COMMISSION IMPLEMENTING DECISION (EU) 2015/686

of 24 April 2015

authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean MON 87769 (MON-87769-7) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

(notified under document C(2015) 2757)

(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 14 September 2009, Monsanto Europe SA submitted to the competent authority of the United Kingdom 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 87769 soybean ('the application').

(2) The application also covers the placing on the market of MON 87769 soybean in products consisting of it or containing it for any other uses than food and feed as any other soybean, 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 16 May 2014, the European Food Safety Authority ('EFSA') gave a favourable opinion ([3]) in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003. It concluded that MON 87769 soybean, as described in the application, is as safe as its conventional counterpart and is unlikely to have adverse effects on human and animal health and the environment in the context of the scope of the application.

(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) 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.

(7) In addition, EFSA recommended a post-market monitoring plan to be implemented, focusing on the collection of consumption data for the European population.

(8) Taking into account those considerations, authorisation should be granted to the products.

(9) A unique identifier should be assigned to each genetically modified organism ('GMO') as provided for in Commission Regulation (EC) No 65/2004 ([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]) EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2014. Scientific Opinion on application EFSA-GMO-UK-2009-76 for the placing on the market of soybean MON87769 genetically modified to contain stearidonic acid, for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Monsanto. *EFSA Journal* 2014; 12(5):3644, 41 pp. doi:10.2903/j.efsa.2014.3644.
([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).

(10) Food, food ingredients and feed containing, consisting of, or produced from soybean MON 87769 should be labelled in accordance with the requirements provided for in Article 13(1) and Article 25(2)(a) and (b) of Regulation (EC) No 1829/2003.

(11) On the basis of the EFSA opinion, confirming that fatty acid composition of the seeds of MON 87769 soybean and derived oil has been changed in relation to the conventional counterpart, specific labelling appears to be necessary in accordance with Articles 13(2)(a) and 25(2)(c). This specific labelling should ensure informed choice without misleading the consumers.

(12) In order to ensure the use of the products containing or consisting of MON 87769 soybean within the limits of the authorisation provided for by this Decision, the labelling of these products, with the exception of food products, should be complemented by a clear indication that the products in question must not be used for cultivation.

(13) Regulation (EC) No 1830/2003 of the European Parliament and of the Council [1] 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.

(14) 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 [2]. The EFSA opinion does not justify the imposition of specific conditions for the protection of particular ecosystems/environment and/or geographical areas, as provided for in Article 6(5)(e) and Article 18(5)(e) of Regulation (EC) No 1829/2003.

(15) The authorisation holder should also submit annual reports on the implementation and the results of the activities set out in the post-market monitoring plan.

(16) All relevant information on the authorisation of the products should be entered in the Community register of genetically modified food and feed, as provided for in 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 [3].

(18) 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 soybean (*Glycine max* (L.) Merr.) MON 87769, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier MON-87769-7, as provided for in Regulation (EC) No 65/2004.

[1] 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).

[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 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 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-87769-7 soybean;

(b) feed containing, consisting of, or produced from MON-87769-7 soybean;

(c) MON-87769-7 soybean 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 'soybean'.

2. For the purposes of the labelling requirements laid down in Article 13(2)(a) and Article 25(2)(c) of Regulation (EC) No 1829/2003, the words 'with stearidonic acid' shall appear after the name of the organism on the label or, where appropriate, in the documents accompanying the products.

3. The words 'not for cultivation' shall appear on the label of and in the documents accompanying products containing or consisting of MON-87769-7 soybean 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

Post-market monitoring in accordance with Article 6(5)(e) of Regulation (EC) No 1829/2003

1. The authorisation holder shall ensure that the post-market monitoring plan of the MON-87769-7 soybean oil, as set out in point (g) 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 post-market monitoring plan for the duration of the authorisation.

Article 6

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

Article 7

Authorisation holder

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

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 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.

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

1. foods and food ingredients containing, consisting of, or produced from MON-87769-7 soybean;

2. feed containing, consisting of, or produced from MON-87769-7 soybean;

3. MON-87769-7 soybean 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-87769-7 soybean, as described in the application, expresses Δ15 desaturase which results in conversion of linoleic acid to α-linolenic acid and Δ6 desaturase which results in conversion of α-linolenic acid to stearidonic acid (SDA). SDA is a normal intermediate in the formation of the long-chain omega-3 polyunsaturated fatty acids.

(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. For the purposes of the labelling requirements laid down in Article 13(2)(a) and Article 25(2)(c) of Regulation (EC) No 1829/2003, the words 'with stearidonic acid' shall appear after the name of the organism on the label or, where appropriate, in the documents accompanying the products.

3. The words 'not for cultivation' shall appear on the label of and in the documents accompanying products containing or consisting of MON-87769-7 soybean with the exception of products referred to in point (a) of Article 2.

(d) **Method for detection:**

1. Event-specific real-time PCR based method for the quantification of MON-87769-7 soybean.

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

3. Reference Material: AOCS 0809-B and AOCS 0906-A are accessible via the American Oil Chemists Society at http://www.aocs.org/tech/crm

(e) **Unique identifier:**

MON-87769-7

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

Biosafety Clearing-House, Record ID: see (*to be completed when notified*).

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

Post-market monitoring in accordance with Article 6(5)(e) of Regulation (EC) No 1829/2003

1. The authorisation holder shall collect the following information:

   (i) quantities of MON-87769-7 soybean oil and MON-87769-7 soybeans for oil extraction, imported into the European Union for the placing on the market as or in products for food;

   (ii) in case of import of products referred to in point (i), results of searches in the FAOSTAT database on the quantities of vegetable oil consumption by Member State, including shifts in quantities between the different types of oils consumed;

   (iii) in case of import of products referred to in point (i), data on the different categories of food and feed uses of MON-87769-7 oil in the EU.

2. The authorisation holder shall, based on the information collected and reported, review the nutritional assessment conducted as part of the risk assessment.

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

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

(Link: *plan published on the internet*)

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.