

REPORT OF EFSA

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-2007-43) for the placing on the market of the herbicide tolerant genetically modified soybean 356043 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Pioneer¹

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 soybean 356043 in accordance with the requirements of Articles 6 and 18 of Regulation (EC) No 1829/2003.

The scope of this application EFSA-GMO-UK-2007-43 is for food and feed uses, foods and feeds containing, consisting of or produced from soybean 356043, 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 soybean 356043 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003. In conclusion, the EFSA GMO Panel considers that the information available for soybean 356043 addresses the scientific comments raised by the Member States and that the soybean 356043, as described in this application, is as safe as its conventional counterpart with respect to potential effects on human and animal health and 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 soybean 356043 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.

¹ On request from the Competent Authority of The United Kingdom for an application (EFSA-GMO-UK-2007-43) submitted by Pioneer, Questions No EFSA-Q-2011-00856 (EFSA overall opinion) and EFSA-Q-2007-087 (Scientific opinion of the EFSA GMO Panel), issued on 26 July 2011.

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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 soybean 356043.

KEY WORDS

Overall opinion, GMO, soybean, 356043, herbicide tolerance, food and feed uses, import and processing, food safety, feed safety, environmental safety, Regulation (EC) No 1829/2003.

TABLE OF CONTENTS

Summary	1
Table of contents	3
Background	4
Terms of reference	4
Considerations.....	5
1. Applicant(s).....	5
2. Designation and specification of the product.....	5
3. Scientific opinion of the EFSA GMO Panel	5
4. Cartagena Protocol	5
5. Labelling.....	5
6. Method for detection	6
7. Certified reference materials	6
8. Post-market environmental monitoring	6
9. Member States' Comments	6
Conclusions	6
List of annexes	7

BACKGROUND

On 11 April 2007, the European Food Safety Authority (EFSA) received from the Competent Authority of the United Kingdom an application for authorisation of genetically modified soybean 356043 (DP-356043-5) submitted by Pioneer within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (reference EFSA-GMO-UK-2007-43).

The scope of application EFSA-GMO-UK-2007-43 covers genetically modified soybean 356043 for food and feed uses³ and foods and feeds containing, produced from or consisting of genetically modified soybean 356043. 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 website⁴ on 20 April 2007. 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 20 February 2007, the Community Reference Laboratory (CRL) 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 28 September 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 28 December 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 20 December 2007 to 3 February 2011.⁵

The overall opinion on application EFSA-GMO-UK-2007-43 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 Community 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

The European Food Safety Authority (EFSA) received from the Competent Authority of The United Kingdom an application for authorisation of genetically modified soybean 356043 (DP-356043-5) submitted by Pioneer within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (reference EFSA-GMO-UK-2007-43). EFSA was requested to issue an

³This does include genetically modified soybean 356043 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-2011-00856>

⁵Request for additional information from the EFSA GMO Panel: requested (1) on 20/12/2007 - received on 12/02/2008; requested (2) on 27/02/2008 - received on 15/04/2008 and 06/10/2009; requested (3) on 22/07/2008 - received on 08/09/2008; requested (4) on 08/09/2008 - received on 15/10/2008; requested (5) on 14/01/2010 - received on 05/03/2010; complementary information was submitted spontaneously by the applicant on 21/04/2010; requested (6) on 28/05/2010 - received on 12/07/2010; requested (7) on 22/10/2010 - received on 07/12/2010 and clock restarted on 03/02/2011. Complementary information was submitted spontaneously by the applicant on 11/03/2011 and 19/07/2011.

overall opinion in line with the requirements of the Regulation (EC) No 1829/2003 (Articles 6 and 18).

CONSIDERATIONS

1. Applicant(s)

The application was submitted by

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U.S.A.

Pioneer Overseas Corporation
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2. Designation and specification of the product

The scope of application EFSA-GMO-UK-2007-43 covers genetically modified soybean 356043 for food and feed uses⁶ and foods and feeds containing, consisting of or produced from soybean 356043. The scope does not include cultivation.

The 356043 soybean has been genetically modified for herbicide tolerance. This was achieved by the introduction of the *gat4601* and the *gm-hra* coding sequences surrounded by their necessary regulatory components.

3. Scientific opinion of the EFSA GMO Panel

The EFSA GMO Panel has carried out the scientific assessment of the genetically modified soybean 356043 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003 and adopted its scientific opinion on 6 July 2011. 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 soybean 356043 addresses the scientific comments raised by the Member States and that the soybean 356043, as described in this application, is as safe as its conventional counterpart with respect to potential effects on human and animal health and 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 soybean 356043 for import and processing as designated under part C of Directive 2001/18/EC.

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 soybean 356043 transformation event in soybean DNA. The reports were issued on 22 January 2009 and 29 March 2010. 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 the Commission Regulation (EC) No 641/2004 (Annexes D1, D2, D3).

7. Certified reference materials

The certified reference materials of soybean 356043 (ERM-AD425) 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

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 soybean 356043.

LIST OF ANNEXES⁷

Annex A:	Scientific opinion of the EFSA GMO Panel (soybean 356043)
Annex B:	Cartagena Protocol (soybean 356043)
Annex C:	Labelling (soybean 356043)
Annex D1:	Validation report (soybean 356043)
Annex D2:	Validated method (soybean 356043)
Annex D3:	Sampling and extraction (soybean 356043)
Annex E1:	Certified reference materials report (soybean 356043)
Annex F:	Post-market environmental monitoring plan (soybean 356043)
Annex G:	Member States' comments (soybean 356043)

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-2011-00856>