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## COMMISSION IMPLEMENTING DECISION

of **XXX**

**amending Implementing Decision (EU) 2021/1385 as regards the renewal of the authorisation for the placing on the market of food containing, consisting of or produced from genetically modified oilseed rape GT73 (MON-00073-7), with the exception of isolated seed protein, and feed produced from genetically modified oilseed rape GT73 (MON-00073-7) and as regards the authorisation for the placing on the market of isolated seed protein produced from genetically modified oilseed rape GT73 (MON-00073-7) for food uses**

(Text with EEA relevance)

(Only the Dutch text is authentic)

# COMMISSION IMPLEMENTING DECISION

of **XXX**

**amending Commission Implementing Decision (EU) 2021/1388 as regard the scope extension of the authorisation and repealing Decision (EU) 2015/701**

(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<sup>1</sup>, and in particular Article 9(2) and Articles 11(3) and 23(3) thereof,

Whereas:

- (1) Commission Implementing Decision (EU) 2015/701<sup>2</sup> authorised the placing on the market of food containing or consisting of or produced from genetically modified oilseed rape GT73, with the exception of isolated seed protein, and feed produced from genetically modified oilseed rape GT73.
- (2) On 19 February 2021, Bayer Agriculture BV, based in Belgium, submitted an application on behalf of Bayer CropScience LP, based in the United States, to the Commission, in accordance with Article 11(3) and Article 23(3) of Regulation (EC) No 1829/2003, for the renewal of that authorisation.
- (3) On 19 February 2021, Bayer Agriculture BV, based in Belgium, submitted an application on behalf of Bayer CropScience LP, based in the United States, to the Commission, in accordance with Article 9(2) of Regulation (EC) No 1829/2003, for modification of the terms of the authorisation granted by Implementing Decision (EU) 2015/701, regarding the placing on the market of isolated seed protein produced from genetically modified oilseed rape GT73 for food.
- (4) Commission Implementing Decision (EU) 2021/1385<sup>3</sup> renewed the authorisation for the placing on the market of feed containing or consisting of genetically modified oilseed rape GT73 and products containing or consisting of genetically modified oilseed rape GT73 for uses other than food and feed, with the exception of cultivation.

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<sup>1</sup> OJ L 268, 18.10.2003, p. 1.

<sup>2</sup> Commission Implementing Decision (EU) 2015/701 of 24 April 2015 authorising the placing on the market of food containing or consisting of genetically modified oilseed rape GT73, or food and feed produced from that genetically modified organism pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 112, 30.4.2015, p.86).

<sup>3</sup> 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 and 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 (OJ L 300, 24.8.2021, p.4).

- (5) On 6 October 2022, the European Food Safety Authority ('the Authority') issued a favourable opinion<sup>4</sup> on the assessment of genetically modified oilseed rape GT73 for renewal authorisation in accordance with Article 6 of Regulation (EC) No 1829/2003. The Authority concluded that the renewal application did not contain 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<sup>5</sup>.
- (6) 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.
- (7) On 4 November 2022, the Authority issued a favourable opinion<sup>6</sup> on the assessment of genetically modified oilseed rape GT73 for placing on the market of isolated seed protein for food in accordance with Article 6 of Regulation (EC) No 1829/2003. The Authority concluded that genetically modified oilseed rape GT73 is as safe as its conventional counterpart with respect to potential effects on human and animal health and the environment, and that those conclusions also apply to the placing on the food market of isolated seed protein produced from genetically modified oilseed rape GT73.
- (8) In both opinions, 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.
- (9) Taking into account those considerations, the authorisation for the placing on the market of the products covered by Implementing Decision (EU) 2015/701 should be renewed and the placing on the market of isolated seed protein for food from genetically modified GT73 should be authorised.
- (10) On 4 November 2022, the applicant Bayer Agriculture BV asked the Commission to merge into a single authorisation the uses of genetically modified oilseed rape GT73 covered by the renewal application for food containing or consisting of or produced from genetically modified oilseed rape GT73, with the exception of isolated seed protein, and feed produced from genetically modified oilseed rape GT73, the application for placing on the market of isolated seed protein from genetically modified oilseed rape GT73 and the uses of this genetically modified oilseed rape covered by Implementing Decision (EU) 2021/1385. By a letter dated 31 January 2023, the Commission informed the applicant that the merger would take effect through the extension of the scope of Implementing Decision (EU) 2021/1385 to the products concerned by the renewal application and application for placing on the market of isolated seed protein from this genetically modified oilseed rape of 19 February 2021.

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<sup>4</sup> EFSA Panel on Genetically Modified Organisms (EFSA GMO Panel), 2022. Scientific Opinion on the assessment of genetically modified oilseed rape GT73 for renewal authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-026/1). EFSA Journal 2022; 20(10):7563, 10 pp. <https://doi.org/10.2903/j.efsa.2022.7563>.

<sup>5</sup> EFSA GMO Panel, 2004. 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; The EFSA Journal (2004)29, 1-19; <https://doi.org/10.2903/j.efsa.2004.29>.

<sup>6</sup> EFSA GMO Panel, 2022. Scientific Opinion on the assessment of genetically modified oilseed rape GT73 for placing on the market of isolated seed protein for food under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-026/2). EFSA Journal 2022; 20(10):7590, 11 pp. <https://doi.org/10.2903/j.efsa.2022.7590>.

- (11) As the request of the applicant is justified in the interest of simplification, Implementing Decision (EU) 2021/1385 should be amended to incorporate into its scope the products currently covered by Implementing Decision (EU) 2015/701 and isolated seed protein for food from genetically modified oilseed rape GT73.
- (12) A unique identifier has been assigned to genetically modified oilseed rape GT73, in accordance with Commission Regulation (EC) No 65/2004<sup>7</sup>, in the context of its initial authorisation by Commission Implementing Decision 2005/635/EC<sup>8</sup>. That unique identifier should continue to be used.
- (13) Based on the opinions of the Authority, 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<sup>9</sup>, appear to be necessary for the products covered by this Decision. However, to ensure that the use of those products remains within the limits of the authorisation granted by this Decision, the labelling of the products containing and consisting of genetically modified oilseed rape GT73, with the exception of foods and food ingredients, should contain a clear indication that they are not intended for cultivation.
- (14) All relevant information on the authorisation products 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) Implementing Decision (EU) 2015/701 should be repealed.
- (16) 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), point (c), of Regulation (EC) No 1946/2003 of the European Parliament and of the Council<sup>10</sup>.
- (17) 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*

#### **Amendments**

Implementing Decision (EU) 2021/1385 is amended as follows:

- (1) the title is replaced by the following:

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<sup>7</sup> 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).

<sup>8</sup> 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).

<sup>9</sup> 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).

<sup>10</sup> 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).

‘Commission Implementing Decision (EU) 2021/1385 of 17 August 2021 authorising the placing on the market of food and feed containing, consisting of or produced from genetically modified oilseed rape GT73 (MON-ØØØ73-7) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council’;

- (2) Article 2 is replaced by the following:

*‘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 genetically modified oilseed rape MON-ØØØ73-7;
  - (b) feed containing, consisting of or produced from genetically modified oilseed rape MON-ØØØ73-7;
  - (c) products containing or consisting of genetically modified oilseed rape MON-ØØØ73-7 for uses other than those provided for in points (a) and (b), with the exception of cultivation.’;
- (3) in Article 3, a second paragraph is added:

‘The words “not for cultivation” shall appear on the label of and in the documents accompanying products containing or consisting of genetically modified oilseed rape as referred to in Article 1, with the exception of products referred to in Article 2, point (a).’;

- (4) Article 9 is replaced by the following:

*‘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, Scheldelaan 460, 2040 Antwerp, Belgium.’;

- (5) the Annex is amended in accordance with the Annex to this Decision.

*Article 2*

**Repeal**

Decision (EU) 2015/701 is repealed.

*Article 3*

**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, Scheldelaan 460, 2040 Antwerp, Belgium.

Done at Brussels,

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