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COMMISSION IMPLEMENTING DECISION

of **XXX**

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

(Only the Dutch and French texts are authentic)

(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 Council¹, and in particular Article 11(3) and Article 23(3) thereof,

Whereas:

- (1) Commission Implementing Decision 2015/686² authorised the placing on the market of food and feed containing, consisting of or produced from genetically modified soybean MON 87769. The scope of that authorisation also covered the placing on the market of products other than food and feed containing or consisting of genetically modified soybean MON 87769, for the same uses as any other soybean, with the exception of cultivation.
- (2) On 8 March 2024, Bayer Agriculture B.V., based in Belgium, submitted on behalf of Bayer CropScience LP, based in the United States ('the applicant'), an application to the Commission for renewal of that authorisation.
- (3) On 19 January 2026, the European Food Safety Authority ('the Authority') issued a favourable scientific opinion³. It concluded that the renewal application did not contain evidence for any new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on genetically modified soybean MON 87769, issued by the Authority in 2014⁴.

¹ Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268, 18.10.2003, p. 1, ELI: <http://data.europa.eu/eli/reg/2003/1829/oj>).

² 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 (OJ L 112, 30.4.2015, p. 16, ELI: http://data.europa.eu/eli/dec_impl/2015/686/oj).

³ EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2026. Scientific Opinion on the assessment on genetically modified soybean MON 87769 for renewal authorisation under Regulation (EC) No 1829/2003 (dossier GMFF-2023-21253). EFSA Journal 2026; 24(1):9845; <https://doi.org/10.2903/j.efsa.2026.9845>.

⁴ 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 MON 87769 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; <https://doi.org/10.2903/j.efsa.2014.3644>.

- (4) In its scientific opinion, the Authority 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.
- (5) The Authority also concluded that the monitoring plan for the environmental effects, consisting of a general surveillance plan, submitted by the applicant, is in line with the intended uses of the products containing or consisting of genetically modified soybean MON 87769.
- (6) In addition to that, the Authority recommended in its scientific opinion a post-market monitoring plan for food and considered that such a plan for feed is not needed, in line with the scientific opinion issued by the Authority in 2014⁴ and Commission Implementing Decision (EU) 2015/686.
- (7) Taking into account the Authority's conclusions, the authorisation for the placing on the market of food and feed containing, consisting of or produced from genetically modified soybean MON 87769 and of products containing it or consisting of it for uses other than food and feed, with the exception of cultivation, should be renewed.
- (8) By the letter of 19 January 2026, Bayer Agriculture B.V., based in Belgium, informed the Commission that Bayer CropScience LP converted its legal form and changed its name to Bayer CropScience LLC as of 1 January 2026.
- (9) A unique identifier has been assigned to genetically modified soybean MON 87769, in accordance with Commission Regulation (EC) No 65/2004⁵, in the context of its initial authorisation by Implementing Decision (EU) 2015/686. That unique identifier should continue to be used.
- (10) Food, food ingredients and feed containing, consisting of, or produced from genetically modified soybean MON 87769 should be labelled in accordance with the requirements provided for in Article 13(1) and Article 25(2), points (a) and (b), of Regulation (EC) No 1829/2003.
- (11) Taking into account the opinion of the Authority confirming that the fatty acid composition of the seeds of soybean MON 87769 and derived oil has been changed in relation to the conventional counterpart, and in the absence of new information provided by the applicant to change the initial assessment, a specific labelling, containing the same words as in Commission Implementing Decision (EU) 2015/686, should continue to be required in accordance with Articles 13(2)(a) and 25(2)(c) of Regulation (EC) No 1829/2003.
- (12) 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.
- (13) The labelling requirements for products containing or consisting of GMOs for pre-packaged products and for non-pre-packaged products should be followed, in

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>).

accordance with Article 4(6), points (a) and (b), of Regulation (EC) No 1830/2003 of the European Parliament and of the Council⁶.

- (14) 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/EC⁷.
- (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) 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 87769, or for the protection of particular ecosystems, the environment or geographical areas, as provided for in Article 6(5), point (e), and Article 18(5), point (e) of Regulation (EC) No 1829/2003.
- (17) 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.
- (18) 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 Council⁸.
- (19) 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 87769, as specified in point (b) in the Annex to this Decision, is assigned the unique identifier MON-87769-7, in accordance with Regulation (EC) 65/2004.

Article 2

Renewal of the authorisation

The authorisation for placing on the market of the following products is renewed as regards:

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

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, ELI: <http://data.europa.eu/eli/reg/2003/1830/oj>).

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, ELI: <http://data.europa.eu/eli/dec/2009/770/oj>).

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, ELI: <http://data.europa.eu/eli/reg/2003/1946/oj>).

- (b) feed containing, consisting of or produced from genetically modified soybean MON-87769-7;
- (c) products containing or consisting of genetically modified soybean MON-87769-7, 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), points (a) and (b), 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 the products containing or consisting of the genetically modified soybean 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-87769-7.

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 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 soybean MON-87769-7 for food, 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 in paragraph 1 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 LLC, United States, represented in the Union by Bayer Agriculture B.V., Belgium.

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 LLC, 800 N. Lindbergh Boulevard, St. Louis, Missouri 63167, United States, represented in the Union by Bayer Agriculture B.V., Scheldelaan 460, 2040, Antwerp, Belgium.

Done at Brussels,

For the Commission
Olivér Várhelyi
Member of the Commission