

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-NL-2005-23) for the placing on the market of genetically modified maize 59122 for food and feed uses, import, processing and cultivation under Regulation (EC) No 1829/2003 from Pioneer Hi-Bred International and Dow AgroSciences LLC¹

European Food Safety Authority²

European Food Safety Authority (EFSA), Parma, Italy

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 EFSA-GMO-NL-2005-23 is for food and feed uses, import, processing. The scope includes cultivation.

The Scientific Panel on Genetically Modified Organisms (EFSA GMO Panel) 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. The EFSA GMO Panel considers that the information available for maize 59122 addresses the scientific issues indicated by the Guidance Document of the EFSA GMO Panel and the scientific comments raised by the Member States. In conclusion, the EFSA GMO Panel considers that maize 59122 is unlikely to have any adverse effect on the environment, except for the possible resistance evolution to the Cry34Ab1/Cry35Ab1 proteins in coleopteran target pests. The EFSA GMO Panel recommends the implementation of appropriate and diversified insect resistance management strategies and case-specific monitoring to delay and monitor the possible evolution of resistance to the Cry34Ab1/Cry35Ab1 proteins in coleopteran target pests, respectively. In addition, the EFSA GMO Panel requests that its recommendations made to revise the applicant's insect resistance management plan and to strengthen the proposed post-market environmental monitoring plan are implemented. The remaining non-critical scientific uncertainties pertaining to the modelling predictions of resistance in WCR populations owing to the cultivation of maize 59122, and the potential of the Cry34Ab1/Cry35Ab1 proteins to accumulate in soil following subsequent years of continuous maize 59122 cultivation are to be resolved with data acquired during post-market environmental monitoring. Although maize 59122 is tolerant to glufosinate-ammonium-based

¹ On request from the Competent Authority of the Netherlands for an application (EFSA-GMO-NL-2005-23) submitted by Pioneer Hi-Bred International and Dow AgroSciences LLC, Questions No EFSA-Q-2013-00256 (EFSA overall opinion) and EFSA- EFSA-Q-2005-250 (Scientific opinion of the EFSA GMO Panel), issued on 26 March 2013.

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herbicides, the EFSA GMO Panel did not assess potential adverse effects associated with the use of such herbicides on maize 59122, as maize 59122 will not be marketed in the EU for the purpose of herbicide tolerance. This Scientific Opinion also updates the previous Panel safety evaluation of the food and feed uses, import and processing of maize 59122 and derived products. The EFSA GMO Panel concludes that the information available for maize 59122 addresses the scientific comments raised by Member States and that maize 59122, as described in this application, is as safe as its conventional counterpart and commercial maize varieties with respect to potential adverse effects on human and animal health. If subjected to appropriate management measures, the cultivation of maize 59122 is unlikely to raise safety concerns for the environment. 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 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 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 59122.

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KEY WORDS

Overall opinion, GMO, maize (*Zea mays*), 59122, insect resistance, herbicide tolerance, *cry34Ab1*, *cry35Ab1*, *pat*, risk assessment, food and feed safety, environment, environmental safety, food and feed uses, import and processing, cultivation, Regulation (EC) No 1829/2003.

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BACKGROUND

On 21 October 2005, the European Food Safety Authority (EFSA) received from the Competent Authority of the Netherlands an application for authorisation of genetically modified maize 59122 (Unique Identifier DAS-59122-7) submitted by Pioneer Hi-Bred International and Dow AgroSciences LLC within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (reference EFSA-GMO-NL-2005-23).

The scope of this application EFSA-GMO-NL-2005-23 is for food and feed uses.³ The scope includes 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 website⁴ on 13 November 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 6 April, 10 and 11 May 2005, 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 9 March 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 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 9 July 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 13 March 2007 to 13 April 2007; from 30 July 2007 to 14 May 2008 and from 29 May 2008 to 9 January 2013.⁵

In accordance with Articles 6(3)(c) and 18(3)(c) of Regulation (EC) No 1829/2003, EFSA requested the Dutch Competent Authority to carry out an initial Environmental Risk Assessment (ERA) of application EFSA-GMO-NL-2005-23 concerning the placing on the market of maize 59122 for food and feed uses, import, processing and cultivation. The report was received on 13 May 2008 (Annex H).

The overall opinion on application EFSA-GMO-NL-2005-23 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, viii) the Member States' comments submitted during the three-month consultation period and ix) the Environmental Risk Assessment report of the Dutch Competent Authority.

³ This does include genetically modified maize 59122 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 the EFSA/NL CA; requested (1) on 13/03/2007 - received on 02/04/2007 and clock re-started on 13/04/2007; requested (2) on 30/07/2007 and (3) on 08/10/2007 - received on 20/12/2007 and clock re-started on 14/05/2008.

Request for additional information from the EFSA GMO Panel: requested (1) on 29/05/2008 - received on 22/09/2008; requested (2) on 01/10/2008 - received on 08/01/2009; requested (3) on 13/02/2009 – received on 28/04/2009 and on 27/01/2010; requested (4) on 28/05/2009 – received on 27/01/2010; requested (5) on 30/04/2010 – received on 16/01/2012; requested (6) on 29/02/2012 – received on 02/10/2012 and clock re-started on 09/01/2013.
The applicant provided additional information spontaneously on 23/01/2013 and on 11/02/2013.

TERMS OF REFERENCE AS PROVIDED BY THE COMPETENT AUTHORITY OF THE NETHERLANDS

The European Food Safety Authority (EFSA) received from the Competent Authority of the Netherlands an application for authorisation of genetically modified maize 59122 (Unique Identifier DAS-59122-7) submitted by Pioneer Hi-Bred International and Dow AgroSciences LLC within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (reference EFSA-GMO-NL-2005-23). EFSA was requested to issue an overall opinion in line with the requirements of the Regulation (EC) No 1829/2003 (Articles 6 and 18).

CONSIDERATIONS

1. Applicant

The application was submitted by

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U.S.A.

Inc. Mycogen Seeds
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9330 Zionsville Road
Indianapolis, IN 46268-1054
U.S.A.

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

Represented by:
Dow AgroSciences LLC
2nd Floor, 3 Milton Park
Oxon OX14 4 RN
United Kingdom

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

The scope of this application EFSA-GMO-NL-2005-23 is for food and feed uses.⁶ The scope includes cultivation.

Maize 59122 expresses the *cry34Ab1* and *cry35Ab1* genes from *Bacillus thuringiensis* conferring resistance to coleopteran insect pests belonging to the genus *Diabrotica* such as the larvae of western corn rootworm (WCR; *Diabrotica virgifera virgifera*), and the *pat* coding sequence from *Streptomyces viridochromogenes* which renders maize 59122 tolerant to the herbicidal active substance glufosinate-ammonium.

3. Scientific opinion of the EFSA GMO Panel

The EFSA 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 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 59122 addresses the scientific issues indicated by the Guidance Document of the EFSA GMO Panel and the scientific comments raised by the Member States. In conclusion, the EFSA GMO Panel considers that maize 59122 is unlikely to have any adverse effect on the environment, except for the possible resistance evolution to the Cry34Ab1/Cry35Ab1 proteins in coleopteran target pests. The EFSA GMO Panel recommends the implementation of appropriate and diversified insect resistance management strategies and case-specific monitoring to delay and monitor the possible evolution of resistance to the Cry34Ab1/Cry35Ab1 proteins in coleopteran target pests, respectively. In addition, the EFSA GMO Panel requests that its recommendations made to revise the applicant's insect resistance management plan and to strengthen the proposed post-market environmental monitoring plan are implemented. The remaining non-critical scientific uncertainties

⁶ This includes genetically modified maize 59122 for import and processing as designated under part C of Directive 2001/18/EC.

pertaining to the modelling predictions of resistance in WCR populations owing to the cultivation of maize 59122, and the potential of the Cry34Ab1/Cry35Ab1 proteins to accumulate in soil following subsequent years of continuous maize 59122 cultivation are to be resolved with data acquired during post-market environmental monitoring. Although maize 59122 is tolerant to glufosinate-ammonium-based herbicides, the EFSA GMO Panel did not assess potential adverse effects associated with the use of such herbicides on maize 59122, as maize 59122 will not be marketed in the EU for the purpose of herbicide tolerance. This Scientific Opinion also updates the previous Panel safety evaluation of the food and feed uses, import and processing of maize 59122 and derived products. The EFSA GMO Panel concludes that the information available for maize 59122 addresses the scientific comments raised by Member States and that maize 59122, as described in this application, is as safe as its conventional counterpart and commercial maize varieties with respect to potential adverse effects on human and animal health. If subjected to appropriate management measures, the cultivation of maize 59122 is unlikely to raise safety concerns for the environment (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 Article 13(2)(a) and 25(2)(c) (Annex C).

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 59122 transformation event in maize DNA. The reports were issued on 6 and 7 October 2005 and 8 June 2007. 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 59122 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).

10. Environmental Risk Assessment by a National Competent Authority

In accordance with Articles 6(3)(c) and 18(3)(c) of Regulation (EC) No 1829/2003, EFSA requested the Dutch Competent Authority to carry out an initial Environmental Risk Assessment (ERA) of application EFSA-GMO-NL-2005-23 concerning the placing on the market of maize 59122 for food and feed uses, import, processing and cultivation. The report was received on 13 May 2008 (Annex H).

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 59122.

LIST OF ANNEXES⁷

Annex A:	Scientific opinion of the EFSA GMO Panel (maize 59122)
Annex B:	Cartagena Protocol (maize 59122)
Annex C:	Labelling (maize 59122)
Annex D1:	Validation report (maize 59122)
Annex D2:	Validated method (maize 59122)
Annex D3:	Sampling and extraction (maize 59122)
Annex E:	Certified reference materials report (maize 59122)
Annex F:	Post-market environmental monitoring plan (maize 59122)
Annex G:	Member States' comments (maize 59122)
Annex H:	Environmental Risk Assessment report of the Dutch Competent Authority (maize 59122)

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-2013-00256>