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-NL-2008-52) for the placing on the market of the genetically modified soybean A5547-127 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Bayer CropScience [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 A5547-127 in accordance with the requirements of Articles 6 and 18 of Regulation (EC) No 1829/2003.

The scope of this application EFSA-GMO-NL-2008-52 is for food and feed uses, food and feed containing, consisting of or produced from soybean A5547-127, 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 A5547-127 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 soybean A5547-127 addresses the scientific comments raised by the Member States and that the soybean A5547-127, 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 A5547-127 can be accessed at the American Oil Chemists' Society.

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 soybean A5547-127.

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[1] On request from the Competent Authority of The Netherlands for an application (EFSA-GMO-NL-2008-52) submitted by Bayer BioScience NV, Questions No EFSA-Q-2011-00292 (EFSA overall opinion) and EFSA-Q-2008-290 (Scientific opinion of the EFSA GMO Panel), issued on 10 May 2011.

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KEY WORDS

Overall opinion, GMO, soybean, *Glycine max*, A5547-127, herbicide tolerance, food and feed uses, import and processing, food safety, feed safety, environmental safety, Regulation (EC) No 1829/2003.

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BACKGROUND

On 3 April 2008, the European Food Safety Authority (EFSA) received from the Competent Authority of The Netherlands an application for authorisation of genetically modified soybean A5547-127 (ACS-GMØØ6-4) submitted by Bayer BioScience NV within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (reference EFSA-GMO-NL-2008-52).

The scope of application EFSA-GMO-NL-2008-52 covers genetically modified soybean A5547-127 for food and feed uses[3], food and feed containing, produced from or consisting of genetically modified soybean A5547-127. 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 18 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. On 27 February 2008, 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 18 July 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 28 October 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 5 December 2008 to 7 March 2011.[5]

The overall opinion on application EFSA-GMO-NL-2008-52 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 Netherlands an application for authorisation of genetically modified soybean A5547-127 (ACS-GMØØ6-4) submitted by Bayer BioScience NV within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (reference EFSA-GMO-NL-2008-52). 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 soybean A5547-127 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-2008-290

[5]Request for additional information from the EFSA GMO Panel: requested (1) on 05/12/2008 - received on 16/04/2009; requested (2) on 29/06/2009 - received on 09/12/2010 and clock restarted on 07/03/2011.

CONSIDERATIONS

1. Applicant(s)

The application was submitted by

Bayer CropScience AG
Alfred-Nobel-Strasse 50
D - 40789 Monheim am Rhein
Germany

Bayer BioScience NV
Technologiepark 38
B-9052 Gent
Belgium

2. Designation and specification of the product

The scope of application EFSA-GMO-NL-2008-52 covers genetically modified soybean A5547-127 for food and feed uses[6] and food and feed containing, consisting of or produced from soybean A5547-127. The scope does not include cultivation.

Soybean A5547-127 expresses the *pat* gene leading to the production of the enzyme phosphinothricin acetyl-transferase (PAT) that acetylates L-glufosinate. The PAT enzyme confers tolerance to glufosinate-ammonium containing herbicides.

3. Scientific opinion of the EFSA GMO Panel

The EFSA GMO Panel has carried out the scientific assessment of the genetically modified soybean A5547-127 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003 and adopted its scientific opinion on 13 April 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 A5547-127 addresses the scientific comments raised by the Member States and that the soybean A5547-127, 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. 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

[6] This does include genetically modified soybean A5547-127 for import and processing as designated under part C of Directive 2001/18/EC.

detect and quantify the A5547-127 transformation event in soybean DNA. The reports were issued on 14 May 2007 and 20 January 2009. 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 genetically modified soybean A5547-127 can be accessed at the American Oil Chemists' Society (AOCS-USA) (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 A5547-127.

LIST OF ANNEXES[7]

Annex A:	Scientific opinion of the EFSA GMO Panel (soybean A5547-127)
Annex B:	Cartagena Protocol (soybean A5547-127)
Annex C:	Labelling (soybean A5547-127)
Annex D1:	Validation report (soybean A5547-127)
Annex D2:	Validated method (soybean A5547-127)
Annex D3:	Sampling and Extraction (soybean A5547-127)
Annex E:	Certified reference materials report (soybean A5547-127)
Annex F:	Post-market environmental monitoring plan (soybean A5547-127)
Annex G:	Member States' comments (soybean A5547-127)

[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-2011-00292