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-2005-15

Application for the placing on the market of insect-resistant and herbicide-tolerant genetically modified maize 1507 x 59122 for food and feed uses from Dow AgroSciences and Pioneer Hi-Bred International, Inc.

(Question No. EFSA-Q-2005-123)

6 May 2009

Summary

This document provides an overall opinion of the European Food Safety Authority on genetically modified maize 1507 x 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 1507 x 59122 for food and feed uses[1], food and feed containing, consisting of or produced from maize 1507 x 59122. The scope does not include cultivation.

The Scientific Panel on Genetically Modified Organisms has carried out the scientific assessment of genetically modified maize 1507 x 59122 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003 and considers that the genetically modified maize 1507 x 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 the method validated as fit for the purpose of regulatory compliance. The certified reference materials of maize 1507 and 59122 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.

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 1507 x 59122.

[1] This does include GM maize 1507 x 59122 for import and processing as designated under part C of Directive 2001/18/EC.

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Background

On 30 May 2005, the European Food Safety Authority (EFSA) received from the Competent Authority of The Netherlands an application for authorisation of GM maize 1507 x 59122 (DAS-Ø15Ø7-1xDAS-59122-7) submitted by Dow AgroSciences and Pioneer Hi-Bred International, Inc. within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (reference EFSA-GMO-NL-2005-15).

The scope of this application is genetically modified maize 1507 x 59122 for food and feed uses[2], food and feed containing, consisting of or produced from maize 1507 x 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 2 June 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 11 and 19 April 2005 and 14 March 2006, 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 13 July 2007 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 13 October 2007) 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 24 October 2007 to 06 March 2009 [4].

The overall opinion on application EFSA-GMO-NL-2005-15 includes the scientific opinion of the Scientific Panel on Genetically Modified Organisms (GMO Panel) together with the particulars

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[2] This does include maize 1507 x 59122 for import and processing as designated under part C of Directive 2001/18/EC.

[3] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2005-123

[4] Request for additional information from EFSA-GMO Panel: requested (1) on 24/10/2007 - received on 30/11/2007, requested (2) on 14/12/2007 - received on 14/02/2008, requested (3) on 18/04/2008 - received on 24/04/2008, requested (4) on 31/07/2008 - received on 17/09/2008, and clock restarted on 06/03/2009.

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, vii) the monitoring plan and viii) Member States' comments submitted during the three-month consultation period.

Applicant

The application was submitted by

Dow AgroSciences Europe
European Development Centre
3 Milton Park, Abingdon
Oxon OX14 4RN
United Kingdom

Mycogen Seeds
c/o Dow AgroSciences LLC
9330 Zionsville Road
Indianapolis, IN 46268-1054
U.S.A.

Pioneer Overseas Corporation
Avenue des Arts, 44
B-1040 Brussels
Belgium

Pioneer Hi-Bred International, Inc
7100 NW 62nd Avenue
P.O. Box 1014
Johnston, IA 50131-1014, U.S.A.

Designation and specification of the product

The scope of this application is genetically modified maize 1507 x 59122 for food and feed uses[5], food and feed containing, consisting of or produced from GM maize 1507 x 59122. The scope does not include cultivation.

Genetically modified maize 1507 x 59122 expresses i) the Cry1F protein to confer resistance to certain lepidopteran pests, ii) the Cry34Ab1, Cry35Ab1 proteins to confer resistance to certain coleopteran pests and iii) the PAT proteins to confer tolerance to glufosinate-ammonium herbicide.

Scientific opinion of the GMO Panel

The GMO Panel has carried out the scientific assessment of the genetically modified maize 1507 x 59122 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003 and adopted its scientific opinion on 21 April 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 1507 x 59122 addresses the scientific comments raised by the Member States and considers that GM maize 1507 x 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).

[5] This does include GM maize 1507 x 59122 for import and processing as designated under part C of Directive 2001/18/EC

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 1507 x 59122 is compositionally and phenotypically equivalent to its non-genetically modified maize 1507 x 59122 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 an in-house verification study to assess the performance of two quantitative event specific methods on the hybrid maize line 1507 x 59122 which combines the 1507 and 59122 transformation events. The reports were published on 9 March 2005, 11 October 2005 and 12 June 2006. The Community Reference Laboratory considers that the methods are applicable in accordance with the requirements of Annex I-2.C.2. to Commission Regulation (EC) No 641/2004 (Annexes D1, D2a, D2b).

Certified reference materials

The certified reference materials of genetically modified maize 1507 (ERM-BF418) and 59122 (ERM-BF424) can be accessed at the Joint Research Centre of the European Commission, Institute for Reference Materials and Measurements (Annexes E1, E2).

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 1507 x 59122)
Annex B:	Cartagena Protocol (maize 1507 x 59122)
Annex C:	Labelling (maize 1507 x 59122)
Annex D1:	Validation report (maize 1507 x 59122)
Annex D2a:	Validated method (maize 1507)

Annex D2b: Validated method (maize 59122)
Annex E1: Certified reference materials report (maize 1507)
Annex E2: Certified reference materials report (maize 59122)
Annex F: Post market monitoring plan (maize 1507 x 59122)
Annex G: Member States' comments (maize 1507 x 59122)