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-2007-45) for the placing on the market of herbicide tolerant, high oleic acid genetically modified soybean 305423 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 soybean 305423 in accordance with the requirements of Articles 6 and 18 of Regulation (EC) No 1829/2003.

The scope of this application EFSA-GMO-NL-2007-45 is for food and feed uses, food and feed containing, consisting of or produced from soybean 305423, 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 305423 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 305423 addresses the scientific issues indicated by the Guidance document of the EFSA GMO Panel and the scientific comments raised by the Member States, and that soybean 305423 is as safe as its conventional counterpart and is unlikely to have adverse effects on human and animal health and the environment in the context of the scope of this application. The European Union Reference Laboratory for GM Food and Feed (EURL-GMFF) considers the method validated as fit for the purpose of regulatory compliance. The certified reference materials of soybean 305423 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 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 soybean 305423.

[1] On request from the Competent Authority of the Netherlands for an application (EFSA-GMO-NL-2007-45) submitted by Pioneer, Questions No EFSA-Q-2013-00988 (EFSA overall opinion) and EFSA-Q-2007-122 (Scientific opinion of the EFSA GMO Panel), issued on 18 December 2013.

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KEY WORDS

Overall opinion, GMO soybean 305423, herbicide tolerance, high oleic acid, RNAi and HRA proteins, food feed uses and import and processing, Regulation (EC) No 1829/2003

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BACKGROUND AS PROVIDED BY THE COMPETENT AUTHORITY OF THE NETHERLANDS

On 18 June 2007, the European Food Safety Authority (EFSA) received from the Competent Authority of the Netherlands an application for authorisation of genetically modified soybean 305423 (DP-3Ø5423-1) submitted by Pioneer within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (reference EFSA-GMO-NL-2007-45).

The scope of application EFSA-GMO-NL-2007-45 covers genetically modified soybean 305423 for food and feed uses[3], food and feed containing, produced from or consisting of genetically modified soybean 305423. 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 25 June 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 April 2007 and 4 May 2007, the European Union Reference Laboratory 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 22 October 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 22 January 2008) 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 17 May 2011 and from 30 May 2012 to 5 September 2013.[5]

The overall opinion on application EFSA-GMO-NL-2007-45 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.

[3] This does include genetically modified soybean 305423 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-2007-122

[5] Request for additional information from the EFSA GMO Panel: requested (1) on 20/12/2007 – received on 12/02/2008; requested (2) on 28/02/2008 – received on 28/04/2008 and on 06/10/2009; requested (3) on 22/05/2008 – received on 04/07/2008; requested (4) on 13/08/2008 – received on 24/11/2008 and on 06/10/2009; requested (5) on 11/02/2009 – received on 19/03/2009; requested (6) on 08/01/2010 – received on 09/02/2010; requested (7) on 27/04/2010 – received on 09/06/2010; requested (8) on 05/08/2010 – received on 21/09/2010; requested (9) on 21/10/2010 – received on 18/11/2010; requested (10) on 22/12/2010 – received on 09/02/2011 and clock re-started on 17/05/2011. Further additional information was submitted by the applicant on 14/07/2011, 28/11/2011, 17/01/2012 and on 05/03/2012; requested (11) on 30/05/2012 – received on 05/06/2012; requested (12) on 19/09/2012 – received on 31/10/2012; requested (13) on 08/02/2013 – received on 02/05/2013; requested (14) on 20/02/2013 received on 02/05/2013; requested (15) on 12/04/2013 – received on 02/05/2013; requested (16) on 26/06/2013 – received on 28/06/2013 and clock re-started on 05/09/2013. The applicant provided additional information on 03/10/2013.

TERMS OF REFERENCE AS PROVIDED BY THE APPLICANT

The European Food Safety Authority (EFSA) received from the Competent Authority of the Netherlands an application for authorisation of genetically modified soybean 305423 (DP-3Ø5423-1) submitted by Pioneer within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (reference EFSA-GMO-NL-2007-45). 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

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

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

2. Designation and specification of the product

The scope of application EFSA-GMO-NL-2007-45 covers genetically modified soybean 305423 for food and feed uses[6] and food and feed containing, consisting of or produced from soybean 305423. The scope does not include cultivation.

Soybean 305423 expresses the *Glycine max-hra (gm-hra)* gene conferring tolerance to acetolactate synthase (ALS)-inhibiting herbicides. Soybean 305423 also expresses a fragment of the endogenous *fad2-1* gene resulting, through RNA interference, in the silencing of the endogenous *fad2-1* gene, which leads to a decreased level of the omega-6 fatty acid desaturase and a high oleic acid phenotype.

3. Scientific opinion of the EFSA GMO Panel

The EFSA GMO Panel carried out the scientific assessment of the genetically modified soybean 305423 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003 and adopted its scientific opinion on 4 December 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. In conclusion, the EFSA GMO Panel considers that the information available for soybean 305423 addresses the scientific issues indicated by the Guidance document of the EFSA GMO Panel and the scientific comments raised by the Member States, and that soybean 305423 is as safe as its conventional counterpart and is unlikely to have adverse effects on human and animal health and the environment in the context of the scope of this application. Considering the intended altered soybean 305423 nutritional composition, a proposal for a post-market monitoring (PMM) plan needs to be provided by the applicant (EFSA, 2006b, 2011c). EFSA recommends that the PMM should focus on the collection of consumption data for the European population (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).

[6] This does include genetically modified soybean 305423 for import and processing as designated under part C of Directive 2001/18/EC.

5. Labelling

Considering the altered composition and nutritional values of soybean 305423, the EFSA GMO Panel considered a specific labelling proposal provided by the applicant in accordance with Articles 13(2)(a) and 25(2)(c) of Regulation (EC) No 1829/2003. The applicant proposed that, food and feed products within the scope of the application should be labelled as "genetically modified soybean with altered fatty acid profile". The GMO Panel is of the opinion that the compositional data show that the fatty acid composition of seeds of soybean 305423 and derived oil has indeed been changed in relation to the conventional counterpart.

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 305423 transformation event in soybean DNA. The reports were issued on 19 and 22 January 2009 and 29 March 2010. The European Union 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 305423 (ERM-BF426) 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 305423.

LIST OF ANNEXES[7]

Annex A: Scientific opinion of the EFSA GMO Panel (soybean 305423)
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[7] 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-2013-00988