Final Health and Environmental Risk Assessment of Genetically Modified Maize 59122

Åshild Andreassen1*, Per Brandtzæg2, Merethe Aasmo Finne3, Askild Lorentz Holck4, Anne-Marthe Jevnaker3, Olavi Junttila4, Heidi Sjursen Konestabo5, Richard Meadow6, Arne Mikalsen3, Kåre M. Nielsen7, Rose Vikse1, Ville Erling Sipinen3 and Hilde-Gunn Opsahl-Sorteberg6

1Norwegian Scientific Committee for Food Safety (VKM), Norwegian Institute of Public Health (FHI), Norway.
2Norwegian Scientific Committee for Food Safety (VKM), University of Oslo, Norway.
3Norwegian Scientific Committee for Food Safety (VKM), Norway.
4Nofima, Norway.
5University of Oslo, Norway.
6Norwegian Scientific Committee for Food Safety (VKM), Norwegian University of Life Sciences, Norway.
7Norwegian Scientific Committee for Food Safety (VKM), Oslo and Akershus University College of Applied Sciences, Norway.

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 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.

*Corresponding author: Email: tron.gifstad@vkm.no;
The herbicide-tolerant and insect-resistant genetically modified maize 59122 from Pioneer HiBred/Mycogen Seeds (Unique Identifier DAS-59122-7) is approved under EU Regulation 1829/2003/EC for food and feed uses, import and processing since 24 October 2007 (Application EFSA/GMO/NL/2005/12, Commission Decision 2007/702/EC). An application for granting consent to all uses of 59122 maize, including cultivation, was submitted by Pioneer in accordance with articles 5 and 17 of the Regulation (EC) No. 1829/2003 21 October, 2005 (EFSA/GMO/NL/2005/23).

VKM participated in the 90 days public consultation of the application for placing on the market of maize 59122 for food and feed uses, import and processing (EFSA/GMO/NL/2005/12) in 2005, and submitted a preliminary opinion in December 2005 (VKM 2005a). Maize 59122 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). Maize 59122 has also been evaluated by the VKM GMO Panel as a component of several stacked GM maize events under Regulation (EC) 1829/2003 (VKM 2007a,b,c, VKM 2008b, VKM 2009, VKM 2012a,b, VKM 2013a,b,c,d). 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 event 59122.

The updated food/feed and environmental risk assessment of the maize 59122 is based on information provided by the applicant in the applications EFSA/GMO/NL/2005/12 and EFSA/GMO/NL/2005/23 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 59122 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 59122 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, target and non-target organisms, and effects on biogeochemical processes.

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.

Genetically modified maize 59122 expresses the cry34Ab1 and cry35Ab1 genes from Bacillus thuringiensis, conferring resistance to certain coleopteran target pests belonging to the genus Diabrotica, such as the larvae of western corn rootworm (D. virgifera virgifera), northern corn rootworm (D. barberi) and the southern corn rootworm (D. undecimpunctata howardi). None of the target pests for maize 59122 are present in the Norwegian agriculture. Maize 59122 also expresses the phosphinothricin-N-acetyltransferase (pat) gene, from the soil bacterium Streptomyces viridochromogenes. The encoded PAT protein confers tolerance to the herbicidal active substance glufosinate-ammonium. The PAT protein produced by maize 59122 has been used as a selectable marker to facilitate the selection process of transformed plant cells and is not intended for weed management purposes.
Molecular Characterization:

Appropriate analyses of the transgenic DNA insert, its integration site, number of inserts and flanking sequences in the maize genome, have been performed. The results show that only one copy of the insert is present in maize 59122. Homology searches with databases of known toxins and allergens have not indicated any potential production of harmful proteins or polypeptides caused by the genetic modification in maize 59122. Southern blot analyses and segregation studies show that the introduced genes cry34Ab1, cry35Ab1 and pat are stably inherited and expressed over several generations along with the phenotypic characteristics of maize 59122. The VKM GMO Panel considers the molecular characterisation of maize 59122 satisfactory.

Comparative assessment Comparative analyses of maize 59122 to its non-GM conventional counterpart have been performed during multiple field trials in representative areas for maize cultivation in Chile (2002/2003), North America (2003, 2004) and Europe (2003, 2004). With the exception of small intermittent variations, no biologically significant differences were found between maize 59122 and the conventional non-GM control. Based on the assessment of available data, the VKM GMO Panel concludes that maize 59122 is compositionally, agronomical and phenotypically equivalent to its conventional counterpart, except for the introduced characteristics.

Food and Feed Risk Assessment:

A 90-day subchronic feeding study in rats, as well as whole food feeding studies on broilers, laying hens, lactating dairy cows, feedlot steers, and growing-finishing pigs, have not indicated any adverse effects of maize 59122, and shows that maize 59122 is nutritionally equivalent to conventional maize. The PAT, Cry34Ab1 and Cry35Ab1 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 59122 is nutritionally equivalent to conventional maize varieties. It is unlikely that the PAT, Cry34Ab1 and Cry35Ab1 proteins will introduce a toxic or allergic potential in food or feed based on maize 59122 compared to conventional maize.

Environmental Risk Assessment:

Considering the intended uses of maize 59122, 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.

Maize 59122 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. Maize is the only representative of the genus Zea in Europe, and there are no cross-compatible wild or weedy relatives outside cultivation. The risk of gene flow from occasional feral GM maize plants to conventional maize varieties is negligible. Considering the intended use as food and feed, interactions with the biotic and abiotic environment are not considered to be an issue.

Overall Conclusion:

Based on current knowledge, the VKM GMO Panel concludes that maize 59122 is nutritionally equivalent to conventional maize varieties. It is unlikely that the PAT, Cry34Ab1 and Cry35Ab1 proteins will introduce a toxic or allergic potential in food or feed based on maize 59122 compared to conventional maize. The VKM GMO Panel likewise concludes that maize 59122, 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; EFSA/GMO/NL/2005/12; insect resistance; Cry34Ab1; Cry35AB1; herbicide tolerance; pat gene; PAT protein; glufosinate ammonium; food and feed safety assessment; environmental risk assessment; Regulation (EC) No 1829/2003.

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NOTE:

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COMPETING INTERESTS

Authors have declared that no competing interests exist.

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