TECHNICAL REPORT OF EFSA

Overall opinion of the European Food Safety Authority in accordance with Article 6 of Regulation (EC) No 1829/2003 on the application (reference EFSA-GMO-RX-GT73$_{[8.1a]}$) for renewal of the authorisation of existing products produced from glyphosate tolerant genetically modified oilseed rape GT73 for food uses from Monsanto[1]

European Food Safety Authority[2]

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

This document provides an overall opinion of the European Food Safety Authority on genetically modified oilseed rape GT73 in accordance with the requirements of Article 6 of Regulation (EC) No 1829/2003.

The scope of the application EFSA-GMO-RX-GT73$_{[8.1a]}$ covers the continued marketing of existing foods produced from oilseed rape GT73 (refined oil) which were lawfully placed on the market in the Community before the date of entry into force of Regulation (EC) No 1829/2003. The scope does not include cultivation.

The Scientific Panel on Genetically Modified Organisms (EFSA GMO Panel) has carried out the scientific assessment of genetically modified oilseed rape GT73 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003 and considers that the genetically modified oilseed rape GT73 is unlikely to have any adverse effect on human and animal health or on the environment in the context of its intended uses. The Community Reference Laboratory considers the method validated as fit for the purpose of regulatory compliance. The certified reference materials of oilseed rape GT73 can be accessed at the American Oil Chemists' Society (AOCS-USA).

The information presented for the labelling proposal is in line with Regulation (EC) No 1829/2003.

Under the terms of the Regulation (EC) No 1829/2003, the overall opinion fulfils the requirements of Article 6 for the placing on the market of genetically modified oilseed rape GT73.

[1] On request from the European Commission for an application (EFSA-GMO-RX-GT73$_{[8.1a]}$) submitted by Monsanto, Questions No EFSA-Q-2009-00952 (EFSA overall opinion) and EFSA-Q-2007-148 (Scientific opinion of the EFSA GMO Panel), issued on 15 December 2009.

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KEY WORDS

Overall opinion, GMO, oilseed rape, *Brassica napus*, oilseed rape, GT73, herbicide tolerance, food uses, food safety, environmental safety, Regulation (EC) No 1829/2003, renewal, existing product.

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BACKGROUND

On 29 June 2007, the European Food Safety Authority (EFSA) received from the European Commission an application for renewal of the authorisation for continued marketing of existing products derived from oilseed rape GT73 (MON-ØØØ73-7) submitted by Monsanto within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (reference EFSA-GMO-RX-GT73$_{[8.1a]}$) .

The scope of application EFSA-GMO-RX-GT73$_{[8.1a]}$ covers the continued marketing of existing foods produced from oilseed rape GT73 (refined oil) 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 entry into force of Regulation (EC) No 1829/2003 these products were notified to the European Commission according to Article 8 of that Regulation and included in the Community Register of genetically modified food and feed[3]. The scope does not include cultivation.

In accordance with Article 5 of Regulation (EC) No 1829/2003, EFSA informed the Member States and the European Commission and made the summary of the application publicly available on the EFSA website[4] on 4 July 2007. EFSA initiated a completeness check of the application to check compliance with the requirements laid down in Article 5 of Regulation (EC) No 1829/2003. The Community Reference Laboratory (CRL) confirmed receipt of the detection method, samples and control samples in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003. EFSA declared the application valid on 28 March 2008 and started the clock in accordance with Article 6 of Regulation (EC) No 1829/2003.

From that date, EFSA has endeavoured to respect a time limit of six months in giving its overall opinion (Article 6(1)). EFSA made the valid application available to Member States and the European Commission. Following the procedure laid down in Article 6(4) of Regulation (EC) No 1829/2003, EFSA consulted the Member States. In this context, the Member States risk assessment bodies, as well as the national competent authorities under Directive 2001/18/EC, were given three months after the date of receipt of the valid application (*i.e.* until 28 June 2008) within which to make their opinion known.

Making use of the provisions under Article 6(2), EFSA requested additional information from the applicant and the clock was stopped from 30 September 2008 to 27 October 2009[5].

The overall opinion on application EFSA-GMO-RX-GT73$_{[8.1a]}$ includes the scientific opinion of the Scientific Panel on Genetically Modified Organisms together with the particulars required under Article 6(5)(a-g) of Regulation (EC) No 1829/2003i) the name and address of the applicant, ii) the designation of the food and its specification, iii) the labelling proposal, iv) the method for detection, validated by the Community Reference Laboratory, including sampling, identification of the transformation event in the food-feed and/or foods-feeds produced from it, v) an indication of where appropriate reference materials can be accessed, and vi) the Member States' comments submitted during the three-month consultation period.

[3] http://ec.europa.eu/food/dyna/gm_register/gm_register_auth.cfm?pr_id=4
[4] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2007-148

[5] Request for additional information from the EFSA GMO Panel: requested (1) on 30 September 2008 - received on 20 April 2009, requested (2) on 8 June 2009- received on 1 October 2009, and clock restarted on 27 October 2009.

TERMS OF REFERENCE

The European Food Safety Authority (EFSA) received from the European Commission application for renewal of the authorisation for continued marketing of existing products derived from oilseed rape GT73 (MON-ØØØ73-7) submitted by Monsanto within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (reference EFSA-GMO-RX-GT73[8.1a]). EFSA was requested to issue an overall opinion in line with the requirements of the Regulation (EC) No 1829/2003 (Article 6).

CONSIDERATIONS

1. Applicant

The application was submitted by

Monsanto Europe S.A.
Avenue de Tervuren 270-272
B-1150 Brussels
Belgium

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

2. Designation and specification of the product

The scope of application EFSA-GMO-RX-GT73[8.1a] covers the continued marketing of existing foods produced from oilseed rape GT73 (refined oil) 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 entry into force of Regulation (EC) No 1829/2003 these products were notified to the European Commission according to Article 8 of that Regulation and included in the Community Register of genetically modified food and feed[6]. The scope does not include cultivation.

Oilseed rape GT73 has been modified with two genes encoding the CP4 EPSPS and GOX proteins that confer glyphosate tolerance and resistance, respectively.

3. Scientific opinion of the EFSA GMO Panel

The EFSA GMO Panel has carried out the scientific assessment of the genetically modified oilseed rape GT73 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003 and adopted its scientific opinion on 2 December 2009. The EFSA GMO Panel considered all comments submitted by Member State bodies and where deemed necessary, requested additional information from the applicant before finalising its scientific assessment. The EFSA GMO Panel concludes that the information available for GM oilseed rape GT73 addresses the scientific comments raised by the Member States and considers that the genetically modified oilseed rape GT73 is unlikely to have any adverse effect on human and animal health or the environment in the context of its intended uses (Annex A).

4. Cartagena Protocol (not applicable)

Due to the scope of the application, there are no requirements for a Cartagena Protocol.

5. Labelling

The labelling proposal provided in the application is in line with the requirements in Regulation (EC) No 1829/2003. On the basis of the scientific opinion of the EFSA GMO Panel that GM oilseed rape GT73 is compositionally and phenotypically equivalent to its non-genetically modified oilseed rape except for the introduced traits, EFSA is of the opinion that there is no need for a specific labelling in accordance with Article 13(2)(a) (Annex C).

[6] http://ec.europa.eu/food/dyna/gm_register/gm_register_auth.cfm?pr_id=4

6. Method for detection

The Joint Research Centre (JRC) as Community Reference Laboratory for the GM Food and Feed has carried out a collaborative study to assess the performance of a quantitative event-specific method to detect and quantify the GT73 transformation event in oilseed rape DNA. The reports were published on 7 February 2007. The Community Reference Laboratory considers that the method is applicable to the control samples provided, in accordance with the requirements of Annex I-2.C.2. to Commission Regulation (EC) No 641/2004 (Annexes D1, D2, D3).

7. Certified reference materials

The certified reference materials of genetically modified oilseed rape GT73 can be accessed at the American Oil Chemists' Society (AOCS-USA) (Annex E).

8. Post-market environmental monitoring (not applicable)

Due to the scope of the application, there are no requirements for a post-market environmental monitoring plan for oilseed rape GT73.

9. Member States' Comments

The EFSA GMO Panel has addressed the comments submitted by the Member States during the three-month consultation period (Annex G).

CONCLUSIONS

Under the terms of the Regulation (EC) No 1829/2003, the overall opinion fulfils the requirements of Article 6 for the renewal of authorisation of genetically modified oilseed rape GT73.

LIST OF ANNEXES[7]

Annex A: Scientific opinion of the EFSA GMO Panel (oilseed rape GT73)
Annex B: not applicable
Annex C: Labelling (oilseed rape GT73[8.1a])
Annex D1: Validation report (oilseed rape GT73)
Annex D2: Validated method (oilseed rape GT73)
Annex D3: Sampling and extraction (oilseed rape GT73)
Annex E1: Certified reference materials report (oilseed rape GT73)
Annex F: not applicable
Annex G: Member States' comments (oilseed rape GT73[8.1a] and [8.1b/20.1b])

[7] The annexes of the EFSA overall opinion can be found in the Register of Questions ("Question documents") on the EFSA website under the following link: http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2007-148