



**Food/Feed and Environmental Risk Assessment of
Insect Resistant Genetically Modified Maize 1507 for
Cultivation, Import, Processing, Food and Feed
Uses under Directive 2001/18/EC and Regulation
(EC) No 1829/2003 (C/ES/01/01, C/NL/00/10,
EFSA/GMO/NL/2004/02)**

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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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Grey Literature

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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.

Four notifications/applications for placing on the market of insect resistant genetically modified maize 1507 from Pioneer HiBreed & Dow AgroSciences (Unique Identifier DAS-Ø15Ø7-1) have been taken into account:

- Application EFSA/GMO/NL/2004/02 for placing on the market of insect-tolerant genetically modified maize 1507 for food use under Regulation (EC) 1829/2003 Food and food ingredients containing, consisting of or produced from maize 1507 approved since 3 March 2006 (Commission Decision 2006/197/EC)
- Notification C/NL/00/10 for import and processing use under Part C of Directive 2001/18/EC. Approved for importation, processing and feed use since 3 November 2005 (Commission Decision 2005/772/EC)
- Application EFSA/GMO/RX/1507 for renewal of authorisation of existing products of maize 1507 under Regulation (EC) no 1829/2003 Renewing of the authorisation of existing feed products from maize 1507 granted since 17 June 2011 (Commission Decision 2011/365/EC).
- Notification C/ES/01/01 for cultivation, import, processing and use as any other maize (excluding food uses) under Directive 2001/18/EC on the deliberate release of GMOs into the environment. The application is still pending for authorisation.

Genetically modified maize 1507 has previously been assessed as food and feed by the VKM GMO Panel commissioned by the Norwegian Food Safety Authority in connection with the EFSA official hearing of the application EFSA/GMO/NL/2004/02 in 2004 (VKM 2004). Maize 1507 has also been evaluated by the VKM GMO Panel as a component of several stacked GM maize events under Regulation (EC) 1829/2003 (VKM 2005b, 2007a,b, 2008a,b, 2009a,b, 2012a,b,c, 2013 a,b,c,d,e).

The food/feed and environmental risk assessment of the GM maize 1507 is based on information provided by the applicant in the notifications C/ES/01/01 and C/NL/00/10 and the applications EFSA/GMO/NL/2004/02 and EFSA/GMO/RX/1507, previous risk assessments performed by the VKM GMO Panel and scientific opinions and comments from EFSA and other member states made available on the EFSA website GMO Extranet. The risk assessment is also based on a risk analysis report of 1507 from the Australia New Zealand Food Authority (FSANZ 2002) and a review and assessment of relevant peer-reviewed scientific literature.

The VKM GMO Panel has evaluated maize 1507 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 1507 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 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 1507 has been developed to provide protection against certain lepidopteran target pests, such as the European corn borer (ECB, *Ostrinia nubilalis*), and some species belonging to the genus *Sesamia*. The insect resistance is achieved through expression of a synthetic version of the truncated cry1F gene derived from *Bacillus thuringiensis* subsp. *aizawai*, a common soil bacterium.

Maize 1507 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 1507 has been used as a selectable marker to facilitate the selection process of transformed plant cells and is not intended for weed management purposes. Since the scope of the notification C/ES/01/01 does not cover the use of glufosinate-ammonium-containing herbicides on maize 1507, potential effects due to the use of such herbicides on maize 1507 are not considered by VKM.

Molecular Characterisation:

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 1507. 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 1507. Southern blot analyses and segregation studies show that the introduced genes *cry1F* and *pat* are stably inherited and expressed over several generations along with the phenotypic characteristics of maize 1507. The VKM GMO Panel considers the molecular characterisation of maize 1507 satisfactory.

Comparative Assessment:

Comparative analyses of maize 1507 to its non-GM conventional counterpart have been performed during multiple field trials located at representative sites and environments in Chile (1998/99), USA (1999) and in Europe (1999, 2000 and 2002). With the exception of small intermittent variations, no biologically significant differences were found between maize 1507 and the conventional maize. Based on the assessment of available data, the VKM GMO Panel concludes that maize 1507 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 Safety Assessment:

Whole food feeding studies on rats, broilers, pullets, pigs and cattle have not indicated any adverse health effects of maize 1507. These studies also indicate that maize 1507 is nutritionally equivalent to conventional maize. The PAT and Cry1F 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 1507 is nutritionally equivalent to conventional maize varieties. It is unlikely that the PAT and Cry1F proteins will introduce a toxic or allergenic potential in food or feed based on maize 1507 compared to conventional maize.

Environmental Risk:

There are no reports of the target lepidopteran species attaining pest status on maize in Norway. Since there are no Bt-based insecticides approved for use in Norway, and lepidopteran pests have not been registered in maize, issues related to resistance evolution in target pests are not relevant at present for Norwegian agriculture.

There are only a limited number of published scientific studies on the environmental effects of Cry1F protein. Published scientific studies showed that the likelihood of negative effects of Cry1F protein on non-target arthropods that live on or in the vicinity of maize plants is low. Cultivation of maize 1507 is not considered to represent a threat to the prevalence of red-listed species in Norway.

Few studies have been published examining potential effects of Cry1F toxin on ecosystems in soil, mineralization, nutrient turnover and soil communities. Some field studies have indicated that root exudates and decaying plant material containing Cry proteins may affect population size and activity of rhizosphere organisms (soil protozoa and microorganisms). Most studies conclude that effects on soil microorganisms and microbial communities are transient and minor compared to effects caused by agronomic and environmental factors. However, data are only available from short term experiments and predictions of potential long term effects are difficult to deduce.

The VKM GMO Panel concludes that, although the data on the fate of the Cry1F protein and its potential interactions in soil are limited, the relevant scientific publications analysing the Cry1F protein, together with the relatively broad knowledge about the environmental fate of other Cry1 proteins, do not indicate significant direct effects on the soil environment.

Few studies have assessed the impact of Cry proteins on non-target aquatic arthropods and the fate of these proteins in senescent and decaying maize detritus in aquatic environments, and no specific lower-tier studies, assessing the impact of the Cry1F protein on non-target aquatic arthropods have been reported in the scientific literature so far. However, exposure of non-target organisms to Cry proteins in aquatic ecosystems is likely to be very low, and potential exposure of Bt toxins to nontarget organisms in aquatic ecosystems in Norway is considered to be negligible. Maize is the only representative of the genus *Zea* in Europe, and there are no cross-compatible wild or weedy relatives outside cultivation with which maize can hybridise and form backcross progeny. Vertical gene transfer in maize therefore depends on cross-pollination with other conventional or organic maize varieties. In addition, unintended admixture of genetically modified material in seeds represents a possible way for gene flow between different crop cultivations. The risk of pollen flow from maize volunteers is negligible under Norwegian growing conditions.

Overall Conclusion:

Based on current knowledge, the VKM GMO Panel concludes that maize 1507 is nutritionally equivalent to conventional maize varieties. It is unlikely that the Cry1 and PAT proteins will introduce a toxic or allergenic potential in food or feed derived from maize 1507 compared to conventional maize.

The VKM GMO Panel likewise concludes that cultivation of maize 1507 is unlikely to have any adverse effect on the environment and agriculture in Norway.

Keywords: *Maize; Zea mays L.; genetically modified maize 1507; EFSA/GMO/NL/2004/02; C/NL/00/10; C/ES/01/01; EFSA/GMO/RX/1507; insect-resistance; herbicide-tolerance;*

cry1F; PAT; glufosinateammonium; cultivation; food/feed risk assessment; environmental risk assessment; Regulation (EC) No 1829/2003; Directive 2001/18.

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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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