European Food Safety Authority

GMO Unit

Opinion of the European Food Safety Authority in accordance with Articles 6 and 18 of Regulation (EC) No. 1829/2003 on application EFSA-GMO-UK-2005-19 for the placing on the market of glyphosate-tolerant genetically modified maize GA21 for food and feed uses, import and processing and application EFSA-GMO-RX-GA21 for renewal of the authorisation of maize GA21 as existing products in the sense of Articles 8 and 20 of that Regulation (food additives, feed materials and feed additives produced from genetically modified maize GA21) submitted by Syngenta Seeds S.A.S. on behalf of Syngenta Crop Protection AG.

(Questions No. EFSA-Q-2005-226 and EFSA-Q-2007-147)

02 October 2007

Summary

This document provides an overall opinion of the European Food Safety Authority on genetically modified maize GA21 in accordance with the requirements of Articles 6 and 18 of Regulation (EC) No. 1829/2003.

The scope of these applications includes genetically modified maize GA21 for food and feed uses[1], food and feed containing, consisting of or produced from maize GA21. The scope does not include cultivation.

The Scientific Panel on Genetically Modified Organisms has carried out the scientific assessment of genetically modified maize GA21 (applications EFSA-GMO-UK-2005-19 and EFSA-GMO-RX-GA21) in accordance with Articles 6(6) and 18(6) of Regulation (EC) No. 1829/2003 and considers that the GM maize 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 GM maize GA21 can be accessed at the American Oil Chemist's Society (AOCS – USA).

The information presented for the Cartagena Protocol, the labelling proposal and the monitoring plan are 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 GA21.

[1] This does include GM maize for import and processing as designated under part C of Directive 2001/18/EC.

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Background

Application EFSA-GMO-UK-2005-19

On 8 August 2005, the European Food Safety Authority (EFSA) received from the Competent Authority of the United Kingdom an application for authorisation of GM maize GA21 (unique identifier MON-ØØØ21-9) submitted by Syngenta Seeds S.A.S. on behalf of Syngenta Crop Protection AG within the framework of Regulation (EC) No. 1829/2003 on genetically modified food and feed (reference EFSA-GMO-UK-2005-19).

The scope of this application is genetically modified maize GA21 for food and feed uses[2], food and feed containing, consisting of or produced from maize GA21. 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 8 September 2005. 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 1 August 2005, the Community Reference Laboratory (CRL) received 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 7 April 2006 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 6 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 7 July 2006) 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 10 April 2006 to 6 June 2007 [4].

Application EFSA-GMO-RX-GA21

On 29 June 2007, EFSA received from the European Commission an application for renewal of the authorisation of maize GA21 (EFSA-GMO-RX-GA21) (unique identifier MON-ØØØ21-9), submitted by Syngenta Seeds on behalf of Syngenta Crop Protection AG within the framework of Regulation (EC) No. 1829/2003 on genetically modified food and feed.

The scope of this application is renewal of the authorisation of maize GA21 as existing products (food additives, feed materials and feed additives produced from genetically modified maize GA21). The scope does not include cultivation.

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[2] This does include GM maize for import and processing as designated under part C of Directive 2001/18/EC.
[3] http://www.efsa.eu.int/science/gmo/gm_ff_applications/catindex_en.html
[4] Request for additional information from JRC-CRL: requested on 10 April 2006, accepted on 30 May 2007.
Request for additional information from EFSA-GMO Panel: requested on 19 May 2006, remain stopped on 06 July 2006, remain stopped on 07 December 2006, remain stopped on 02 April 2007, accepted on 6 June 2007.

After receiving the application EFSA-GMO-RX-GA21 and in accordance with Articles 5(2)(b) and 17(2)b of Regulation (EC) No 1829/2003, EFSA informed the Member States and the European Commission and made the summary of the dossier available to the public on the EFSA website.
EFSA initiated a formal review of the application to check compliance with the requirements laid down in Articles 5(3), 5(5), 17(3), 17(5) as well as 11(2) and 23(2) of Regulation (EC) No. 1829/2003. On 6 September 2007, EFSA declared the application as valid in accordance with Articles 6(1) and 18(1) of Regulation (EC) No. 1829/2003.

All data required for the risk assessment of the application EFSA-GMO-RX-GA21 have also been provided in application EFSA-GMO-UK-2005-19.

The GMO Panel performed one single comprehensive risk assessment for all intended uses of genetically modified maize GA21 and issued a single comprehensive scientific opinion for both applications submitted under Regulation (EC) No. 1829/2003.

The overall opinion on applications EFSA-GMO-UK-2005-19 and EFSA-GMO-RX-GA21 includes the scientific opinion of the Scientific Panel on Genetically Modified Organisms (GMO Panel) 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 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) Member States' comments submitted during the three-month consultation period.

Applicant

The application was submitted by
Syngenta Seeds S.A.S.
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PO Box 27
31790 saint-Sauveur
France

On behalf of Syngenta Crop Protection AG, Basel Switzerland and all affiliated companies
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Switzerland

Designation and specification of the product

The scope of these applications is genetically modified maize GA21 for food and feed uses[5], food and feed containing, consisting of or produced from GM maize GA21.

Genetically modified maize GA21 expresses a modified EPSPS (5-enol pyruvylshikimate-3-phosphate synthetase) protein that confer tolerance to glyphosate.

[5] This does include GM maize for import and processing as designated under part C of Directive 2001/18/EC.

Scientific opinion of the GMO Panel

The GMO Panel has carried out the scientific assessment of the genetically modified maize GA21 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No. 1829/2003 and adopted its scientific opinion on 13 September 2007. The 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 GMO Panel concludes that the information available for GM maize GA21 addresses the scientific comments raised by the Member States and considers that GM maize 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).

Cartagena Protocol

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

Labelling

The labelling proposal provided in these applications is in line with the requirements in Regulation (EC) No. 1829/2003. On the basis of the scientific opinion of the GMO Panel that GM maize GA21 is compositionally and phenotypically equivalent to its non-genetically modified maize except for the introduced trait, 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).

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 GA21 transformation event in maize DNA. The reports were published on 7 September 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).

Certified reference materials

The certified reference materials of genetically modified maize GA21 can be accessed at American Oil Chemist's Society (AOCS – USA). The reports were published on 14 September 2007 (Annexes E1, E2, E3).

Post market environmental monitoring

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

Member States' Comments

In line with the procedure[6] adopted by EFSA, the GMO Panel has addressed the comments submitted by the Member States during the three months consultation period (Annex G).

List of annexes:

Annex A: Scientific opinion of the GMO Panel (maize GA21)
Annex B: Cartagena Protocol (maize GA21)
Annex C: Labelling (maize GA21)
Annex D1: Validation report (maize GA21)
Annex D2: Validated method (maize GA21)
Annex D3: Sampling and extraction (maize GA21)
Annex E1: Certified reference materials report (maize GA21)
Annex E2: Certified reference materials (maize GA21)
Annex E3: Certified reference materials (maize GA21)
Annex F: Monitoring plan (maize GA21)
Annex G: Member States' comments (maize GA21)

[6] EFSA Strategy document
http://www.efsa.europa.eu/etc/medialib/efsa/science/gmo/109.Par.0010.File.dat/gmo_actionplan1.pdf