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COMMISSION

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COMMISSION IMPLEMENTING DECISION

of XXX

authorising the placing on the market of products containing, consisting of or produced from genetically modified soybean MON 87705 × MON 87708 × MON 89788 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

(Text with EEA relevance)

(Only the Dutch text is authentic)

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(Text with EEA relevance)

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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 11 September 2015, Monsanto Europe S.A./N.V. on behalf of Monsanto Company, based in the United States, submitted to the national competent authority of the Netherlands an application for the placing on the market of foods, food ingredients and feed containing, consisting of or produced from genetically modified soybean MON 87705 × MON 87708 × MON 89788, in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003 ('the application'). The application also covered the placing on the market of products containing or consisting of genetically modified soybean MON 87705 × MON 87708 × 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) 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.

(4) 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.

[1] OJ L 268, 18.10.2003, p. 1, ELI: http://data.europa.eu/eli/reg/2003/1829/oj.

[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, ELI: http://data.europa.eu/eli/dir/2001/18/oj).

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

(6) On 18 May 2020, the European Food Safety Authority ('the Authority') issued a scientific opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003[3] on genetically modified soybean MON 87705 × MON 87708 × MON 89788. The Authority had considered all the questions and concerns raised by the Member States in the context of the consultation with the national competent authorities, as provided for in Article 6(4) and Article 18(4) of Regulation (EC) No 1829/2003.

(7) 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.

(8) However, the Authority was not able to finalise the risk assessment and to conclude on the safety of genetically modified soybean MON 87705 × MON 87708 × MON 89788 because of the absence of a 90-day study on genetically modified soybean MON 87705 and of the absence a post-market monitoring plan taking into consideration the altered fatty acid profile of this soybean stack.

(9) On 20 March 2024, Bayer Agriculture BV provided a 90-day study on genetically modified soybean MON 87705 and the post-market monitoring plan, which considered the altered fatty acid profile of genetically modified soybean MON 87705 × MON 87708 × MON 89788.

(10) On 28 October 2024, the Authority issued a statement complementing its scientific opinion of 18 May 2020, based on the additional data provided by the applicant[4]. The Authority concluded that genetically modified soybean MON 87705 × MON 87708 × MON 89788, as described in the application, is as safe as its conventional counterpart and the tested non-genetically modified soybean reference varieties with respect to the potential effects on human and animal health and the environment. The Authority also concluded that the consumption of genetically modified soybean MON 87705 × MON 87708 × MON 89788 does not represent any nutritional concern.

(11) In addition, the Authority recommended implementing a post-market monitoring plan, focusing on the collection of data of imports entering into the Union of genetically modified soybean MON 87705 × MON 87708 × MON 89788 and products derived from it for food, and on the collection of consumption data for humans, to verify that the conditions of use of genetically modified soybean MON 87705 × MON 87708 × MON 89788 are those considered during the pre-marketing risk assessment.

(12) Taking into account the conclusions contained in the statement of the Authority of 28 October 2024, the placing on the market of products containing, consisting of or

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[3] EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2020. Scientific Opinion on the assessment of genetically modified soybean MON 87705 × MON 87708 × MON 89788 for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2015-126). EFSA Journal 2020;18(5):6111, https://doi.org/10.2903/j.efsa.2020.6111.

[4] EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2024. Statement complementing the EFSA Scientific Opinion on application (EFSA-GMO-NL-2015-126) for authorisation of food and feed containing, consisting of and produced from genetically modified soybean MON 87705 × MON 87708 × MON 89788. EFSA Journal 2024;22:e9061, https://doi.org/10.2903/j.efsa.2024.9061.

produced from genetically modified soybean MON 87705 × MON 87708 × MON 89788 should be authorised for the uses listed in the application.

(13) A unique identifier should be assigned to genetically modified soybean MON 87705 × MON 87708 × MON 89788 in accordance with Commission Regulation (EC) No 65/2004[5].

(14) Food, food ingredients and feed containing, consisting of, or produced genetically modified soybean MON 87705 × MON 87708 × 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.

(15) On the basis of the EFSA opinion, confirming that fatty acid composition of the seeds of genetically modified soybean MON 87705 × MON 87708 × MON 89788 and derived oil has been changed in relation to the conventional counterpart, a specific labelling appears to be necessary in accordance with Articles 13(2)(a) and 25(2)(c) of Regulation (EC) No 1829/2003.

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

(17) 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 for which authorisation is requested, with the exception of food products should be complemented by a clear indication that the products in question must not be used for cultivation.

(18) 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[6].

(19) 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.

(20) The opinion of the Authority does not justify the imposition of other specific conditions or restrictions for the placing on the market, for the use and handling of genetically modified soybean MON 87705 × MON 87708 × MON 89788 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.

(21) 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.

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

6 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).

(22) 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[7].

(23) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS DECISION:

Article 1

Genetically modified organism and unique identifier

Genetically modified soybean (*Glycine max* (L.) Merr.) MON 87705 × MON 87708 × MON 89788, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier MON-877Ø5-6 × MON-877Ø8-9 × 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-877Ø5-6 × MON-877Ø8-9 × MON-89788-1;

(b) feed containing, consisting of or produced from genetically modified soybean MON-877Ø5-6 × MON-877Ø8-9 × MON-89788-1;

(c) products containing or consisting of genetically modified soybean MON-877Ø5-6 × MON-877Ø8-9 × 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’.

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 increased monounsaturated fat and reduced polyunsaturated fat’ 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 the products containing or consisting of genetically modified soybean

[7] 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).

MON-877Ø5-6 × MON-877Ø8-9 × MON-89788-1 as referred to in Article 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-877Ø5-6 × MON-877Ø8-9 × MON-89788-1.

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

Post-market monitoring

1. The authorisation holder shall ensure that the post-market monitoring plan for genetically modified soybean MON-877Ø5-6 × MON-877Ø8-9 × MON-89788-1, 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.

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, Haven 627, Scheldelaan 460, B-2040 Antwerp, Belgium.

Done at Brussels,

For the Commission,
Olivér Várhelyi
Member of the Commission