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# **Food/Feed and Environmental Risk Assessment of Herbicide-tolerant and Insect-resistant Genetically Modified Maize NK603 x MON810 for Import, Processing, Food and Feed Uses under Regulation (EC) No 1829/2003 (EFSA/GMO/UK/2004/01)**

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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

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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 herbicide-tolerant and insect-resistant genetically modified maize NK603 x MON810 (Unique Identifier MON-ØØ6Ø3-6 x MON-ØØ81Ø2-6) from Monsanto Company is approved under Regulation (EC) No 1829/2003 for food and feed uses, import and processing since 24 October 2007 (Commission Decision 2007/701/EC).

VKM participated in the 90 days public consultation of the application for placing on the market of maize NK603 x MON810 for food and feed uses, import and processing (EFSA/GMO/ UK/2004/01) in 2005, and submitted a preliminary opinion in June 2005 (VKM 2005a). Maize NK603 x MON810 has also been assessed as food and feed by the VKM GMO Panel, commissioned by the Norwegian Environment Agency and the Norwegian Food Safety Authority in connection with the national finalisation of the application in 2008 (VKM 2008a). In addition, NK603 and MON810 has been evaluated by the VKM GMO Panel as single events and as a component of several stacked GM maize events (VKM 2005 a,b,c,d,e, VKM 2007 a,b,c,d,e, 2008b, 2009, 2010 a,b, 2011, 2012 a,b, 2013a,b,c,d,e,f,g,h,i,j). Due to the publication of new scientific literature and updated guidelines for risk assessment of genetically modified plants, the VKM GMO Panel has decided to deliver an updated food/feed and environmental risk assessment of maize NK603 x MON810.

The food/feed and environmental risk assessment of the maize NK603 x MON810 is based on information provided by the applicant in the applications EFSA/GMO/UK/2004/01 and EFSA/GMO/2005/26, 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 NK603 x MON810 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 NK603 x MON810 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 characterisation** The stacked maize NK603 x MON810 was produced by conventional crossing of the single maize events NK603 and MON810. Southern blot and PCR analyses have shown that the recombinant inserts from the parental events are retained in the stacked event, and

that their structures are intact. Genotypic stability of the inserts has previously been demonstrated for the single events. Protein measurements show comparable levels of CP4 EPSPS and Cry1Ab in forage and grain samples from maize NK603 x MON810 to those measured in maize NK603 and MON810, respectively.

The VKM GMO Panel considers the molecular characterisation of maize NK603 x MON810 and its parental events NK603 and MON810 satisfactory.

**Comparative assessment** The applicant has performed comparative analyses of data from field trials located in maize growing regions of Europe and USA in 2000 and 2002. With the exception of small intermittent variations and the insect resistance and herbicide tolerance conferred by the Cry1Ab and CP4 EPSPS proteins, the results showed no biologically significant differences between maize stack NK603 x MON810 and conventional control. Based on the assessment of available data, the VKM GMO Panel concludes that maize NK603 x MON810 is compositionally, agronomically and phenotypically equivalent to its conventional counterpart, except for the introduced characteristics, and that its composition fell within the normal ranges of variation observed among non-GM varieties. **Food and feed risk assessment** A whole food feeding study performed on broilers did not indicate any adverse health effects of maize NK603 x MON810, and shows that maize NK603 x MON810 is nutritionally equivalent to conventional maize. The CP4 EPSPS or Cry1Ab 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 NK603 x MON810 is nutritionally equivalent to conventional maize varieties. It is unlikely that the Cry1Ab or CP4-EPSPS proteins will introduce a toxic or allergenic potential in food or feed based on maize NK603 x MON810 compared to conventional maize.

**Environmental risk assessment** Considering the intended uses of maize NK603 x MON810, 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 NK603 x MON810.

Maize NK603 x MON810 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 NK603 x MON810. 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 NK603 x MON810 is nutritionally equivalent to conventional maize varieties. It is unlikely that the CP4 EPSPS and Cry1Ab proteins will introduce a toxic or allergenic potential in food or feed based on maize NK603 x MON810 compared to conventional maize.

The VKM GMO Panel likewise concludes that maize NK603 x MON810, 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 NK603 x MON810; EFSA/GMO/UK/2004/01; insect-resistance; herbicide-tolerance; cry protein; cry1Ab; Cry1Ab; cp4 epsps; CP4 EPSPS; glyphosate; food and feed risk assessment; environmental risk assessment; Regulation (EC) No 1829/2003.*

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**COMPETING INTERESTS**

Authors have declared that no competing interests exist.

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