TECHNICAL REPORT

Overall opinion of the European Food Safety Authority in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003 on application (reference EFSA-GMO-UK-2008-53) for the placing on the market of herbicide tolerant genetically modified maize 98140 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Pioneer[1]

European Food Safety Authority[2]

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

This document provides an overall opinion of the European Food Safety Authority on genetically modified maize 98140 in accordance with the requirements of Articles 6 and 18 of Regulation (EC) No 1829/2003.

The scope of this application EFSA-GMO-UK-2008-53 is for food and feed uses, import and processing. The scope does not include cultivation.

The Scientific Panel on Genetically Modified Organisms (EFSA GMO Panel) has carried out the scientific assessment of genetically modified maize 98140 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003. The EFSA GMO Panel considers that the information available for maize 98140 does not address sufficiently all the scientific issues indicated by the Guidance Document of the EFSA GMO Panel. In this application the minimum standards for the design of field trials set in EFSA GMO Panel the Guidance Document were not met and therefore the EFSA GMO Panel cannot conclude on the comparative assessment of compositional, agronomic and phenotypic characteristics, on the basis of the data provided. In the absence of an appropriately performed comparative assessment by the applicant, the EFSA GMO Panel was not in the position to complete its risk assessment on maize 98140 and therefore does not conclude on the safety of maize 98140 compared with its conventional counterpart with respect to potential effects on human and animal health. However, the EFSA GMO Panel concludes that the maize event 98140 is unlikely to have any adverse effect on the environment in the context of its intended uses. The European Union Reference Laboratory for GM Food and Feed (EU-RL – GMFF) considers the method validated as fit for the purpose of regulatory compliance. The certified reference materials of maize 98140 can be accessed at the Joint Research Centre of the European Commission.

[1] On request from the Competent Authority of the United Kingdom for an application (EFSA-GMO-UK-2008-53) submitted by Pioneer, Questions No EFSA-Q-2013-00266 (EFSA overall opinion) and EFSA- EFSA-Q-2005-250 (Scientific opinion of the EFSA GMO Panel), issued on 16 April 2013

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The information presented for the Cartagena Protocol, the labelling proposal and the monitoring plan 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 Articles 6 and 18 for the placing on the market of genetically modified maize 98140.

KEY WORDS

Overall opinion, GMO, maize, *Zea mays*, 98140, herbicide tolerance, risk assessment, food and feed safety, environment, environmental safety, food and feed uses, import and processing, Regulation (EC) No 1829/2003.

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BACKGROUND

On 15 April 2008, the European Food Safety Authority (EFSA) received from the Competent Authority of the United Kingdom an application for authorisation of genetically modified maize 98140 (Unique Identifier DP-Ø9814Ø-6) submitted by Pioneer within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (reference EFSA-GMO-UK-2008-53).

The scope of this application EFSA-GMO-UK-2008-53 is for food and feed uses.[3] 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[4] on 26 April 2008. 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. The EU-RL – GMFF received 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 12 November 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 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, were given three months after the date of receipt of the valid application (*i.e.* until 12 February 2009) 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 23 January 2009 to 30 November 2012.[5]

The overall opinion on application EFSA-GMO-UK-2008-53 includes the scientific opinion of the Scientific Panel on Genetically Modified Organisms 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 European Union 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) the Member States' comments submitted during the three-month consultation period.

TERMS OF REFERENCE AS PROVIDED BY THE COMPETENT AUTHORITY OF THE UNITED KINGDOM

The European Food Safety Authority (EFSA) received from the Competent Authority of the United Kingdom an application for authorisation of genetically modified maize 98140 (Unique Identifier DP-Ø9814Ø-6) submitted by Pioneer within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (reference EFSA-GMO-UK-2008-53). EFSA was requested to issue an overall opinion in line with the requirements of the Regulation (EC) No 1829/2003 (Articles 6 and 18).

[3] This does include genetically modified maize 98140 for import and processing as designated under part C of Directive 2001/18/EC.

[4] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2005-250

[5] Request for additional information from EFSA GMO Panel: requested (1) on 23/01/2009 - received on 17/03/2009 and on 06/10/2009; requested (2) on 20/05/2009 – received on 05/03/2010; requested (3) on 28/05/2010 – received on 12/07/2010; requested (4) on 26/10/2010 – received on 22/12/2010; requested (5) on 10/02/2011 – received on 08/03/2012; requested (6) on 24/05/2012 – received on 13/07/2012 and clock re-started on 30/11/2012.

CONSIDERATIONS

1. Applicant

The application was submitted by

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

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

2. Designation and specification of the product as provided by the applicant

The scope of this application EFSA-GMO-UK-2008-53 is for food and feed uses.[6] The scope does not include cultivation.

Maize 98140 has been genetically modified to express the GAT4621 and Zm-HRA proteins. The GAT4621 protein is a glyphosate acetyltransferase (GAT), encoded by an optimized form of the *gat4621* gene from *Bacillus licheniformis*, that confers tolerance to the glyphosate herbicides. The Zm-HRA protein is an acetolactate synthase (ALS), encoded by an optimized form of the endogenous *als* gene from *Zea mays*, that confers tolerance to ALS-inhibiting herbicides, such as chlorimuron and thifensulfuron.

3. Scientific opinion of the EFSA GMO Panel

The EFSA GMO Panel has carried out the scientific assessment of the genetically modified maize 98140 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003 and adopted its scientific opinion on 6 March 2013. 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 considers that the information available for maize 98140 does not address sufficiently all the scientific issues indicated by the Guidance Document of the EFSA GMO Panel. In this application the minimum standards for the design of field trials set in EFSA GMO Panel the Guidance Document were not met and therefore the EFSA GMO Panel cannot conclude on the comparative assessment of compositional, agronomic and phenotypic characteristics, on the basis of the data provided. In the absence of an appropriately performed comparative assessment by the applicant, the EFSA GMO Panel was not in the position to complete its risk assessment on maize 98140 and therefore does not conclude on the safety of maize 98140 compared with its conventional counterpart with respect to potential effects on human and animal health. However, the EFSA GMO Panel concludes that the maize event 98140 is unlikely to have any adverse effect on the environment in the context of its intended uses (Annex A).

4. 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 EFSA GMO Panel (Annex B).

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, 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).

[6] This does include genetically modified maize 98140 for import and processing as designated under part C of Directive 2001/18/EC.

6. Method for detection

The EU-RL – GMFF has carried out a collaborative study to assess the performance of a quantitative event-specific method to detect and quantify the maize 98140 transformation event in maize DNA. The reports were issued on 22 February 2005 and on 7 January 2011. The EU-RL – GMFF considers that the method is applicable to the control samples provided, in accordance with the requirements of Annex I-2.C.2. of the Commission Regulation (EC) No 641/2004 (Annexes D1, D2, D3).

7. Certified reference materials

The certified reference materials of genetically modified maize 98140 can be accessed at the Joint Research Centre of the European Commission, Institute for Reference Materials and Measurements (Annex E1).

8. Post-market environmental monitoring

The EFSA GMO Panel evaluated the post-market environmental monitoring plan proposed by the applicant. The EFSA GMO Panel considered that the monitoring plan provided by the applicant is in line with the intended uses for the GMO (Annex F).

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 Articles 6 and 18 for the placing on the market of genetically modified maize 98140.

LIST OF ANNEXES[7]

Annex A: Scientific opinion of the EFSA GMO Panel (maize 98140)
Annex B: Cartagena Protocol (maize 98140)
Annex C: Labelling (maize 98140)
Annex D1: Validation report (maize 98140)
Annex D2: Validated method (maize 98140)
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Annex F: Post-market environmental monitoring plan (maize 98140)
Annex G: Member States' comments (maize 98140)

[7] The annexes of the EFSA overall opinion can be found in the Register of Questions ("Question documents") on the EFSA website under the following link: http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2013-00266