



## **Final Health and Environmental Risk Assessment of Genetically Modified Maize MON 89034 x NK 603**

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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.*

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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.

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The insect-resistant and glyphosate-tolerant genetically modified maize MON 89034 x NK 603 from Monsanto (Unique Identifier MON-89Ø34-3 x MON-ØØ6Ø3-6) was approved under Regulation (EC) No 1829/2003 in the EU for food and feed uses, import and processing on 28 July 2010 (Commission Decision 2010/420/EC).

Genetically modified maize MON 890314 x NK 603 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/2007/38 and EFSA/GMO/NL/2009/72 in 2007 and 2009/2010 (VKM 2008a, VKM 2010a). In addition, the parental lines MON 89034 and NK 603 have been evaluated by the VKM GMO Panel as single events and as a component of several stacked GM maize events (VKM 2005a,b,c,d,e, VKM 2007a,b, VKM 2008b,c,d, VKM 2009a,b, VKM 2010 a,b, VKM 2011, VKM 2012a,b, VKM 2013 a,b, VKM 2014).

The food/feed and environmental risk assessment of the maize MON 89034 x NK 603 is based on information provided by the applicant in the applications EFSA/GMO/NL/2007/38 EFSA/GMO/NL/2009/72 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 89034 x NK 603 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).

The scientific risk assessment of maize MON 89034 x NK 603 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 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. 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 NK 603 has been produced by conventional crosses between inbred lines containing MON 89034 and NK 603 events to combine resistance to certain 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. *izawai* and *kurstaki*. Maize NK 603 has been developed to provide tolerance to glyphosate by the introduction, of a gene coding for 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) from *Agrobacterium* sp. strain CP4 (CP4 EPSPS).

#### **Molecular Characterisation:**

Southern and PCR analyses indicate that the recombinant inserts in the single maize events MON 89034 and NK 603 are retained in maize stack MON 89034 x NK603. Genetic stability of the inserts has previously been demonstrated in the parental lines MON 89034 and NK603. The level of Cry1A.105, Cry2Ab2 and CP4 EPSPS 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 NK 603 satisfactory. 6 VKM Report 2016: 17.

#### **Comparative Assessment:**

The applicant has performed comparative analyses of data from field trials located at representative sites and environments in Argentina in 2004/2005 and Europe in 2007. With the exception of small intermittent variations and the insect resistance and herbicide tolerance conferred by the Cry1A.105, Cry2Ab2 and CP4 EPSPS proteins, the results showed no biologically relevant differences between maize stack MON 89034 x NK 603 and conventional control. Based on the assessment of available data, the VKM GMO Panel concludes that maize MON 89034 x NK 603 is compositionally, agronomical and phenotypically equivalent to its conventional counterpart, except for the new proteins.

#### **Food/feed Safety Assessment:**

A whole food feeding study on broilers has not indicated any adverse health effects of maize MON 89034 x NK 603, and shows that it is nutritionally equivalent to conventional maize varieties. The Cry1A.105, Cry2Ab2, and CP4 EPSPS proteins do not show 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 NK 603 is nutritionally equivalent to conventional maize varieties. It is unlikely that the Cry1A.105, Cry2Ab2, and CP4 EPSPS proteins will cause toxic or IgE-mediated allergic reactions to food or feed based on maize MON 89034 x NK 603 compared to conventional maize.

#### **Environmental Risk:**

Considering the intended uses of maize MON 89034 x NK603, 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 NK603.

Maize MON 89034 x NK 603 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 NK603. 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. 7 VKM Report 2016: 17.

#### **Overall Conclusion:**

Based on current knowledge, the VKM GMO Panel concludes that maize MON 89034 x NK 603 is compositionally, nutritionally, agronomically and phenotypically equivalent to its conventional

counterpart except for the new proteins. It is unlikely that the Cry1A.105, Cry2Ab2 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 NK 603 compared to conventional maize varieties.

The VKM GMO Panel concludes that maize MON 89034 x NK603, 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 NK603; EFSA/GMO/NL/2007/38; insect-resistance; herbicidetolerance; cry1A.105; cry2Ab2; cp4 epsps; glyphosate; food/feed safety assessment; environmental risk assessment; Regulation (EC) No 1829/2003; Directive 2001/18.

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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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