
Summary of the opinion of the Scientific Panel on Genetically Modified Organisms on applications (references EFSA-GMO-UK-2005-19 and EFSA-GMO-RX-GA21) for the placing on the market of glyphosate-tolerant genetically modified maize GA21, for food and feed uses, import and processing and for renewal of the authorisation of maize GA21 as existing product, both under Regulation (EC) No 1829/2003 from Syngenta Seeds S.A.S. on behalf of Syngenta Crop Protection AG ¹

(Questions No EFSA-Q-2005-226 and EFSA-Q-2007-147)

Opinion adopted on 13 September 2007

This document provides the opinion of the Scientific Panel on Genetically Modified Organisms (GMO Panel) of the European Food Safety Authority (EFSA) on herbicide-tolerant genetically modified maize GA21 (Unique Identifier MON-ØØØ21-9) developed to provide tolerance to glyphosate by expressing a modified version of the EPSPS protein.

In delivering its opinion the GMO Panel considered the new application EFSA-GMO-UK-2005-19, additional information provided by the applicant (Syngenta Seeds on behalf of Syngenta Crop Protection AG) and the scientific comments submitted by the Member States. The scope of application EFSA-GMO-UK-2005-19 is for food and feed uses, import and processing of maize GA21 and all derived products, excluding cultivation. Information provided in the context of the application for renewal of the authorisation of maize GA21 as existing product, submitted under Regulation (EC) No 1829/2003 (Reference EFSA-GMO-RX-GA21), was also taken into account. The scope of application EFSA-GMO-RX-GA21 covers the continued marketing of existing food additives, feed materials and feed additives produced from maize GA21.

A single risk assessment for all intended uses of maize GA21 has been performed by the GMO Panel and one single scientific opinion for both applications submitted under Regulation (EC) No 1829/2003 is issued. The GMO Panel assessed maize GA21 with reference to the intended uses and the 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 characterization of the inserted DNA and expression of the new protein. A comparative analysis of agronomic traits and composition was undertaken and the safety of the new protein and the whole food/feed was evaluated with respect to nutritional quality, potential toxicity and allergenicity. An assessment of environmental impacts and the post-market environmental monitoring plan were undertaken.

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Maize GA21 was transformed by particle bombardment of maize cells and expresses a modified EPSPS (5-enol pyruvylshikimate-3-phosphate synthase) protein. The molecular characterisation data established that maize GA21 contains a single insert having four intact and two truncated fragments of the introduced DNA. Appropriate analyses of the integration site including flanking sequences and bioinformatic analysis have been performed. Bioinformatic analysis of the insert and junction regions demonstrated the absence of any ORF potentially coding for known toxic or allergenic proteins. The expression of the genes introduced by genetic modification has been sufficiently analysed and the stability of the genetic modification has been demonstrated over several generations.

The GMO Panel is of the opinion that the molecular characterisation of the DNA insert and flanking regions of maize GA21 does not raise safety concerns, and that sufficient evidence for the stability of the insert structure was provided.

Based on the results of compositional analysis of samples from a representative range of environments and seasons, the GMO Panel concludes that forage and kernels of maize GA21 are compositionally equivalent to those of conventional maize, except for the presence of the mEPSPS protein. In addition, field trials did not show changes in phenotypic characteristics and agronomic performance except for the introduced trait.

The mEPSPS protein did not induce adverse effects in a study on acute oral toxicity in mice. There were no adverse effects in a subchronic (90-day) feeding study with rats fed diets including kernels from maize GA21. A feeding study on broiler chickens provided evidence of nutritional equivalence of maize GA21 to conventional maize. In addition the overall allergenicity of the whole plant is not changed. The GMO Panel is of the opinion that maize GA21 is as safe as conventional maize. Maize GA21 and derived products are unlikely to have any adverse effect on human and animal health in the context of the intended uses.

The applications for maize GA21 concern food and feed uses, import and processing of maize GA21 and all derived products. There is therefore no requirement for scientific assessment of possible environmental effects associated with the cultivation of maize GA21. There are no indications of increased likelihood of establishment or survival of feral maize plants in case of accidental release into the environment of GA21 seeds during transportation and processing. The scope of the post-market environmental monitoring plan provided by the applicant is in line with the intended uses of maize GA21.

In conclusion, the GMO Panel considers that the information available for maize GA21 addresses the scientific comments raised by the Member States and that maize GA21 is as safe as its non genetically modified counterparts with respect to potential effects on human and animal health or the environment. Therefore the GMO Panel concludes that maize GA21 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: GMO, maize, GA21, glyphosate tolerance, EPSPS, MON-00021-9, human and animal health, environment, import, processing, food, feed, Regulation (EC) No 1829/2003, renewal, existing product.