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COMMISSION IMPLEMENTING DECISION

of **XXX**

authorising the placing on the market of food containing or consisting of genetically modified oilseed rape GT73, or food and feed produced from those genetically modified organisms pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

(Text with EEA relevance)

(Only the Dutch and French texts are authentic)

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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 feed¹, and in particular Article 7(3), Article 11(3), Article 19(3) and Article 23(3) thereof,

Whereas:

- (1) On 17 and 18 April 2007, Monsanto Europe S.A. submitted to the Commission applications, in accordance with Article 8(4) and Article 20(4) of Regulation (EC) No 1829/2003, for renewal of the authorisations of existing food and feed produced from GT73 oilseed rape. The scope of the two renewal applications covers the continued marketing of existing food produced from oilseed rape GT73 (refined oil and food additives) and existing feed produced from oilseed rape GT73 (feed materials and feed additives) which were lawfully placed on the market in the Community before the date of entry into force of Regulation (EC) No 1829/2003. After the date of the entry into force of Regulation (EC) No 1829/2003, these products were notified to the European Commission according to Articles 8(1)(a) and 8(1)(b)/20(1)(b) of that Regulation and included in the Community Register of genetically modified food and feed.
- (2) On 15 December 2009, the European Food Safety Authority ('EFSA') gave a favourable opinion on the renewal application in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003. It concluded that it is unlikely that the continued marketing of the food and feed produced from oilseed rape GT73 as described in the application will have any adverse effects on human or animal health or the environment, in the context of their intended uses².
- (3) On 26 August 2010, Monsanto Europe S.A. submitted to the competent authority of the Netherlands an application, in accordance with Article 5 of Regulation (EC) No 1829/2003, for the placing on the market of foods and food ingredients containing, consisting of, or produced from oilseed rape GT73 (including pollen of oilseed rape

¹ OJ L 268, 18.10.2003, p. 1.

² <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2009-00952>
<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2009-00953>

GT73 and the accidental unintentional presence of viable seeds), with the exception of processed oil and food additives. The application does not include cultivation in the EU.

- (4) In accordance with Article 5(5) and Regulation (EC) No 1829/2003, that application includes the data and information required by Annexes III and IV to 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/EEC³, and information and conclusions about the risk assessment carried out in accordance with the principles set out in Annex II to Directive 2001/18/EC. It also includes a monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.
- (5) On 12 February 2013, the European Food Safety Authority ('EFSA') gave a favourable opinion on the new application in accordance with Article 6 Regulation (EC) No 1829/2003. It concluded that there is no indication of safety concerns for the human health in the context of the uses covered by the application, and in particular in either oilseed rape GT73 pollen/pollen-containing dietary supplements or the adventitious presence of trace levels of seeds in human foods⁴. However, due to the lack of availability of relevant consumption and safety data, EFSA could not perform an equivalent assessment with isolated seed protein. EFSA also concluded that the environmental risk assessment of GT73 did not identify any safety concerns, in the context of its intended uses.
- (6) On 19 March 2013, the Commission asked EFSA to complete its assessment to cover all possible uses of oilseed rape GT73 requested in the application.
- (7) Subsequently, on 8 May 2013, Monsanto Europe S.A. informed the Commission that it does not intend to market isolated protein products from GT73 in the EU. Taking into account the fact that this particular use is very limited and accidental presence of the isolated seed protein in the food chain is very unlikely, it could be excluded from the scope of this Decision.
- (8) In both opinions, EFSA considered all the specific questions and concerns raised by the Member States in the context of the consultations of the national competent authorities as provided for in Article 6(4) of Regulation (EC) No 1829/2003.
- (9) The environmental monitoring plan, consisting of a general surveillance plan, submitted by the applicant is in line with the intended uses of the products.
- (10) The use of feed containing or consisting of GT73 oilseed-rape and products other than food and feed containing it or consisting of it with the exception of cultivation, have already been authorised by Commission Decision 2005/635/EC⁵.
- (11) Taking into account those considerations, authorisation (renewal and new authorisation) should be granted to the foods and food ingredients containing, consisting of GT73 oilseed rape, with the exception of isolated seed protein, and to the food and feed produced from GT73 oilseed rape.
- (12) A unique identifier should be assigned to each genetically modified organism (hereinafter 'GMO') as provided for in Commission Regulation (EC) No 65/2004 of

³ OJ L 106, 17.4.2001, p. 1.

⁴ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2013-00078>

⁵ OJ L 228, 3.9.2005, p. 11.

14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms⁶.

- (13) On the basis of the two EFSA opinions, no specific labelling requirements other than those provided for in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003, appear to be necessary for foods, food ingredients containing or consisting of, and food and feed produced from oilseed rape GT73.
- (14) 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/EC⁷, lays down labelling requirements in Article 4(6) for products containing or consisting of GMOs. Traceability requirements for products containing or consisting of GMOs are laid down in paragraphs 1 to 5 of Article 4 of that Regulation and those for food and feed produced from GMOs are laid down in Article 5 of that Regulation.
- (15) The authorisation holder should submit annual reports on the implementation and the results of the activities set out in the monitoring plan for environmental effects. Those results should be presented in accordance with 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 Council⁸. The EFSA opinions do not justify the imposition of specific conditions or restrictions for the placing on the market and/or specific conditions or restrictions for the use and handling, including post-market monitoring requirements for the use of the food and feed, or of specific conditions for the protection of particular ecosystems/environment and/or geographical areas, as provided for in point (e) of Article 6(5) and in Article 18(5) of Regulation (EC) No 1829/2003.
- (16) All relevant information on the authorisation of the products should be entered in the Community register of genetically modified food and feed, as provided for in Regulation (EC) No 1829/2003.
- (17) 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 point (c) of Article 15(2) of Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms⁹.
- (18) The applicant has been consulted on the measures provided for in this Decision.
- (19) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

⁶ OJ L 10, 16.1.2004, p. 5.

⁷ OJ L 268, 18.10.2003, p. 24.

⁸ OJ L 275, 21.10.2009, p. 9.

⁹ OJ L 287, 5.11.2003, p. 1.

HAS ADOPTED THIS DECISION:

Article 1

Genetically modified organism and unique identifiers

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, 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-ØØØ73-7 oilseed rape, with the exception of isolated seed protein;
- (b) feed produced from MON-ØØØ73-7 oilseed rape.

Article 3

Labelling

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 'oilseed rape'.

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

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.

Article 6

Authorisation holder

The authorisation holder shall be Monsanto Europe S.A., Belgium, representing Monsanto Company, United States of America.

Article 7

Validity

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

Article 8
Addressee

This Decision is addressed to Monsanto Europe S.A., Belgium, Avenue de Tervueren 270-272, B-1150 Brussels, Belgium, representing Monsanto Company, 800 N. Lindbergh Boulevard St. Louis, Missouri 63167, U.S.A.

Done at Brussels,

For the Commission,
Tonio BORG
Member of the Commission

ANNEX

(a) Applicant and Authorisation holder:

Name: Monsanto Europe S.A., Belgium,

Address: Avenue de Tervueren 270-272, B-1150 Brussels, Belgium

on behalf of Monsanto Company, 800 N. Lindbergh Boulevard, St. Louis, Missouri 63167, U.S.A.

(b) Designation and specification of the products:

(1) foods and food ingredients containing, consisting of, or produced from MON-ØØØ73-7 oilseed rape, with the exception of isolated seed protein;

(2) feed produced from MON-ØØØ73-7 oilseed rape.

The genetically modified MON-ØØØ73-7 oilseed rape, as described in the applications, expresses the CP4 5-enolpyruvylshikimate-3-phosphate synthase (CP4 EPSPS) and glyphosate oxidoreductase variant 247 (GOXv247) proteins which confer tolerance to glyphosate-based herbicides.

(c) Labelling:

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 'oilseed rape'.

(d) Method for detection:

- Event specific real-time PCR based method for the quantification of MON-ØØØ73-7 oilseed rape;
- Validated on genomic DNA, extracted from seeds by the EU Reference Laboratory established under Regulation (EC) No 1829/2003, published at <http://gmo-crl.jrc.ec.europa.eu/statusofdossiers.aspx>
- Reference Material: AOCS 0304-A and AOCS 0304-B are accessible via the American Oil Chemists Society at <http://www.aocs.org/tech/crm>

(e) Unique identifier:

MON-ØØØ73-7

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

Biosafety Clearing-House [*to be entered 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:

Not required.

(h) Monitoring plan:

Monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC [*to be entered in the Community register of genetically modified food and feed when notified*].

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

Not required.