



2024/1828

4.7.2024

COMMISSION IMPLEMENTING DECISION (EU) 2024/1828

of 2 July 2024

renewing the authorisation for the placing on the market of feed containing, consisting of and of food and feed products produced from genetically modified maize MON 810 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council and repealing Commission Implementing Decision (EU) 2017/1207

(notified under document C(2024) 4493)

(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 ⁽¹⁾, and in particular Article 11(3) and 23(3) thereof,

Whereas:

- (1) Commission Implementing Decision 2013/649/EU ⁽²⁾ authorised the placing on the market of pollen produced from genetically maize MON 810, as or in foods and food ingredients.
- (2) Commission Implementing Decision (EU) 2017/1207 ⁽³⁾ renewed the authorisation for placing on the market of existing foods and food ingredients produced from genetically modified maize MON 810, with the exception of pollen, of feed containing, consisting of or produced from genetically modified maize MON 810 and of products containing or consisting of genetically modified maize MON 810 for any other use than food or feed, with the exception of cultivation.
- (3) On 6 October 2022, Bayer Agriculture BV, based in Belgium, submitted on behalf of Bayer CropScience LP, based in the United States, an application to the Commission for the renewal of Implementing Decision 2013/649/EU and of Implementing Decision (EU) 2017/1207. In accordance with Article 11(4) of Regulation (EC) No 1829/2003, the period of authorisation of genetically modified pollen produced from genetically modified maize MON 810 for food uses covered by Implementing Decision 2013/649/EU has been automatically extended until a decision is taken on the renewal application.

⁽¹⁾ OJ L 268, 18.10.2003, p. 1, ELI: <http://data.europa.eu/eli/reg/2003/1829/oj>.

⁽²⁾ Commission Implementing Decision 2013/649/EU of 6 November 2013 authorising the placing on the market of pollen produced from maize MON 810 (MON-ØØ81Ø-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 302, 13.11.2013, p. 44, ELI: http://data.europa.eu/eli/dec_impl/2013/649/oj).

⁽³⁾ Commission Implementing Decision (EU) 2017/1207 of 4 July 2017 renewing the authorisation for the placing on the market of genetically modified maize MON 810 (MON-ØØ81Ø-6) products pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 173, 6.7.2017, p. 18, ELI: http://data.europa.eu/eli/dec_impl/2017/1207/oj).

- (4) On 19 January 2024, the European Food Safety Authority ('the Authority') issued a favourable scientific opinion ⁽⁴⁾. 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 assessments on genetically modified maize MON 810, adopted by the Authority in 2009 ⁽⁵⁾ and in 2012 ⁽⁶⁾.
- (5) 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.
- (6) 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.
- (7) Taking into account those conclusions, the authorisation for the placing on the market of feed containing, consisting of or produced from genetically modified maize MON 810, of foods and food ingredients produced from genetically modified maize MON 810, including pollen produced from genetically modified maize MON 810, as or in foods and food ingredients, and of products containing or consisting of genetically modified maize MON 810 for uses other than food and feed, with the exception of cultivation, should be renewed.
- (8) Unique identifiers have been assigned to genetically modified maize MON 810, in accordance with Commission Regulation (EC) No 65/2004 ⁽⁷⁾, in the context of the initial authorisation by Implementing Decision 2013/649/EU.
- (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 ⁽⁸⁾, appear to be necessary.
- (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 ⁽⁹⁾.

⁽⁴⁾ EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2024. Scientific Opinion on the assessment of genetically modified maize MON 810 for renewal authorisation under Regulation (EC) No 1829/2003 (dossier GMFF-2022-9450). EFSA Journal 2024;22:e8489, 13 pp. <https://doi.org/10.2903/j.efsa.2024.8489>.

⁽⁵⁾ EFSA GMO Panel, 2009. Scientific Opinion on applications (EFSA-GMO-RX-MON810) for renewal of authorisation for the continued marketing of (1) existing food and food ingredients produced from genetically modified insect resistant maize MON810; (2) feed consisting of and/or containing maize MON810, including the use of seed for cultivation; and of (3) food and feed additives, and feed materials produced from maize MON810, all under Regulation (EC) No 1829/2003 from Monsanto; EFSA Journal 2009;1149, 1-85, 85 pp. <https://doi.org/10.2903/j.efsa.2009.1149>.

⁽⁶⁾ EFSA GMO Panel, 2012. Scientific Opinion on an application (EFSA-GMO-NL-2012-107) for the placing on the market of maize MON 810 pollen under Regulation (EC) No 1829/2003 from Monsanto; EFSA Journal 2012;10(12):3022, 9 pp. <https://doi.org/10.2903/j.efsa.2012.3022>.

⁽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, ELI: <http://data.europa.eu/eli/reg/2004/65/oj>).

⁽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, ELI: <http://data.europa.eu/eli/reg/2003/1830/oj>).

⁽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, ELI: <http://data.europa.eu/eli/dec/2009/770/oj>).

- (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 feed containing, consisting of or produced from genetically modified maize MON 810 and of foods and food ingredients produced from genetically modified maize MON 810, 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.
- (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) As the provisions of this Decision overlap with the provisions of Implementing Decision (EU) 2017/1207 and for reasons of legal certainty, Implementing Decision (EU) 2017/1207 should be repealed.
- (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 ⁽¹⁰⁾.
- (15) The Standing Committee on Plants, Animals, Food and Feed has not delivered an opinion within the time limit laid down by its Chairman. This implementing act was deemed to be necessary and the chair submitted it to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

HAS ADOPTED THIS DECISION:

Article 1

Genetically modified organisms and unique identifiers

Genetically modified maize (*Zea mays* L.) MON 810, as specified in point (b) of the Annex to this Decision, is assigned the unique identifiers 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 as regards:

- (a) foods and food ingredients produced from genetically modified maize MON-ØØ81Ø-6;
- (b) feed containing, consisting of or produced from genetically modified maize MON-ØØ81Ø-6;
- (c) products containing or consisting of genetically modified maize MON-ØØ81Ø-6, for uses other than those provided for in points (a) and (b), with the exception of cultivation.

Article 3

Labelling

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'.

⁽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, ELI: <http://data.europa.eu/eli/reg/2003/1946/oj>).

*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-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***Repeal**

Implementing Decision (EU) 2017/1207 is repealed.

*Article 8***Authorisation holder**

The authorisation holder shall be Bayer CropScience LP, represented in the Union by Bayer Agriculture BV.

*Article 9***Validity**

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

*Article 10***Addressee**

This Decision is addressed to Bayer CropScience LP, 800 N. Lindbergh Boulevard St. Louis, Missouri 63167, United States, represented in the Union by Bayer Agriculture BV, Haven 627, Scheldelaan 460, B-2040 Antwerp, Belgium.

Done at Brussels, 2 July 2024.

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

Represented in the Union by: Bayer Agriculture BV, Haven 627, Scheldelaan 460, B-2040 Antwerp, Belgium.

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

- (1) foods and food ingredients produced from genetically modified maize MON-ØØ81Ø-6;
- (2) feed containing, consisting of or produced from genetically modified maize MON-ØØ81Ø-6;
- (3) products containing or consisting of genetically modified maize MON-ØØ81Ø-6 for uses other than those provided for in points (1) and (2), with the exception of cultivation.

Genetically modified maize MON-ØØ81Ø-6 expresses the *Cry1Ab* gene, which confers protection against predation by certain lepidopteran insect pests, including the European corn borer (*Ostrinia nubilalis*) and pink borers (*Sesamia* spp.).

(c) **Labelling:**

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'.

(d) **Method for detection:**

- (1) Event specific real-time quantitative PCR based method for detection of the genetically modified maize MON-ØØ81Ø-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-BF413 and ERM-AD413 accessible via the Joint Research Centre (JRC) of the European Commission at <https://crm.jrc.ec.europa.eu/>.

(e) **Unique identifier:**

MON-ØØ81Ø-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 plan:**
Not required.

Note: *inks 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, ELI: <http://data.europa.eu/eli/dir/2001/18/oj>).