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 application (reference EFSA-GMO-UK-2007-49) for the placing on the market of the genetically modified insect resistant and herbicide tolerant maize Bt11 x GA21 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Syngenta Seeds S.A.S.[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 maize Bt11 x GA21 in accordance with the requirements of Articles 6 and 18 of Regulation (EC) No 1829/2003.

The scope of application EFSA-GMO-UK-2007-49 is for food and feed uses, food and feed containing, consisting of or produced from maize Bt11 x GA21. 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 maize Bt11 x GA21 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003 and considers that the genetically modified maize Bt11 x GA21 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 maize Bt11 and GA21 can be accessed the Joint Research Centre of the European Commission, Institute for Reference Materials and Measurements and at the American Oil Chemists' Society (AOCS-USA), respectively.

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 Articles 6 and 18 for the placing on the market of genetically modified maize Bt11 x GA21.

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1 On request from the Competent Authority of the United Kingdom for an application (reference EFSA-GMO-UK-2007-49) submitted by Syngenta Seeds S.A.S., Question No EFSA-Q-2007-195 (EFSA overall opinion) and EFSA-Q-2009-00747 (Scientific opinion of the EFSA GMO Panel), issued on 22 September 2009.

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KEY WORDS

Overall opinion, GMO, maize, *Zea mays*, Bt11 x GA21, insect resistance, herbicide tolerance, risk assessment, food and feed uses, import, processing, food safety, feed safety environmental safety, Regulation (EC) No 1829/2003.

TABLE OF CONTENTS

BACKGROUND

On 14 November 2007, the European Food Safety Authority (EFSA) received from the Competent Authority of the United Kingdom an application for authorisation of GM maize Bt11 x GA21 (SYN-BTØ11-1 x MON-ØØØ21-9) submitted by Syngenta Seeds S.A.S. within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (reference EFSA-GMO-UK-2007-49).

The scope of application EFSA-GMO-UK-2007-49 covers genetically modified maize Bt11 x GA21 for food and feed uses[3], food and feed containing of or consisting from maize Bt11 x GA21.

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 19 November 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. On 9 and 11 November 2007, 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 19 February 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 19 May 2008) within which to make their opinion known.

Making use of the provisions under Articles 6(2) and 18(2), EFSA and the JRC requested additional information from the applicant and the clock was stopped from 26 February 2008 to 16 April 2008, from 24 June 2008 to 19 November 2008, and from 20 February to 9 September 2009[5].

The overall opinion on application EFSA-GMO-UK-2007-49 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 Community Reference Laboratory, including 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.

[3] This does include GM maize Bt11 x GA21 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-2007-195
[5] Request for additional information from the EFSA GMO Panel: requested (1) on 24/06/2008 - received on 06/08/2008, requested (2) on 05/09/2008 - received on 30/09/2008, clock restarted on 19/11/2008, requested (3) on 20/02/2009 – received on 27/02/2009, requested (4) on 01/04/2009 – received on 14/04/2009, requested (5) on 20/05/2009 – received on 17/06/2009, requested (6) on 03/08/2009 – received on 24/08/2009, and clock restarted on 09/09/2009.
Request for additional information from JRC-CRL: requested on 26 February 2008 – received on 3 March 2008, and clock restarted on 16 April 2008

TERMS OF REFERENCE

The European Food Safety Authority (EFSA) received from the Competent Authority of the United Kingdom an application for authorisation of GM maize Bt11 x GA21 (SYN-BTØ11-1 x MON-ØØØ21-9) submitted by Syngenta Seeds S.A.S. within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (reference EFSA-GMO-UK-2007-49). 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

Syngenta Seeds S.A.S.
12, Chemin de l'Hobit
BP 27
F-31790 Saint-Sauveur
France

Syngenta Crop Protection AG
Schwarzwaldallee 215
CH 4058 Basle
Switzerland

2. Designation and specification of the product

The scope of application EFSA-GMO-UK-2007-49 covers genetically modified maize Bt11 x GA21 for food and feed uses[6]. The scope does not include cultivation.

Maize B11xGA21 is produced by crosses between maize inbred lines containing the single events Bt11 and GA21. Maize Bt11 x GA21 expresses i) the Cry1Ab protein to confer resistance to certain lepidopteran pests (Bt11 trait) ii) the PAT protein to confer tolerance to glufosinate-containing herbicides (Bt11 trait) and iii) the mEPSPS protein to confer tolerance to glyphosate-containing herbicides (GA21 trait).

3. Scientific opinion of the EFSA GMO Panel

The EFSA GMO Panel has carried out the scientific assessment of the genetically modified maize Bt11 x GA21 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003 and adopted its scientific opinion on 15 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 maize Bt11 x GA21 addresses the scientific comments raised by the Member States and considers that the genetically modified maize Bt11 x GA21 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

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 that GM maize Bt11 x GA21 is compositionally and phenotypically equivalent to its non-genetically modified maize 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] This does include GM maize Bt11 x GA21 for import and processing as designated under part C of Directive 2001/18/EC.

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 on the hybrid maize line Bt11 x GA21 which combines the Bt11 and GA21 transformation events. The report was published on 7 November 2008. The two methods have been validated individually on single-trait events, to detect and quantify each event in maize samples. 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 maize Bt11 (ERM-BF412) can be accessed at the Joint Research Centre of the European Commission, Institute for Reference Materials and Measurements (Annex E1).The certified reference materials of genetically modified maize GA21 can be accessed at the American Oil Chemists' Society (AOCS-USA) (Annex 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 maize Bt11 x GA21.

LIST OF ANNEXES[7]

Annex A: Scientific opinion of the EFSA GMO Panel (maize Bt11 x GA21)
Annex B: Cartagena Protocol (maize Bt11 x GA21)
Annex C: Labelling (maize Bt11 x GA21)
Annex D1: Validation report (maize Bt11 x GA21)
Annex D2a: Validated method (maize Bt11)
Annex D2b: Validated method (maize GA21)
Annex E1: Certified reference materials report (maize Bt11)
Annex E2: Certified reference materials report (maize GA21)
Annex F: Post-market environmental monitoring plan (maize Bt11 x GA21)
Annex G: Member States' comments (maize Bt11 x GA21)

[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-2007-195