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# **Food/Feed and Environmental Risk Assessment of Application (Reference EFSA/GMO/UK/2008/56) for Authorization of Insect Resistant and Herbicide Tolerant Genetically Modified Maize Bt11 x MIR604 x GA21 for Food and Feed Uses, Import and Processing under Regulation (EC) No 1829/2003 from Syngenta Seeds**

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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 Environment Agency has requested the Norwegian Food Safety Authority to give final opinions on 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 within the Authority's sectorial responsibility. The Norwegian Food Safety Authority has therefore, by letter dated 13 February 2013 (ref. 2012/150202), requested the Norwegian Scientific Committee for Food Safety (VKM) to carry out scientific risk assessments of 39 GMOs and products containing or consisting of GMOs that are authorized in the European Union. 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 requests VKM to consider whether updates or other changes to earlier submitted assessments are necessary.

The insect-resistant and herbicide-tolerant genetically modified maize Bt11 x MIR604 x GA21 (Unique Identifier SYN-BTØ11-1 x SYN-IR6Ø4-5 x MON-ØØØ21-9 ) from Syngenta Seeds is approved under Regulation (EC) No 1829/2003 for food and feed uses, import and processing since 22 December 2011 (Commission Decision 2011/893/EC).

Genetically modified maize Bt11 x MIR604 x GA21 has previously been risk assessed by the VKM Panel on Genetically Modified Organisms (GMO), commissioned by the Norwegian Food Safety Authority and the Norwegian Environment Agency related to the EFSA's public hearing of the application EFSA/GMO/UK/2008/56 in 2008 (VKM 2008a). In addition, Bt11, MIR604 and GA21 has been evaluated by the VKM GMO Panel as single events and as a component of several stacked GM maize events (VKM 2005a,b,c, 2007, 2009a,b,c,d, 2010, 2011, 2012a,b,).

The food/feed and environmental risk assessment of the maize Bt11 x MIR604 x GA21 is based on information provided by the applicant in the application EFSA/GMO/UK/2008/56 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 Bt11 x MIR604 x 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) and selection of comparators for the risk assessment of GM plants (EFSA 2011b).

The scientific risk assessment of maize Bt11 x MIR604 x 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.

The genetically modified maize stack Bt11 x MIR604 x GA21 has been produced by conventional crossing between inbred lines of maize containing the single events Bt11, MIR604 and GA21. The

F1 hybrid was developed to provide protection against certain lepidopteran and coleopteran target pests, and to confer tolerance to glufosinate-ammonium glyphosate-based herbicides.

**Molecular Characterisation:**

Southern blot and PCR analyses have indicated that the recombinant inserts in the parental maize lines Bt11, MIR604 and GA21 are retained in the stacked maize Bt11 x MIR604 x GA21. Genetic stability of the inserts has previously been demonstrated in the parental maize lines. Protein levels measured by ELISA show comparable levels of the Cry1Ab, PAT, mCry3A, PMI and mEPSPS proteins between the stacked and single maize lines. Phenotypic analyses also indicate stability of the insect resistance and herbicide tolerance traits in the stacked maize. The VKM Panel on GMO considers the molecular characterisation of maize Bt11 x MIR604 x GA21 and its parental events Bt11, MIR604 and GA21 as adequate.

**Comparative Assessment:**

Comparative analyses of data from field trials located at representative sites and environments in North America during the 2006 growing season indicate that maize stack Bt11 x MIR604 x GA21 is compositionally, agronomically and phenotypically equivalent to its conventional counterpart, with the exception of the insect resistance and the herbicide tolerance, conferred by the expression of Cry1Ab, mCry3A, PAT, PMI and mEPSPS proteins.

Based on the assessment of available data, the VKM GMO Panel is of the opinion that conventional crossing of maize Bt11, MIR604 and GA21 to produce the hybrid Bt11 x MIR604 x GA21 does not result in interactions between the newly expressed proteins affecting composition and agronomic characteristics.

**Food and Feed Risk Assessment:**

A whole food feeding study on broilers has not indicated any adverse health effects of maize Bt11 x MIR604 x GA21, and shows that maize Bt11 x MIR604 x GA21 is nutritionally equivalent to conventional maize. The Cry1Ab, PAT, mEPSPS, mCry3A or PMI proteins do not show sequence resemblance to other known toxins or IgE allergens, nor have they been reported to cause IgE mediated allergic reactions. Some studies have however indicated a potential role of Cry-proteins as adjuvants in allergic reactions.

Based on current knowledge, the VKM GMO Panel concludes that maize Bt11 x MIR604 x GA21 is nutritionally equivalent to conventional maize varieties. It is unlikely that the Cry1Ab, PAT, mEPSPS, mCry3A or PMI proteins will introduce a toxic or allergenic potential in food or feed based on maize Bt11 x MIR604 x GA21 compared to conventional maize.

**Environmental Risk Assessment:**

The scope of the application EFSA/GMO/UK/2008/56 includes import and processing of maize stack Bt11 x MIR604 x GA21 for food and feed uses. Considering the intended uses of maize Bt11 x MIR604 x 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 Bt11 x MIR604 x GA21.

Maize Bt11 x MIR604 x 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 Bt11 x MIR604 x GA21 is nutritionally equivalent to conventional maize varieties. It is unlikely that the Cry1Ab, PAT, mEPSPS, mCry3A or PMI proteins will introduce a toxic or allergenic potential in food or feed based on maize Bt11 x MIR604 x GA21 compared to conventional maize.

The VKM GMO Panel likewise concludes that maize Bt11 x MIR604 x 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 Bt11 x MIR604 x GA21; EFSA/GMO/UK/2008/56; insect- resistance; herbicide-tolerance; Cry proteins; Cry1Ab; PAT; mEPSPS; mCry3A; MIR604 PMI; glufosinate-ammonium; glyphosate; 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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