Food and Environmental Risk Assessment of Herbicide-tolerant Genetically Modified Maize NK603 for Food Uses, Import and Processing under Directive 2001/18/EC (Notification C/ES/00/01)

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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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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 authorised 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 genetically modified maize NK603 from Monsanto (Unique Identifier MONØØ6Ø3-6) is approved under Directive 2001/18/EC as feed since 19 July 2004 (Commission Decision 2004/643/EC). Foods and food ingredients derived from NK603 was authorised under Novel Foods Regulation (EC) No 258/97 3 March 2005 (Commission Decision 2005/448/EC) (EC 2013).

Genetically modified maize NK603 has previously been risk assessed by the VKM Panel on Genetically Modified Organisms (GMOs), commissioned by the NFSA in connection with the national finalisation of the procedure of the notification in 2005 (VKM 2005a). NK603 has also been evaluated by the VKM GMO Panel as a component of several stacked GM maize events (VKM 2005b,c,d,e VKM 2007a,b, VKM 2008a,b, VKM 2009, VKM 2010, VKM 2011, VKM 2012a, VKM 2013a,b). 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 risk assessment of NK603. This updated assessment only covers health and environmental risks with regard to maize NK603 in food products.

The risk assessment of maize NK603 is based on information provided by the applicant in the notification C/EC/00/01, the applications EFSA/GMO/NL/2005/22 and EFSA/GMO/RX/NK603, and scientific comments from EFSA and other member states made available on the EFSA website GMO Extranet. The risk assessment also considers other relevant peer-reviewed scientific literature.

The VKM GMO Panel has assessed maize NK603 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 NK603 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 and evaluations of the post-market environmental plan.

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.

The genetically modified maize NK603 has been developed to provide tolerance to glyphosate by the introduction, via particle gun acceleration, of a gene coding for 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) from Agrobacterium sp. strain CP4 (CP4 EPSPS).
Molecular Characterization:

NK603 was developed for tolerance to glyphosate by the introduction of the gene cp4 epsps from Agrobacterium sp. strain CP4, via a particle acceleration method. The molecular characterisation data indicate that only one copy of the tandem cp4 epsps cassette is integrated in the DNA of maize NK603, 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. No potential new ORFs with sequence similarities to known toxins or allergens were detected. The Chi square analyses of the segregation results for the glyphosate tolerance trait in the progeny are also consistent with a single active site of insertion. The VKM GMO Panel considers the molecular characterisation of maize NK603 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 NK603 is compositionally, agronomically and phenotypically equivalent to conventional maize, with the exception of the glyphosate tolerance conferred by the CP4 EPSPS protein.

Food and Feed Risk Assessment:

Whole food feeding studies on rats have not indicated any adverse effects of maize NK603. Nutritional feeding studies on broilers, pigs, steers and cows indicate that NK603 is nutritionally equivalent to conventional maize. The CP4 EPSPS protein does not show resemblance to any known toxins or IgE allergens, nor has CP4 EPSPS been reported to cause IgE mediated allergic reactions. An acute oral toxicity test in mice did not indicate toxic effects of purified E. coli produced CP4 EPSPS protein. However, such a test does not provide any additional information about possible adverse effects of maize NK603.

Based on current knowledge, the VKM GMO Panel concludes that maize NK603 is nutritionally equivalent to conventional maize varieties, and that it is unlikely that the CP4 EPSPS protein will introduce a toxic or allergenic potential in food derived from maize NK603 compared to conventional maize.

Environmental Assessment:

The authorisations of maize NK603 under Directive 2001/18/EC and the Novel Foods Regulation (EC) No 258/97 include import and processing of maize NK603 for food and feed uses. Considering the intended uses of maize NK603, excluding cultivation, the environmental risk assessment has been concerned with accidental release into the environment of viable grains during transportation and processing.

The available data indicate that NK603 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. 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, 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 is nutritionally equivalent to conventional maize varieties, and that it is unlikely that the CP4 EPSPS protein will
introduce a toxic or allergenic potential in food derived from maize NK603 compared to conventional maize. The VKM GMO Panel likewise concludes that maize NK603, 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; C/ES/00/01; herbicide-tolerance; CP4 EPSPS; glyphosate; food risk assessment; environmental risk assessment; Directive 2001/18/EC; 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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