TECHNICAL REPORT

Overall opinion of the European Food Safety Authority in accordance with Article 6 of Regulation (EC) No 1829/2003 on application (reference EFSA-GMO-NL-2010-87) for the placing on the market of genetically modified herbicide-tolerant oilseed rape GT73 for food containing or consisting of and food produced from or containing ingredients produced from oilseed rape GT73 (with the exception of refined oil and food additives) under Regulation (EC) No 1829/2003 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 this application EFSA-GMO-NL-2010-87 is for food containing or consisting of, and food produced from or containing ingredients produced from oilseed rape GT73 (with the exception of refined oil and food additives). 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 Article 6(6) of Regulation (EC) No 1829/2003. In conclusion, the EFSA GMO Panel considers that the information available for oilseed rape GT73 addresses the scientific issues indicated by the Guidance Document of the EFSA GMO Panel and the scientific comments raised by the Member States. While the EFSA GMO Panel is not in a position to conclude on the safety of oilseed rape pollen in general, it concludes that the genetic modification in oilseed rape GT73 does not constitute an additional health risk if oilseed rape GT73 pollen were to replace non-GM oilseed rape pollen. The environmental risk assessment of oilseed rape GT73 did not identify any safety concerns, in the context of its intended uses. The EFSA GMO Panel conclusions on the previous applications on oilseed rape GT73, i.e., Notification reference C/NL/98/11 and Application for renewal reference EFSA-GMO-RX-GT73, remain valid and applicable (EFSA, 2004, 2009). The European Union Reference Laboratory for GM

[1] On request from the Competent Authority of the Netherlands for an application (EFSA-GMO-NL-2010-87) submitted by Monsanto, Questions No EFSA-Q-2013-00078 (EFSA overall opinion) and EFSA-Q-2010-01088 (Scientific opinion of the EFSA GMO Panel), issued on 12 February 2013.

[2] Correspondence: gmo@efsa.europa.eu

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Food and Feed (EU-RL – GMFF) 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 Cartagena Protocol, the labelling proposal and the monitoring plan 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.

KEY WORDS

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

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BACKGROUND

On 31 August 2010, the European Food Safety Authority (EFSA) received from the Competent Authority of the Netherlands an application for authorisation of genetically modified oilseed rape GT73 (Unique Identifier MON-ØØØ73-7) submitted by Monsanto within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (reference EFSA-GMO-NL-2010-87).

The scope of this application EFSA-GMO-NL-2010-87 is for food containing or consisting of and food produced from or containing ingredients produced from oilseed rape GT73 (with the exception of refined oil and food additives).[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 30 September 2010. 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. On 19 January 2005, the EU-RL – GMFF received the detection method, samples and control samples in accordance with Article 5 of Regulation (EC) No 1829/2003. EFSA declared the application valid on 22 November 2011 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 22 February 2012) 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 27 January 2012 to 31 December 2012.[5]

The overall opinion on application EFSA-GMO-NL-2010-87 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 1829/2003: i) the name and address of the applicant, ii) the designation of the food and its specification, iii) the information required under Annex II to the Cartagena Protocol, iv) the labelling proposal, v) the method for detection, validated by the European Union Reference Laboratory, including sampling, identification of the transformation event in the food-feed and/or foods-feeds produced from it, vi) an indication of where appropriate reference materials can be accessed, vii) the monitoring plan and, viii) the Member States' comments submitted during the three-month consultation period.

TERMS OF REFERENCE AS PROVIDED BY THE COMPETENT AUTHORITY OF THE NETHERLANDS

The European Food Safety Authority (EFSA) received from the Competent Authority of the Netherlands an application for authorisation of genetically modified oilseed rape GT73 (Unique Identifier MON-ØØØ73-7) submitted by Monsanto within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (reference EFSA-GMO-NL-2010-87). EFSA was requested to issue an overall opinion in line with the requirements of the Regulation (EC) No 1829/2003 (Article 6).

[3] This does not include genetically modified oilseed rape GT73 for import and processing as designated under part C of Directive 2001/18/EC.

[4] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2010-01088

[5] Request for additional information from the EFSA GMO Panel: requested (1) on 27/01/2012 - received on 23/04/2012; requested (2 and 3) on 13/06/2012 and 05/07/2012 - received on 14/09/2012 and clock re-started on 13/12/2012.

CONSIDERATIONS

1. Applicant

The application was submitted by

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

Monsanto Company
800 N. Lindbergh Boulevard
St. Louis, Missouri 63167
USA

2. Designation and specification of the product as provided by the applicant

The scope of this application EFSA-GMO-NL-2010-87 is for food containing or consisting of and food produced from or containing ingredients produced from oilseed rape GT73 (with the exception of refined oil and food additives).[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.

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 Article 6(6) and of Regulation (EC) No 1829/2003 and adopted its scientific opinion on 23 January 2013. 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. In conclusion, the EFSA GMO Panel considers that the information available for oilseed rape GT73 addresses the scientific issues indicated by the Guidance Document of the EFSA GMO Panel and the scientific comments raised by the Member States. While the EFSA GMO Panel is not in a position to conclude on the safety of oilseed rape pollen in general, it concludes that the genetic modification in oilseed rape GT73 does not constitute an additional health risk if oilseed rape GT73 pollen were to replace non-GM oilseed rape pollen. The environmental risk assessment of oilseed rape GT73 did not identify any safety concerns, in the context of its intended uses. The EFSA GMO Panel conclusions on the previous applications on oilseed rape GT73, i.e., Notification reference C/NL/98/11 and Application for renewal reference EFSA-GMO-RX-GT73, remain valid and applicable (EFSA, 2004, 2009) (Annex A).

4. Cartagena Protocol

The information presented in the application and as required under Annex II of the Cartagena Protocol on Biosafety is in line with the scientific opinion of the EFSA GMO Panel (Annex B).

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, EFSA is of the opinion that there is no need for a specific labelling in accordance with Article 13(2)(a) (Annex C).

6. Method for detection

The EU-RL – GMFF has carried out a collaborative study to assess the performance of a quantitative event-specific method to detect and quantify the oilseed rape GT73 transformation event in oilseed rape DNA. The reports were issued on 7 February 2007. The EU-RL – GMFF considers that the method is applicable to the control samples provided, in accordance with the requirements of Annex I-2.C.2. of the Commission Regulation (EC) No 641/2004 (Annexes D1, D2, D3).

[6] This does not include genetically modified oilseed rape GT73 for import and processing as designated under part C of Directive 2001/18/EC.

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 E1).

8. Post-market environmental monitoring

The EFSA GMO Panel evaluated the post-market environmental monitoring plan proposed by the applicant. The EFSA GMO Panel considered that the monitoring plan provided by the applicant is in line with the intended uses for the GMO (Annex F).

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 placing on the market of genetically modified oilseed rape GT73.

REFERENCES

EFSA (European Food Safety Authority), 2004. Opinion of the Scientific Panel on genetically modified organisms (GMO) on a request from the Commission related to the Notification (Reference C/NL/98/11) for the placing on the market of herbicide-tolerant oilseed rape GT73, for import and processing, under Part C of Directive 2001/18/EC from Monsanto. EFSA Journal, 29, 1-19.

EFSA (European Food Safety Authority), 2009. Scientific Opinion on applications (EFSA-GMO-RX-GT73) for renewal of the authorisation for continued marketing of existing (1) food and food ingredients produced from oilseed rape GT73; and of (2) feed materials, feed additives and food additives produced from oilseed rape GT73, all under Regulation (EC) No 1829/2003 from Monsanto. EFSA Journal, 1417, 1-12.

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[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-2013-00078