

## 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-2005-16) for the placing on the market of insect resistant genetically modified cotton (*Gossypium hirsutum* L.) 281-24-236 x 3006-210-23 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Dow AgroSciences<sup>1</sup>**

#### **European Food Safety Authority<sup>2</sup>**

European Food Safety Authority (EFSA), Parma, Italy

#### **SUMMARY**

This document provides an overall opinion of the European Food Safety Authority on genetically modified cotton 281-24-236 x 3006-210-23 in accordance with the requirements of Articles 6 and 18 of Regulation (EC) No 1829/2003.

The scope of this application EFSA-GMO-NL-2005-16 is for food and feed uses, food and feed containing, consisting of or produced from cotton 281-24-236 x 3006-210-23, 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 cotton 281-24-236 x 3006-210-23 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003. In conclusion, the EFSA GMO Panel considers that information available for cotton 281-24-236 x 3006-210-23 addresses the scientific comments raised by Member States and that the cotton 281-24-236 x 3006-210-23 as described in this application is as safe as its conventional counterpart and other appropriate comparators with respect to potential effects on human and animal health and the environment in the context of its intended uses. The EFSA GMO Panel concludes that cotton event 281-24-236 x 3006-210-23 is unlikely to have any adverse effect 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 cotton 281-24-236 x 3006-210-23 can be accessed at the Joint Research Centre of the European Commission, Institute for Reference Materials.

The information presented for the Cartagena Protocol, the labelling proposal and the monitoring plan is in line with Regulation (EC) No 1829/2003.

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<sup>1</sup> On request from the Competent Authority of The Netherlands for an application (EFSA-GMO-NL-2005-16) submitted by Dow AgroSciences, Questions No EFSA-Q-2010-00863 (EFSA overall opinion) and EFSA-Q-2005-124 (Scientific opinion of the EFSA GMO Panel), issued on 15 June 2010.

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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 cotton 281-24-236 x 3006-210-23.

**KEY WORDS**

Overall opinion, GMO, cotton, *Gossypium hirsutum* L., 281-24-236 x 3006-210-23, insect resistance, food and feed uses, import and processing, food safety, feed safety, environmental safety, Regulation (EC) No 1829/2003, Regulation (EC) No 1829/2003.

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## BACKGROUND

On 28 June 2008, the European Food Safety Authority (EFSA) received from the Competent Authority of the United Kingdom an application for authorisation of genetically modified cotton 281-24-236 x 3006-210-23 (DAS-24236-5 x DAS-21Ø23-5) submitted by Dow AgroSciences within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (reference EFSA-GMO-NL-2005-16).

The scope of application EFSA-GMO-NL-2005-16 covers genetically modified cotton 281-24-236 x 3006-210-23 for food and feed uses<sup>3</sup>, food and feed containing, produced from or consisting of genetically modified cotton 281-24-236 x 3006-210-23. 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<sup>4</sup> on 1 July 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 23 June and 6 September 2005, 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 3 August 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 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 4 November 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 21 October 2005 to 30 March 2010<sup>5</sup>.

The overall opinion on application EFSA-GMO-NL-2005-16 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 cotton 281-24-236 x 3006-210-23 (DAS-24236-5 x DAS-21Ø23-5) submitted by Dow AgroSciences within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (reference EFSA-GMO-NL-

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<sup>3</sup>This does include genetically modified cotton 281-24-236 x 3006-210-23 for import and processing as designated under part C of Directive 2001/18/EC.

<sup>4</sup><http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2010-00863>

<sup>5</sup>Request for additional information from the EFSA GMO Panel: requested (1) on 21/10/2005 - received on 02/11/2005; requested (2) on 15/12/2005 - received on 21/03/2006; requested (3) on 07/07/2006 - received on 25/08/2006; requested (4) on 14/11/2006 - received on 09/12/2008; requested (5) on 17/03/2009 - received on 29/09/2009; requested (6) on 21/10/2009 - received on 12/03/2010 and clock restarted on 30/03/2010.

2005-16). 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(s)

The application was submitted by

Dow AgroSciences Europe  
European Development Centre  
3 Milton Park, Abingdon  
Oxon OX14 4RN  
United Kingdom

Agrigenetics, Inc. *d/b/a* Mycogen Seeds  
c/o DowAgroSciences LLC  
9330 Zionsville Road  
Indianapolis, IN 46268-1054  
U.S.A.

### 2. Designation and specification of the product

The scope of application EFSA-GMO-NL-2005-16 covers genetically modified cotton 281-24-236 x 3006-210-23 for food and feed uses<sup>6</sup> and food and feed containing, consisting of or produced from cotton 281-24-236 x 3006-210-23. The scope does not include cultivation.

Cotton 281-24-236 x 3006-210-23 has been produced by conventional crossing the single events 281-24-236 and 3006-210-23, and subsequently self-pollinated for five generations to obtain the GM cotton 281-24-236 x 3006-210-23 homozygous for both inserts to achieve insect resistance traits against certain lepidopteran pests, such as *Heliothis zea* (cotton bollworm), *Heliothis virescens* (tobacco budworm) and *Pectinophora gossypiella* (pink bollworm), by the expression of Cry1F and Cry1Ac proteins. The PAT protein was used as a selectable marker during transformation processes.

### 3. Scientific opinion of the EFSA GMO Panel

The EFSA GMO Panel has carried out the scientific assessment of the genetically modified cotton 281-24-236 x 3006-210-23 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003 and adopted its scientific opinion on 26 May 2010. 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 information available for cotton 281-24-236 x 3006-210-23 addresses the scientific comments raised by Member States and that the cotton 281-24-236 x 3006-210-23 as described in this application is as safe as its conventional counterpart and other appropriate comparators with respect to potential effects on human and animal health and the environment in the context of its intended uses. The EFSA GMO Panel concludes that cotton event 281-24-236 x 3006-210-23 is unlikely to have any adverse effect 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).

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<sup>6</sup> This does include genetically modified cotton 281-24-236 x 3006-210-23 for import and processing as designated under part C of Directive 2001/18/EC.

## **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 genetically modified Food and Feed has carried out an in-house verification study to assess the performance of two quantitative event specific methods on the hybrid cotton line 281-24-236 x 3006-210-23 which combines the 281-24-236 and 3006-210-23 transformation events. The two methods have been validated individually on single-trait events, to detect and quantify each event in maize samples. The reports were issued on 21 April 2006. The Community Reference Laboratory considers that the methods are applicable to the control samples provided in accordance with the requirements of Annex I-2.C.2. of Commission Regulation (EC) No 641/2004 (Annexes D1, D2a, D2b, D3).

## **7. Certified reference materials**

The certified reference materials of genetically modified cotton 281-24-236 and cotton 3006-210-23 (ERM -BF422) 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 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 cotton 281-24-236 x 3006-210-23.

## LIST OF ANNEXES<sup>7</sup>

- Annex A: Scientific opinion of the EFSA GMO Panel (cotton 81-24-236 x 3006-210-23)
- Annex B: Cartagena Protocol (cotton 81-24-236 x 3006-210-23)
- Annex C: Labelling (cotton 81-24-236 x 3006-210-23)
- Annex D1: Validation report (cotton 81-24-236 x 3006-210-23)
- Annex D2a: Validated method (cotton 81-24-236)
- Annex D2b: Validated method (cotton 3006-210-23)
- Annex D3: Sampling and extraction (cotton 81-24-236 x 3006-210-23)
- Annex E: Certified reference materials report (cotton 81-24-236 x 3006-210-23)
- Annex F: Post-market environmental monitoring plan  
(cotton 281-24-236 x 3006-210-23)
- Annex G: Member States' comments (cotton 81-24-236 x 3006-210-23)

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<sup>7</sup> 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-2010-00863>