European Food Safety Authority

Opinion in accordance with Article 6 of Regulation (EC) No 1829/2003

on genetically modified food and feed

Application EFSA-GMO-NL-2004-02 from Pioneer Hi-Bred International/Mycogen Seeds regarding the placing on the market of insect-tolerant genetically modified maize 1507 for food use

submitted on 3 March 2005

Background

On 10 June 2004 EFSA received from the Dutch Competent Authority a transformed application submitted by Pioneer Overseas Corporation and Mycogen Seeds within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed. This application is for the placing on the market of insect–tolerant genetically modified maize 1507 for food use.

In accordance with Article 5(2)(b) of Regulation (EC) No 1829/2003, EFSA informed the Member States and the Commission and made the summary of the dossier publicly available on the EFSA website[1] on 25 June 2004. EFSA initiated a formal compliance check of the dossier with the requirements laid down in Article 5(3) of Regulation (EC) No 1829/2003. On 27 July 2004, the Community Reference Laboratory confirmed receipt of the detection methods and samples of the food and control samples in accordance with Article 5(3)(i) and (j). On 9 August 2004 EFSA requested additional information from the applicant. Following the receipt of additional information from the applicant on 20 August 2004 and subsequent check for adequacy, EFSA declared the application as valid and started the clock in accordance with Article 6(1) Regulation (EC) No 1829/2003 on 3 September 2004.

EFSA made the valid application available to the Member States and the Commission and consulted nominated risk assessment bodies of the Member States, including the national Competent Authorities within the meaning of Directive 2001/18/EC following the requirements of Article 6(4) Regulation (EC) No 1829/2003, to request their opinion concerning placing the

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

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product on the market. The Member State bodies were given three months after the date of receipt of the request (until 3 December 2004) within which to make their opinion known.

The Scientific Panel on Genetically Modified Organisms carried out a scientific assessment of the genetically modified maize 1507 for food use, in accordance with Article 6(6) of Regulation (EC) No 1829/2003 taking into consideration the opinions of the Member States. The opinion of the GMO Panel was adopted on 19 January 2005.

The current opinion also includes the particulars required under Article 6(5)(a) to (g) of Regulation (EC) No 1829/2003 as received by the applicant : 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 and/or foods produced from it and, vi) the monitoring plan referred to in Article 5(5)(b).

The validated detection and identification method has been submitted to EFSA by the Community Reference Laboratory on 28 February 2005. EFSA evaluated the monitoring plan required under Article 6(5)(g). However, EFSA has not evaluated the particulars referred to in i) - v) above as they are related to regulatory and/or risk management matters and, consequently, EFSA was not responsible for their content.

In accordance with Article 6(1) of Regulation (EC) No 1829/2003 EFSA has, in giving its opinion to the Commission, the Member States and the applicant, endeavoured to respect a time limit of six months as from the receipt of a valid application.

Conclusion

Based on the risk assessment by the GMO Panel, it can be concluded that there is no evidence to indicate that placing of maize line 1507 and derived products on the market is likely to cause adverse effects on human or animal health or the environment in the context of its proposed use.

Based on the outcome of the risk assessment it is advised that no specific conditions or restrictions should be imposed on the placing of 1507 maize on the market for food use. No specific conditions or restrictions for food use and handling, including post-market monitoring requirements regarding the use of 1507 maize for human consumption, are regarded as necessary. Furthermore, the risk assessment identified no need for specific conditions for the protection of particular ecosystems/environment and/or geographical areas.

The opinion of the Scientific Panel on Genetically Modified Organisms on application No EFSA-GMO-NL-2004-02, in accordance with Article 6(6) of Regulation (EC) 1829/2003 can be found in Annex A.

The JRC as Community reference laboratory considers the method validated as fit for the purpose of regulatory compliance.

Further information included in the opinion as required under Article 6(5)(a) to (g) of Regulation (EC) No 1829/2003:

a) *the name and address of the applicant*

This is a notification jointly submitted by Pioneer Hi-Bred and Mycogen Seeds.

Pioneer Hi-Bred International, Inc. as represented by Pioneer Overseas Corporation

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(b) the designation of the food, and its specification

The product consists of foods from maize grain produced from genetically modified *Bt* maize line 1507 and progeny derived from conventional breeding between 1507 maize with any traditionally bred non-GM maize, the 1507 maize has been genetically modified to express Cry1F protein, conferring resistance to certain lepidopteran insect pests, such as the European corn borer and *Sesamia* spp., and PAT protein, conferring tolerance to glufosinate-ammonium herbicide. Food use of 1507 maize will be consistent with current food uses of commercial maize products. Labelling of 1507 maize food products will be carried out in accordance with Community law.

(c) where applicable, the information required under Annex II to the Cartagena Protocol

The information provided by the applicant can be found in Annex B.

(d) the proposal for the labelling of the food and/or foods produced from it

The labelling proposal provided by the applicant can be found in Annex C.

(e) where applicable, any conditions or restrictions which should be imposed on the placing on the market and/or specific conditions or restrictions for use and handling, including post-market monitoring requirements based on the outcome of the risk assessment and, in the case of GMOs or food containing or consisting of GMOs, conditions for the protection of particular ecosystems/environment and/or geographical areas

No conditions or restrictions are recommended.

(f) the method, validated by the Community reference laboratory, for detection, including sampling, identification of the transformation event and, where applicable, for the detection and identification of the transformation event in the food and/or in foods produced from it; an indication of where appropriate reference material can be accessed

The relevant particulars provided by CRL-JRC can be found in Annex D.

Regarding to where the reference materials can be assessed the applicant stated the following:

> "*samples of 1507 maize and control samples have been sent to the EC JRC Institute of Reference Materials and Measurements in Geel for the production of certified reference material*."

(g) where appropriate, the monitoring plan referred to in Article 5(5)(b)

The monitoring plan provided by the applicant and accepted by the GMO Panel can be found in Annex E