



**Opinion of the European Food Safety Authority in accordance with
Articles 6 and 18 of Regulation (EC) No 1829/2003 on
application EFSA-GMO-UK-2004-08**

**Application for the placing on the market of products produced from
glyphosate-tolerant genetically modified sugar beet H7-1 for food and feed
uses from KWS SAAT AG and Monsanto**

(Question No EFSA-Q-2004-164)

20 December 2006

Summary

This document provides an overall opinion of the European Food Safety Authority on genetically modified sugar beet H7-1 in accordance with the requirements of Articles 6 and 18 of Regulation (EC) No 1829/2003.

The scope of this application is for food produced from or containing ingredients produced from genetically modified sugar beet H7-1 and feed produced from genetically modified sugar beet H7-1. The genetically modified sugar beet H7-1 has been developed to be tolerant to glyphosate containing herbicides.

The Scientific Panel on Genetically Modified Organisms has carried out the scientific assessment of the genetically modified sugar beet H7-1 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003 and considers that products produced from genetically modified sugar beet H7-1 are unlikely to have any adverse effect on human and animal health or 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 genetically modified sugar beet H7-1 can be accessed at the Joint Research Centre, Institute for Reference Materials and Measurements.

The labelling proposal 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 sugar beet H7-1.



Background

On 26 November 2004, the European Food Safety Authority (EFSA) received from the United Kingdom Competent Authority an application for authorisation of products produced from genetically modified sugar beet H7-1 (unique identifier KM-ØØØH71-4) submitted jointly by KWS SAAT AG and Monsanto within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (reference EFSA-GMO-UK-2004-08).

The scope of this application is for food produced from or containing ingredients produced from genetically modified sugar beet H7-1 and feed produced from genetically modified sugar beet H7-1. The genetically modified sugar beet H7-1 has been developed to be tolerant to glyphosate containing herbicides.

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 website¹ on 14 December 2004. 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 15 December 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 20 May 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. Although the products does not contain or consist of GMOs, EFSA, following its established procedures, consulted the Member States. In this context, the Member States risk assessment bodies, including national competent authorities under Directive 2001/18/EC, were given three months after the date of receipt of the valid application (until 20 August 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 24 October 2005 to 24 October 2006 and from 31 October 2006 to 20 December 2006².

The overall opinion on application EFSA-GMO-UK-2004-08 includes the scientific opinion of the Scientific Panel on Genetically Modified Organisms (GMO Panel) together with the applicable 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 product and its specification, iii) the labelling proposal, iv) the method for detection and quantification, validated by the Community Reference Laboratory, including sampling and DNA extraction and v) an indication of where appropriate reference materials can be accessed.

¹ http://www.efsa.europa.eu/science/gmo/gm_ff_applications/catindex_en.html

² Request for additional information from EFSA GMO Panel: requested on 24/10/2005 and 6/03/2006, accepted on 24/10/2006.

Request for additional information from EFSA (Certified Reference Materials): requested on 31/10/2006, received on 18/12/2006.

Applicant

The application was jointly submitted by

KWS SAAT AG
Grimsehlstrasse-31
D37574 Einbeck
Germany

and Monsanto Company, represented by Monsanto Europe S.A.

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Avenue de Tervuren 270-272
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Belgium

Monsanto Company
800 N. Lindbergh Boulevard
St. Louis, Missouri 63167
USA

Designation and specification of the product

The scope of this application is for food produced from or containing ingredients produced from genetically modified sugar beet H7-1 and feed produced from genetically modified sugar beet H7-1.

Genetically modified sugar beet H7-1 expresses the CP4 EPSPS protein after insertion of the *cp4 epsps* gene from *Agrobacterium* sp. strain CP4 into sugar beet (*Beta vulgaris* subsp. *vulgaris*). The CP4 EPSPS protein confers tolerance to glyphosate containing herbicides. The unique identifier of the genetically modified sugar beet H7-1 is KM-~~000~~H71-4.

Scientific opinion of the GMO Panel

The GMO Panel has carried out the scientific assessment of the genetically modified sugar beet H7-1 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003 and adopted its scientific opinion on 5 December 2006. The GMO Panel considered all comments submitted by Member State bodies (Annex G) and where deemed necessary, requested additional information from the applicant before finalising its scientific assessment. The GMO Panel concludes that the information available for genetically modified sugar beet H7-1 addresses the scientific comments raised by the Member States and considers that products produced from genetically modified sugar beet H7-1 is unlikely to have any adverse effect on human and animal health or the environment in the context of its intended uses (Annex A).

Cartagena Protocol

Not applicable. The scope of this application is for food produced from or containing ingredients produced from genetically modified sugar beet H7-1 and feed produced from genetically modified sugar beet H7-1. No information is therefore required under Annex II of the Cartagena Protocol.

Labelling

The labelling proposal provided in the application is in line with the requirements of Regulation (EC) No 1829/2003. On the basis of the scientific opinion of the GMO Panel that genetically modified sugar beet H7-1 is compositionally and phenotypically equivalent to non-genetically modified sugar beet 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) of Regulation (EC) No 1829/2003 (Annex C).

Method for detection

The Joint Research Centre as the 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 H7-1 transformation event in sugar beet DNA (KM-000H71-4). The reports were published on 31 January 2006. The Community Reference Laboratory considers the method validated as fit for the purpose of regulatory compliance. An observation is reported regarding the glutamine synthetase (GS) reference gene (Annexes D1, D2 and D3).

Certified reference materials

The certified reference materials of genetically modified sugar beet H7-1 (ERM-BF419) can be accessed at the Joint Research Centre, Institute for Reference Materials and Measurements (JRC-IRMM) of the European Commission (Annex E).

Post market environmental monitoring

Not applicable. Since the scope of this application is for food produced from or containing ingredients produced from genetically modified sugar beet H7-1 and feed produced from genetically modified sugar beet H7-1, a post market environmental monitoring plan is not required.

Member States' Comments

In line with the procedure³ 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 (Not applicable and therefore not included)
Annex C:	Labelling
Annex D1:	Validation report (sugar beet line H7-1)
Annex D2:	Validated method (sugar beet line H7-1)
Annex D3:	Sampling and DNA extraction (sugar beet H7-1)
Annex E:	Certified reference materials
Annex F:	Monitoring plan (Not applicable and therefore not included)
Annex G:	Member States' comments

³ EFSA Strategy document

http://www.efsa.europa.eu/etc/medialib/efsa/science/gmo/109.Par.0010.File.dat/gmo_actionplan1.pdf