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COMMISSION IMPLEMENTING DECISION (EU) 2016/1217

of 22 July 2016

authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean MON 87705 × MON 89788 (MON-877Ø5-6 × MON-89788-1) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

(notified under document C(2016) 4582)

(Only the Dutch and French texts are authentic)

(Text with EEA relevance)

(OJ L 199, 26.7.2016, p. 28)

Amended by:

		Official Journal		
		No	page	date
►**M1**	Commission Implementing Decision (EU) 2019/1579 of 18 September 2019	L 244	8	24.9.2019
►**M2**	Commission Implementing Decision (EU) 2021/184 of 12 February 2021	L 55	4	16.2.2021

▼B

COMMISSION IMPLEMENTING DECISION (EU) 2016/1217

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(notified under document C(2016) 4582)

(Only the Dutch and French texts are authentic)

(Text with EEA relevance)

Article 1

Genetically modified organism and unique identifier

Genetically modified soybean (*Glycine max* (L.) Merr.) MON 87705 × MON 89788, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier MON-877Ø5-6 × MON-89788-1, as provided for in Regulation (EC) No 65/2004.

Article 2

Authorisation

The following products are authorised for the purposes of Articles 4(2) and 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-877Ø5-6 × MON-89788-1 soybean;

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

(c) MON-877Ø5-6 × MON-89788-1 soybean in products containing it or consisting of it for any other use than those provided 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.

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3. The words ‘not for cultivation’ shall appear on the label of and in the documents accompanying products containing or consisting of MON-877Ø5-6 × MON-89788-1 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-877Ø5-6 × MON-89788-1 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.

▼M2

Article 7

Authorisation holder

The authorisation holder shall be Bayer Agriculture BV, Belgium, representing Bayer CropScience LP, United States.

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Article 8

Validity

This Decision shall apply for a period of 10 years from the date of its notification.

▼**M2**

Article 9

Addressee

This Decision is addressed to Bayer Agriculture BV, Scheldelaan 460, 2040 Antwerp, Belgium.

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ANNEX

▼M2

(a) **Applicant and Authorisation holder:**

Name: Bayer Agriculture BV

Address: Scheldelaan 460, 2040 Antwerp, Belgium

On behalf of Bayer CropScience LP, 800 N. Lindbergh Boulevard, St. Louis, Missouri 63167, United States.

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

(1) foods and food ingredients containing, consisting of, or produced from MON-877Ø5-6 × MON-89788-1 soybean;

(2) feed containing, consisting of, or produced from MON-877Ø5-6 × MON-89788-1 soybean;

(3) MON-877Ø5-6 × MON-89788-1 soybean in products containing it or consisting of it for any other use than those provided in points (1) and (2), with the exception of cultivation.

The genetically modified MON-877Ø5-6 × MON-89788-1 soybean, as described in the application, has a reduced expression of fatty acid Δ12-desaturase (FAD2) and palmitoyl acyl carrier protein thioesterase (FATB) enzymes, which results in increased oleic acid and reduced linoleic acid profile and expresses the CP4 EPSPS protein which confers tolerance to glyphosate 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 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 accompanying documents of the products containing or consisting of MON-877Ø5-6 × MON-89788-1 soybean with the exception of products referred to in point (a) of Article 2.

(d) **Method for detection:**

(1) Event specific real-time quantitative PCR based methods for MON-877Ø5-6 and MON-89788-1 soybeans; the detection methods are validated on the single-trait events and verified on genomic DNA extracted from seeds of MON-877Ø5-6 × MON-89788-1 soybean;

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(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 0210-A and AOCS 0906-A (for MON-877Ø5-6) and AOCS 0906-B and AOCS 0906-A (for MON-89788-1) are accessible via the American Oil Chemists Society at http://www.aocs.org/LabServices/content.cfm?ItemNumber=19248.

(e) **Unique identifier:**

MON-877Ø5-6 × 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:**

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-877Ø5-6 × MON-89788-1 soybean oil and MON-877Ø5-6 × MON-89788-1 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 mentioned under (i), results of database 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.

(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 in the Community register of genetically modified food and feed*]

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.