

Application (EFSA-GMO-RX-1507) for renewal of authorisation for the continued marketing of existing products produced from maize 1507 for feed use, under Regulation (EC) No 1829/2003 from Pioneer Hi-Bred International, Inc./Mycogen Seeds¹

Scientific Opinion of the Panel on Genetically Modified Organisms

(Question No EFSA-Q-2007-144)

Adopted on 28 May 2009

SUMMARY

This document provides the scientific opinion of the Panel on Genetically Modified Organisms (GMO Panel) of the European Food Safety Authority (EFSA) on an application submitted under Regulation (EC) No 1829/2003 (reference EFSA-GMO-RX-1507) for renewal of the authorisation of existing products derived from genetically modified maize 1507.

The scope of this application covers the continued marketing of existing feed produced from maize 1507 (feed materials and feed additives), which were lawfully placed on the market in the Community before the date of entry into force of Regulation (EC) No 1829/2003. After the date of entry into force of Regulation (EC) 1829/2003 these products were notified to the European Commission according to Article 20 of that Regulation and included in the Community Register of genetically modified food and feed².

Maize 1507 was developed to provide protection against specific lepidopteran pests and tolerance to the herbicide glufosinate by the introduction of Cry1F and PAT proteins.

The EFSA GMO Panel has previously issued scientific opinions related to notifications C/NL/00/10 for the placing on the market of maize 1507 for import and processing and C/ES/01/01 for the placing on the market of maize 1507 for import, feed and industrial processing and cultivation, under Part C of Directive 2001/18/EC. In addition to this, a scientific opinion for food use of maize 1507 under Regulation (EC) No 1829/2003 was issued and published. In these scientific opinions the EFSA GMO Panel concluded that maize 1507 will not have an adverse effect on human and animal health or the environment in the context of its proposed uses. In addition, maize 1507 has been assessed in several applications related to stacked events.

In delivering its opinion the EFSA GMO Panel considered the information provided in the renewal application (reference EFSA-GMO-RX-1507) as well as additional information

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² http://ec.europa.eu/food/dyna/gm_register/gm_register_auth.cfm?pr_id=2

submitted by the applicant on request of the Panel. In accordance with the Guidance Document for renewal of authorisations of existing EFSA GMO products, the EFSA GMO Panel has taken into account the new information, experience and data, which have become available during the authorisation period.

According to information provided by the applicant, feed products produced from maize 1507 and from maize containing 1507 event stacked with other GM events that have been approved in the EU, have been consumed without reports of adverse effects. Scientific publications, which have become available since the previous evaluation of maize 1507 by the EFSA GMO Panel, did not raise safety issues. Additional bioinformatics studies using updated databases have confirmed the results of the previous studies showing that no relevant similarities exist between the newly expressed proteins Cry1F and PAT and known toxic proteins for human and mammals or allergens. Bioinformatics analysis of the flanking regions showed homology to retrotransposable elements which raises no safety concern.

The scope of this application is for feed materials and feed additives which are produced from maize 1507. Thus the scope only includes products produced from maize 1507 which contain no viable plant parts. Therefore, there are no requirements for scientific information on environmental safety assessment of accidental release or cultivation of maize 1507. A post market environmental monitoring plan for maize 1507 is not required.

The EFSA GMO Panel concludes that the new information provided by the applicant and a review of the scientific literature that has been published since the previous opinions of the EFSA GMO Panel does not require changes of the previous scientific opinions on maize 1507 and addresses the scientific comments raised by the Member States. Therefore, the EFSA GMO Panel reiterates the previous conclusions that genetically modified maize 1507 is unlikely to have an adverse effect on human and animal health or the environment in the context of its proposed uses. This includes the use of feed materials and feed additives produced from maize 1507.

Key words: GMO, maize, *Zea mays*, 1507, insect protection, Cry1F, PAT, feed safety, animal health, Regulation (EC) No 258/97, Regulation (EC) No 1829/2003, Directive 70/524/EEC, Directive 2001/18/EC, renewal, existing product.