



2023/2143

17.10.2023

**COMMISSION IMPLEMENTING DECISION (EU) 2023/2143**

**of 13 October 2023**

**renewing the authorisation for placing on the market of products containing, consisting of or produced from genetically modified maize MIR162 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council and amending Commission Implementing Decisions (EU) 2016/1685, (EU) 2019/1305 and (EU) 2019/2087 as regards the reference material**

*(notified under document C(2023) 6736)*

**(Only the texts in Dutch and French 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 <sup>(1)</sup>, and in particular Article 9(2), Article 11(3), Article 21(2) and Article 23(3) thereof,

Whereas:

- (1) Commission Implementing Decision 2012/651/EU <sup>(2)</sup> authorised the placing on the market of food and feed containing, consisting of or produced from genetically modified maize MIR162. The scope of that authorisation also covered the placing on the market of products other than food and feed containing or consisting of genetically modified maize MIR162, for the same uses as any other maize, with the exception of cultivation.
- (2) On 12 February 2021, Syngenta Crop Protection NV/SA, based in Belgium, submitted, on behalf of Syngenta Crop Protection AG, based in Switzerland, an application to the Commission, in accordance with Articles 11 and 23 of Regulation (EC) No 1829/2003, for renewal of the authorisation.
- (3) On 22 September 2022, the European Food Safety Authority ('the Authority') issued a favourable scientific opinion <sup>(3)</sup>. 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 MIR162, adopted by the Authority in 2012 <sup>(4)</sup>.
- (4) In its scientific 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.

<sup>(1)</sup> OJ L 268, 18.10.2003, p. 1.

<sup>(2)</sup> Commission Implementing Decision 2012/651/EU of 18 October 2012 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MIR162 (SYN-IR162-4) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 290, 20.10.2012, p. 14).

<sup>(3)</sup> EFSA Panel on Genetically Modified Organisms (EFSA GMO Panel), 2022. Scientific Opinion on Assessment of genetically modified maize MIR162 for renewal authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-025). *EFSA Journal* 2022;20(9):7562, p. 13. <https://doi.org/10.2903/j.efsa.2022.7562>.

<sup>(4)</sup> EFSA Panel on Genetically Modified Organisms (EFSA GMO Panel), 2012. Scientific Opinion on application (EFSA-GMO-DE-2010-82) for the placing on the market of insect-resistant genetically modified maize MIR162 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Syngenta. *EFSA Journal* 2012; 10(6):2756, p. 37. <https://doi.org/10.2903/j.efsa.2012.2756>.

- (5) The Authority also concluded that the monitoring plan for the environmental effects, consisting of general surveillance plan, submitted by the applicant, is in line with the intended uses of the products.
- (6) On 17 April 2023, the Authority issued a statement complementing its scientific opinion <sup>(5)</sup>, taking into account additional information provided by the public. The Authority did not identify any implication of the additional information on the safety of genetically modified maize MIR162 for food and feed or for the environment and confirmed that the conclusions of its scientific opinion remain valid.
- (7) 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 MIR162 and of products containing it or consisting of it for uses other than food and feed, with the exception of cultivation, should be renewed.
- (8) A unique identifier has been assigned to genetically modified maize MIR162, in accordance with Commission Regulation (EC) No 65/2004 <sup>(6)</sup>, in the context of its initial authorisation by Implementing Decision 2012/651/EU. That unique identifier should continue to be used.
- (9) For the products covered by this Decision, no specific labelling requirements, other than those provided for in 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 <sup>(7)</sup>, appear to be necessary. However, in order to ensure that the use of products containing or consisting of genetically modified maize MIR162 remains within the limits of the authorisation granted by this Decision, the labelling of such products, with the exception of food 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 <sup>(8)</sup>.
- (11) The opinion of the Authority does not justify the imposition of specific conditions or restrictions for the placing on the market for use and handling, including post-market monitoring requirements regarding the consumption of food and feed containing, consisting of or produced from genetically modified maize MIR162, or for the protection of particular ecosystems/environment and/or geographical areas, as provided for in Article 6(5), point (e), and Article 18(5), point (e) of Regulation (EC) No 1829/2003.

<sup>(5)</sup> EFSA Panel on Genetically Modified Organisms (EFSA GMO Panel), 2023. Statement on the risk assessment of additional information on maize MIR162. *EFSA Journal* 2023;21(4):7935, p. 8 <https://10.0.11.87/j.efsa.2023.7935>

<sup>(6)</sup> 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).

<sup>(7)</sup> 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).

<sup>(8)</sup> 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) On 26 October 2022, Syngenta Crop Protection NV/SA, on behalf of Syngenta Crop Protection AG, informed the Commission about a change of the provider of the reference material of genetically modified maize MIR162. Therefore, Commission Implementing Decisions (EU) 2016/1685 <sup>(9)</sup>, (EU) 2019/1305 <sup>(10)</sup> and (EU) 2019/2087 <sup>(11)</sup> should be amended in order to update the indications as regards website links for accession to the respective certified reference materials for the of genetically modified maize MIR162.
- (13) 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.
- (14) This Decision is to be notified through the Biosafety Clearing-House to the Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, pursuant to Article 9(1) and Article 15(2), point (c) of Regulation (EC) No 1946/2003 of the European Parliament and of the Council <sup>(12)</sup>.
- (15) The Standing Committee on Plants, Animals, Food and Feed has not delivered an opinion within the time limit laid down by its Chairman. This implementing act was deemed to be necessary and the chair submitted it to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

HAS ADOPTED THIS DECISION:

#### Article 1

### Genetically modified organism and unique identifier

Genetically modified maize (*Zea mays* L.) MIR162, as specified in the Annex, is assigned the unique identifier SYN-IR162-4, in accordance with Regulation (EC) No 65/2004.

#### Article 2

### Renewal of the authorisation

The authorisation for placing on the market of the following products is renewed as regards:

- (a) foods and food ingredients containing, consisting of or produced from genetically modified maize SYN-IR162-4;
- (b) feed containing, consisting of or produced from genetically modified maize SYN-IR162-4;
- (c) products containing or consisting of genetically modified maize SYN-IR162-4, for uses other than those provided for in points (a) and (b), with the exception of cultivation.

<sup>(9)</sup> Commission Implementing Decision (EU) 2016/1685 of 16 September 2016 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize Bt11 × MIR162 × MIR604 × GA21, and genetically modified maize combining two or three of the events Bt11, MIR162, MIR604 and GA21, and repealing Decisions 2010/426/EU, 2011/892/EU, 2011/893/EU and 2011/894/EU (OJ L 254, 20.9.2016, p. 22).

<sup>(10)</sup> 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).

<sup>(11)</sup> Commission Implementing Decision (EU) 2019/2087 of 28 November 2019 authorising the placing on the market of products containing, consisting of or produced from genetically modified maize Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21 and genetically modified maize combining two, three, four or five of the single events Bt11, MIR162, MIR604, 1507, 5307 and GA21 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 316, 6.12.2019, p. 94).

<sup>(12)</sup> Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms (OJ L 287, 5.11.2003, p. 1).

*Article 3***Labelling**

1. For the purposes of the labelling requirements laid down in 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-IR162-4 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 SYN-IR162-4.

*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***Amendment of Implementing Decision (EU) 2016/1685**

In the Annex, point (d)(3) is replaced by the following:

- ‘(3) Reference Material: ERM®-BF412 (for SYN-BTØ11-1), ERM®-BF446 (for SYN-IR162-4) and ERM®-BF423 (for SYN-IR6Ø4-5) accessible via the Joint Research Centre (JRC) of the European Commission, at <https://crm.jrc.ec.europa.eu/> and AOCS 0407-A and AOCS 0407-B (for MON-ØØØ21-9) accessible via the American Oil Chemists Society at <https://www.aocs.org/crm>.’

*Article 10***Amendment of Implementing Decision (EU) 2019/1305**

In the Annex, point (d)(3) is replaced by the following:

- ‘(3) Reference Material: ERM®-BF412 (for SYN-BTØ11-1), ERM®-BF446 (for SYN-IR162-4) and ERM®-BF418 (for DAS-Ø15Ø7-1) are accessible via the Joint Research Centre (JRC) of the European Commission at <https://crm.jrc.ec.europa.eu/>, and, AOCS 0407-A and AOCS 0407-B (for MON-ØØØ21-9) are accessible via the American Oil Chemists Society at <https://www.aocs.org/crm>.’

*Article 11***Amendment of Implementing Decision (EU) 2019/2087**

In the Annex, point (d)(3) is replaced by the following:

- ‘(3) Reference Material: ERM®-BF412 (for SYN-BTØ11-1), ERM®-BF446 (for SYN-IR162-4), ERM®-BF423 (for SYN-IR6Ø4-5) and ERM®-BF418 (for DAS-Ø15Ø7-1) are accessible via the Joint Research Centre (JRC) of the European Commission at <https://crm.jrc.ec.europa.eu/>, and AOCS 0411-C and 0411-D (for SYN-Ø53Ø7-1) and AOCS 0407-A and 0407-B (for MON-ØØØ21-9) are accessible via the American Oil Chemists Society at <https://www.aocs.org/crm>.’

*Article 12***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, 1050 Brussels, Belgium.

Done at Brussels, 13 October 2023.

*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-IR162-4;
- (2) feed containing, consisting of or produced from genetically modified maize SYN-IR162-4;
- (3) products containing or consisting of genetically modified maize SYN-IR162-4 for uses other than those provided for in points (1) and (2), with the exception of cultivation.

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

**(c) Labelling:**

- (1) For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003, and in Article 4(6) of Regulation (EC) No 1830/2003, the name of the organism shall be 'maize';
- (2) The words 'not for cultivation' shall appear on the label of and in documents accompanying the products containing or consisting of the genetically modified maize SYN-IR162-4, with the exception of the 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-IR162-4;
- (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®-BF446 is accessible via the Joint Research Centre (JRC) of the European Commission, at <https://crm.jrc.ec.europa.eu/>.

**(e) Unique identifier:**

SYN-IR162-4

**(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 <sup>(1)</sup>.

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

<sup>(1)</sup> 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.*

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