Food/feed and Environmental Risk Assessment of Insect-resistant and Herbicide-tolerant Genetically Modified Maize 59122 x NK603 for Food and Feed Uses, Import and Processing under Regulation (EC) No 1829/2003 (EFSA/GMO/UK/2005/20)

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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

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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 insect-resistant and herbicide-tolerant genetically modified maize 59122 x NK603 from Pioneer Hi-Bred International, Inc. (Unique Identifier DAS-59122-7 x MONØØ6Ø3-6) is approved under Regulation (EC) No 1829/2003 for food and feed uses, import and processing since 30 October 2009 (Commission Decision 2009/815/EC).

Genetically modified maize 59122 x NK603 has previously been risk assessed by the VKM Panel on Genetically Modified Organisms (GMO), commissioned by the Norwegian Food Safety Authority related to the EFSAs public hearing of the application EFSA/GMO/UK/2005/20 in 2007 (VKM 2007a). In addition 59122 x NK603 has been evaluated by the VKM GMO Panel as single events and as a component of several stacked GM maize events (VKM 2005a,b,d, VKM 2007b,c, VKM 2008b,c, VKM 2009a,b, VKM 2012). The food/feed and environmental risk assessment of the maize 59122 x NK603 is based on information provided by the applicant in the application EFSA/GMO/UK/2005/20, and scientific comments from EFSA and other member states made available on the EFSAs website GMO Extranet. The risk assessment also considered other peer-reviewed scientific literature as relevant.

The VKM GMO Panel has evaluated 59122 x 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 59122 x 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.

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.

The genetically modified maize stack 59122 x NK603 was produced by conventional breeding between inbred lines of maize containing the 59122 and NK603 events. The hybrid was developed to provide protection against certain coleopteran target pests, and to confer tolerance to glufosinateammonium and glyphosate herbicides.

**Molecular characterization:**

Southern and PCR analyses has been performed and indicate that the recombinant inserts in the single maize events 59122 and NK603 are retained in maize stack 59122xNK603. Genetic stability of the inserts has previously been demonstrated in the parental lines 59122 and NK603. The level
of Cry34Ab1/Cry35Ab1, PAT and CP4 EPSPS proteins in seed and forage from the stacked event were measured using ELISA and are comparable to the levels in the single events. Phenotypic analyses also indicate stability of the insect resistance and herbicide tolerance traits of the stacked event.

**Comparative Assessment:**

Comparative analyses of data from field trials located at representative sites and environments in North America indicate that maize stack 59122 x NK603 is compositionally, agronomically and phenotypically equivalent to its conventional counterpart, with the exception of the introduced insect resistance and herbicide tolerance, conferred by the expression of the Cry34Ab1, Cry35Ab1, PAT and CP4 EPSPS proteins. Based on the assessment of available data, the VKM GMO Panel is of the opinion that conventional crossing of maize 59122 and NK603 to produce the hybrid 59122 x NK603 does not result in interactions that cause compositional, agronomic and phenotypic changes that would raise safety concerns.

**Food and Feed Risk Assessment:**

Whole food feeding study has not been performed using 59122 x NK603 maize. The applicant has, however, provided a nutritional study on broilers using the triple stacked event 59122 x 1507 x NK603 maize as test material. Bioinformatics analyses have not revealed expression of any known ORFs in the parental maize lines, and none of the newly expressed proteins show resemblance to any known toxins or IgE allergens. Nor have the newly expressed proteins been reported to cause IgE mediated allergic reactions. Some studies have however indicated a potential role of Cry-proteins as adjuvants in allergic reactions.

Acute and repeated toxicity tests in rodents have not indicated toxic effects of the newly expressed proteins. However, these tests do not provide any additional information about possible adverse effects of the stacked event maize 59122 x NK603.

Based on the current knowledge, the VKM GMO Panel concludes that 59122 x NK603 maize is nutritionally equivalent to its conventional maize, and that it is unlikely that newly expressed proteins will introduce a toxic or allergic potential of food/feed derived from maize 59122 x NK603 compared to conventional maize.

**Environmental Risk Assessment:**

The scope of the application EFSA/GMO/UK/2005/20 includes import and processing of maize stack 59122 x NK603 for food and feed uses. Considering the intended uses of maize 59122 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 59122 x NK603.

Maize 59122 x 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 59122 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.

**Overall Conclusion:**

The VKM GMO Panel has not identified toxic or altered nutritional properties of maize 59122 x NK603 or its processed products compared to conventional maize. Based on current knowledge, it is also unlikely that the Cry34Ab1 and Cry35Ab1 protein will increase the allergenic potential of
food and feed derived from maize 59122 x NK603 compared to conventional maize varieties. The VKM GMO Panel likewise concludes that maize 59122 x 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 59122 x NK603; EFSA/GMO/NL/2005/20; insect-resistance; herbicide-tolerance; Cry proteins; cry34Ab1; cry35Ab1; PAT; CP4 EPSPS; glufosinateammonium; glyphosate; food and feed risk assessment; environmental risk assessment; 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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