

Opinion on application reference EFSA-GMO-RX-Bt11 for renewal of the authorisation of existing products produced from insect-resistant genetically modified maize Bt11, under Regulation (EC) No 1829/2003 from Syngenta¹

Scientific Opinion of the Panel on Genetically Modified Organisms

(Question No EFSA-Q-2007-146)

Adopted on 28 January 2009

SUMMARY

This document provides the opinion of the Scientific 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-Bt11) for renewal of the authorisation of existing products derived from genetically modified maize Bt11.

The scope of this application covers the continued marketing of existing food and food ingredients containing, consisting of or produced from maize Bt11, food additives produced from maize Bt11, feed containing, consisting of or produced from maize Bt11 (feed materials and feed additives) to be used as any other maize grain but not for cultivation, and other products containing or consisting of maize Bt11 with the exception of cultivation 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) No 1829/2003 these products were notified to the European Commission according to Articles 8 and 20 of that Regulation and included in the Community Register of genetically modified food and feed².

Maize Bt11 was developed to provide protection against specific lepidopteran pests. The maize also contains a gene providing tolerance to the herbicide glufosinate ammonium.

The EFSA GMO Panel has previously issued a scientific opinion related to notification C/F/96/05.10 for the placing on the market of insect-resistant genetically modified maize Bt11, for cultivation, feed and industrial processing under Directive 2001/18/EC (EFSA, 2005). In this opinion the Panel concluded that maize Bt11 is unlikely to have an adverse effect on human and animal health or the environment in the context of its proposed uses.

In delivering its present opinion, the GMO Panel considered information provided in the renewal application (reference EFSA-GMO-RX-Bt11) as well as additional information submitted by the applicant on request of the Panel. In accordance with the Guidance

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² http://ec.europa.eu/food/dyna/gm_register/gm_register_auth.cfm?pr_id=1

Document for renewal of authorisations of existing GMO products (EFSA, 2006a), the Panel has taken into account the new information, experience and data, which have become available during the authorisation period.

New information was provided in this renewal application with regards to 1) a review of peer-reviewed scientific data on Bt11 maize; 2) a report on areas and quantity of production, importation, use in Europe of Bt11 maize and information on known and estimated human and animal exposure; 3) an updated molecular characterisation, including sequence data for the flanking regions; 4) an updated information on the levels of expression of the specific proteins and metabolites resulting from the genetic modification and on the composition of the GMO; 5) an updated information on allergenicity and toxicology; and 6) a post-market environmental monitoring plan.

The updated molecular and bioinformatic analyses provided for the maize Bt11 event do not indicate any safety concerns and the GMO Panel maintains its previous opinion on the safety of this event,

New information from an updated literature review and from additional studies performed by the applicant does not prompt the Panel to change its previous opinion that maize Bt11 is as safe and as nutritious as its non-GM counterparts.

The application for renewal of authorisation of existing products derived from maize Bt11 excludes cultivation of the crop in the EU. There is therefore no requirement for scientific assessment of possible environmental effects associated with the cultivation of maize Bt11. The scope of the post-market environmental monitoring plan provided by the applicant is in line with the intended uses of maize Bt11 since cultivation is excluded and is in line with the EFSA Guidance Document (EFSA, 2006b) and the Opinion of the GMO Panel on post-market environmental monitoring (EFSA, 2006c).

The GMO Panel concludes that the new information provided by the applicant and the review of the literature that has been published since the previous scientific opinion of the GMO Panel does not require changes of the previous scientific opinion on maize Bt11 and addresses the scientific comments raised by the Member States. Therefore, the Panel reiterates the previous conclusion that genetically modified maize Bt11 is unlikely to have an adverse effect on human and animal health or the environment in the context of its proposed uses. This also applies to the products which are the subject of the present application.

Key words: GMO, maize, *Zea mays*, Bt11, insect-resistant, herbicide-tolerant, Cry1Ab, PAT, feed safety, food safety, human health, Regulation (EC) No 258/97, Regulation (EC) No 1829/2003, Directive 90/220/EEC, Directive 2001/18/EC, renewal, existing product.