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► **B** **COMMISSION IMPLEMENTING DECISION**  
of 10 February 2012

as regards the renewal of the authorisation for continued marketing of products containing, consisting of, or produced from genetically modified soybean 40-3-2 (MON-Ø4Ø32-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

*(notified under document C(2012) 700)*

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

**(Text with EEA relevance)**

(2012/82/EU)

(OJ L 40, 14.2.2012, p. 14)

Amended by:

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

**▼B****COMMISSION IMPLEMENTING DECISION****of 10 February 2012**

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(2012/82/EU)

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

Genetically modified soybean 40-3-2, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier MON-Ø4Ø32-6, 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-Ø4Ø32-6 soybean;
- (b) feed containing, consisting of, or produced from MON-Ø4Ø32-6 soybean;
- (c) products other than food and feed containing or consisting of MON-Ø4Ø32-6 soybean 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-Ø4Ø32-6 soybean referred to in Article 2(b) and (c).

**▼ B***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 the requirements set in Decision 2009/770/EC.

*Article 5***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 6***Authorisation holder**

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

**▼ B***Article 7***Repeal**

Decision 96/281/EC shall be repealed from 13 February 2012.

*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.

**▼ B***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.

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

- (1) Foods and food ingredients containing, consisting of, or produced from MON-Ø4Ø32-6 soybean.
- (2) Feed containing, consisting of, or produced from MON-Ø4Ø32-6 soybean.
- (3) Products other than food and feed containing or consisting of MON-Ø4Ø32-6 soybean for the same uses as any other soybean with the exception of cultivation.

The genetically modified MON-Ø4Ø32-6 soybean, as described in the applications, expresses the CP4 EPSPS protein which confers tolerance to the glyphosate herbicide.

**(c) Labelling**

- (1) For the purposes of the specific labelling requirements laid down in Articles 13(1) and 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-Ø4Ø32-6 soybean referred to in Article 2(b) and (c).

**(d) Method for detection**

- Event-specific real-time PCR-based method for the quantification of MON-Ø4Ø32-6 soybean,
- validated 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: ERM®-BF410 accessible via the Joint Research Centre (JRC) of the European Commission, Institute for Reference Materials and Measurements (IRMM) at <https://irmm.jrc.ec.europa.eu/mcatalogue>

**(e) Unique identifier**

MON-Ø4Ø32-6

**(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]

**▼ B**

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

Not required.

**(h) Monitoring plan**

Monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC of the European Parliament and of the Council <sup>(1)</sup>

[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 Community register of genetically modified food and feed.

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<sup>(1)</sup> OJ L 106, 17.4.2001, p. 1.