European Food Safety Authority

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-2005-14

Application for the placing on the market of genetically modified potato EH92-527-1 with altered starch composition, for production of starch and food/feed uses from BASF Plant Science Holding GmbH

(Question No EFSA-Q-2005-070)

10 November 2006

Summary

This document provides an overall opinion of the European Food Safety Authority on genetically modified potato EH92-527-1 with altered starch composition in accordance with the requirements of Articles 6 and 18 of Regulation (EC) No 1829/2003.

The scope of this application is genetically modified potato EH92-527-1 for food and feed uses[1], food and feed containing, consisting of or produced from potato EH92-527-1. The scope does not include cultivation. The GM potato EH92-527-1 has been developed for amylopectin production and contains a higher amylopectin/amylose ratio. Amylopectin starch potatoes are mainly being used in technical non-food products such as paper. By-products of the starch extraction process are used for other purposes including animal feed (*e.g.* pulp) or for other conventional non-food purposes (*e.g.* potato juice used as soil fertilizer). The GM potato tubers are not intended for direct human consumption.

The Scientific Panel on Genetically Modified Organisms has carried out the scientific assessment of the genetically modified potato EH92-527-1 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003 and considers that the GM potato EH92-527-1 is unlikely to have an 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 potato EH92-527-1 can be accessed at the Joint Research Centre, Institute for Reference Materials and Measurements.

The information presented for the Cartagena Protocol, the labelling proposal and the monitoring plan are in line with the intended uses and the requirements of 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 potato EH92-527-1.

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

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Background

On 25 April 2005, the European Food Safety Authority (EFSA) received from the UK competent authority an application for authorisation of GM potato EH92-527-1 (unique identifier BPS-25271-9) submitted by BASF Plant Science Holding GmbH within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (reference EFSA-GMO-UK-2005-14).

The scope of this application is genetically modified potato EH92-527-1 for food and feed uses[2], food and feed containing, consisting of or produced from Potato EH92-527-1. The scope does not include cultivation.

The GM potato EH92-527-1 has been developed for amylopectin production and contains a higher amylopectin/amylose ratio. Amylopectin starch potatoes are mainly used in technical non-food products such as paper. By-products of the starch extraction process are used for other purposes including animal feed (*e.g.* pulp) or other conventional non-food purposes (*e.g.* potato juice used as soil fertilizer). The GM potato tubers are not intended for direct human consumption. However, since it cannot be excluded that the GM potato EH92-527-1 and derived products may be used as or may be present in food, the GMO panel was therefore requested to carry out a comprehensive scientific risk assessment of the GM potato for all uses.

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 27 April 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 10 March 2005, 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 12 July 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 subsequently consulted the nominated risk assessment bodies of the Member States as well as the national competent authorities within the meaning of Directive 2001/18/EC who had three months after the date of receipt of the valid application (*i.e.* until 12 October 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 26 July 2005 to 09 December 2005 and from 22 February 2006 to 08 August 2006[4].

The overall opinion on application EFSA-GMO-UK-2005-14 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-feed produced from it, vi)

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

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

[4] Request for additional information from CRL: requested on 26/07/2005, accepted on 09/12/2005
Request for additional information from EFSA-GMO Panel: requested on 22/09/2005, accepted on 13/10/2005
Request for additional information from CRL: requested on 22/02/2006, accepted on 08/08/2006

an indication of where appropriate reference material 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 BASF Plant Science.

BASF Plant Science Holding GmbH
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Germany

Designation and specification of the product

The scope of this application is genetically modified potato EH92-527-1 for food and feed uses[5], food and feed containing, consisting of or produced from potato EH92-527-1.

The GM potato EH92-527-1 has been developed for amylopectin production and contains a higher amylopectin/amylose ratio. Amylopectin starch potatoes are mainly used in technical non-food products such as paper, by-products of the starch extraction process are used for other purposes including animal feed (*e.g.* pulp) or other conventional non-food purposes (*e.g.* potato juice used as soil fertilizer). The GM potato tubers are not intended for direct human consumption. However, since it cannot be excluded that the GM potato EH92-527-1 and derived products may be used as or may be present in food, the scope of this application comprises food and feed uses.

GM potato EH92-527-1 was developed from the cultivar Prevalent and has an altered starch composition (higher amylopectin/amylose ratio). The modification implies inhibition of the expression of granule bound starch synthase protein (GBSS) responsible for amylose biosynthesis. As a result, the starch produced has little or no amylose and consists of amylopectin which modifies the physical properties of the starch. A *nptII* gene, conferring kanamycin resistance, was used as a selectable marker in the genetic modification process.

Scientific opinion of the GMO Panel

The GMO Panel has carried out the scientific assessment of the genetically modified potato EH92-527-1 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003 and adopted its scientific opinion on 7 December 2005. The GMO Panel considered all comments submitted by the Member States (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 GM potato EH92-527-1 addresses the scientific comments raised by the Member States and considers that GM potato EH92-527-1 and derived products are 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

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).

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

Labelling

The labelling proposal provided in the application is in line with the intended uses of the GM potato EH92-527-1. With respect to the by-products of the GM potato EH92-527-1, on the basis of the scientific opinion of the GMO Panel that from a compositional and nutritional point of view the GM potato pulp is considered equivalent to pulp processed from conventional potatoes, EFSA is of the opinion that, in the context of the intended uses, there is no need for a specific labelling of the by-products of the GM potato EH92-527-1 in accordance with Articles 13(2)(a) and 25(2)(c) of Regulation (EC) 1829/2003 (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 EH92-527-1 potato transformation event in potato DNA. The reports were published on 14 September 2006. The Community Reference Laboratory considers the method validated as fit for the purpose of regulatory compliance. Considerations are reported regarding the UGPase reference system (Annexes D1, D2, D3).

Certified reference material

The certified reference materials of GM potato EH92-527-1 (ERM-BF421) can be accessed at the Joint Research Centre (JRC-IRMM) of the European Commission (Annex E).

Post market environmental monitoring

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

List of annexes:

Annex A:	Scientific opinion of the GMO Panel
Annex B:	Cartagena Protocol
Annex C:	Labelling
Annex D1:	Validation report (EH92-527-1 Potato)
Annex D2:	Validated method (EH92-527-1 Potato)
Annex D3:	Sampling and extraction (EH92-527-1 Potato)
Annex E:	Certified reference material
Annex F:	Monitoring plan
Annex G:	Member States' comments