products.

(6) Taking into account those conclusions, the authorisation for the placing on the market of food and feed containing, consisting of or produced from genetically modified maize Bt 11 and of products containing or consisting of it for uses other than food or feed, with the exception of cultivation, should be renewed.

([1]) OJ L 268, 18.10.2003, p. 1.

([2]) Commission Decision 2010/419/EU of 28 July 2010 renewing the authorisation for continued marketing of products containing, consisting of, or produced from genetically modified maize Bt11 (SYN-BTØ11-1), authorising foods and food ingredients containing or consisting of field maize Bt11 (SYN-BTØ11-1) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council and repealing Decision 2004/657/EC (OJ L 197, 29.7.2010, p. 11).

([3]) EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2020. Scientific Opinion on the assessment of genetically modified maize Bt11 for renewal authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-016). EFSA Journal 2021;19 (1):6347.

([4]) EFSA GMO Panel, 2009. Scientific Opinion on application reference EFSA-GMO-RX-Bt11 for renewal of the authorisation of existing products produced from insect-resistant genetically modified maize Bt11, under Regulation (EC) No 1829/2003 from Syngenta. EFSA Journal 2009;7(2):977, p. 13.

(7) A unique identifier has been assigned to genetically modified maize Bt11, in accordance with Commission Regulation (EC) No 65/2004 ([5]), in the context of its initial authorisation by Decision 2004/657/EC ([6]). That unique identifier should continue to be used.

(8) For the products covered by this Decision, no specific labelling requirements, other than those provided for in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003 of the European Parliament and of the Council ([7]) appear to be necessary. However, in order to ensure that the use of products containing or consisting of genetically modified maize Bt11 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.

(9) 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 ([8]).

(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 food and feed containing, consisting of or produced from genetically modified maize Bt 11, or for the protection of particular ecosystems/environment or geographical areas, as provided for in Article 6(5)(e) and Article 18(5)(e) of Regulation (EC) No 1829/2003.

(11) All relevant information on the authorisation of the products covered by this Decision should be entered in the Community register of genetically modified food and feed referred to in Article 28(1) of Regulation (EC) No 1829/2003.

(12) This Decision is to be notified through the Biosafety Clearing-House to the Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, pursuant to Article 9(1) and Article 15(2)(c) of Regulation (EC) No 1946/2003 of the European Parliament and of the Council ([9]).

(13) The Standing Committee on Plants, Animals, Food and Feed has not delivered an opinion within the time limit laid down by its Chair. 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.) Bt11, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier SYN-BTØ11-1, 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]) Commission Decision 2004/657/EC of 19 May 2004 authorising the placing on the market of sweet corn from genetically modified maize line Bt11 as a novel food or novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (OJ L 300, 25.9.2004, p. 48).

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

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

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

Article 2

Renewal of the authorisation

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

(a) foods and food ingredients containing, consisting of or produced from genetically modified maize SYN-BTØ11-1;

(b) feed containing, consisting of or produced from genetically modified maize SYN-BTØ11-1;

(c) products containing or consisting of genetically modified maize SYN-BTØ11-1 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 the products containing or consisting of genetically modified maize SYN-BTØ11-1, 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 SYN-BTØ11-1.

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 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, represented in the Union by Syngenta Crop Protection NV/SA.

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 AG, Rosentalstrasse 67, CH-4058 Basel, Switzerland, represented in the Union by Syngenta Crop Protection NV/SA, Avenue Louise, 489, BE-1050 Brussels, Belgium.

Done at Brussels, 17 August 2021.

For the Commission,
Stella KYRIAKIDES
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 SYN-BTØ11-1;

(2) feed containing, consisting of or produced from genetically modified maize SYN-BTØ11-1;

(3) products containing or consisting of genetically modified maize SYN-BTØ11-1 for uses other than those provided for in points (1) and (2), with the exception of cultivation.

The genetically modified maize SYN-BTØ11-1, as described in the application, expresses the Cry1Ab protein, which confers resistance against certain lepidopteran pests and the PAT protein, which confers tolerance to the glufosinate-ammonium herbicide.

(c) **Labelling:**

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

(2) The words 'not for cultivation' shall appear on the label of and in the documents accompanying the products containing or consisting of genetically modified maize SYN-BTØ11-1, 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 maize SYN-BTØ11-1.

(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: ERM®-BF412 accessible via the Joint Research Centre (JRC) of the European Commission, Institute for Reference Materials and Measurements (IRMM) at https://crm.jrc.ec.europa.eu/

(e) **Unique identifier:**

SYN-BTØ11-1

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

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

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

Not required.

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

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

[Link: *plan published in the 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) 2021/1393

of 17 August 2021

renewing the authorisation for the placing on the market of products containing, consisting of or produced from genetically modified maize MON 88017 × MON 810 (MON-88Ø17-3 × MON-ØØ81Ø-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

(notified under document C(2021)6001)

(Only the Dutch text is authentic)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to 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 Article 11(3) and Article 23(3) thereof,

Whereas:

(1) Commission Decision 2010/429/EU ([2]) authorised the placing on the market of food and feed containing, consisting of or produced from genetically modified maize MON 88017 × MON 810. The scope of that authorisation also covers the placing on the market of products, other than food and feed, containing or consisting of genetically modified maize MON 88017 × MON 810 for the same uses as any other maize, with the exception of cultivation.

(2) By letter dated 27 August 2018, Monsanto Europe N.V. informed the Commission that it has converted its legal form and changed its name to Bayer Agriculture BVBA, Belgium.

(3) On 27 June 2019, Bayer Agriculture BVBA, based in Belgium, on behalf of Monsanto Company, based in the United States, 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.

(4) By letter dated 28 July 2020, Bayer Agriculture BVBA, informed the Commission that, as of 1 August 2020, it changes its name to Bayer Agriculture BV.

(5) By letter dated 28 July 2020, Bayer Agriculture BVBA, informed the Commission that, as of 1 August 2020, Monsanto Company, converts its legal form and changes its name to Bayer CropScience LP, based in the United States.

(6) On 29 January 2021, 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 any new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on genetically modified maize MON 88017 × MON 810, issued by the Authority in 2009 ([4]).

([1]) OJ L 268, 18.10.2003, p. 1.

([2]) Commission Decision 2010/429/EU of 28 July 2010 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON 88017 × MON 810 (MON-88Ø17-3 × MON-ØØ81Ø-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 201, 3.8.2010, p. 46).

([3]) EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2020. Assessment of genetically modified maize MON 88017 × MON 810 for renewal of authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-017). EFSA Journal 2021; 19 (1):6375. https://doi.org/10.2903/j.efsa.2021.6375.

([4]) EFSA GMO Panel, 2009. Scientific Opinion of the Panel on Genetically Modified Organisms on an application (Reference EFSA-GMO-CZ-2006-33) for the placing on the market of the insect-resistant and glyphosate-tolerant genetically modified maize MON 88017 × MON 810, for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Monsanto. EFSA Journal 2009; 7(7):1192. https://doi.org/10.2903/j.efsa.2009.1192.

(7) 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 Article 6(4) and Article 18(4) of Regulation (EC) No 1829/2003.

(8) 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.

(9) Taking into account those conclusions, the authorisation for the placing on the market of food and feed containing, consisting of or produced from genetically modified maize MON 88017 × MON 810 and of products consisting of it or containing it for other uses than food or feed, with the exception of cultivation, should be renewed.

(10) A unique identifier has been assigned to genetically modified maize MON 88017 × MON 810, in accordance with Commission Regulation (EC) No 65/2004 ([5]), in the context of its initial authorisation by Decision 2010/429/EU. That unique identifier should continue to be used.

(11) For the products covered by this Decision, 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 ([6]), appear to be necessary. However, in order to ensure that the use of products containing or consisting of genetically modified maize MON 88017 × MON 810 remains within the limits of the authorisation granted by this Decision, the labelling of such products, with the exception of foods and food ingredients, should contain a clear indication that they are not intended for cultivation.

(12) 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 effect. Those results should be presented in accordance with the requirements laid down in Commission Decision 2009/770/EC ([7]).

(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 containing, consisting of, or produced from genetically modified maize MON 88017 × MON 810, 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 covered by this Decision 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 ([8]).

(16) The Standing Committee on Plants, Animals, Food and Feed has not delivered an opinion within the time limit laid down by its Chair. 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,

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([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 maize (*Zea mays* L.) MON 88017 × MON 810, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier MON-88Ø17-3 × MON-ØØ81Ø-6, 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 maize (*Zea mays* L.) MON-88Ø17-3 × MON-ØØ81Ø-6;

(b) feed containing, consisting of or produced from genetically modified maize (*Zea mays* L.) MON-88Ø17-3 × MON-ØØ81Ø-6;

(c) products containing or consisting of genetically modified maize (*Zea mays* L.) MON-88Ø17-3 × MON-ØØ81Ø-6 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 the products containing or consisting of genetically modified maize MON-88Ø17-3 × MON-ØØ81Ø-6, 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 MON-88Ø17-3 × MON-ØØ81Ø-6.

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 Bayer CropScience LP, represented in the Union by Bayer Agriculture BV.

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 CropScience LP, 800 N. Lindbergh Boulevard, St. Louis, Missouri 63167, United States of America, represented in the Union by Bayer Agriculture BV, Scheldelaan 460, 2040 Antwerp, Belgium.

Done at Brussels, 17 August 2021.

For the Commission,
Stella KYRIAKIDES
Member of the Commission

ANNEX

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

Name: Bayer CropScience LP

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

Represented in the Union by: Bayer Agriculture BV, 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 maize (*Zea mays* L.) MON-88Ø17-3 × MON-ØØ81Ø-6;

(2) feed containing, consisting of or produced from genetically modified maize (*Zea mays* L.) MON-88Ø17-3 × MON-ØØ81Ø-6;

(3) products containing or consisting of genetically modified maize (*Zea mays* L.) MON-88Ø17-3 × MON-ØØ81Ø-6 for uses other than those provided for in points (1) and (2), with the exception of cultivation.

The genetically modified maize MON-88Ø17-3 × MON-ØØ81Ø-6 expresses the Cry3Bb1 and Cry1Ab proteins which respectively confer protection against certain coleopteran and lepidopteran pests and the CP4 EPSPS protein which confers tolerance to glyphosate- based herbicides.

(c) **Labelling:**

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

(2) The words 'not for cultivation' shall appear on the label of and in documents accompanying the products containing or consisting of the genetically modified maize MON-88Ø17-3 × MON-ØØ81Ø-6, with the exception of products referred to in point (b)(1).

(d) **Method for detection:**

(1) Event-specific real-time quantitative PCR methods validated for genetically modified maize MON-88Ø17-3 and MON-ØØ81Ø-6 and verified on MON-88Ø17-3 x MON-ØØ81Ø-6 maize;

(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 0406-D2 (for MON-88Ø17-3) accessible via the American Oil Chemists Society at https://www.aocs.org/crm#maize and ERM®-BF413 (for MON-ØØ81Ø-6) accessible via the Joint Research Centre JRC) of the European Commission, Institute for reference Materials and Measurements (IRMM) accessible at https://crm.jrc.ec.europa.eu/

(e) **Unique identifier:**

MON-88Ø17-3 × MON-ØØ81Ø-6

(f) **Information required pursuant to 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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of 17 August 2021

authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 and genetically modified maize combining two, three, four or five of the single events MON 87427, MON 87460, MON 89034, 1507, MON 87411 and 59122, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

(notified under document C(2021)6002)

(Only the Dutch text is authentic)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to 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 15 February 2017, Monsanto Europe S.A./N.V., based in Belgium, submitted, on behalf of Monsanto Company, based in the United States, 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 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122, in accordance with Article 5 and Article 17 of Regulation (EC) No 1829/2003. The application also concerned the placing on the market of products containing or consisting of genetically modified maize MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 for uses other than food and feed, with the exception of cultivation.

(2) In addition, the application concerned the placing on the market of products containing, consisting of or produced from fifty-six sub-combinations of the single transformation events constituting maize MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122.

(3) Seventeen of those sub-combinations were already authorised as follows: MON 89034 × 1507 × 59122, MON 89034 × 1507, MON 89034 × 59122, authorised by Commission Implementing Decision 2013/650/EU ([2]); 1507 × 59122, authorised by Commission Implementing Decision (EU) 2018/1110 ([3]); MON 87427 × MON 89034 × 1507 × 59122, MON 87427 × MON 89034 × 1507, MON 87427 × MON 89034 × 59122, MON 87427 × 1507 × 59122, MON 87427 × 1507, MON 87427 × 59122 authorised by Commission Implementing Decision (EU)

([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 x 1507 x MON 88017 x 59122 ((MON-89Ø34-3 × 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]) 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).

2018/2046 ([4]); MON 87427 × MON 89034 authorised by Commission Implementing Decision (EU) 2021/60 ([5]); MON 87427 × MON 87460 × MON 89034, MON 87427 × MON 87460, MON 87460 × MON 89034 authorised by Commission Implementing Decision (EU) 2021/61 ([6]); MON 87427 × MON 89034 × MON 87411, MON 87427 × MON 87411, MON 89034 × MON 87411 authorised by Commission Implementing Decision (EU) 2021/65 ([7]).

(4) This Decision covers the thirty-nine remaining sub-combinations in the application: MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411, MON 87427 × MON 87460 × MON 89034 × 1507 × 59122, MON 87427 × MON 87460 × MON 89034 × MON 87411 × 59122, MON 87427 × MON 87460 × 1507 × MON 87411 × 59122, MON 87427 × MON 89034 × 1507 × MON 87411 × 59122, MON 87460 × MON 89034 × 1507 × MON 87411 × 59122, MON 87427 × MON 87460 × MON 89034 × 1507, MON 87427 × MON 87460 × MON 89034 × MON 87411, MON 87427 × MON 87460 × MON 89034 × 59122, MON 87427 × MON 87460 × 1507 × MON 87411, MON 87427 × MON 87460 × 1507 × 59122, MON 87427 × MON 87460 × MON 87411 × 59122, MON 87427 × MON 89034 × 1507 × MON 87411, MON 87427 × MON 89034 × MON 87411 × 59122, MON 87427 × 1507 × MON 87411 × 59122, MON 87460 × MON 89034 × 1507 × MON 87411, MON 87460 × MON 89034 × 1507 × 59122, MON 87460 × MON 89034 × MON 87411 × 59122, MON 87460 × 1507 × MON 87411 × 59122, MON 89034 × 1507 × MON 87411 × 59122, MON 87427 × MON 87460 × 1507, MON 87427 × MON 87460 × MON 87411, MON 87427 × MON 87460 × 59122, MON 87427 × 1507 × MON 87411, MON 87427 × MON 87411 × 59122, MON 87460 × MON 89034 × 1507, MON 87460 × MON 89034 × MON 87411, MON 87460 × MON 89034 × 59122, MON 87460 × 1507 × MON 87411, MON 87460 × 1507 × 59122, MON 87460 × MON 87411 × 59122, MON 89034 × 1507 × MON 87411, MON 89034 × MON 87411 × 59122, 1507 × MON 87411 × 59122, MON 87460 × 1507, MON 87460 × MON 87411, MON 87460 × 59122, 1507 × MON 87411 and MON 87411 × 59122 ('the sub-combinations concerned').

(5) 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 ([8]). 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.

(6) By a letter dated 27 August 2018, Monsanto Europe S.A./N.V. informed the Commission that, as of 23 August 2018, it converted its legal form and changed its name to Bayer Agriculture BVBA, based in Belgium.

(7) By a letter dated 28 July 2020, Bayer Agriculture BVBA informed the Commission that, as of 1 August 2020, it changes its name to Bayer Agriculture BV, based in Belgium.

([4]) 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).

([5]) Commission Implementing Decision (EU) 2021/60 of 22 January 2021 authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MON 87427 × MON 89034 × MIR162 × NK603 and genetically modified maize combining two or three of the single events MON 87427, MON 89034, MIR162, NK603, and repealing Implementing Decision (EU) 2018/1111 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 26, 26.1.2021, p. 5).

([6]) Commission Implementing Decision (EU) 2021/61 of 22 January 2021 authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603 and genetically modified maize combining two, three or four of the single events MON 87427, MON 87460, MON 89034, MIR162 and NK603, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 26, 26.1.2021, p. 12).

([7]) Commission Implementing Decision (EU) 2021/65 of 22 January 2021 authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MON 87427 × MON 89034 × MIR162 × MON 87411 and genetically modified maize combining two or three of the single events MON 87427, MON 89034, MIR162 and MON 87411 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 26, 26.1.2021, p. 37).

([8]) 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) By a letter dated 28 July 2020, Bayer Agriculture BVBA, representing Monsanto Company, informed the Commission that, as of 1 August 2020, Monsanto Company converts its legal form and changes its name to Bayer CropScience LP, based in the United States.

(9) On 19 January 2021, the European Food Safety Authority ('the Authority') issued a favourable opinion in accordance with Article 6 and Article 18 of Regulation (EC) No 1829/2003 ([9]). The Authority concluded that genetically modified maize MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 and its sub-combinations, as described in the application, are as safe as their non-genetically modified comparator and the selected non-genetically modified reference varieties with respect to the potential effects on human and animal health and the environment.

(10) No new safety concerns were identified for the previously assessed sub-combinations and therefore previous conclusions on those sub-combinations remain valid. As regards the remaining sub-combinations, the Authority concluded that they are expected to be as safe as the single transformation events MON 87427, MON 87460, MON 89034, 1507, MON 87411 and 59122, the previously assessed sub-combinations and the six-event stack maize MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122.

(11) 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 Article 6(4) and Article 18(4) of Regulation (EC) No 1829/2003.

(12) The Authority also concluded that the monitoring plan for the environmental effects, submitted by the applicant, consisting of a general surveillance plan, is in line with the intended uses of the products.

(13) Taking into account those conclusions, the placing on the market of products containing, consisting of or produced from genetically modified maize MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122, and of the thirty-nine sub-combinations concerned, should be authorised for the uses listed in the application.

(14) A unique identifier should be assigned to genetically modified maize MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122, and to the thirty-nine sub-combinations concerned, in accordance with Commission Regulation (EC) No 65/2004 ([10]).

(15) For the products covered by this Decision, 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 ([11]), appear to be necessary. 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.

(16) 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 ([12]).

([9]) EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2021. Scientific Opinion on the assessment of genetically modified MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 and subcombinations, for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2017-139). EFSA Journal 2021; 19(1):6351. https://doi.org/10.2903/j.efsa.2021.6351

([10]) 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).

([11]) 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]) 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).

(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, consisting of or produced from genetically modified maize MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 and all sub-combinations thereof, 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.

(18) All relevant information on the authorisation of the products covered by this Decision 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 Article 9(1) and Article 15(2)(c) of Regulation (EC) No 1946/2003 of the European Parliament and of the Council ([13]).

(20) The Standing Committee on Plants, Animals, Food and Feed has not delivered an opinion within the time limit laid down by its Chair. 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-87427-7 × MON-8746Ø-4 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-87411-9 × DAS-59122-7 for genetically modified maize MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122;

(b) the unique identifier MON-87427-7 × MON-8746Ø-4 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-87411-9 for genetically modified maize MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411;

(c) the unique identifier MON-87427-7 × MON-8746Ø-4 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × DAS-59122-7 for genetically modified maize MON 87427 × MON 87460 × MON 89034 × 1507 × 59122;

(d) the unique identifier MON-87427-7 × MON-8746Ø-4 × MON-89Ø34-3 × MON-87411-9 × DAS-59122-7 for genetically modified maize MON 87427 × MON 87460 × MON 89034 × MON 87411 × 59122;

(e) the unique identifier MON-87427-7 × MON-8746Ø-4 × DAS-Ø15Ø7-1 × MON-87411-9 × DAS-59122-7 for genetically modified maize MON 87427 × MON 87460 × 1507 × MON 87411 × 59122;

(f) the unique identifier MON-87427-7 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-87411-9 × DAS-59122-7 for genetically modified maize MON 87427 × MON 89034 × 1507 × MON 87411 × 59122;

(g) the unique identifier MON-8746Ø-4 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-87411-9 × DAS-59122-7 for genetically modified maize MON 87460 × MON 89034 × 1507 × MON 87411 × 59122;

(h) the unique identifier MON-87427-7 × MON-8746Ø-4 × MON-89Ø34-3 × DAS-Ø15Ø7-1 for genetically modified maize MON 87427 × MON 87460 × MON 89034 × 1507;

(i) the unique identifier MON-87427-7 × MON-8746Ø-4 × MON-89Ø34-3 × MON-87411-9 for genetically modified maize MON 87427 × MON 87460 × MON 89034 × MON 87411;

([13]) 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 MON-87427-7 × MON-8746Ø-4 × MON-89Ø34-3 × DAS-59122-7 for genetically modified maize MON 87427 × MON 87460 × MON 89034 × 59122;

(k) the unique identifier MON-87427-7 × MON-8746Ø-4 × DAS-Ø15Ø7-1 × MON-87411-9 for genetically modified maize MON 87427 × MON 87460 × 1507 × MON 87411;

(l) the unique identifier MON-87427-7 × MON-8746Ø-4 × DAS-Ø15Ø7-1 × DAS-59122-7 for genetically modified maize MON 87427 × MON 87460 × 1507 × 59122;

(m) the unique identifier MON-87427-7 × MON-8746Ø-4 × MON-87411-9 × DAS-59122-7 for genetically modified maize MON 87427 × MON 87460 × MON 87411 × 59122;

(n) the unique identifier MON-87427-7 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-87411-9 for genetically modified maize MON 87427 × MON 89034 × 1507 × MON 87411;

(o) the unique identifier MON-87427-7 × MON-89Ø34-3 × MON-87411-9 × DAS-59122-7 for genetically modified maize MON 87427 × MON 89034 × MON 87411 × 59122;

(p) the unique identifier MON-87427-7 × DAS-Ø15Ø7-1 × MON-87411-9 × DAS-59122-7 for genetically modified maize MON 87427 × 1507 × MON 87411 × 59122;

(q) the unique identifier MON-8746Ø-4 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-87411-9 for genetically modified maize MON 87460 × MON 89034 × 1507 × MON 87411;

(r) the unique identifier MON-8746Ø-4 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × DAS-59122-7 for genetically modified maize MON 87460 × MON 89034 × 1507 × 59122;

(s) the unique identifier MON-8746Ø-4 × MON-89Ø34-3 × MON-87411-9 × DAS-59122-7 for genetically modified maize MON 87460 × MON 89034 × MON 87411 × 59122;

(t) the unique identifier MON-8746Ø-4 × DAS-Ø15Ø7-1 × MON-87411-9 × DAS-59122-7 for genetically modified maize MON 87460 × 1507 × MON 87411 × 59122;

(u) the unique identifier MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-87411-9 × DAS-59122-7 for genetically modified maize MON 89034 × 1507 × MON 87411 × 59122;

(v) the unique identifier MON-87427-7 × MON-8746Ø-4 × DAS-Ø15Ø7-1 for genetically modified maize MON 87427 × MON 87460 × 1507;

(w) the unique identifier MON-87427-7 × MON-8746Ø-4 × MON-87411-9 for genetically modified maize MON 87427 × MON 87460 × MON 87411;

(x) the unique identifier MON-87427-7 × MON-8746Ø-4 × DAS-59122-7 for genetically modified maize MON 87427 × MON 87460 × 59122;

(y) the unique identifier MON-87427-7 × DAS-Ø15Ø7-1 × MON-87411-9 for genetically modified MON 87427 × 1507 × MON 87411;

(z) the unique identifier MON-87427-7 × MON-87411-9 × DAS-59122-7 for genetically modified maize MON 87427 × MON 87411 × 59122;

(aa) the unique identifier MON-8746Ø-4 × MON-89Ø34-3 × DAS-Ø15Ø7-1 for genetically modified MON 87460 × MON 89034 × 1507;

(bb) the unique identifier MON-8746Ø-4 × MON-89Ø34-3 × MON-87411-9 for genetically modified maize MON 87460 × MON 89034 × MON 87411;

(cc) the unique identifier MON-8746Ø-4 × MON-89Ø34-3 × DAS-59122-7 for genetically modified maize MON 87460 × MON 89034 × 59122;

(dd) the unique identifier MON-8746Ø-4 × DAS-Ø15Ø7-1 × MON-87411-9 for genetically modified maize MON 87460 × 1507 × MON 87411;

(ee) the unique identifier MON-8746Ø-4 × DAS-Ø15Ø7-1 × DAS-59122-7 for genetically modified maize MON 87460 × 1507 × 59122;

(ff) the unique identifier MON-8746Ø-4 × MON-87411-9 × DAS-59122-7 for genetically modified maize MON 87460 × MON 87411 × 59122;

(gg) the unique identifier MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-87411-9 for genetically modified maize MON 89034 × 1507 × MON 87411;

(hh) the unique identifier MON-89Ø34-3 × MON-87411-9 × DAS-59122-7 for genetically modified maize MON 89034 × MON 87411 × 59122;

(ii) the unique identifier DAS-Ø15Ø7-1 × MON-87411-9 × DAS-59122-7 for genetically modified maize 1507 × MON 87411 × 59122;

(jj) the unique identifier MON-8746Ø-4 × DAS-Ø15Ø7-1 for genetically modified maize MON 87460 × 1507;

(kk) the unique identifier MON-8746Ø-4 × MON-87411-9 for genetically modified maize MON 87460 × 87411;

(ll) the unique identifier MON-8746Ø-4 × DAS-59122-7 for genetically modified maize MON 87460 × 59122;

(mm) the unique identifier DAS-Ø15Ø7-1 × MON-87411-9 for genetically modified maize 1507 × MON 87411;

(nn) the unique identifier MON-87411-9 × DAS-59122-7 for genetically modified maize MON 87411 × 59122.

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 Article 2, point (a).

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 Bayer CropScience LP, represented in the Union by Bayer Agriculture BV.

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 CropScience LP, 800 N. Lindbergh Boulevard, St. Louis, Missouri 63167, United States of America, represented in the Union by Bayer Agriculture BV, Scheldelaan 460, 2040 Antwerp, Belgium.

Done at Brussels, 17 August 2021.

For the Commission,
Stella KYRIAKIDES
Member of the Commission

ANNEX

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

Name: Bayer CropScience LP

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

Represented in the Union by: Bayer Agriculture BV, 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 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-87427-7 expresses the *cp4 epsps* gene, which confers tolerance to glyphosate-containing herbicides.

The genetically modified maize MON-8746Ø-4 expresses a *Bacillus subtilis* modified *cspB* gene, which aims to reduce yield loss caused by drought stress. In addition, the *nptII* gene, conferring kanamycin and neomycin resistance, was used as a selection marker in the genetic modification process.

The genetically modified maize MON-89Ø34-4 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-87411-9 expresses the *cp4 epsps* gene, which confers tolerance to glyphosate-containing herbicides, the *cry3Bb1* gene and the DvSnf7 dsRNA, which confer protection against corn rootworm (*Diabrotica spp.*).

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.

(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).

(d) **Method for detection:**

(1) The quantitative event-specific PCR detection methods are those individually validated for genetically modified maize MON-87427-7, MON-8746Ø-4, MON-89Ø34-3, DAS-Ø15Ø7-1, MON-87411-9, DAS-59122-7 and further verified on maize stack MON-87427-7 × MON-8746Ø-4 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-87411-9 × DAS-59122-7;

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

(3) Reference Material: AOCS 0512 (for MON-87427-7), AOCS 0709 (for MON-8746Ø-4), AOCS 0906 (for MON-89Ø34-3) and AOCS 0215 (for MON-87411-9) are accessible via the American Oil Chemists Society at https://www.aocs.org/crm and ERM®-BF418 (for DAS-Ø15Ø7-1) and ERM®-BF424 (for DAS-59122-7) are accessible via the Joint Research Center (JRC) of the European Commission at https://crm.jrc.ec.europa.eu/.

(e) **Unique identifier:**

MON-87427-7 × MON-8746Ø-4 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-87411-9 × DAS-59122-7;

MON-87427-7 × MON-8746Ø-4 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-87411-9;

MON-87427-7 × MON-8746Ø-4 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × DAS-59122-7;

MON-87427-7 × MON-8746Ø-4 × MON-89Ø34-3 × MON-87411-9 × DAS-59122-7;

MON-87427-7 × MON-8746Ø-4 × DAS-Ø15Ø7-1 × MON-87411-9 × DAS-59122-7;

MON-87427-7 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-87411-9 × DAS-59122-7;

MON-8746Ø-4 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-87411-9 × DAS-59122-7;

MON-87427-7 × MON-8746Ø-4 × MON-89Ø34-3 × DAS-Ø15Ø7-1;

MON-87427-7 × MON-8746Ø-4 × MON-89Ø34-3 × MON-87411-9;

MON-87427-7 × MON-8746Ø-4 × MON-89Ø34-3 × DAS-59122-7;

MON-87427-7 × MON-8746Ø-4 × DAS-Ø15Ø7-1 × MON-87411-9;

MON-87427-7 × MON-8746Ø-4 × DAS-Ø15Ø7-1 × DAS-59122-7;

MON-87427-7 × MON-8746Ø-4 × MON-87411-9 × DAS-59122-7;

MON-87427-7 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-87411-9;

MON-87427-7 × MON-89Ø34-3 × MON-87411-9 × DAS-59122-7;

MON-87427-7 × DAS-Ø15Ø7-1 × MON-87411-9 × DAS-59122-7;

MON-8746Ø-4 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-87411-9;

MON-8746Ø-4 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × DAS-59122-7;

MON-8746Ø-4 × MON-89Ø34-3 × MON-87411-9 × DAS-59122-7;

MON-8746Ø-4 × DAS-Ø15Ø7-1 × MON-87411-9 × DAS-59122-7;

MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-87411-9 × DAS-59122-7;

MON-87427-7 × MON-8746Ø-4 × DAS-Ø15Ø7-1;

MON-87427-7 × MON-8746Ø-4 × MON-87411-9;

MON-87427-7 × MON-8746Ø-4 × DAS-59122-7;

MON-87427-7 × DAS-Ø15Ø7-1 × MON-87411-9;

MON-87427-7 × MON-87411-9 × DAS-59122-7;

MON-8746Ø-4 × MON-89Ø34-3 × DAS-Ø15Ø7-1;

MON-8746Ø-4 × MON-89Ø34-3 × MON-87411-9;

MON-8746Ø-4 × MON-89Ø34-3 × DAS-59122-7;

MON-8746Ø-4 × DAS-Ø15Ø7-1 × MON-87411-9;

MON-8746Ø-4 × DAS-Ø15Ø7-1 × DAS-59122-7;

MON-8746Ø-4 × MON-87411-9 × DAS-59122-7;

MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-87411-9;

MON-89Ø34-3 × MON-87411-9 × DAS-59122-7;

DAS-Ø15Ø7-1 × MON-87411-9 × DAS-59122-7;

MON-8746Ø-4 × DAS-Ø15Ø7-1;

MON-8746Ø-4 × MON-87411-9;

MON-8746Ø-4 × DAS-59122-7;

DAS-Ø15Ø7-1 × MON-87411-9;

MON-87411-9 × DAS-59122-7.

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

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

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

Not required.

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

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

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

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

Not required.

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

COMMISSION IMPLEMENTING DECISION (EU) 2021/1395

of 20 August 2021

amending the Annex to Implementing Decision (EU) 2021/641 concerning emergency measures in relation to outbreaks of highly pathogenic avian influenza in certain Member States

(notified under document C(2021) 6253)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law') ([1]), and in particular Article 259(1), point (c) thereof,

Whereas:

(1) Highly pathogenic avian influenza (HPAI) is an infectious viral disease in birds and may have a severe impact on the profitability of poultry farming causing disturbance to trade within the Union and exports to third countries. HPAI viruses can infect migratory birds, which can then spread these viruses over long distances during their autumn and spring migrations. Therefore, the presence of HPAI viruses in wild birds poses a continuous threat for the direct and indirect introduction of these viruses into holdings where poultry or captive birds are kept. In the event of an outbreak of HPAI, there is a risk that the disease agent may spread to other holdings where poultry or captive birds are kept.

(2) Regulation (EU) 2016/429 establishes a new legislative framework for the prevention and control of diseases that are transmissible to animals or humans. HPAI falls within the definition of a listed disease in that Regulation, and it is subject to the disease prevention and control rules laid down therein. In addition, Commission Delegated Regulation (EU) 2020/687 ([2]) supplements Regulation (EU) 2016/429 as regards the rules for the prevention and control of certain listed diseases, including disease control measures for HPAI.

(3) Commission Implementing Decision (EU) 2021/641 ([3]) was adopted within the framework of Regulation (EU) 2016/429, and it lays down disease control measures in relation to outbreaks of HPAI.

(4) More particularly, Implementing Decision (EU) 2021/641 provides that the protection and surveillance zones established by the Member States following outbreaks of HPAI, in accordance with Delegated Regulation (EU) 2020/687, are to comprise at least the areas listed as protection and surveillance zones in the Annex to that Implementing Decision.

(5) The Annex to Implementing Decision (EU) 2021/641 was recently amended by Commission Implementing Decision (EU) 2021/1307 ([4]) to extend the duration of the restrictions applicable in the protection and surveillance zones established by the competent authority of France for an outbreak in the Pyrénées-Atlantiques department.

(6) Since the date of adoption of Implementing Decision (EU) 2021/1307, Poland has notified the Commission of an outbreak of HPAI of subtype H5N8 in a holding where poultry or captive birds were kept in the Mazowieckie voivodship of that Member State.

([1]) OJ L 84, 31.3.2016, p. 1.

([2]) Commission Delegated Regulation (EU) 2020/687 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and the Council, as regards rules for the prevention and control of certain listed diseases (OJ L 174, 3.6.2020, p. 64).

([3]) Commission Implementing Decision (EU) 2021/641 of 16 April 2021 concerning emergency measures in relation to outbreaks of highly pathogenic avian influenza in certain Member States (OJ L 134, 20.4.2021, p. 166).

([4]) Commission Implementing Decision (EU) 2021/1307 of 6 August 2021 amending the Annex to Implementing Decision (EU) 2021/641 concerning emergency measures in relation to outbreaks of highly pathogenic avian influenza in certain Member States (OJ L 285, 9.8.2021, p. 1).

(7) That outbreak in Poland is located outside the areas currently listed in the Annex to Implementing Decision (EU) 2021/641 and the competent authority of that Member State has taken the necessary disease control measures required in accordance with Delegated Regulation (EU) 2020/687, including the establishment of protection and surveillance zones around this outbreak.

(8) The Commission has examined the disease control measures taken by Poland in collaboration with that Member State, and it is satisfied that the boundaries of the protection and surveillance zones established by the competent authority of Poland are at a sufficient distance from the holding where the recent outbreak of HPAI has been confirmed.

(9) In order to prevent any unnecessary disturbance to trade within the Union and to avoid unjustified barriers to trade being imposed by third countries, it is necessary to rapidly describe at Union level, in collaboration with Poland, the new protection and surveillance zones established by that Member State in accordance with Delegated Regulation (EU) 2020/687.

(10) Therefore, protection and surveillance zones should be listed for Poland in the Annex to Implementing Decision (EU) 2021/641.

(11) Accordingly, the Annex to Implementing Decision (EU) 2021/641 should be amended to update regionalisation at Union level to take account of the protection and surveillance zones duly established by Poland, in accordance with Delegated Regulation (EU) 2020/687, and the duration of the restrictions applicable therein.

(12) Implementing Decision (EU) 2021/641 should therefore be amended accordingly.

(13) Given the urgency of the epidemiological situation in the Union as regards the spread of HPAI, it is important that the amendments to be made to the Annex to Implementing Decision (EU) 2021/641 by this Decision take effect as soon as possible.

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

HAS ADOPTED THIS DECISION:

Article 1

The Annex to Implementing Decision (EU) 2021/641 is replaced by the text set out in the Annex to this Decision.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 20 August 2021.

For the Commission
Stella KYRIAKIDES
Member of the Commission

ANNEX

'*ANNEX*

Part A

Protection zones as referred to in Articles 1 and 2:

Member State: France

Area comprising:	**Date until applicable in accordance with Article 39 of Delegated Regulation (EU) 2020/687**
Les communes suivantes dans le département: Pyrénées-Atlantiques (64)	
BIDACHE; CAME	26.8.2021

Member State: Poland

Area comprising:	**Date until applicable in accordance with Article 39 of Delegated Regulation (EU) 2020/687**
Mazowieckie voivodship, żuromiński district	
— The following localities in the Bieżuń municipality: Karniszyn, Karniszyn-Parcele, Sadłowo, Sadłowo-Parcele, Strzeszewo; — The following localities in the Żuromin municipality: Chamsk, Młudzyn.	3.9.2021

Part B

Surveillance zones as referred to in Articles 1 and 3:

Member State: France

Area comprising:	**Date until applicable in accordance with Article 55 of Delegated Regulation (EU) 2020/687**
Les communes suivantes dans le département: Landes (40)	
CAUNEILLE; HASTINGUES; OEYREGAVE; ORTHEVIELLE; PEYREHORADE; SORDE-L'ABBAYE	4.9.2021
Les communes suivantes dans le département: Pyrénées-Atlantiques (64)	
BIDACHE; CAME	From 27.8.2021 until 4.9.2021
ARANCOU; ARRAUTE-CHARRITTE; AUTERRIVE; BARDOS; BERGOUEY-VIELLENAVE; CARRESSE-CASSABER; ESCOS; GUICHE; LABASTIDE-VILLEFRANCHE; LABETS-BISCAY; LEREN; MASPARRAUTE; OREGUE; SAINT-DOS; SAINT-PE-DE-LEREN; SAMES	4.9.2021

Member State: Poland

Area comprising:	Date until applicable in accordance with Article 55 of Delegated Regulation (EU) 2020/687
Mazowieckie voivodship, żuromiński district	
— The following localities in the Bieżuń municipality: Kocewo, Myślin, Dąbrówki, Mak, Władysławowo, Stanisławowo, Pozga, Bielawy Gołuskie, Gołuszyn, Dźwierzno, Kobyla Łąka, Sławęcin, Zgliczyn Pobodzy, Stawiszyn-Łaziska, Wilewo, Stawiszyn-Zwalewo, Wieluń-Zalesie, Pełki, Małocin, Trzaski; — City of Bieżuń; — The following localities in the Lutocin municipality: Siemcichy, Chromakowo, Przeradz Mały, Przeradz Nowy, Przeradz Wielki, Swojęcin, Mojnowo, Obręb, Parlin, Lutocin, Seroki, Zimolza, Elżbiecin, Felcyn, Jonne; — The following localities in the Siemiątkowo municipality: Sokołowy Kąt, Siciarz; — The following localities in the in Żuromin municipality: Będzymin, Rzężawy, Kruszewo, Brudnice, Poniatowo, Wiadrowo, Dąbrowa, Cierpigórz, Franciszkowo, Olszewo, Kosewo, Dębsk, Kliczewo Małe, Kliczewo Duże, Wólka Kliczewska, Nowe Nadratowo, Stare Nadratowo, Sadowo; — City of Żuromin.	12.9.2021
— The following localities in the Bieżuń municipality: Karniszyn, Karniszyn-Parcele, Sadłowo, Sadłowo-Parcele, Strzeszewo; — The following localities in the Żuromin municipality: Chamsk, Młudzyn.	From 4.9.2021 until 12.9.2021
Mazowieckie voivodship, mławski district	
— The following localities in the Radzanów municipality: Zgliczyn-Glinki, Zgliczyn Witowy; — The following localities in the Szreńsk municipality: Ługi, Słowikowo.	12.9.2021’

DECISION (EU) 2021/1396 OF THE EUROPEAN CENTRAL BANK

of 13 August 2021

amending Decision ECB/2014/29 on the provision to the European Central Bank of supervisory data reported to the national competent authorities by the supervised entities pursuant to Commission Implementing Regulations (EU) No 680/2014 and (EU) 2016/2070 (ECB/2021/39)

THE GOVERNING COUNCIL OF THE EUROPEAN CENTRAL BANK,

Having regard to Council Regulation (EU) No 1024/2013 of 15 October 2013 conferring specific tasks on the European Central Bank concerning policies relating to prudential supervision of credit institutions ([1]), and in particular Article 6(2) thereof,

Having regard to Regulation (EU) No 468/2014 of the European Central Bank of 16 April 2014 establishing the framework for cooperation within the Single Supervisory Mechanism between the European Central Bank and national competent authorities and with national designated authorities (SSM Framework Regulation) (ECB/2014/17) ([2]), and in particular Article 21 and Article 140(4) thereof,

Having regard to the proposal of the Supervisory Board,

Whereas:

(1) Decision ECB/2014/29 ([3]) lays down procedures concerning the submission to the European Central Bank (ECB) of data reported to the national competent authorities by the supervised entities on the basis of Commission Implementing Regulation (EU) No 680/2014 ([4]) and Commission Implementing Regulation (EU) 2016/2070 ([5]).

(2) On 17 December 2020, the European Commission adopted Commission Implementing Regulation (EU) 2021/451 ([6]) which repeals and replaces Implementing Regulation (EU) No 680/2014 and sets new standards with regard to supervisory reporting that are applicable from 28 June 2021.

(3) On 15 March 2021, the Commission adopted Commission Implementing Regulation (EU) 2021/453 ([7]), which further specifies the new standards with regard to the specific reporting requirements for market risk.

(4) Decision ECB/2014/29 provides for the collection and quality review of data reported by supervised entities to national competent authorities in accordance with the relevant Union law. As a consequence, Decision ECB/2014/29 must provide for the collection and quality review of the data to be reported by supervised entities to the national competent authorities pursuant to Implementing Regulation (EU) 2016/2070, Implementing Regulation (EU) 2021/451 and Implementing Regulation (EU) 2021/453. Decision ECB/2014/29 must be therefore updated to reflect the adoption of Implementing Regulation (EU) 2021/451 and Implementing Regulation (EU) 2021/453 to ensure that the relevant data is submitted by the national compentent authorities to the ECB.

([1]) OJ L 287, 29.10.2013, p. 63.
([2]) OJ L 141, 14.5.2014, p. 1.
([3]) Decision ECB/2014/29 of 2 July 2014 on the provision to the European Central Bank of supervisory data reported to the national competent authorities by the supervised entities pursuant to Commission Implementing Regulations (EU) No 680/2014 and (EU) 2016/2070 (OJ L 214, 19.7.2014, p. 34).
([4]) Commission Implementing Regulation (EU) No 680/2014 of 16 April 2014 laying down implementing technical standards with regard to supervisory reporting of institutions according to Regulation (EU) No 575/2013 of the European Parliament and of the Council (OJ L 191, 28.6.2014, p. 1).
([5]) Commission Implementing Regulation (EU) 2016/2070 of 14 September 2016 laying down implementing technical standards for templates, definitions and IT-solutions to be used by institutions when reporting to the European Banking Authority and to competent authorities in accordance with Article 78(2) of Directive 2013/36/EU of the European Parliament and of the Council (OJ L 328, 2.12.2016, p. 1).
([6]) Commission Implementing Regulation (EU) 2021/451 of 17 December 2020 laying down implementing technical standards for the application of Regulation (EU) No 575/2013 of the European Parliament and of the Council with regard to supervisory reporting of institutions and repealing Implementing Regulation (EU) No 680/2014 (OJ L 97, 19.3.2021, p. 1).
([7]) Commission Implementing Regulation (EU) 2021/453 of 15 March 2021 laying down implementing technical standards for the application of Regulation (EU) No 575/2013 of the European Parliament and of the Council with regard to the specific reporting requirements for market risk (OJ L 89, 16.3.2021, p. 3).

(5) Furthermore, the European Banking Authority (EBA) repealed and replaced the EBA Decision of 23 September 2015 on reporting by competent authorities to the EBA (EBA/DC/2015/130) ([8]) with EBA Decision of 5 June 2020 concerning supervisory reporting by competent authorities to the EBA (EBA/DC/2020/334) ([9]). That decision requires competent authorities, including the ECB, to submit supervisory and financial reporting data to the EBA, among others. To this end, EBA Decision EBA/DC/2020/334 specifies the dates of submission for that data by competent authorities to the EBA.

(6) In addition, the EBA repealed and replaced the EBA Decision of 31 May 2016 on data for supervisory benchmarking (EBA/DC/2016/156) ([10]) with EBA Decision of 5 June 2020 concerning data for supervisory benchmarking (EBA/DC/2020/337) ([11]). That decision requires competent authorities, including the ECB, to submit to the EBA supervisory benchmarking data. To this end, EBA Decision EBA/DC/2020/337 specifies the date of submission of such data by competent authorities to the EBA.

(7) Decision ECB/2014/29 must therefore also be updated to ensure that the ECB receives that data from the national competent authorities in a timely manner which the ECB then submits to the EBA in accordance with the EBA Decisions EBA/DC/2020/334 and EBA/DC/2020/337.

(8) Therefore, Decision ECB/2014/29 should be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

Amendments

Decision ECB/2014/29 is amended as follows:

1. the title is replaced by the following:

   'Decision of the European Central Bank of 2 July 2014 on the provision to the European Central Bank of supervisory data reported to the national competent authorities by the supervised entities (ECB/2014/29)';

2. Article 1 is replaced by the following:

   'Article 1

   Scope

   Pursuant to Article 21 of the SSM Framework Regulation, this Decision lays down procedures concerning the submission to the ECB of data reported to the national competent authorities by the supervised entities on the basis of Commission Implementing Regulation (EU) 2016/2070 *[1], Commission Implementing Regulation (EU) 2021/451 *[2], and Commission Implementing Regulation (EU) 2021/453 *[3].

   *[1] Commission Implementing Regulation (EU) 2016/2070 of 14 September 2016 laying down implementing technical standards for templates, definitions and IT-solutions to be used by institutions when reporting to the European Banking Authority and to competent authorities in accordance with Article 78(2) of Directive 2013/36/EU of the European Parliament and of the Council (OJ L 328, 2.12.2016, p. 1).

   *[2] Commission Implementing Regulation (EU) 2021/451 of 17 December 2020 laying down implementing technical standards for the application of Regulation (EU) No 575/2013 of the European Parliament and of the Council with regard to supervisory reporting of institutions and repealing Implementing Regulation (EU) No 680/2014 (OJ L 97, 19.3.2021, p. 1).

   *[3] Commission Implementing Regulation (EU) 2021/453 of 15 March 2021 laying down implementing technical standards for the application of Regulation (EU) No 575/2013 of the European Parliament and of the Council with regard to the specific reporting requirements for market risk (OJ L 89, 16.3.2021, p. 3).';

([8]) Available on the EBA website.
([9]) Available on the EBA website.
([10]) Available on the EBA website.
([11]) Available on the EBA website.

3. Article 3 is replaced by the following:

'Article 3

Remittance dates

1. National competent authorities shall submit to the ECB the data referred to in Implementing Regulation (EU) 2021/451 and Implementing Regulation (EU) 2021/453 and reported to them by the supervised entities in accordance with the following:

(a) National competent authorities shall submit to the ECB data relating to the following entities by 12 noon Central European Time (CET) *[4] on the 10th working day following the relevant remittance dates referred to in Article 3 and Article 20(3) of Implementing Regulation (EU) 2021/451 and the relevant reporting dates referred to in Article 1(2) of Implementing Regulation (EU) 2021/453:

(i) significant supervised entities reporting at the highest level of consolidation within the participating Member States;

(ii) significant supervised entities that are not part of a supervised group;

(iii) supervised entities which are classified as significant in accordance with the three most significant credit institutions criterion in their Member State and which report on a consolidated basis or on an individual basis, if they are not required to report on a consolidated basis;

(iv) other supervised entities reporting on a consolidated basis or on an individual basis, if they are not required to report on a consolidated basis, which are the 'Largest Institutions in the Member State' as defined in Article 2(3) of EBA Decision of 5 June 2020 concerning supervisory reporting by competent authorities to the EBA (EBA/DC/2020/334) *[5];

(b) where point (a) does not apply, national competent authorities shall submit to the ECB data relating to the following entities by 12 noon CET on the 25th working day following the relevant remittance dates referred to in Article 3 of Implementing Regulation (EU) 2021/451 and the relevant reporting dates referred to in Article 1(2) of Implementing Regulation (EU) 2021/453:

(i) significant supervised entities;

(ii) less significant supervised entities.

2. National competent authorities shall report to the ECB the data referred to in Implementing Regulation (EU) 2016/2070 in accordance with the following:

(a) National competent authorities shall report to the ECB data relating to the following entitites by 12 noon CET on the 10th working day following the relevant remittance dates referred to in the relevant provision for each data item in Implementing Regulation (EU) 2016/2070:

(i) significant supervised entities reporting at the highest level of consolidation within the participating Member States;

(ii) significant supervised entities that are not part of a supervised group;

(iii) supervised entities which are classified as significant in accordance with the three most significant credit institutions criterion in their Member State and which report on a consolidated basis or on an individual basis, if they are not required to report on a consolidated basis;

(iv) less significant supervised entities reporting at the highest level of consolidation within participating Member States insofar as they are the highest level of consolidation in the Union and less significant supervised entities reporting on an individual basis if they are not part of a supervised group, in accordance with Article 1(2) of Decision EBA/DC/2020/337 of the EBA

(b) Where point (a) does not apply, national competent authorities shall report to the ECB data relating to the following entities by close of business on the 25th working day following the relevant remittance dates referred to in the relevant provision for each data item in Implementing Regulation (EU) 2016/2070:

(i) significant supervised entities;

(ii) less significant supervised entities.

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*4 CET takes account of the change to Central European Summer Time.

*5 Available on the EBA website.';

4. the following Article 7b is inserted:

'*Article 7b*

First reporting following the taking effect of Decision (EU) 2021/1396 of the European Central Bank (ECB/2021/39)

National competent authorities shall submit the data reported to them pursuant to Implementing Regulation (EU) 2016/2070, Implementing Regulation (EU) 2021/451, and Implementing Regulation (EU) 2021/453 in accordance with Decision (EU) 2021/1396 of the European Central Bank (ECB/2021/39) * beginning with the first applicable remittance or reporting dates which occur after that Decision takes effect.

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* Decision (EU) 2021/1396 of the European Central Bank of 13 August 2021 amending Decision ECB/2014/29 on the provision to the European Central Bank of supervisory data reported to the national competent authorities by the supervised entities pursuant to Commission Implementing Regulations (EU) No 680/2014 and (EU) 2016/2070 (ECB/2021/39) (OJ L 300, 24.8.2021, p.74).'.

Article 2

Taking effect

This Decision shall take effect on the day of its notification to the addressees.

Article 3

Addressees

This Decision is addressed to the national competent authorities of the participating Member States.

Done at Frankfurt am Main, 13 August 2021.

The President of the ECB
Christine LAGARDE

ACTS ADOPTED BY BODIES CREATED BY INTERNATIONAL AGREEMENTS

DECISION No 1/EC/2021

of 28 July 2021

of the Joint Committee set up under the Agreement on Mutual Recognition between the European Community and Japan related to the registration of a conformity assessment body under the Sectoral Annex on Telecommunications Terminal Equipment and Radio Equipment [2021/1397]

THE JOINT COMMITTEE,

Having regard to the Agreement on Mutual Recognition between the European Community and Japan and, in particular, Article 8(3)(a) and Article 9(1)(b) thereof,

Whereas the Joint Committee is to take a Decision to register a conformity assessment body or bodies under a Sectoral Annex,

HAS DECIDED AS FOLLOWS:

1. The conformity assessment body indicated below is registered under the Sectoral Annex on Telecommunications Terminal Equipment and Radio Equipment of the Agreement, for the products and conformity assessment procedures as indicated below.

Name, acronym and contact details of the Conformity Assessment Body:
Name: LGAI Technological Center, S.A. (APPLUS)
Address:
Campus de la UAB, Ronda de la Font del Carme, s/n 08193 Bellaterra Barcelona, SPAIN
Telephone number: +34 93 567 20 00
Fax number: +93 567 20 01
E-mail address: elabscert@applus.com
URL address: http://www.applus.com
Contact persons of the designated CAB: Francisca Asensio Ferreira/Davide Brandano

Scope of registration in terms of products and conformity assessment procedures:
For Radio Law:
Registered Certification Body
— Specified Radio Equipment specified in Article 38-2-2, paragraph (1), item 1) of the Radio Law

2. This Decision, done in duplicate, shall be signed by the Co-Chairs. The Decision shall be effective from the date of the later of these signatures.

Tokyo, 30 June 2021
On behalf of Japan
Daisuke NIHEI

Brussels, 28 July 2021
On behalf of the European Union
Lucian CERNAT

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

Publications Office
of the European Union
L-2985 Luxembourg
LUXEMBOURG

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