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-NL-2005-12

Application for the placing on the market of insect-resistant genetically modified maize 59122 for food and feed uses from Pioneer Hi-Bred International, Inc. and Mycogen Seeds, c/o Dow Agrosciences LLC.

(Question No. EFSA-Q-2005-045)

30 March 2007

Summary

This document provides an overall opinion of the European Food Safety Authority on genetically modified maize 59122 in accordance with the requirements of Articles 6 and 18 of Regulation (EC) No. 1829/2003.

The scope of this application is genetically modified maize 59122 for food and feed uses[1], food and feed containing, consisting of or produced from maize 59122. The scope does not include cultivation.

The Scientific Panel on Genetically Modified Organisms has carried out the scientific assessment of genetically modified maize 59122 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No. 1829/2003 and considers that the maize 59122 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 that the method validated as fit for the purpose of regulatory compliance. The certified reference materials of maize 59122 can be accessed at the Joint Research Centre, 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.

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 59122.

[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

On 26 January 2005, the European Food Safety Authority (EFSA) received from the Dutch Competent Authority an application for authorisation of GM maize 59122 (unique identifier DAS-59122-7) submitted jointly by Pioneer Hi-Bred and Mycogen Seeds within the framework of Regulation (EC) No. 1829/2003 on genetically modified food and feed (reference EFSA-GMO-NL-2005-12).

The scope of this application is genetically modified maize 59122 for food and feed uses[2], food and feed containing, consisting of or produced from maize 59122. 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 17 February 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 07 April 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 16 September 2005 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 16 December 2005) 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 February 2006 to 16 February 2007[4].

The overall opinion on application EFSA-GMO-NL-2005-12 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,

[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 EFSA-GMO Panel: requested on 10/02/2006, remain stopped on 24/05/2006, 12/07/2006, 26/01/2007, accepted on 17/02/2007.

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 jointly submitted by Pioneer Hi-Breed International, Inc. and Mycogen Seeds.

Pioneer Hi-Bred International, Inc.
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Johnston, IA 50131-0552, USA
Represented by: Pioneer Overseas Corporation
Avenue des Arts, 44
B-1040 Brussels, Brussels

Mycogen Seeds
9330 Zionsville Road
Indianapolis, IN 46268-1054, USA
Represented by: Dow AgroSciences
2nd Floor, 3 Milton Park
Oxon OX14 4 RN, United Kingdom

Designation and specification of the product

The scope of this application is genetically modified maize 59122 for food and feed uses[5], food and feed containing, consisting of or produced from GM maize 59122.

Genetically modified maize 59122 expresses the CRY34Ab1 and CRY35Ab1 proteins from *Bacillus thuringiensis* to confer tolerance to certain coleopteran pests such as the western corn rootworm larvae (*Diabrotica virgifera virgifera* LeConte) and expresses the phosphinothricin-N-acetyltransferase (PAT) enzyme from *Streptomyces viridochromogenes* to confer tolerance to glufosinate-containing herbicides.

Scientific opinion of the GMO Panel

The GMO Panel has carried out the scientific assessment of the genetically modified maize 59122 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No. 1829/2003 and adopted its scientific opinion on 23 March 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 59122 addresses the scientific comments raised by the Member States and considers that GM maize 59122 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 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).

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

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 59122 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).

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 59122 transformation event in maize DNA. The reports were published on 6 October 2005. The Community Reference Laboratory considers the method validated as fit for the purpose of regulatory compliance (Annexes D1, D2, D3).

Certified reference materials

The certified reference materials of genetically modified maize 59122 (ERM-BF424) can be accessed at the Joint Research Centre (JRC-IRMM) of the European Commission (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

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
Annex B:	Cartagena Protocol
Annex C:	Labelling
Annex D1:	Validation report (maize 59122)
Annex D2:	Validated method (maize 59122)
Annex D3:	Sampling and extraction (maize 59122)
Annex E:	Certified reference materials
Annex F:	Monitoring plan
Annex G:	Member States' comments

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