European Food Safety Authority

GMO Unit

Opinion of the European Food Safety Authority in accordance with Articles 6 and 18 of Regulation (EC) No. 1829/2003 on application EFSA-GMO-NL-2005-13

Application for the placing on the market of glufosinate-tolerant genetically modified LLcotton25 for food and feed uses, import and processing from Bayer CropScience

(Question No. EFSA-Q-2005-047)

13 April 2007

Summary

This document provides an overall opinion of the European Food Safety Authority on genetically modified LLcotton25 in accordance with the requirements of Articles 6 and 18 of Regulation (EC) No. 1829/2003.

The scope of this application is genetically modified LLcotton25 for food and feed uses[1], food and feed containing, consisting of or produced from LLcotton25. The scope does not include cultivation.

The Scientific Panel on Genetically Modified Organisms has carried out the scientific assessment of genetically modified LLcotton25 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No. 1829/2003 and considers that the LLcotton25 is unlikely to have any adverse effect on human and animal health or on the environment in the context of its intended uses.

The Community Reference Laboratory considers that the method validated as fit for the purpose of regulatory compliance. The certified reference materials of GM LLcotton25 can be accessed at American Oil Chemist's Society (AOCS).

The information presented for the Cartagena Protocol, the labelling proposal and the monitoring plan are 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 LLcotton25.

Background

On 7 March 2005, the European Food Safety Authority (EFSA) received from the Dutch Competent Authority an application for authorisation of GM LLcotton25 (unique identifier ACS-GHØØ1-3) submitted by Bayer CropScience within the framework of Regulation (EC) No. 1829/2003 on genetically modified food and feed (reference EFSA-GMO-NL-2005-13).

[1] This does include GM cotton for import and processing as designated under part C of Directive 2001/18/EC

The scope of this application is genetically modified LLcotton25 for food and feed uses[2], food and feed containing, consisting of or produced from LLcotton25. 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[3] on 10 March 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 7 October 2004, the Community Reference Laboratory (CRL) confirmed receipt of 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 2 September 2005 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 6 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 2 December 2005) 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 15 September 2005 to 22 January 2007[4].

The overall opinion on application EFSA-GMO-NL-2005-13 includes the scientific opinion of the Scientific Panel on Genetically Modified Organisms (GMO Panel) 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) Member States' comments submitted during the three-month consultation period.

Applicant

The application was submitted by

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

[2] This does include GM cotton for import and processing as designated under part C of Directive 2001/18/EC

[3] http://www.efsa.eu.int/science/gmo/gm_ff_applications/catindex_en.html

[4] Request for additional information from the JRC-CRL: requested on 15/09/2005 and accepted on 3/11/2005, requested on 27/10/2006 and accepted on 22/01/2007.
Request for additional information from EFSA-GMO Panel: requested on 26/01/2006 and accepted on 23/10/2006.

Designation and specification of the product

The scope of this application is genetically modified LLcotton25 for food and feed uses[5], food and feed containing, consisting of or produced from LLcotton25.

Genetically modified LLcotton25 is derived from the cotton variety Coker312 which was transformed by *Agrobacterium*-mediated gene transfer technology. LLcotton25 expresses the *bar* gene leading to the production of the phosphinothricin-N-acetyltransferase (PAT) enzyme conferring tolerance to glufosinate-containing herbicides.

Scientific opinion of the GMO Panel

The GMO Panel has carried out the scientific assessment of the genetically modified LLcotton25 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No. 1829/2003 and adopted its scientific opinion on 6 December 2006. The GMO Panel considered all scientific comments submitted by Member State bodies and where deemed necessary, requested additional information from the applicant before finalising its scientific assessment. The GMO Panel concludes that the information available for LLcotton25 addresses the scientific comments raised by the Member States and considers that LLcotton25 is unlikely to have any adverse effect on human and animal health or on the environment in the context of its intended uses (Annex A).

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 GMO Panel (Annex B).

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 GMO Panel that LLcotton25 is compositionally and phenotypically equivalent to its non-genetically modified counterpart except for the introduced trait, 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).

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 LLcotton25 transformation event in cotton DNA. The reports were published on 14 March 2007. 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 Commission Regulation (EC) No. 641/2004 (Annexes D1, D2, D3).

Certified reference materials

The certified reference materials of genetically modified LLcotton25 (AOCS 0306-A and AOCS 0306-E) can be accessed at the American Oil Chemist's Society (AOCS), W. Bradley Avenue

[5] This does include GM cotton for import and processing as designated under part C of Directive 2001/18/EC

2211, Champaign, Illinois 61821, USA, (http://www.aocs.org/tech/crm/bayer_cotton.asp) (Annex E).

Post market environmental monitoring

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

Member States' Comments

In line with the procedure[6] adopted by EFSA, the GMO Panel has addressed the comments submitted by the Member States during the three months consultation period (Annex G).

List of annexes:

Annex A:	Scientific opinion of the GMO Panel
Annex B:	Cartagena Protocol
Annex C:	Labelling
Annex D1:	Validation report (LLcotton25)
Annex D2:	Validated method (LLcotton25)
Annex D3:	Sampling and extraction (LLcotton25)
Annex E:	Certified reference materials
Annex F:	Monitoring plan
Annex G:	Member States' comments

[6] EFSA Strategy document http://www.efsa.europa.eu/etc/medialib/efsa/science/gmo/109.Par.0010.File.dat/gmo_actionplan1.pdf