EUROPEAN
COMMISSION

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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 87701 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

(Text with EEA relevance)

(Only the text in Dutch 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[1], and in particular Article 11(3) and Article 23(3) thereof,

Whereas:

(1) Commission Implementing Decision 2012/83/EU authorised the placing on the market of food and feed containing, consisting of or produced from genetically modified soybean MON 87701. 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 87701, for the same uses as any other soybean, with the exception of cultivation.

(2) On 18 December 2020, Bayer Agriculture BV, based in Belgium, submitted on behalf of Bayer CropScience LP, based in the United States, an application to the Commission, in accordance with Articles 11 and 23 of Regulation (EC) No 1829/2003, for renewal of that authorisation.

(3) On 15 November 2022, the European Food Safety Authority ('the Authority') issued a favourable scientific opinion[2]. 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 87701, adopted by the Authority in 2011[3].

(4) In its scientific opinion, 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.

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1 OJ L 268, 18.10.2003, p. 1.

2 EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2022. Scientific Opinion on the assessment on genetically modified soybean MON 87701 for renewal authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-021). EFSA Journal 2022;20(12):7683, 12 pp.; https://doi.org/10.2903/j.efsa.2022.7683.

3 EFSA GMO Panel, 2011. Scientific Opinion on application (EFSA-GMO-BE-2010-79) for the placing on the market of insect resistant genetically modified soybean MON 87701 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Monsanto. EFSA Journal 2011; 9(7):2309, 31 pp.; https://doi.org/10.2903/j.efsa.2011.2309.

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

(6) Taking into account those conclusions, the authorisation for the placing on the market of food and feed containing, consisting of or produced from genetically modified soybean MON 87701 and of products containing it or consisting of it for uses other than food and feed, with the exception of cultivation, should be renewed.

(7) A unique identifier has been assigned to genetically modified soybean MON 87701, in accordance with Commission Regulation (EC) No 65/2004[4], in the context of its initial authorisation by Implementing Decision 2012/83/EU. That unique identifier should continue to be used.

(8) For the products covered by this Decision, no specific labelling requirements, other than those 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[5], appear to be necessary. However, in order to ensure that the use of products containing or consisting of genetically modified soybean MON 87701 remains within the limits of the authorisation granted by this Decision, the labelling of such products, with the exception of food and food ingredients, should contain a clear indication that they are not intended for cultivation.

(9) 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].

(10) The opinion of the Authority does not justify the imposition of specific conditions or restrictions for the placing on the market for use and handling, including post-market monitoring requirements regarding the consumption of food and feed containing, consisting of or produced from genetically modified soybean MON 87701, 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.

(11) 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.

(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,

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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).

5 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).

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).

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].

(13) 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)* MON 87701, as specified in the Annex, is assigned the unique identifier MON-877Ø1-2, 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-877Ø1-2;

(b) feed containing, consisting of or produced from genetically modified soybean MON-877Ø1-2;

(c) products containing or consisting of genetically modified soybean MON-877Ø1-2, 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. 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 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-877Ø1-2.

[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).

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

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 7

Authorisation holder

The authorisation holder shall be Bayer CropScience LP, United States, represented in the Union by Bayer Agriculture BV.

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 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
Stella KYRIAKIDES
Member of the Commission