Environmental Risk Assessment of Insect-resistant and Herbicide-tolerant Genetically Modified Maize 1507 x 59122 for Food and Feed Uses, Import and Processing under Regulation (EC) No 1829/2003 (EFSA/GMO/NL/2005/15)

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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) to conduct final 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 requests VKM to consider whether updates or other changes to earlier submitted assessments are necessary.

The insect-resistant and herbicide-tolerant genetically modified maize 1507 x 59122 from Dow AgroSciences and Pioneer Hi-Bred International, Inc. (Unique Identifier DAS-Ø15Ø7-1 x DAS59122-7) is approved under Regulation (EC) No 1829/2003 for food and feed uses, import and processing since 28 July 2010 (Commission Decision 2010/432/EC).

Genetically modified maize 1507 x 59122 has previously been risk assessed by the VKM Panel on Genetically Modified Organisms (GMO), commissioned by the NFSA and the Norwegian Environment Agency related to the EFSAs public hearing of the applications EFSA/GMO/NL/2005/15 and EFSA/GMO/NL/2005/28 in 2007 (VKM 2007a, 2008a). The stack 1507 x 59122 has also been evaluated by the VKM GMO Panel as single events and as a component of several other stacked GM maize events (VKM 2004, VKM 2005a,b, VKM 2007b,c, VKM 2008b,c, VKM 2009a,b, VKM 2012). The environmental risk assessment of the maize 1507 x 59122 is based on information provided by the applicant in the applications EFSA/GMO/NL/2005/15 and EFSA/GMO/NL/2005/28, 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 1507 x 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 2010), the 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 1507 x 59122 include molecular characterisation of the inserted DNA and expression of novel proteins, comparative assessment of agronomic and phenotypic characteristics, 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 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 1507 x 59122 was produced by conventional breeding between inbred lines of maize containing the 1507 and 59122 events. The hybrid was developed to provide protection against certain lepidopteran and coleopteran target pests, and to confer tolerance to glufosinate-ammonium herbicides.

Molecular Characterization:

As conventional breeding methods were used in the production of maize 1507 x 59122, no additional genetic modification was involved. Southern and PCR analyses demonstrated that the recombinant insert in the single 1507 and 59122 events were retained in maize stack 1507 x 59122.
Genetic stability of the inserts has been demonstrated in the parental lines 1507 and 59122. Phenotypic analyses demonstrated stability of the insect resistance and herbicide tolerance traits in the hybrid. The expression levels of Cry1F, Cry34Ab1/Cry35Ab1 and PAT proteins in seeds and forage were considered comparable with those in the single events.

The characterisation of the recombinant insert and the physical, chemical and functional characteristics of the single events maize 1507 (VKM 2004) and maize 59122 (VKM 2005a, 2008b), have previously been evaluated by the VKM GMO Panel and considered adequate.

**Comparative Assessment:**

Comparative analyses of data from field trials located at representative sites and environments in the USA, Canada and Europe indicate that maize 1507 x 59122 is agronomically and phenotypically equivalent to the conventional counterpart, with the exception of the lepidopteran and coleopteran protection traits and herbicide tolerance, conferred by the expression of the Cry1F, Cry34Ab1/Cry35Ab1 and PAT proteins. The field evaluations support the applicant’s conclusion of no other phenotypic changes indicative of increased plant weed/pest potential of 1507 x 59122 compared to conventional maize.

The VKM GMO Panel has previously assessed these data and concluded that maize 1507 x 59122 is agronomically and phenotypically equivalent to the conventional comparators, except for the newly introduced traits (VKM 2007a, 2008a).

**Environmental assessment:**

The scope of the application EFSA/GMO/NL/2005/15 includes import and processing of maize 1507 x 59122 for food and feed uses. Considering the intended uses of maize 1507 x 59122, excluding cultivation, the environmental risk assessment has been 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 1507 x 59122.

The available data indicate that 1507 x 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 1507 x 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 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 concludes that maize 1507 x 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 1507 x 59122; EFSA/GMO/NL/2005/15; insect- resistance; herbicide-tolerance; Cry proteins; cry34Ab1; cry35Ab1; cry1F; PAT; glufosinateammonium, 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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