

SCIENTIFIC OPINION

Application (Reference EFSA-GMO-NL-2008-51) for the placing on the market of glyphosate tolerant genetically modified cotton GHB614, for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Bayer CropScience¹

Scientific Opinion of the Panel on Genetically Modified Organisms

(Question No EFSA-Q-2008-016)

Adopted on 05 March 2009

PANEL MEMBERS*

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SUMMARY

This document provides a scientific opinion of the Scientific Panel on Genetically Modified Organisms (GMO Panel) of the European Food Safety Authority (EFSA) on genetically modified (GM) cotton GHB614 (Unique Identifier BCS-GHØØ2-5) developed to provide tolerance to glyphosate-based herbicides.

In delivering its scientific opinion, the EFSA GMO Panel considered the application EFSA-GMO-NL-2008-51, additional information supplied by the applicant and scientific comments submitted by Member States. The scope of application EFSA-GMO-NL-2008-51 is for food and feed uses, import and processing of cotton GHB614 and all derived products, but excludes cultivation in the EU. The EFSA GMO Panel assessed cotton GHB614 with reference to the intended uses and appropriate principles described in the guidance document of the Scientific Panel on Genetically Modified Organisms for the risk assessment of genetically modified plants and derived food and feed. The scientific assessment included molecular characterisation of the inserted DNA and expression of target proteins. A comparative analysis of agronomic traits and composition was undertaken, and the safety of the new protein and the

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* (minority opinion) This opinion is not shared by 0 members of the Panel. / (conflict of interest) 0 members of the Panel did not participate in (part of) the discussion on the subject referred to above because of possible conflicts of interest.

whole food/feed were evaluated with respect to potential toxicity, allergenicity and nutritional quality. An assessment of environmental impacts and the post-market environmental monitoring plan were undertaken.

Cotton GHB614 is derived from the cotton variety Coker 312 that was transformed by *Agrobacterium*-mediated gene transfer technology. Cotton GHB614 expresses a modified *epsps* (*2mepsps*) maize gene leading to the production of a modified 5-enolpyruvyl-shikimate-3-phosphate synthase (2mEPSPS) enzyme that confers tolerance to glyphosate-based herbicides.

The molecular characterisation data established that a single insert with one copy of the intact modified *epsps* (*2mepsps*) expression cassette is integrated in the cotton genomic DNA. Appropriate analyses of the integration site including sequence determination of the inserted DNA and flanking regions and bioinformatics analysis have been performed. Bioinformatics analysis of junction regions demonstrated the absence of any potential new open reading frames coding for known toxins or allergens. The expression of the gene introduced by genetic modification has been sufficiently analysed and the stability of the genetic modification has been demonstrated over several generations. The EFSA GMO Panel is of the opinion that the molecular characterisation of the DNA insert and flanking regions of cotton GHB614 does not raise any safety concern, and that sufficient evidence for the stability of the genetic modification was provided.

Based on comparative analyses, the EFSA GMO Panel concluded that cotton GHB614 is compositionally and agronomically equivalent to the non-GM counterpart and other conventional cotton except for the introduced trait. The risk assessment included an analysis of data from analytical studies, bioinformatics, and *in vitro* and *in vivo* studies. The EFSA GMO Panel considers it unlikely that the overall allergenicity of the whole plant is changed by the genetic modification and concludes that cotton GHB614 is as safe as the non-GM counterpart and other conventional cotton.

The application EFSA-GMO-NL-2008-51 concerns food and feed uses, import and processing. Therefore, there is no requirement for scientific information on possible environmental effects associated with the cultivation of cotton GHB614. The EFSA GMO Panel agrees that unintended environmental effects due to the establishment and spread of cotton GHB614 will not be different from that of conventionally bred cotton.

Considering the intended uses of cotton GHB614, the monitoring plan provided by the applicant is in line with both the EFSA GMO Panel guidance document on the risk assessment of GM plants and the opinion of the EFSA GMO Panel on post-market environmental monitoring. However, the EFSA GMO Panel is aware that, due to physical characteristics of cotton seeds and methods of transportation, accidental spillage is unavoidable. Therefore, the EFSA GMO Panel recommends that specific measures are introduced to actively monitor the occurrence of feral cotton plants in areas where seed spillage is likely to occur.

In conclusion, the EFSA GMO Panel considers that the information available for cotton GHB614 addresses the scientific comments raised by Member States and that cotton GHB614 is as safe as its conventional counterpart with respect to potential effects on human and animal health and the environment. The EFSA GMO Panel thus concludes that cotton GHB614 is unlikely to have any adverse effect on human and animal health or on the environment in the context of its intended uses.

Key words: GMOs, cotton, GHB614, BCS-GHØØ2-5, glyphosate tolerant, 2mEPSPS, food/feed safety, animal and human health, environment, import, processing, Regulation (EC) No 1829/2003