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 application (reference EFSA-GMO-BE-2010-81) for the placing on the market of the genetically modified herbicide-tolerant oilseed rape Ms8, Rf3 and Ms8 x Rf3 for food containing or consisting of, and food produced from or containing ingredients produced from genetically modified oilseed rape Ms8, Rf3 and Ms8 x Rf3 (with the exception of processed oil) under Regulation (EC) No 1829/2003 from Bayer[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 (OSR) Ms8, Rf3 and 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-BE-2010-81 covers genetically modified OSR Ms8, Rf3 and Ms8 x Rf3 for food containing or consisting of, and food produced from or containing ingredients produced from genetically modified OSR Ms8, Rf3 and Ms8 x Rf3 (with the exception of processed oil). 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 OSR Ms8, Rf3 and Ms8 x Rf3 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003. In conclusion, the EFSA GMO Panel considers that the information available for OSR Ms8, Rf3 and Ms8 x Rf3 addresses the scientific comments raised by Member States and that the OSR Ms8, Rf3 and Ms8 x Rf3 are unlikely to have an adverse effect on human and animal health or on the environment, in the content of their intended uses. The European Union Reference Laboratory for GM Food and Feed (EURL-GMFF) considers the method validated as fit for the purpose of regulatory compliance. The certified reference materials of OSR Ms8, Rf3 and Ms8 x Rf3 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.

---

[1] On request from the Competent Authority of Belgium for an application (EFSA-GMO-BE-2010-81) submitted by Bayer, Questions No EFSA-Q-2012-0000794 (EFSA overall opinion) and EFSA-Q-2010-00947 (Scientific opinion of the EFSA GMO Panel), issued on 26 September 2012.

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

For citation purposes: European Food Safety Authority; Overall opinion of the European Food Safety Authority in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003 on application (reference EFSA-GMO-BE-2010-81) for the placing on the market of the genetically modified herbicide-tolerant oilseed rape Ms8, Rf3 and Ms8 x Rf3 for food containing or consisting of, and food produced from or containing ingredients produced from genetically modified oilseed rape Ms8, Rf3 and Ms8 x Rf3 (with the exception of processed oil) under Regulation (EC) No 1829/2003 from Bayer.

Under the terms of the Regulation (EC) No 1829/2003, the overall opinion fulfils the requirements of Articles 6 and 18 for the placing on the market of genetically modified OSR Ms8, Rf3 and Ms8 x Rf3.

KEY WORDS

Overall opinion, GMO, oilseed rape, Ms8, Rf3, Ms8 x Rf3, herbicide tolerant, human and animal health, food, Regulation (EC) No 1829/2003.

TABLE OF CONTENTS

BACKGROUND

On 23 June 2010, the European Food Safety Authority (EFSA) received from the Competent Authority of Belgium an application for authorisation of genetically modified OSR Ms8, Rf3 and Ms8 x Rf3 (ACS-BNØØ5-8, ACS-BNØØ3-6, ACS-BNØØ5-8 x ACS-BNØØ3-6) submitted by Bayer within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (reference EFSA-GMO-BE-2010-81).

The scope of this application EFSA-GMO-BE-2010-81 covers genetically modified OSR Ms8, Rf3 and Ms8 x Rf3 for food containing or consisting of, and food produced from or containing ingredients produced from genetically modified OSR Ms8, Rf3 and Ms8 x Rf3 (with the exception of processed oil). 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[3] on 9 July 2010. 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 European Union Reference Laboratory received the detection method, samples and control samples in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003 on 3 September 2004 and on 22 March 2005. EFSA declared the application valid on 10 May 2011 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 10 August 2011) 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 November 2011 to 11 July 2012.[4]

The overall opinion on application EFSA-GMO-BE-2010-81 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 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

The European Food Safety Authority (EFSA) received from the Competent Authority of Belgium an application for authorisation of genetically modified OSR Ms8, Rf3 and Ms8 x Rf3 (ACS-BNØØ5-8, ACS-BNØØ3-6, ACS-BNØØ5-8 x ACS-BNØØ3-6) submitted by Bayer within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (reference EFSA-GMO-BE-

[3] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2010-00947

[4] Request for additional information from the EFSA GMO Panel: requested (1) on 29/11/2011 - received on 03/04/2012; requested (2) on 25/01/2012 - received on 03/04/2012; requested (3) on 24/05/2012 - received on 29/05/2012 and clock restarted on 11/07/2012.

2010-81). 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

Bayer BioScience NV
Technologiepark 38
B-9052 Gent
Belgium

2. Designation and specification of the product

The scope of this application EFSA-GMO-BE-2010-81 covers genetically modified OSR Ms8, Rf3 and Ms8 x Rf3 for food containing or consisting of, and food produced from or containing ingredients produced from genetically modified OSR Ms8, Rf3 and Ms8 x Rf3 (with the exception of processed oil). The scope does not include cultivation.

In OSR Ms8 the genes *bar* and *barnase* are introduced conferring herbicide tolerance and male sterility, respectively. OSR Rf3 is also herbicide tolerant and expresses a restorer of fertility as a consequence of the introduced genes *bar* and *barstar*. Molecular analysis confirmed that the Ms8 and Rf3 inserts are present and that their structures are retained in OSR Ms8 x Rf3.

3. Scientific opinion of the EFSA GMO Panel

The EFSA GMO Panel has carried out the scientific assessment of the genetically modified OSR 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 6 September 2012. 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 OSR Ms8, Rf3 and Ms8 x Rf3 addresses the scientific comments raised by Member States and that OSR Ms8, Rf3 and Ms8 x Rf3 are unlikely to have an adverse effect on human and animal health or on the environment, in the content of their intended uses (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 Articles 13(2)(a) and 25(2)(c) (Annex C).

6. Method for detection

The European Union Reference Laboratory for GM Food and Feed has carried out an in-house verification study to assess the performance of two quantitative event specific methods on the hybrid OSR lines Ms8, Rf3 and Ms8 x Rf3 which combines the Ms8 and Rf3 transformation events. The two methods have been validated individually on single-trait events, to detect and quantify each event on OSR samples. The reports were issued on 11 January 2007, 15 January 2007 and 21 January 2007. The European Union 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 the Commission Regulation (EC) No 641/2004 (Annexes D1a, D1b, D2a, D2b, D3).

7. Certified reference materials

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

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 Articles 6 and 18 for the placing on the market of genetically modified OSR Ms8, Rf3 and Ms8 x Rf3.

LIST OF ANNEXES[5]

Annex A:	Scientific opinion of the EFSA GMO Panel (oilseed rape Ms8, Rf3 and Ms8 x Rf3)
Annex B:	Cartagena Protocol (oilseed rape Ms8, Rf3 and Ms8 x Rf3)
Annex C:	Labelling (oilseed rape Ms8, Rf3 and Ms8 x Rf3)
Annex D1a:	Validation report (oilseed rape Ms8)
Annex D1b:	Validated method (oilseed rape Ms8)
Annex D2a:	Validation report (oilseed rape Rf3)
Annex D2b:	Validated method (oilseed rape Rf3)
Annex D3:	Validation report (oilseed rape Ms8, Rf3 and Ms8 x Rf3)
Annex D4:	Sampling and extraction (oilseed rape,Rf3)
Annex E1:	Certified reference materials report (oilseed rape Ms8)
Annex E2:	Certified reference materials report (oilseed rape Rf3)
Annex F:	Post-market environmental monitoring plan (oilseed rape Ms8, Rf3 and Ms8 x Rf3)
Annex G:	Member States' comments (oilseed rape Ms8, Rf3 and Ms8 x Rf3)

[5] 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-2012-0000794