European Food Safety Authority

EFSA Scientific Report (2009) 309, 1-8

TECHNICAL REPORT OF EFSA

Overall opinion of the European Food Safety Authority in accordance with Article 18 of Regulation (EC) No 1829/2003 on application EFSA-GMO-RX-1507 for renewal of the authorisation of existing products produced from insect resistant and herbicide tolerant genetically modified maize 1507 for feed uses from Pioneer Hi-Bred International, Inc. and Mycogen Seeds[1]

Report of the GMO Unit

(Question No EFSA-Q-2007-144)

Issued on 11 June 2009

SUMMARY

This document provides an overall opinion of the European Food Safety Authority on genetically modified maize 1507 in accordance with the requirements of Article 18 of Regulation (EC) No 1829/2003.

The scope of this application covers the continued marketing of existing feed produced from maize 1507 (feed materials and feed additives) 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 Panel on Genetically Modified Organisms (EFSA GMO Panel) has carried out the scientific assessment of genetically modified maize 1507 in accordance with Article 18(6) of Regulation (EC) No 1829/2003 and considers that the genetically modified maize 1507 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 1507 can be accessed at the Joint Research Centre of the European Commission, Institute for Reference Materials and Measurements.

The information presented for the labelling proposal 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 Article 18 for the renewal of authorisation of genetically modified maize 1507 and derived products.

[1] For citation purposes: Technical report of EFSA prepared by the GMO Unit on application EFSA-GMO-RX-1507 for renewal of the authorisation of existing products produced from insect resistant and herbicide tolerant genetically modified maize 1507 for feed uses from Pioneer Hi-Bred International, Inc. and Mycogen Seeds. ***EFSA Scientific Report*** (2009) 309, 1-8.

Key words: overall opinion, GMO, maize, *Zea mays*, 1507, insect protection, Cry1F, PAT, feed safety, animal health, Regulation (EC) No 1829/2003, renewal, existing product.

TABLE OF CONTENTS

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 genetically modified maize 1507 (DAS-Ø15Ø7-1) submitted by Pioneer Hi-Bred International, Inc. and Mycogen Seeds within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (reference EFSA-GMO-RX-1507).

The scope of this application covers the continued marketing of existing feed produced from maize 1507 (feed materials and feed additives) 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.

In accordance with Article 17 of Regulation (EC) No 1829/2003, EFSA informed the Member States and made the summary of the application publicly available on the EFSA website[2] on 3 July 2007. EFSA initiated a completeness check of the application to check compliance with the requirements laid down in Article 17 of Regulation (EC) No 1829/2003. On 7 June 2004 and 7 July 2004, the Community Reference Laboratory (CRL) confirmed receipt of the detection method, samples and control samples in accordance with Article 17 of Regulation (EC) No 1829/2003. EFSA declared the application valid on 15 April 2008 and started the clock in accordance with Article 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 (Article 18(1)). EFSA made the valid application available to Member States and the European Commission. Following the procedure laid down in Article 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 15 July 2008) within which to make their opinion known.

Making use of the provisions under Article 18(2), EFSA requested additional information from the applicant and the clock was stopped from 24 April 2008 to 3 March 2009 [3].

The EFSA overall opinion on application EFSA-GMO-RX-1507 includes the scientific opinion of the Panel on Genetically Modified Organisms together with the particulars required under Article 18(5) 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 labelling proposal, iv) 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, v) an indication of where appropriate reference materials can be accessed, and vi) the Member States' comments submitted during the three-month consultation period.

TERMS OF REFERENCE

EFSA received from the European Commission an application, submitted by Pioneer International, Inc. and Mycogen Seeds under Article 20(4) of Regulation (EC) No 1829/2003, for the renewal of authorisation of existing products derived from maize 1507 (EFSA-GMO-RX-1507) for feed use

[2] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2007-144

[3] Request for additional information from EFSA-GMO Panel: requested (1) on 24/04/2008 - received on 03/09/2008, requested (2) on 19/09/2008 - received on 06/10/2008, requested (3) on 06/11/2008 - received on 22/12/2008, and clock restarted on 03/03/2009.

which were notified according to Article 20(1)(b) of Regulation (EC) No 1829/2003. EFSA was requested to issue an overall opinion in line with the requirements of the Regulation (EC) No 1829/2003 (Article 18).

ACKNOWLEDGEMENTS

This technical report was prepared by the GMO Unit. The European Food Safety Authority wishes to thank the members of its staff Christina Ehlert and Karine Lheureux for the preparation of this report.

RESULTS

1. Applicants

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.

2. Designation and specification of the product

The scope of this application covers the continued marketing of existing feed produced from maize 1507 (feed materials and feed additives) 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.

Genetically modified maize 1507 expresses the Cry1F protein to confer resistance to certain lepidopteran pests and the PAT protein to confer tolerance to glufosinate-ammonium herbicides.

3. Scientific opinion of the EFSA GMO Panel

The EFSA GMO Panel has carried out the scientific assessment of the genetically modified maize 1507 in accordance with Article 18(6) of Regulation (EC) No 1829/2003 and adopted its scientific opinion on 28 May 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 1507 addresses the scientific comments raised by the Member States and considers that GM maize 1507 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 (not applicable)

Due to the scope of the application, there are no requirements for a Cartagena Protocol.

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 1507 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 Article 25(2)(c) (Annex C).

6. 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 1507 transformation event in maize DNA. The reports were published on 15 February 2005. 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).

7. Certified reference materials

The certified reference materials of maize 1507 (ERM-BF418) can be accessed at the Joint Research Centre of the European Commission, Institute for Reference Materials and Measurements (Annex E).

8. Post-market environmental monitoring (not applicable)

Due to the scope of the application, there are no requirements for a post-market environmental monitoring plan for maize 1507.

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 Article 18 for the renewal of authorisation of genetically modified maize 1507 and derived products.

LIST OF ANNEXES

Annex A: Scientific opinion of the EFSA GMO Panel (maize 1507)
Annex B: (not applicable)
Annex C: Labelling (maize 1507)
Annex D1: Validation report (maize 1507)
Annex D2: Validated method (maize 1507)
Annex D3: Sampling and extraction (maize 1507)
Annex E: Certified reference materials report (maize 1507)
Annex F: (not applicable)
Annex G: Member States' comments (maize 1507)