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► **B**

**COMMISSION IMPLEMENTING DECISION**

**of 28 June 2012**

**authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean MON 87701 × MON 89788 (MON-87701-2 × MON-89788-1) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council**

*(notified under document C(2012) 4312)*

**(Only the Dutch and French texts are authentic)**

**(Text with EEA relevance)**

(2012/347/EU)

(OJ L 171, 30.6.2012, p. 13)

Amended by:

		Official Journal		
		No	page	date
► <b>M1</b>	Commission Implementing Decision (EU) 2019/1579 of 18 September 2019	L 244	8	24.9.2019

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*Article 1***Genetically modified organism and unique identifier**

Genetically modified soybean MON 87701 × MON 89788 is assigned the unique identifier MON-877Ø1-2 × MON-89788-1, as provided for in 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 MON-877Ø1-2 × MON-89788-1 soybean;
- (b) feed containing, consisting of, or produced from MON-877Ø1-2 × MON-89788-1 soybean;
- (c) MON-877Ø1-2 × MON-89788-1 soybean present in products other than food and feed containing it or consisting of it, for the same uses as any other soybean 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 documents accompanying products containing or consisting of MON-877Ø1-2 × MON-89788-1 soybean referred to in points (b) and (c) of Article 2.

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*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*

**EU register**

The information set out in the Annex to this Decision shall be entered in the EU register of genetically modified food and feed, as provided for in Article 28 of Regulation (EC) No 1829/2003.

▼ **M1**

*Article 6*

**Authorisation holder**

The authorisation holder shall be Monsanto Company, United States of America, represented by Bayer Agriculture BVBA, Belgium.

▼ **B**

*Article 7*

**Validity**

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

▼ **M1**

*Article 8*

**Addressee**

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

**▼B**

## ANNEX

**▼M1****(a) Applicant and authorisation holder**

Name: Monsanto Company

Address: 800 N. Lindbergh Boulevard, St. Louis, Missouri 63167, United States of America

Represented by Bayer Agriculture BVBA, Scheldelaan 460, 2040 Antwerp, Belgium.

**▼B****(b) Designation and specification of the products**

- (1) Foods and food ingredients containing, consisting of, or produced from MON-87701-2 × MON-89788-1 soybean.
- (2) Feed containing, consisting of, or produced from MON-87701-2 × MON-89788-1 soybean.
- (3) Products other than food and feed containing or consisting of MON-87701-2 × MON-89788-1 soybean for the same uses as any other soybean with the exception of cultivation.

The genetically modified MON-87701-2 × MON-89788-1 soybean, as described in the application, is produced by crosses between soybean containing MON-87701-2 and MON-89788-1 events and expresses the Cry1Ac protein which confers protection against certain lepidopteran pests and CP4 EPSPS protein which confers tolerance to the glyphosate herbicide.

**(c) Labelling**

- (1) For the purposes of the specific 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 documents accompanying products containing or consisting of MON-87701-2 × MON-89788-1 soybean referred to in points (b) and (c) of Article 2 of this Decision.

**(d) Method for detection**

- Event specific real time PCR-based method for the quantification of MON-87701-2 × MON-89788-1 soybean,
- validated on seeds by the Community Reference Laboratory established under Regulation (EC) No 1829/2003, published at <http://gmo-crl.jrc.ec.europa.eu/statusofdoss.htm>
- reference material: AOCS 0809-A and AOCS 0906-A (for MON87701) and AOCS 0906-B and AOCS 906-A (for MON89788) accessible via the American Oil Chemists Society at <http://www.aocs.org/tech/crm>

**(e) Unique identifier**

MON-87701-2 × 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: see [to be completed when notified]

**(g) Conditions or restrictions on the placing on the market, use or handling of the products**

Not required.

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(h) **Monitoring plan**

Monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.

[Link: *plan published on the internet*]

(i) **Post-market monitoring requirements for the use of the food for human consumption**

Not required.

*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 EU register of genetically modified food and feed.