



## **Final Health- and Environmental Risk Assessment of Genetically Modified Maize MON 89034 x MON 88017**

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### **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.*

### **Article Information**

DOI: 10.9734/EJNFS/2018/42112

**Grey Literature**

**Received 15<sup>th</sup> May 2018**  
**Accepted 18<sup>th</sup> May 2018**  
**Published 25<sup>th</sup> May 2018**

### **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 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.

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The insect-resistant and glyphosate-tolerant genetically modified maize MON 89034 x MON 88017 from Monsanto (Unique Identifier MON-89Ø34-3 x MON-88Ø17-3) was approved under Regulation (EC) No 1829/2003 in the EU for food and feed uses, import and processing on 17th of June 2011 (Commission Decision 2011/366/EC).

Genetically modified maize MON 890314 x 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/NL/2007/39 and EFSA/GMO/BE/2009/71 in 2007 and 2009/2010 (VKM 2008a, VKM 2010a). In addition, the parental lines MON 89034 and MON 88017 have been evaluated by the VKM GMO Panel as single events and as a component of several stacked GM maize events (VKM 2007a,b, VKM 2008b, VKM 2009a,b,c, VKM 2010b,c, VKM 2012, VKM 2013, VKM 2014).

The food/feed and environmental risk assessment of the maize MON 89034 x MON 88017 is based on information provided by the applicant in the applications EFSA/GMO/NL/2007/39 EFSA/GMO/BE/2009/71 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 when relevant.

The VKM GMO Panel has evaluated MON 89034 x 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 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 MON 89034 x 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, effects on biogeochemical processes and interactions between the GM plant and target and non-target organisms.

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. Likewise, the VKM mandate does not include evaluations of herbicide residues in food and feed from genetically modified plants. The hybrid maize MON 89034 x MON 88017 has been produced by conventional crosses between inbred lines containing MON 89034 and MON 88017 events to combine resistance to certain coleopteran and lepidopteran pests, and to confer tolerance towards glyphosate-containing herbicides. Maize MON 89034 was developed to provide protection against specific lepidopteran target pest, including *Ostrinia nubilalis*, *S. podoptera* spp. and *Agrotis ipsilon*. Protection is achieved through expression in the plant of two insecticidal Cry proteins, Cry1A.105 and Cry2Ab2, derived from *Bacillus thuringiensis* subsp. *a. izawai* and *kurstaki*.

Maize MON 88017 was developed to express a modified Cry3Bb1 insecticidal protein, derived from *B. thuringiensis* subsp. *kumamotoensis*, which confers protection against coleopteran target pests belonging to the genus *Diabrotica* such as Western corn rootworm (*D. 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:**

Southern and PCR analyses indicate that the recombinant inserts in the single maize events MON 89034 and MON 88017 are retained in the stacked event MON 89034 x MON 88017. Genetic stability of the inserts has previously been demonstrated in the single events. The levels of Cry1A.105, Cry2Ab2, CP4 EPSPS and Cry3Bb1 proteins in grain and forage from the stacked event are comparable to the levels in the corresponding single events. Phenotypic analyses also indicate stability of the insect resistance and herbicide tolerance traits of the stacked event.

Based on current knowledge and the previous assessments of the parental maize events, the VKM GMO Panel considers the molecular characterisation of maize MON 89034 x MON 88017 satisfactory.

#### **Comparative Assessment:**

Comparative analyses of maize MON 89034 x MON 88017 and its conventional counterpart have been performed by the applicant during field trials located at representative sites and environments in USA during 2004, and in Europe in 2007. Several different conventional maize varieties were included in the field trials and used as references. With the exception of small variations, and the insect resistance and herbicide tolerance conferred by the Cry3Bb1, Cry1A105, Cry2Ab2, and CP4 EPSPS proteins, the results from these studies showed no biologically relevant differences between the maize stack MON 89034 x MON 88017 and its conventional counterpart.

Based on the assessment of available data, the VKM GMO Panel concludes that maize MON 89034 x MON 88017 is compositionally, agronomically and phenotypically equivalent to its conventional counterpart, except for the new proteins.

#### **Food and Feed Safety Assessment:**

A whole food feeding study performed on broilers indicates no adverse health effects of maize MON 89034 x MON 88017, and shows that it is nutritionally equivalent to conventional maize varieties. The Cry1A.105, Cry2Ab2, 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 89034 x MON 88017 is nutritionally equivalent to conventional maize varieties. It is unlikely that the Cry1A.105, Cry2Ab2, Cry3Bb1 and CP4 EPSPS proteins will cause toxic or IgE-mediated allergic reactions to food or feed derived from maize MON 89034 x MON 88017 compared to conventional maize.

#### **Environmental Risk:**

Considering the intended uses of maize MON 89034 x 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 89034 x MON 88017.

Maize MON 89034 x 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 89034 x 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.

#### **Overall Conclusion:**

Based on current knowledge, the VKM GMO Panel concludes that maize MON 89034 x MON 88017 is compositionally, nutritionally, agronomically and phenotypically equivalent to its conventional counterpart except for the new proteins. It is unlikely that the Cry1A.105, Cry2Ab2, CryBb1 and CP4 EPSPS proteins will cause an increased risk of toxic or IgE-mediated allergic reactions to food or feed based on maize MON 89034 x MON 88017 compared to conventional maize varieties.

The VKM GMO Panel concludes that maize MON 89034 x MON 88017, based on current knowledge, is comparable to conventional maize varieties concerning environmental risk in Norway with the intended usage.

**Keywords:** VKM; Norwegian Scientific Committee for Food Safety; maize; *Zea mays* L.; genetically modified maize MON 89034 x MON 88017 EFSA/GMO/NL/2007/39; insect-resistance; herbicide-tolerance; cry1A.105; cry2Ab2; cry3Bb1; cp4 epsps; glyphosate; food/feed safety assessment; environmental risk assessment; Regulation (EC) No 1829/2003; Directive 2001/18.

Available: <https://vkm.no/download/18.a665c1015c865cc85bc08ca/1498562053632/4b02fc8551.pdf>

**ISBN:** 978-82-8259-203-1

#### **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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Suggested citation: VKM (2016) Final health and environmental risk assessment of genetically modified maize MON 89034 x MON 88017. Opinion of the Panel on Genetically Modified Organisms of the Norwegian Scientific Committee for Food Safety, ISBN: 978-82-8259-2031, Oslo, Norway.

#### **COMPETING INTERESTS**

Authors have declared that no competing interests exist.

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