Final Health- and Environmental Risk Assessment of Genetically Modified Maize MON 88017

Åshild Andreassen1*, Per Brandtzæg2, Askild Lorentz Holck3, Olavi Junttila2, Heidi Sjursen Konestabo4, Richard Meadow5, Kåre M. Nielsen6, Hilde-Gunn Opsahl-Sorteberg5, Rose Vikse1, Arne Mikalsen2, Anne Marte Jevnaker2, Ville Erling Sipinen2 and Merethe Aasmo Finne2

1Norwegian Scientific Committee for Food Safety (VKM), Norwegian Institute of Public Health (FHI), Norway.
2Norwegian Scientific Committee for Food Safety (VKM).
3Norwegian Scientific Committee for Food Safety (VKM), Nofima, Norway.
4University of Oslo, Norway.
5Norwegian Scientific Committee for Food Safety (VKM), Norwegian University of Life Sciences, Norway.
6Norwegian Scientific Committee for Food Safety (VKM), Oslo and Akershus University College of Applied Sciences, Norway.

Authors’ contributions

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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ABSTRACT

In preparation for a legal implementation of regulation 1829/2003, the Norwegian Scientific Committee for Food Safety (VKM) has been requested by the Norwegian Environment Agency 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.

*Corresponding author: Email: tron.gifstad@vkm.no;
The insect-resistant and glyphosate-tolerant genetically modified maize MON 88017 from Monsanto (Unique Identifier DAS-MON 88017-7) was approved in the EU under Regulation (EC) No 1829/2003 for food and feed uses, import and processing the 30th of October 2009 (Commission Decision 2009/814/EC).

Genetically modified maize MON 88017 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 and to the EFSA public hearing of the applications EFSA/GMO/CZ/2005/27 and EFSA/GMO/CZ/2008/54 in 2007 and 2010 (VKM 2007a, 2010a). In addition, MON 88017 has been evaluated by the VKM GMO Panel as a component of several stacked GM maize events and Regulation (EC) 1829/2003 (VKM 2007b, VKM 2008, VKM 2009, VKM 2010b).

The food/feed and environmental risk assessment of the maize MON 88017 is based on information provided by the applicant in the applications EFSA/GMO/UK/2005/27 and EFSA/CZ/2008/CZ/2008/54, 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 MON 88017 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 2010a), selection of comparators for the risk assessment of GM plants (EFSA 2011b) and for the post-market environmental monitoring of GM plants (EFSA 2011c).

8.04.2016

The scientific risk assessment of maize MON 88017 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, effects on biogeochemical processes. It is emphasised 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.

Genetically modified maize MON 88017 expresses a Cry3Bb1 insecticidal protein, derived from Bacillus thuringiensis subsp. kumamotoensis, which confers protection against coleopteran target pests belonging to the genus Diabrotica such as Western corn rootworm (Diabrotica virgifera virgifera). MON 88017 is also developed to provide tolerance to the herbicidal active substance glyphosate by the introduction of a gene coding for the enzyme 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS), from Agrobacterium tumefaciens strain CP4 (CP4 EPSPS).

**Molecular characterisation**

The molecular characterisation data has established that only one copy of the transgene is integrated in the maize 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 analyses of junction regions have demonstrated the absence of any potential new ORFs coding for known toxins or allergens. The genetic stability of transformation event MON 88017 was demonstrated at the genomic level over multiple generations by Southern analysis. Segregation analysis shows that event MON 88017 is inherited
as a dominant, single locus trait. The VKM GMO Panel considers the molecular characterisation of
maize MON 88017 satisfactory.

Comparative assessment

Comparative analyses of maize MON 88017 and its conventional counterpart have been performed during field trials located at representative sites and environments in Europe and USA. A total of 12-16 different conventional maize varieties were included in the field trials and used as references. With the exception the insect resistance and herbicide tolerance conferred by the Cry3Bb1 and CP4 EPSPS proteins, no biologically relevant differences were found between maize MON 88017 and controls. Based on the assessment of available data, the VKM GMO Panel concludes that maize MON 88017 is compositionally, agronomically and phenotypically equivalent to its conventional counterpart except for the new proteins. 8.04.2016
VKM Report 2016:12

Food and feed safety assessment

Whole food feeding studies on rats and broilers indicate no adverse health effects of maize MON 88017. These studies also show that maize MON 88017 is nutritionally equivalent to conventional maize. The Cry3Bb1 and CP4 EPSPS proteins do not show relevant sequence resemblance to other known toxins or IgE-allergens, nor have they been reported to cause IgE-mediated allergic reactions. However, some studies have indicated a potential role of Cry-proteins as adjuvants in allergic reactions.

Based on current knowledge, the VKM GMO Panel concludes that maize MON 88017 is nutritionally equivalent to conventional maize varieties. It is unlikely that the Cry3Bb1 and CP4 EPSPS proteins will cause toxic or IgE-mediated allergic reactions to food or feed based on maize MON 88017 compared to conventional maize.

Environmental risk assessment

Considering the intended uses of maize MON 88017, 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 MON 88017.

Maize MON 88017 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 MON 88017. 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. 8.04.2016
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Overall conclusion

Based on current knowledge, the VKM GMO Panel concludes that maize MON 88017 is compositionally, nutritionally, agronomically and phenotypically equivalent to its conventional counterpart except for the new proteins. It is unlikely that the Cry3Bb1 and CP4 EPSPS proteins will cause an increased risk of toxic or IgE-mediated allergic reactions to food or feed based on maize MON 88017 compared to conventional maize.

The VKM GMO Panel concludes that maize MON 88017, 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 MON 88017; EFSA/GMO/CZ/2005/27; insect resistance; herbicide-tolerance; cry3Bb1; cp4 epsps; glyphosate; food/feed safety assessment; environmental risk assessment; Regulation (EC) No 1829/2003; Directive 2001/18.Maize.

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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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