Overall opinion of the European Food Safety Authority on an application for renewal of authorisation for continued marketing of maize 1507 and derived food and feed submitted under articles 11 and 23 of Regulation (EC) No 1829/2003[1] by Pioneer Overseas Corporation and Dow AgroSciences LLC[2]

European Food Safety Authority[3]

Summary

This document provides an overall opinion of the European Food Safety Authority on the insect resistant and herbicide tolerant genetically modified (GM) maize 1507 in accordance with the requirements of Articles 6 and 18 of Regulation (EC) No 1829/2003.

The scope of renewal application EFSA-GMO-RX-001 is for food and feed uses, import and processing, but excludes cultivation within the European Union (EU).

At the time of submission of the renewal application EFSA-GMO-RX-001, no EFSA Guidance document was in place to assist the applicant in the preparation and presentation of their renewal application. Therefore, the applicant submitted data in accordance with Articles 11 and 23 of Regulation (EC) No 1829/2003. At the time EFSA validated renewal application EFSA-GMO-RX-001, the 'Guidance for renewal applications of genetically modified food and feed authorised under Regulation (EC) No 1829/2003' (EFSA GMO Panel, 2015) was published and the GMO Panel requested the applicant to update the data package to be in line with these guidelines.

The Scientific Panel on Genetically Modified Organisms (GMO Panel) has carried out the scientific assessment of genetically modified maize 1507 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003. In delivering its scientific opinion, the GMO Panel took into account application EFSA-GMO-RX-001, additional information provided by the applicant, scientific comments submitted by the Member States and relevant scientific publications. The data package received in the frame of the renewal application EFSA-GMO-RX-001 contained: post-market environmental monitoring reports, systematic search and evaluation of literature, updated bioinformatics analyses and additional documents or studies performed by or on behalf of the applicant. The GMO Panel assessed this data package for possible new hazards, modified exposure or new scientific uncertainties identified during the authorisation period and not previously assessed in the frame of the original application.

In conclusion, under the assumption that the DNA sequence of the event in maize 1507 considered for renewal is identical to the corrected sequence of the originally assessed event, the GMO Panel concludes that no new hazards or modified exposure and no new scientific uncertainties were identified for the application for renewal that would change the conclusions of the original risk assessment on maize 1507 (EFSA, 2005b, 2009).

The European Union Reference Laboratory for Genetically Modified Food and Feed (EURL-GMFF) 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 (JRC-IRMM).

[1] Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed. OJ L 268, 18.10.2003, p. 1–23

[2] On request from the European Commission for an application (EFSA-GMO-RX-001) submitted by Pioneer Overseas Corporation and Dow AgroSciences LLC, Questions No EFSA-Q-2016-00817 (EFSA overall opinion) and EFSA-Q-2015-00342 (Scientific opinion of the GMO Panel), issued on 12 January 2017.

The GMO Panel was not requested to give an opinion on information required under Annex II to the Cartagena Protocol. Furthermore, the GMO Panel did not consider proposals for labelling and methods of detection (including sampling and the identification of the specific transformation event in the food/feed and/or food/feed produced from it), which are matters related to risk management.

The GMO Panel is of the opinion that the PMEM plan and the general surveillance system implemented by the applicant is in line with the principles and objectives outlined in Annex VII of Directive 2001/18/EC and Decision 2002/811/EC establishing guidance notes supplementing Annex VII to Directive 2001/18/EC.

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.

Key words: Maize 1507, renewal, GMO, overall opinion, Articles 11 and 23, Regulation (EC) No 1829/2003

Requestor: European Commission (DG SANTE)

Question number: EFSA-Q-2015-00342

Correspondence: GMO@efsa.europa.eu

Panel members: Hanspeter Naegeli, Andrew Nicholas Birch, Josep Casacuberta, Adinda De Schrijver, Mikołaj Antoni Gralak, Philippe Guerche, Huw Jones, Barbara Manachini, Antoine Messéan, Elsa Ebbesen Nielsen, Fabien Nogué, Christophe Robaglia, Nils Rostoks, Jeremy Sweet, Christoph Tebbe, Francesco Visioli, Jean-Michel Wal.

Acknowledgements: The Panel wishes to thank the members of its standing Working Groups on Molecular Characterisation, Food and Feed Safety Assessment and Environmental Risk Assessment for the preparatory work on the Scientific opinion, and EFSA staff members: Fernando Álvarez, Michele Ardizzone, Sylvie Mestdagh and Matthew Ramon for the support provided to this scientific output

Suggested citation: EFSA (European Food Safety Authority), 2017. Overall opinion of the European Food Safety Authority on an application for renewal of authorisation for continued marketing of maize 1507 and derived food and feed submitted under Articles 11 and 23 of Regulation (EC) No 1829/2003 by Pioneer Overseas Corporation and Dow AgroSciences LLC. EFSA supporting publication 2017:EN-1161. 11 pp.

Table of contents

1. Introduction

1.1. Background as provided by the European Commission

On 18 May 2015, the European Food Safety Authority (EFSA) received from the European Commission an application for renewal (reference EFSA-GMO-RX-001) of the authorisation for continued marketing of existing products derived from maize 1507 (DAS-Ø15Ø7-1) submitted by Pioneer Overseas Corporation and Dow AgroSciences LLC within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed.

The scope of application EFSA-GMO-RX-001 covers the continued marketing of existing maize 1507 which was 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.[4] The scope does not include cultivation.

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 application publicly available on the EFSA website.[5] EFSA initiated a completeness check of the application to check compliance with the requirements laid down in Articles 5(3) and 17(3) of Regulation (EC) No 1829/2003. On 7 June and 7 July 2004, the EURL-GMFF 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 3 July 2015 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 six 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[6], were given three months after the date of receipt of the valid application (*i.e.* until 7 October 2015) within which to make their opinion known.

Following the submission of notifications and applications C/NL/00/10, C/ES/01/01, EFSA-GMO-NL-2004-02 and EFSA-GMO-RX-1507 and the publication of EFSA scientific opinions (EFSA 2004, 2005a, 2005b, 2009), the placing on the market of maize 1507 for food/feed uses, except cultivation, was authorised by Commission Decisions 2005/772/EC[7], 2006/197/EC[8] and 2011/365/EU[9]. A copy of these authorisations was provided by the applicant.[10]

[4] http://ec.europa.eu/food/dyna/gm_register/gm_register_auth.cfm?pr_id=2

[5] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00342

[6] Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC. OJ L 106, 12.3.2001, p. 1–38

[7] Commission Decision of 3 November 2005 concerning the placing on the market, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of a maize product (Zea mays L., line 1507) genetically modified for resistance to certain lepidopteran pests and for tolerance to the herbicide glufosinate-ammonium. OJ L 291, 5.11.2005, p. 42–44.

[8] Commission Decision of 3 March 2006 authorising the placing on the market of food containing, consisting of, or produced from genetically modified maize line 1507 (DAS-Ø15Ø7-1) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council. OJ L 70, 9.3.2006, p. 82–86.

[9] Commission Decision of 17 June 2011 amending Decision 2006/197/EC as regards the renewal of the authorisation to place on the market existing feed produced from genetically modified maize line 1507 (DAS-Ø15Ø7-1) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council. OJ L 163, 23.6.2011, p. 52–54.

[10] Dossier: Part II – Section 1.

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 July 2015 to 18 March 2016 and from 25 April 2016 to 10 October 2016.[11]

The overall opinion on application EFSA-GMO-RX-001 includes the scientific opinion of the Scientific Panel on Genetically Modified Organisms together with the particulars required under Articles 6 and 18 of Regulation (EC) No 1829/2003: i) the name and address of the applicant, ii) the designation of the food and its specification, iiii) the labelling proposal, iv) the method for detection, validated by the EURL-GMFF, 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.

1.1. Terms of Reference as provided by EC (DG SANTE)

The European Food Safety Authority (EFSA) received from the European Commission an application for renewal of the authorisation for continued marketing of existing products derived from maize 1507 (Unique identifier DAS-Ø15Ø7-1) submitted by Pioneer Overseas Corporation and Dow AgroSciences LLC within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (reference EFSA-GMO-RX-001). EFSA was requested to issue an overall opinion in line with the requirements of the Regulation (EC) No 1829/2003 (Articles 6 and 18).

[11] Request for additional information from the GMO Panel: Requested(1) on 10/07/2015 - received on 19/10/2015, requested(2) on 21/07/2015 - received on 21/09/2015, requested(3) on 11/12/2015 – received on 12/02/2016, requested(4) on 18/12/2015-– received on 18/03/2016, requested(5) on 11/01/2016 – received on 11/03/2016 and clock re-started on 18/03/2016; requested(6) on 25/04/2016 – received 10/10/2016, requested(7) on 13/05/2016 – received on 11/07/2016 and clock re-started on 10/10/2016.

2. Considerations

2.1. Applicant

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

Dow AgroSciences LLC
Avenue des Arts, 44
1040 Brussels
Belgium

And

Dow AgroSciences LLC
9330 Zionsville Road
Indianapolis, Indiana 46268-1054
U.S.A.

(previously Mycogen Seeds
c/o Dow AgroSciences LLC)

Dow AgroSciences Ltd
European Development Center
3B Park Square
Milton Park, Abingdon
Oxon OX14 4RN
United Kingdom

2.1. Designation and specification of the product

The scope of renewal application EFSA-GMO-RX-001 is for food and feed uses, import and processing, but excludes cultivation within the European Union (EU).

Maize 1507 carries genes encoding for Cry1F and PAT proteins. The Cry1F protein acts to protect against certain lepidopteran pests, such as the European corn borer (ECB, *Ostrinia nubilalis* Hübner), which are major insect pests of maize in agriculture. Maize 1507 also expresses the PAT protein, used as a selectable marker during transformation, which confers tolerance to the application of glufosinate-ammonium herbicide.

3. Scientific opinion of the GMO Panel

The GMO Panel has carried out the scientific assessment of the genetically modified maize 1507 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003 and adopted its scientific opinion on 30 November 2016. In delivering its scientific opinion, the GMO Panel took into account application EFSA-GMO-RX-001, additional information provided by the applicant, scientific comments submitted by the Member States and relevant scientific publications. The data package received in the frame of the renewal application EFSA-GMO-RX-001 contained: post-market environmental monitoring reports, systematic search and evaluation of literature, updated bioinformatics analyses and additional documents or studies performed by or on behalf of the applicant. The GMO Panel assessed this data package for possible new hazards, modified exposure or new scientific uncertainties identified during the authorisation period and not previously assessed in the frame of the original application.

In conclusion, under the assumption that the DNA sequence of the event in maize 1507 considered for renewal is identical to the corrected sequence of the originally assessed event, the GMO Panel concludes that no new hazards or modified exposure and no new scientific uncertainties were identified for the application for renewal that would change the conclusions of the original risk assessment on maize 1507 (EFSA, 2005b, 2009) (Annex A).

4. Cartagena Protocol

The GMO Panel was not requested to give an opinion on information required under Annex II to the Cartagena Protocol. Furthermore, the GMO Panel did not consider proposals for labelling and methods of detection (including sampling and the identification of the specific transformation event in the food/feed and/or food/feed produced from it), which are matters related to risk management (Annex B).

5. Labelling

The labelling proposal provided in the application is in line with the requirements in Regulation (EC) No 1829/2003 (Annex C).

6. Method for detection, sampling and identification and reference material

The EURL-GMFF has carried out a collaborative study to assess the performance of a quantitative event-specific method to detect and quantify the maize 1507 transformation event in maize DNA. The EURL-GMFF 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 (Annex D).

7. Post-market environmental monitoring

The applicant indicated in the dossier that the environmental monitoring plan was appropriate and does not need any changes to the conditions of release and use as laid down in the initial authorisation. The GMO Panel is of the opinion that the PMEM plan and the general surveillance system implemented by the applicant is in line with the principles and objectives outlined in Annex VII of Directive 2001/18/EC and Decision 2002/811/EC establishing guidance notes supplementing Annex VII to Directive 2001/18/EC (Annex E).

8. Member States' Comments

The GMO Panel has addressed the comments submitted by the Member States during the three-month consultation period (Annex F).

9. Conclusions

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 maize 1507 for food and feed uses, import and processing excluding cultivation within the EU.

List of Annexes[12]

Annex A: Scientific opinion of the GMO Panel (maize 1507)

Annex B: Cartagena protocol (maize 1507)

Annex C: Labelling (maize 1507)

Annex D: Methods of detection, sampling and identification and reference material (maize 1507)

Annex E: Certified reference materials report (maize 1507)

Annex F: Member States comments (maize 1507)

[12] The annexes of the EFSA overall opinion can be found in the Register of Questions (tab "Question documents") on the EFSA website under the following link: http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00817