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-RX-Bt11

Application for renewal of the authorisation of existing products produced from insect-resistant genetically modified maize Bt11, under Regulation (EC) No. 1829/2003 from Syngenta

(Question No. EFSA-Q-2007-146)

17 February 2009

Summary

This document provides an overall opinion of the European Food Safety Authority on genetically modified maize Bt11 in accordance with the requirements of Articles 6 and 18 of Regulation (EC) No. 1829/2003.

The scope of this application covers the continued marketing of existing food and food ingredients containing, consisting of or produced from maize Bt11, food additives produced from maize Bt11, feed containing, consisting of or produced from maize Bt11 (feed materials and feed additives) to be used as any other maize grain but not for cultivation, and other products containing or consisting of maize Bt11 with the exception of cultivation 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 has carried out the scientific assessment of genetically modified maize Bt11 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No. 1829/2003 and considers that the genetically modified maize Bt11 is unlikely to have any adverse effect on human and animal health or on the environment in the context of its intended uses. This also applies to the products which are the subject of the present application.

The Community Reference Laboratory considers the method validated as fit for the purpose of regulatory compliance. The certified reference materials of maize Bt11 can be accessed at the Joint Research Centre of the European Commission, Institute for Reference Materials and Measurements.

The information presented for the Cartagena Protocol, the labelling proposal and the monitoring plan are in line with Regulation (EC) No. 1829/2003.

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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 genetically modified maize Bt11 and derived products.

Background

On 29 June 2007, the European Food Safety Authority (EFSA) received from the European Commission an application for renewal of the authorisation of existing products produced from insect-resistant genetically modified maize Bt11 (SYN-BT Ø11-1) submitted by Syngenta within the framework of Regulation (EC) No. 1829/2003 on genetically modified food and feed (reference EFSA-GMO-RX-Bt11).

The scope of this application covers the continued marketing of existing food and food ingredients containing, consisting of or produced from maize Bt11, food additives produced from maize Bt11, feed containing, consisting of or produced from maize Bt11 (feed materials and feed additives) to be used as any other maize grain but not for cultivation, and other products containing or consisting of maize Bt11 with the exception of cultivation 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[2]. 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 20 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. On 18 April 2005 and 21 July 2005, 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 17 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 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 17 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 15 July 2008 to 19 November 2008 [4].

[2] http://ec.europa.eu/food/dyna/gm_register/gm_register_auth.cfm?pr_id=1
[3] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2007-146
[4] Request for additional information from EFSA-GMO Panel: requested (1) on 15/07/2008 - received on 06/08/2008, requested (2) on 05/09/2008 - received on 28/10/2008

The overall opinion on application EFSA-GMO-RX-Bt11 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.
12, Chemin de l'Hobit
BP 27
Saint-Sauveur
France

Syngenta Crop Protection AG
Schwarzwaldallee 215
CH 4058 Basel
Switzerland

Designation and specification of the product

The scope of this application covers the continued marketing of existing food and food ingredients containing, consisting of or produced from maize Bt11, food additives produced from maize Bt11, feed containing, consisting of or produced from maize Bt11 (feed materials and feed additives) to be used as any other maize grain but not for cultivation, and other products containing or consisting of maize Bt11 with the exception of cultivation 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[5]. The scope does not include cultivation.

Genetically modified maize Bt11 expresses the Cry1Ab protein to provide protection against specific lepidopteran pests. The maize also expresses the PAT protein to provide tolerance to the herbicide glufosinate ammonium.

Scientific opinion of the GMO Panel

The GMO Panel has carried out the scientific assessment of the genetically modified maize Bt11 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No. 1829/2003 and adopted its scientific opinion on 28 January 2009. 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 Bt11 addresses the scientific comments raised by the Member States and considers that GM maize Bt11 is unlikely to have any adverse effect on human and animal health or the environment in the context of its intended uses (Annex A).

[5] http://ec.europa.eu/food/dyna/gm_register/gm_register_auth.cfm?pr_id=1

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 GMO Panel (Annex B).

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 GMO Panel that GM maize Bt11 is compositionally and phenotypically equivalent to its non-genetically modified maize Bt11 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).

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 Bt11 transformation event in maize DNA. 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 Bt11 (ERM-BF412) can be accessed at the Joint Research Centre of the European Commission, Institute for Reference Materials and Measurements (Annex E).

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

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 Bt11)
Annex B:	Cartagena Protocol (maize Bt11)
Annex C:	Labelling (maize Bt11)
Annex D1:	Validation report (maize Bt11)
Annex D2:	Validated method (maize Bt11)
Annex D3:	Sampling and extraction (maize Bt11)

Annex E: Certified reference materials report (maize Bt11)
Annex F: Post market monitoring plan (maize Bt11)
Annex G: Member States' comments (maize Bt11)