COMMISSION IMPLEMENTING DECISION (EU) 2022/798

of 19 May 2022

authorising the placing on the market of products containing, consisting of or produced from genetically modified soybean MON 87769 × MON 89788 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

(notified under document C(2022) 3182)

(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 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 27 July 2010, Monsanto Europe S.A./N.V., based in Belgium, submitted on behalf of Monsanto Company, based in the United States, an application to the national competent authority of the Netherlands ('the application') for the placing on the market of foods, food ingredients and feed containing, consisting of or produced from genetically modified soybean MON 87769 × MON 89788, in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003. The application also covered the placing on the market of products containing or consisting of genetically modified soybean MON 87769 × MON 89788 for uses other than food and feed, with the exception of cultivation.

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

(3) On 8 October 2015, the European Food Safety Authority ('the Authority') issued an opinion, in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003 ([3]). The Authority was not able to reach a conclusion on the safety of genetically modified soybean MON 87769 × MON 89788 because of the lack of data on dietary exposure to refined bleached deodorised oil produced from genetically modified soybean MON 87769 × MON 89788, leading to an incomplete nutritional assessment. The Authority concluded that genetically modified soybean MON 87769 × MON 89788 is unlikely to have adverse effects on the environment in the context of the application.

(4) In its opinion of 8 October 2015, 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.

(5) The Authority also concluded that the monitoring plan for environmental effects submitted by the applicant, consisting of a general surveillance plan, is in line with the intended uses of the products.

([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), 2015. Scientific Opinion on an application (EFSA-GMO-NL-2010-85) for the placing on the market of MON 87769 × MON 89788 soybean, genetically modified to contain stearidonic acid and be tolerant to glyphosate for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Monsanto. EFSA Journal 2015;13(10):4256; https://doi.org/10.2903/j.efsa.2015.4256.

(6) By a letter dated 27 August 2018, Monsanto Europe S.A./N.V. informed the Commission that, as of 23 August 2018, it converted its legal form and changed its name to Bayer Agriculture BVBA.

(7) On 8 May 2019, the applicant provided a revised dietary exposure assessment of the genetically modified soybean MON 87769 × MON 89788.

(8) By a letter dated 28 July 2020, Bayer Agriculture BVBA informed the Commission that, as of 1 August 2020, it changed its name to Bayer Agriculture BV.

(9) By a letter dated 28 July 2020, Bayer Agriculture BVBA, representing Monsanto Company, informed the Commission that, as of 1 August 2020, Monsanto Company converted its legal form and changed its name to Bayer CropScience LP.

(10) On 12 May 2021, the Authority published a statement complementing its scientific opinion ([4]), taking into account the revised dietary exposure assessment provided by the applicant for the human nutritional assessment of refined bleached deodorised oil produced from genetically modified soybean MON 87769 × MON 89788. The Authority concluded that the consumption of genetically modified soybean MON 87769 × MON 89788 and its derived products, in particular its refined bleached deodorised oil, does not represent a nutritional concern in humans.

(11) In addition, the Authority recommended a post-market monitoring plan to be implemented, focusing on the collection of import data to Europe of genetically modified soybean MON 87769 × MON 89788 and/or its products, in particular its refined bleached deodorised oil.

(12) Taking into account these conclusions, the placing on the market of products containing, consisting of or produced from genetically modified soybean MON 87769 × MON 89788 should be authorised for the uses listed in the application.

(13) A unique identifier should be assigned to genetically modified soybean MON 87769 × MON 89788, in accordance with Commission Regulation (EC) No 65/2004 ([5]).

(14) Products containing, consisting of or produced from soybean MON 87769 × MON 89788 should be labelled in accordance with the requirements 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 ([6]).

(15) The Authority's statement complementing its scientific opinion confirmed that the nutritional composition of genetically modified soybean MON 87769 × MON 89788 is different from its conventional counterpart due to a different fatty acid profile. Specific labelling is therefore necessary in accordance with Article 13(2)(a) and Article 25(2)(c) of Regulation (EC) No 1829/2003.

(16) In order to ensure that the use of the products containing or consisting of genetically modified soybean MON 87769 × MON 89788 remain within the limits of the authorisation granted by this Decision, the labelling of those products, with the exception of foods and food ingredients, should contain a clear indication that they are not intended for cultivation.

([4]) EFSA GMO Panel, 2021. Scientific Opinion on the statement complementing the EFSA Scientific Opinion on application (EFSA-GMO-NL-2010-85) for authorisation of food and feed containing, consisting of or produced from genetically modified soybean MON 87769 × MON 89788. EFSA Journal 2021;19(5):6589; https://doi.org/10.2903/j.efsa.2021.6589.

([5]) 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).

([6]) 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).

(17) 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 ([7]).

(18) 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.

(19) 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.

(20) 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 ([8]).

(21) The Standing Committee on Plants, Animals, Food and Feed has not delivered an opinion within the time laid down by its Chair. 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 soybean (*Glycine max* (L.) Merr.) MON 87769 × MON 89788, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier MON-87769-7 × MON-89788-1, in accordance with 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 genetically modified soybean MON-87769-7 × MON-89788-1;

(b) feed containing, consisting of or produced from genetically modified soybean MON-87769-7 × MON-89788-1;

(c) products containing or consisting of genetically modified soybean MON-87769-7 × MON-89788-1 for uses other than those provided for in points (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'.

([7]) 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).

([8]) 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).

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 genetically modified soybean MON-87769-7 × MON-89788-1, 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 soybean MON-87769-7 × MON-89788-1.

Article 5

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 the format set out in Decision 2009/770/EC.

Article 6

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 genetically modified soybean MON-87769-7 × MON-89788-1 and its products, in particular its refined bleached deodorised oil, as set out in point (i) 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 7

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 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, Scheldelaan 460, BE-2040 Antwerp, Belgium.

Done at Brussels, 19 May 2022.

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, Scheldelaan 460, 2040 Antwerp, Belgium.

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

(1) foods and food ingredients containing, consisting of or produced from genetically modified soybean MON-87769-7 × MON-89788-1;

(2) feed containing, consisting of or produced from genetically modified soybean MON-87769-7 × MON-89788-1;

(3) products containing or consisting of genetically modified soybean MON-87769-7 × MON-89788-1 for uses other than those provided for in points (1) and (2), with the exception of cultivation.

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

The genetically modified soybean MON-89788-1 expresses the *cp4 epsps* gene, which confers tolerance to glyphosate-containing herbicides.

(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 documents accompanying the products containing or consisting of the soybean specified in point (e), with the exception of products referred to in point (b)(1).

(d) **Method for detection:**

(1) The quantitative event-specific PCR detection methods are those individually validated for genetically modified soybean MON-87769-7 and MON-89788-1 and further verified on soybean stack MON-87769-7 × MON-89788-1;

(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: AOCS 0809 (for MON-87769-7), and AOCS 0906 (for MON-89788-1) are accessible via the American Oil Chemists Society at https://www.aocs.org/crm.

(e) **Unique identifier:**

MON-87769-7 × MON-89788-1.

(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.

[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:**

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 genetically modified soybean MON-87769-7 × MON-89788-1 for oil extraction, imported into the Union for their placing on the market;

(ii) quantities of genetically modified soybean MON-87769-7 × MON-89788-1 oil, imported into the European Union for the placing on the market, in particular, quantities of refined bleached deodorised oil, and;

(iii) quantities of products for food containing this refined bleached deodorised oil, imported into the European Union for the placing on the market;

(iv) in case of import, consumption data for humans of products listed in points (i) to (iii).

(2) The authorisation holder shall, based on the information collected and reported:

(i) review the predicted consumption data of genetically modified soybean MON-87769-7 × MON-89788-1;

(ii) verify that the conditions of use of genetically modified soybean MON-87769-7 × MON-89788-1 are those considered during the pre-market risk assessment.

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.