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## **Food/Feed and Environmental Risk Assessment of Insect-resistant and Herbicide-tolerant Genetically Modified Maize GA21 from Syngenta Seeds for Food and Feed Uses, Import and Processing under Regulation (EC) No 1829/2003 (EFSA/GMO/UK/2005/19)**

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### **Authors' contributions**

*This work was carried out in collaboration among all authors. The opinion has been assessed and approved by the Panel on Genetically Modified Organisms of VKM. All authors read and approved the final manuscript.*

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**Grey Literature**

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## ABSTRACT

In preparation for a legal implementation of EU-regulation 1829/2003, the Norwegian Scientific Committee for Food Safety (VKM) has been requested by the Norwegian Environment Agency (former Norwegian Directorate for Nature Management) and the Norwegian Food Safety Authority (NFSA) to conduct final food/feed and environmental risk assessments for all genetically modified organisms (GMOs) and products containing or consisting of GMOs that are authorized in the European Union under Directive 2001/18/EC or Regulation 1829/2003/EC. The request covers scope(s) relevant to the Gene Technology Act. The request does not cover GMOs that VKM already has conducted its final risk assessments on. However, the Agency and NFSA requests VKM to consider whether updates or other changes to earlier submitted assessments are necessary.

The herbicide-tolerant genetically modified maize GA21 from Syngenta Seeds (Unique Identifier MON-ØØØ21-9) is authorised for the import and placing on the market as food or feed in the EU pursuant to Regulation (EC) 1829/2003 by the Commission Decision 2008/280/EC. An application for granting consent to all uses of GA21 maize including the cultivation was submitted by Syngenta in accordance with articles 5 and 17 of the Regulation (EC) No. 1829/2003 on June 30 2008.

Maize GA21 has previously been assessed as food and feed by the VKM GMO Panel commissioned by the Norwegian Food Safety Authority in connection with the national finalisation of the procedure of the notification C/ES/98/01 in 2005 (VKM 2005a). VKM also participated in the 90 days public consultation of the application for placing on the market of maize GA21 for food and feed uses, import, processing and cultivation (EFSA/GMO/UK/2008/60) in 2009, and submitted a preliminary opinion in April 2010 (VKM 2010). GA21 has also been evaluated by the VKM GMO Panel as a component of several stacked GM maize events under and Regulation (EC) 1829/2003 (VKM 2008, VKM 2009a,b,c,d, VKM 2012a,b, VKM 2013a,b,c). Due to the publication of new scientific literature and updated guidelines for risk assessment of genetically modified plants, the VKM GMO Panel has decided to deliver an updated food/feed and environmental risk assessment of GA21.

The updated food/feed and environmental risk assessment of the maize GA21 is based on information provided by the applicant in the applications EFSA/GMO/UK/2005/19, EFSA/GMO/UK/2008/60 and EFSA/GMO/RX/GA21 and scientific comments from EFSA and other member states made available on the EFSA website GMO Extranet. The risk assessment also considered other peer-reviewed scientific literature as relevant.

The VKM GMO Panel has evaluated GA21 with reference to its intended uses in the European Economic Area (EEA), and according to the principles described in the Norwegian Food Act, the Norwegian Gene Technology Act and regulations relating to impact assessment pursuant to the Gene Technology Act, Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms, and Regulation (EC) No 1829/2003 on genetically modified food and feed. The Norwegian Scientific Committee for Food Safety has also decided to take account of the appropriate principles described in the EFSA guidelines for the risk assessment of GM plants and derived food and feed (EFSA 2011a), the environmental risk assessment of GM plants (EFSA 2010), selection of comparators for the risk assessment of GM plants (EFSA 2011b) and for the post-market environmental monitoring of GM plants (EFSA 2011c).

The scientific risk assessment of maize GA21 include molecular characterisation of the inserted DNA and expression of novel proteins, comparative assessment of agronomic and phenotypic characteristics, nutritional assessments, toxicology and allergenicity, unintended effects on plant fitness, potential for gene transfer, interactions between the GM plant and target and non-target organisms and effects on biogeochemical processes.

It is emphasized that the VKM mandate does not include assessments of contribution to sustainable development, societal utility and ethical considerations, according to the Norwegian Gene Technology Act and Regulations relating to impact assessment pursuant to the Gene

Technology Act. These considerations are therefore not part of the risk assessment provided by the VKM Panel on Genetically Modified Organisms.

Maize GA21 expresses a modified version of 5-enolpyruvylshikimate-3-phosphate synthase (mEPSPS), which is derived from maize EPSPS, and renders maize GA21 tolerant to the herbicidal active substance glyphosate.

**Molecular Characterization:**

The molecular characterisation data indicate that several copies of the GA21 construct are integrated at a single locus in the DNA, and that they are inherited as a dominant, single locus trait. Appropriate analyses of the integration site, inserted DNA sequence, flanking regions, and bioinformatics have been performed. The VKM GMO Panel considers the molecular characterisation of maize GA21 as adequate.

**Comparative Assessment:**

Comparative analyses of maize event GA21 to its conventional counterpart) have been performed during multiple field trials located at representative sites and environments in North America (1997, 2004, and 2005), Europe (1996, 1997, and 2006) and Brazil (2003). With the exception of small intermittent variations, no biologically significant differences were found between maize GA21 and controls. Based on the assessment of available data, the VKM GMO Panel concludes that maize GA21 is compositionally, agronomically and phenotypically equivalent to its conventional counterpart, except for the mEPSPS protein, and that its composition fell within the range observed among nonGM varieties.

**Food and Feed Risk Assessment:**

Whole food feeding studies in rats, broilers and cattles have not indicated any adverse health effects of maize GA21. These studies also indicate that maize GA21 is nutritionally equivalent to conventional maize. The mEPSPS protein does not show sequence resemblance to other known toxins or IgE allergens, nor has mEPSPS been reported to cause IgE mediated allergic reactions.

Based on current knowledge, the VKM GMO Panel concludes that maize GA21 is nutritionally equivalent to conventional maize varieties. It is unlikely that the mEPSPS protein will introduce a toxic or allergenic potential in food or feed based on maize GA21 compared to conventional maize.

**Environmental Risk Assessment:**

The scope of the application EFSA/GMO/UK/2005/19 includes import and processing of maize GA21 for food and feed uses. Considering the intended uses of maize GA21, excluding cultivation, the environmental risk assessment is concerned with accidental release into the environment of viable grains during transportation and processing, and indirect exposure, mainly through manure and faeces from animals fed grains from maize GA21.

Maize GA21 has no altered survival, multiplication or dissemination characteristics, and there are no indications of an increased likelihood of spread and establishment of feral maize plants in the case of accidental release into the environment of seeds from maize GA21. Maize is the only representative of the genus *Zea* in Europe, and there are no cross-compatible wild or weedy relatives outside cultivation. The VKM GMO Panel considers the risk of gene flow from occasional feral GM maize plants to conventional maize varieties to be negligible in Norway. Considering the intended use as food and feed, interactions with the biotic and abiotic environment are not considered by the GMO Panel to be an issue.

**Overall Conclusion:**

Based on current knowledge, the VKM GMO Panel concludes that maize GA21 is nutritionally equivalent to conventional maize varieties. It is unlikely that the mEPSPS protein will introduce a toxic or allergenic potential in food derived from maize GA21 compared to conventional maize.

The VKM GMO Panel likewise concludes that maize GA21, based on current knowledge, is comparable to conventional maize varieties concerning environmental risk in Norway with the intended usage.

**Keywords:** *Maize; Zea mays L.; genetically modified maize GA21; EFSA/GMO/UK/2005/19; herbicidetolerance; glyphosate; mepsps gene; mEPSPS protein; food and feed risk assessment; environmental risk assessment; Regulation (EC) No 1829/2003.*

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**NOTE:**

This work was carried out in collaboration between all authors. The opinion has been assessed and approved by the Panel on Genetically Modified Organisms of VKM. All authors read and approved the final manuscript.

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**COMPETING INTERESTS**

Authors have declared that no competing interests exist.

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