II

(Non-legislative acts)

DECISIONS

COMMISSION IMPLEMENTING DECISION (EU) 2015/683

of 24 April 2015

authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON 87460 (MON 8746Ø-4) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

(notified under document C(2015) 2749)

(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 Article 7(3) and Article 19(3) thereof,

Whereas:

(1) On 29 May 2009, Monsanto Europe SA submitted to the competent authority of The Netherlands an application, in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003, for the placing on the market of foods, food ingredients, and feed containing, consisting of, or produced from MON 87460 maize ('the application').

(2) The application also covers the placing on the market of MON 87460 maize in products consisting of it or containing it for any other uses than food and feed as any other maize, with the exception of cultivation.

(3) In accordance with Article 5(5) and Article 17(5) of Regulation (EC) No 1829/2003, the application includes the data and information required by Annexes III and IV to Directive 2001/18/EC of the European Parliament and of the Council ([2]) and information and conclusions about the risk assessment carried out in accordance with the principles set out in Annex II to Directive 2001/18/EC. It also includes a monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.

(4) On 15 November 2012, the European Food Safety Authority ('EFSA') gave a favourable opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003. It concluded that MON 87460 maize, as described in the application, is as safe as its conventional counterpart and non-GM reference varieties with respect to potential effects on human and animal health and the environment, in the context of its intended use. EFSA performed a specific risk assessment linked to the presence of the antibiotic resistance marker *nptII gene* in MON 87460. The detailed analysis of risks associated with a theoretically possible horizontal gene transfer did not raise safety concerns to human or animal health or to the environment in the context of MON 87460 intended uses. In its

([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).

opinion, EFSA also 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 that Regulation.

(5) In its opinion, EFSA also concluded that the environmental monitoring plan, consisting of a general surveillance plan, submitted by the applicant is in line with the intended uses of the products.

(6) Taking into account those considerations, authorisation should be granted for the products containing, consisting, or produced from MON 87460 maize, as described in the application, called ('the products').

(7) A unique identifier should be assigned to each genetically modified organism (hereinafter 'GMO') as provided for in Commission Regulation (EC) No 65/2004 ([1]).

(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 foods, food ingredients and feed containing, consisting of, or produced from MON 87460 maize. However, in order to ensure the use of the products within the limits of the authorisation provided for by this Decision, the labelling of products containing or consisting of the GMO with the exception of food products for which authorisation is requested should be complemented by a clear indication that the products in question must not be used for cultivation.

(9) Regulation (EC) No 1830/2003 of the European Parliament and of the Council ([2]), lays down labelling requirements in Article 4(6) for products containing or consisting of GMOs. Traceability requirements for products containing or consisting of GMOs are laid down in paragraphs 1 to 5 of Article 4 and those for food and feed produced from GMOs are laid down in Article 5 of that Regulation.

(10) The authorisation holder should submit annual reports on the implementation and the results of the activities set out in the monitoring plan for environmental effects. Those results should be presented in accordance with Commission Decision 2009/770/EC ([3]). The EFSA opinion does not justify the imposition of specific conditions or restrictions for the placing on the market and/or specific conditions or restrictions for the use and handling, including post-market monitoring requirements for the use of the food and feed, or of specific conditions for the protection of particular ecosystems/environment and/or geographical areas, as provided for in point (e) of Article 6(5) and Article 18(5) of Regulation (EC) No 1829/2003.

(11) All relevant information on the authorisation of the products should be entered in the EU register of genetically modified food and feed, as provided for in 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 ([4]).

(13) The applicant has been consulted on the measures provided for in this Decision.

(14) The Standing Committee on the Food Chain and Animal Health 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,

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([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]) 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).

([3]) 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).

([4]) 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 87460, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier MON 8746Ø-4, as provided for in 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 MON 8746Ø-4 maize;

(b) feed containing, consisting of, or produced from MON 8746Ø-4 maize;

(c) MON 8746Ø-4 maize in products containing it or consisting of it for any other use than (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 documents accompanying products containing or consisting of MON 8746Ø-4 maize with the exception of products referred to in point (a) of Article 2.

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, 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 5

EU register

The information set out in the Annex to this Decision shall be entered in the EU register of genetically modified food and feed, as provided for 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, 1150 Brussels, Belgium.

Done at Brussels, 24 April 2015

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, 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 containing, consisting of, or produced from MON 8746Ø-4 maize;
2. feed containing, consisting of, or produced from MON 8746Ø-4 maize;
3. MON 8746Ø-4 maize in products containing it or consisting of it for any other use than 1 and 2, with the exception of cultivation.

The genetically modified MON 8746Ø-4 maize, as described in the application, expresses the cold shock protein B (CspB) which aims to reduce yield loss caused by drought stress. An *nptII* gene, conferring kanamycine and neomycine resistance, was used as a selective marker in the genetic modification process.

(c) **Labelling**

1. For the purposes of the specific 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 products containing or consisting of MON 8746Ø-4 maize with the exception of products referred to in point (a) of Article 2.

(d) **Method for detection**

— Event-specific real-time PCR based method for the quantification of MON 8746Ø-4 maize.

— Validated on genomic DNA, extracted from seeds, by the EU Reference Laboratory established under Regulation (EC) No 1829/2003, published at http://gmo-crl.jrc.ec.europa.eu/statusofdossiers.aspx

— Reference Material: AOCS 0709-A and AOCS 0406-A are accessible via the American Oil Chemists Society at http://www.aocs.org/tech/crm

(e) **Unique identifier**

MON 8746Ø-4

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

Biosafety Clearing-House (to be entered in the EU 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**

Monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC [to be entered in the EU register of genetically modified food and feed when notified).

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

Not required.