

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***(notified under document C(2017) 4453)***(Only the Dutch and French texts are authentic)****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed ⁽¹⁾, and in particular Articles 11(3) and 23(3) thereof,

Whereas:

- (1) On 11 and 18 April 2007, Monsanto Europe SA submitted to the Commission three applications, in accordance with Articles 11 and 23 of Regulation (EC) No 1829/2003, for the renewal of the authorisation of existing foods, food ingredients and feed produced from maize MON 810, of the authorisation of feed containing and consisting of maize MON 810 and of the authorisation of maize MON 810 in products consisting of it or containing it for other uses than food and feed, as any other maize, including cultivation. After the date of the entry into force of Regulation (EC) No 1829/2003, those products were notified to the Commission pursuant to Article 8(1)(a) and (b) and Article 20(1)(b) of that Regulation and included in the Community Register of genetically modified food and feed.
- (2) On 9 March 2016, Monsanto Europe SA sent a letter to the Commission requesting that the part of the application concerning cultivation be considered separately from the rest of the application. Therefore, this Decision does not cover the use of maize MON 810 seeds for cultivation.
- (3) The placing on the market of pollen produced from maize MON 810 was authorised by Commission Implementing Decision 2013/649/EU ⁽²⁾ and is therefore not covered by this Decision.
- (4) On 30 June 2009, the European Food Safety Authority ('EFSA') issued a favourable opinion (updated on 30 July 2009) in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003. It concluded that genetically modified maize MON 810, as described in the application, is as safe as its conventional counterpart with respect to potential adverse effects on human and animal health and is unlikely to have adverse effects on the environment taking into account its intended uses ⁽³⁾.
- (5) In its opinion, EFSA considered all the specific questions and concerns raised by the Member States in the context of the consultation of the national competent authorities as provided for by Article 6(4) and Article 18(4) of Regulation (EC) No 1829/2003.
- (6) Taking into account those considerations, the authorisation should be renewed for food and food ingredients produced from maize MON 810, with the exception of pollen, for feed containing or consisting of, or produced from maize MON 810 and for maize MON 810 in products consisting of it or containing it for other uses than food or feed, with the exception of cultivation.

⁽¹⁾ OJ L 268, 18.10.2003, p. 1.

⁽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).

⁽³⁾ Scientific Opinion of the Panel on Genetically Modified Organisms on applications (EFSA-GMORX-MON810) for the 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, pp. 1-84.

- (7) A unique identifier has been assigned to genetically modified maize MON 810 in accordance with Commission Regulation (EC) No 65/2004 ⁽¹⁾, in the context of the initial authorisation of maize MON 810. That unique identifier should continue to be used.
- (8) On the basis of the EFSA opinion, no specific labelling requirements, other than those provided for in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003, appear to be necessary for food and food ingredients produced from maize MON 810 and for feed containing, consisting of, or produced from maize MON 810.
- (9) The authorisation holder should submit annual reports on the implementation and the results of the activities set out in this monitoring plan. Those results should be presented in accordance with Commission Decision 2009/770/EC ⁽²⁾.
- (10) The EFSA opinion does not justify the imposition of specific conditions or restrictions for the placing on the market and/or for the use and handling of the food and feed, including post-market monitoring requirements.
- (11) All relevant information on the authorisation of the products should be entered in the Community register of genetically modified food and feed referred to in Regulation (EC) No 1829/2003.
- (12) The Standing Committee on Plants, Animals, Food and Feed has not delivered an opinion within the time limit laid down by its Chairman. An implementing act was deemed to be necessary and the chair submitted the draft implementing act to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

HAS ADOPTED THIS DECISION:

Article 1

Genetically modified organism and unique identifier

Genetically modified maize (*Zea mays* L.) MON 810, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier MON-ØØ81Ø-6, in accordance with Regulation (EC) No 65/2004.

Article 2

Renewal of the authorisation

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

- (a) foods and food ingredients produced from MON-ØØ81Ø-6 maize, with the exception of pollen;
- (b) feed containing, consisting of or produced from MON-ØØ81Ø-6 maize;
- (c) MON-ØØ81Ø-6 maize in products containing it or consisting of it for any other use than food or feed, 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 of the European Parliament and of the Council ⁽³⁾, the 'name of the organism' shall be 'maize'.

⁽¹⁾ 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).

⁽²⁾ 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).

⁽³⁾ 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)

*Article 4***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 to this Decision, 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 5***Community register**

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

*Article 6***Authorisation holder**

The authorisation holder shall be Monsanto Europe SA, Belgium, representing Monsanto Company, United States of America.

*Article 7***Validity**

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

*Article 8***Addressee**

This Decision is addressed to Monsanto Europe SA, Avenue de Tervuren 270-272, B-1150 Brussels, Belgium.

Done at Brussels, 4 July 2017.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

ANNEX

(a) Applicant and authorisation holder:

Name: Monsanto Europe SA

Address: Avenue de Tervuren 270-272, B-1150 Brussels — Belgium

On behalf of Monsanto Company — 800 N. Lindbergh Boulevard — St. Louis, Missouri 63167 — United States of America.

(b) Designation and specification of the products:

- (1) foods and food ingredients produced from MON-ØØ81Ø-6 maize, with the exception of pollen;
- (2) feed containing, consisting of, or produced from MON-ØØ81Ø-6 maize;
- (3) MON-ØØ81Ø-6 maize in products containing it or consisting of it for any other use than food or feed, with the exception of cultivation.

The genetically modified MON-ØØ81Ø-6 maize as described in the applications expresses the Cry1Ab protein, derived from *Bacillus thuringiensis* subsp. *kurstaki*, 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 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';

(d) Method for detection:

- (1) Event-specific real-time PCR-based method for the quantification of MON-ØØ81Ø-6 maize;
- (2) Validated by the Federal Institute for Risk assessment (BfR) in collaboration with the Joint Research Centre of the European Commission and other parties, and verified by the EU Reference Laboratory established under Regulation (EC) No 1829/2003 on genomic DNA extracted from maize seeds, published at <http://gmo-crl.jrc.ec.europa.eu/statusofdossiers.aspx>
- (3) Reference Material: ERM-BF413 and ERM-AD413 accessible via the Institute for Reference Materials and Measurements (IRMM) of 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 conforming with Annex VII to Directive 2001/18/EC.

(Link: *plan published in the Community register of genetically modified food and feed*)

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

Not required.

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