



Food/Feed and Environmental Risk Assessment of Insect-Resistant and Herbicide-Tolerant Genetically Modified Maize Bt11 from Syngenta Seeds for Food and Feed Uses, Import and Processing under Regulation (EC) No 1829/2003 (EFSA/GMO/RX/Bt11)

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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

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(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 insect-resistant and herbicide-tolerant genetically modified maize Bt11 from Syngenta Seeds (Unique Identifier SYN-BT Ø11-1) is approved under Regulation (EC) No 1829/2003 for food and feed uses, import and processing (Commission Decision 2010/419/EC).

Genetically modified maize Bt11 has previously been risk assessed by the VKM Panel on Genetically Modified Organisms (GMO) as sweet maize in 2005 (Notification xx) and fodder/field maize in 2007 (Notification C/F/96/05.10) (VKM 2005, VKM 2007). Bt11 has also been evaluated by the VKM GMO Panel as a component of several stacked GM maize events (VKM 2008, VKM 2009a,b,c,d,e VKM 2012a,b, 2013a,b,c).

The food/feed and environmental risk assessment of the maize Bt11 is based on information provided by the applicant in the application EFSA/GMO/RX/Bt11, 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 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 Bt11 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.

Molecular Characterization:

The molecular characterisation data indicate that a single copy of the transgenic insert with the Cry1Ab and pat genes is integrated in the nuclear genome of maize Bt11, and that it is 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 Bt11 as adequate.

Comparative Assessment:

Comparative analyses of data from field trials located at representative sites and environments in North America and Europe indicate that maize Bt11 is compositionally equivalent to its conventional

counterpart, with the exception of the herbicide tolerance and insect resistance traits, conferred by the expression of the Cry1Ab and PAT proteins. However, data on the amino acid tryptophan, is only given in one out of six studies. Based on current knowledge, the VKM GMO panel concludes that maize Bt11 is compositionally equivalent to conventional maize.

The data provided by the applicant are not sufficient to show that Bt11 maize is phenotypically and agronomically equivalent to conventional near-isogenic maize lines. The agronomic assessment data are provided from one growing season in the North America and one growing season in France. This is not considered to be sufficient for representative testing of agricultural environments.

Food and Feed Risk Assessment:

Whole food feeding studies have not indicated any adverse health effects of maize Bt11. These studies also indicate that maize Bt11 is nutritionally equivalent to conventional maize. The Cry1Ab and PAT 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 is nutritionally equivalent to conventional maize varieties. It is unlikely that the Cry1Ab and PAT proteins will introduce a toxic or allergenic potential in food or feed based on maize Bt11 compared to conventional maize.

Environmental Risk Assessment:

The scope of the application EFSA/GMO/RX/Bt11 includes import and processing of maize stack Bt11 for food and feed uses. Considering the intended uses of maize Bt11, 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.

Maize Bt11 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 Bt11. 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 is nutritionally equivalent to conventional maize varieties. It is unlikely that the Cry1Ab and PAT proteins will introduce a toxic or allergenic potential in food or feed derived from maize Bt11 compared to conventional maize.

The VKM GMO Panel likewise concludes that maize Bt11, 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; EFSA/GMO/RX/Bt11; insect-resistance; herbicide-tolerance; cry proteins; Cry1Ab; pat; PAT; glufosinate-ammonium; 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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