TECHNICAL REPORT OF EFSA

Overall opinion of the European Food Safety Authority in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003 on the application (reference EFSA-GMO-RX-Ms8-Rf3) for renewal of the authorisation of existing products produced from herbicide tolerant genetically modified oilseed rape Ms8 x Rf3 for food and feed uses from Bayer CropScience AG[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 Ms8 x Rf3 in accordance with the requirements of Articles 6 and 18 of Regulation (EC) No 1829/2003.

The scope of this application EFSA-GMO-RX-Ms8 x Rf3 covers the continued marketing of (1) existing foods produced from oilseed rape Ms8, Rf3 and Ms8 x Rf3 (processed oil) and (2) existing feeds produced from oilseed rape Ms8, Rf3 and Ms8 x Rf3, 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 Ms8 x Rf3 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003 and considers that the genetically modified oilseed rape Ms8 x Rf3 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 Ms8 and Rf3 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 Articles 6 and 18 for the renewal of authorisation of existing products produced from genetically modified oilseed rape Ms8, Rf3 and Ms8 x Rf3.

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1 On request from the European Commission on an application (reference EFSA-GMO-RX-Ms8-Rf3) submitted by Bayer CropScience AG, Question No EFSA-Q-2009-00748 (EFSA overall opinion) and EFSA-Q-2007-159 (Scientific opinion of the EFSA GMO Panel), issued on 22 September 2009.

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KEY WORDS

Overall opinion, GMO, oilseed rape, *Brassica napus*, Ms8, Rf3, Ms8 x Rf3, herbicide tolerance, risk assessment, food and feed uses, import, processing, food safety, feed safety environmental safety, Regulation (EC) No 1829/2003, renewal, existing products.

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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 Ms8, Rf3 and Ms8 x Rf3 (EFSA-GMO-RX-MS8-RF3) submitted by Bayer CropScience AG within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed.

The scope of application EFSA-GMO-RX-Ms8-Rf3 covers the continued marketing of (1) existing foods produced from oilseed rape Ms8, Rf3 and Ms8 x Rf3 (processed oil) and (2) existing feeds produced from oilseed rape Ms8, Rf3 and Ms8 x Rf3, 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 Articles 8 and 20 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 Articles 5 and 17 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 Articles 5 and 17 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 Articles 6 and 18 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 (Articles 6(1) and 18(1)). EFSA made the valid application available to Member States and the European Commission. Following the procedure laid down in Articles 6.4 and 18.4 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 Articles 6(2) and 18(2), EFSA requested additional information from the applicant and the clock was stopped from 29 September 2008 to 9 July 2009[5].

The overall opinion on application EFSA-GMO-RX-Ms8-Rf3 includes the scientific opinion of the Scientific Panel on Genetically Modified Organisms together with the particulars required under Articles 6(5)(a-g) and 18(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 labelling proposal, iv) the method for detection, validated by the Community Reference Laboratory, including 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=15
[4] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2007-159
[5] Request for additional information from the EFSA GMO Panel: requested (1) on 29/09/2008 - received on 03/02/2009, requested (2) on 12/03/2009 - received on 07/05/2009, and clock restarted on 09/07/2009.

TERMS OF REFERENCE

The European Food Safety Authority (EFSA) received from the European Commission an application for renewal of authorisation of existing products produced from genetically modified oilseed rape Ms8, Rf3 and Ms8 x Rf3 (ACS-BNØØ5-8 x ACS-BNØØ3-6) submitted by Bayer CropScience AG within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (reference EFSA-GMO-RX-Ms8-Rf3). EFSA was requested to issue an overall opinion in line with the requirements of the Regulation (EC) No 1829/2003 (Articles 6 and 18).

CONSIDERATIONS

1. Applicant

The application was submitted by

Bayer CropScience AG
Alfred-Nobel-Strasse 50
D - 40789 Monheim am Rhein
Germany

2. Designation and specification of the product

The scope of this application covers the continued marketing of (1) existing foods produced from oilseed rape Ms8, Rf3 and Ms8 x Rf3 (processed oil) and (2) existing feeds produced from oilseed rape Ms8, Rf3 and Ms8 x Rf3, 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 Articles 8 and 20 of that Regulation and included in the Community Register of genetically modified food and feed6. The scope does not include cultivation.

Hybrid oilseed rape Ms8 x Rf3 has been produced by conventional crossing between the genetically modified (GM) parental lines Ms8 and Rf3. The hybrid system is achieved using a pollination control system by insertion and expression of barnase and barstar genes into two separate oilseed rape lines Ms8 and Rf3. Both lines express the PAT protein conferring tolerance to glufosinate-containing herbicides

3. Scientific opinion of the EFSA GMO Panel

The EFSA GMO Panel has carried out the scientific assessment of the genetically modified oilseed rape Ms8, Rf3 and Ms8 x Rf3 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003 and adopted its scientific opinion on 9 September 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 Ms 8, Rf3 and Ms8 x Rf3 addresses the scientific comments raised by the Member States and considers that the genetically modified oilseed rape Ms8, Rf3 and Ms8 x Rf3 are 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 Ms xRf3 is compositionally and phenotypically equivalent to its non-genetically modified oilseed

[6] http://ec.europa.eu/food/dyna/gm_register/gm_register_auth.cfm?pr_id=15

rape except for the introduced traits, EFSA is of the opinion that there is no need for a specific labelling in accordance with Articles 13(2)(a) and 25(2)(c) (Annex C).

6. Method for detection

The Joint Research Centre (JRC) as Community Reference Laboratory for the GM Food and Feed has carried out an in-house verification study to assess the performance of two quantitative event specific methods for use with the hybrid oilseed rape line Ms8 x Rf3 which combines the Ms8 and Rf3 transformation events. The report was published on 15 January 2007. Both methods have been previously validated on parental lines, to detect and quantify each insert on extracted DNA. The Community Reference Laboratory considers that the methods are 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, D2a, D2b).

7. Certified reference materials

The certified reference materials of genetically modified oilseed rape Ms8 and Rf3 can be accessed at the American Oil Chemists' Society (AOCS-USA) (Annexes E1, E2).

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 Ms8 x Rf3.

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 Articles 6 and 18 for the renewal of authorisation of existing products produced from genetically modified oilseed rape Ms8, Rf3 and Ms8 x Rf3.

LIST OF ANNEXES[7]

Annex A: Scientific opinion of the EFSA GMO Panel (oilseed rape Ms8 x Rf3)
Annex B: Cartagena Protocol (not applicable)
Annex C: Labelling (oilseed rape Ms8 x Rf3)
Annex D1: Validation report (oilseed rape Ms8 x Rf3)
Annex D2a: Validated method (oilseed rape Ms8)
Annex D2b: Validated method (oilseed rape Rf3)
Annex E1: Certified reference materials report (oilseed rape Ms8)
Annex E2: Certified reference materials report (oilseed rape Ms8 and Rf3)
Annex F: Post-market environmental monitoring plan (not applicable)
Annex G: Member States' comments (oilseed rape Ms8 x Rf3)

[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-2007-159