

COMMISSION IMPLEMENTING DECISION (EU) 2021/1385**of 17 August 2021**

renewing the authorisation for the placing on the market of feed and products other than food and feed containing or consisting of genetically modified oilseed rape GT73 (MON-ØØØ73-7) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

(notified under document C(2021) 5992)

(Only the Dutch text is authentic)

(Text with EEA relevance)

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 of 22 September 2003 on genetically modified food and feed⁽¹⁾, and in particular to Articles 11(3) and 23(3) thereof,

Whereas:

- (1) Commission Decision 2005/635/EC⁽²⁾ authorised the placing on the market of feed containing or consisting of genetically modified oilseed rape GT73. The scope of that authorisation also covers products containing or consisting of oilseed rape GT73 for uses other than food or feed, with the exception of cultivation.
- (2) On 18 February 2016, Monsanto Europe N.V., based in Belgium, submitted on behalf of the authorisation holder Monsanto Company, based in the United States, an application to the Commission, in accordance with Articles 11 and 23 of Regulation (EC) No 1829/2003, for the renewal of the authorisation for the placing on the market of the products covered by Decision 2005/635/EC.
- (3) By a letter dated 27 August 2018, Monsanto Europe N.V. informed the Commission that, as of 23 August 2018, it converted its legal form and changed its name to Bayer Agriculture BVBA.
- (4) By a letter dated 28 July 2020, Bayer Agriculture BVBA, Belgium, informed the Commission that, as of 1 August 2020, it changed its name to Bayer Agriculture BV, Belgium.
- (5) By a letter dated 28 July 2020, Bayer Agriculture BVBA, Belgium, representing Monsanto Company, United States, informed the Commission that, as of 1 August 2020, Monsanto Company, United States, converted its legal form and changed its name to Bayer CropScience LP, United States.
- (6) On 29 July 2020, the European Food Safety Authority ('the Authority') issued a favourable opinion⁽³⁾ in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003. 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 oilseed rape GT73, adopted by the Authority in 2004⁽⁴⁾.

⁽¹⁾ OJ L 268, 18.10.2003, p. 1.

⁽²⁾ Commission Decision 2005/635/EC of 31 August 2005 concerning the placing on the market, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of an oilseed rape product (*Brassica napus* L., GT73 line) genetically modified for tolerance to the herbicide glyphosate (OJ L 228, 3.9.2005, p. 11).

⁽³⁾ EFSA Panel on Genetically Modified Organisms (GMO) 2020. Scientific Opinion on the assessment of genetically modified oilseed rape GT73 for renewal authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-002). EFSA Journal 2020;18 (7):6199. <https://doi.org/10.2903/j.efsa.2020.6199>.

⁽⁴⁾ Opinion of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to the Notification (Reference C/NL/98/11) for the placing on the market of glyphosate-tolerant oilseed rape event GT73, for import and processing, under Part C of Directive 2001/18/EC from Monsanto. EFSA Journal 2004;2(3):29. <https://doi.org/10.2903/j.efsa.2004.29>.

- (7) In its 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 Articles 6(4) and 18(4) of Regulation (EC) No 1829/2003.
- (8) The Authority also concluded that the monitoring plan for the environmental effects submitted by the applicant, consisting of a general surveillance plan, is in line with the intended uses of the products.
- (9) Taking into account those conclusions, the authorisation for the placing on the market of the products covered by Decision 2005/635/EC should be renewed.
- (10) A unique identifier has been assigned to genetically modified oilseed rape GT73, in accordance with Commission Regulation (EC) No 65/2004 (5), in the context of its initial authorisation by Decision 2005/635/EC. That unique identifier should continue to be used.
- (11) For the products covered by this Decision, no specific labelling requirements, other than those provided for in Articles 13(1) and 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 (6) appear to be necessary. However, in order to ensure that the use of products containing or consisting of genetically modified oilseed rape GT73 remains within the limits of the authorisation granted by this Decision, the labelling of such products should contain a clear indication that they are not intended for cultivation.
- (12) 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 (7).
- (13) The opinion of the Authority does not justify the imposition of specific conditions or restrictions for the placing on the market, for the use and handling, including post-market monitoring requirements regarding the consumption of feed containing or consisting of genetically modified oilseed rape GT73, or for the protection of particular ecosystems/environment or geographical areas, as provided for in Articles 6(5)(e) and 18(5)(e) of Regulation (EC) No 1829/2003.
- (14) 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.
- (15) 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)(c) of Regulation (EC) No 1946/2003 of the European Parliament and of the Council (8).
- (16) The Standing Committee on Plants, Animals, Food and Feed has not delivered an opinion within the time limit laid down by its Chair. This implementing act was deemed to be necessary and the chair submitted it to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

(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).

(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).

(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).

(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).

HAS ADOPTED THIS DECISION:

Article 1

Genetically modified organism and unique identifier

Genetically modified oilseed rape (*Brassica napus* L.) GT73, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier MON-ØØØ73-7, in accordance with Regulation (EC) No 65/2004.

Article 2

Renewal of the authorisation

The authorisation for the placing on the market of the following products is renewed in accordance with the conditions set out in this Decision:

- (a) feed containing or consisting of genetically modified oilseed rape MON-ØØØ73-7;
- (b) products containing or consisting of genetically modified oilseed rape MON-ØØØ73-7 for uses other than those provided for in point (a) and other than food, with the exception of cultivation.

Article 3

Labelling

1. For the purposes of the 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 'oilseed rape'.
2. The words 'not for cultivation' shall appear on the label of and in the documents accompanying the products covered by this Decision.

Article 4

Method for detection

The method set out in point (d) of the Annex shall apply for the detection of genetically modified oilseed rape MON-ØØØ73-7.

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

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, Belgium.

*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 represented in the Union by Bayer Agriculture BV, Scheldelaan 460, 2040 Antwerp, Belgium.

Done at Brussels, 17 August 2021.

*For the Commission,
Stella KYRIAKIDES
Member of the Commission*

ANNEX

(a) Applicant and authorisation holder:

Name: Bayer CropScience LP

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

Represented in the Union by: Bayer Agriculture BV, Scheldelaan 460, 2040 Antwerp, Belgium.

(b) Designation and specification of the products:

- (1) feed containing or consisting of genetically modified oilseed rape MON-ØØØ73-7;
- (2) products containing or consisting of genetically modified oilseed rape MON-ØØØ73-7 for uses other than those provided in point (1) and other than food, with the exception of cultivation.

The genetically modified oilseed rape MON-ØØØ73-7 expresses the *cp4 epsps* and *goxv247* genes, which confer tolerance to glyphosate-based herbicides.

(c) Labelling:

- (1) For the purposes of the 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 'oilseed rape'.
- (2) The words 'not for cultivation' shall appear on the label of and in the documents accompanying the products referred to in points (b)(1) and (2).

(d) Method for detection:

- (1) Event specific real-time quantitative PCR based method for the detection of genetically modified oilseed rape MON-ØØØ73-7.
- (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 0304-B accessible via the American Oil Chemists Society at <https://www.aocs.org/crm>

(e) Unique identifier:

MON-ØØØ73-7

(f) Information required pursuant to Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity:

[Biosafety Clearing-House, Record ID number: published in the 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:

Not required.

(h) Monitoring plan for environmental effects:

Monitoring plan for environmental effects in accordance with Annex VII to Directive 2001/18/EC of the European Parliament and of the Council (¹).

[Link: plan published in the Community register of genetically modified food and feed]

(¹) Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).

(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.
