



# **Risk Assessment of Insect-resistant and Herbicide Tolerant Genetically Modified Maize 1507 for Cultivation, Import, Processing, Food and Feed Uses under Directive 2001/18/EC and Regulation (EC) No 1829/2003**

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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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## **ABSTRACT**

The Norwegian Environment Agency (NEA) and the Norwegian Food Safety Authority (NFSA) requested the Norwegian Scientific Committee for Food Safety (Vitenskapskomiteen for mattrygghet, VKM) for an opinion of potential risks to biodiversity and agriculture in Norway

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associated with import of seeds for sowing, and cultivation of insect-resistant and herbicide-tolerant genetically modified maize 1507 under Directive 2001/18/EC (Notification C/ES/01/01). The notification is still pending for authorisation in the European Union. VKM is also requested to assess the applicant's post-market environmental monitoring plan, and the management measures suggested in the draft implementing decision of the European Commission.

As VKM delivered a scientific opinion on this application including cultivation in 2014 (VKM, 2014), VKM is asked to assess whether the previous risk assessment is still valid concerning cultivation, and to update the opinion after current knowledge. The assessment shall specifically consider Norwegian conditions. Furthermore, as the notification does not cover food and feed uses of maize 1507, VKM was not asked for a health risk assessment of maize 1507. However, VKM has decided to update the previous safety evaluation of the food and feed uses of maize 1507 and derived products from 2014.

VKM appointed a working group consisting of members from the Panel on Genetically Modified Organisms, the Panel on Alien Organisms and trade in Endangered Species (CITES) and the VKM staff to answer the requests. The Panel on Genetically Modified Organisms has assessed and approved the final report.

The genetically modified maize 1507 was 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 by the 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, derived from the soil bacterium *Streptomyces viridochromogenes*. PAT protein confers tolerance to the herbicidal active substance glufosinate-ammonium. The PAT protein expressed in maize 1507 was 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.

In delivering its scientific opinion, VKM considered relevant peer-reviewed scientific publications and information provided by the applicant in the notifications C/ES/01/01, C/NL/00/10, the applications EFSA/GMO/NL/2004/02 and EFSA/GMO/RX/1507, and scientific opinions and comments from EFSA and other EU member states.

VKM 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.

VKM has also decided to take into account, 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 opinion 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. An evaluation of unintended effects on plant fitness, potential for gene transfer, interactions between the GM plant and target and non-target organisms, effects on biogeochemical processes, the postmarket environmental monitoring plan and coexistence measures at the farm level has also been undertaken.

It is emphasised that VKM's 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 VKM.

#### **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 one copy only 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. VKM 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, VKM 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. The field evaluations support a conclusion of no phenotypic changes indicative of increased plant weed/pest potential of 1507 compared to conventional maize.

#### **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 further 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, VKM 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 Assessment:**

Maize is the only representative of the genus *Zea* in Europe, and there are no cross-compatible wild or weedy relatives outside cultivated maize 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. Since maize 1507 has no altered agronomic and phenotypic characteristics, except for the specific target insect resistance and herbicide tolerance, the likelihood of unintended environmental effects as a consequence of spread of genes from maize 1507 is considered to be extremely low.

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 a limited number of published scientific studies on environmental effects of Cry1F protein. Published scientific studies show 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.

In Norway, the maize cultivation is marginal. The total crop area of forage maize is estimated to 2000-2800 decares, equivalent to less than 0.1 % of the areas with cereal crops. The area of individual fields is limited by the topography such that the quantity of maize pollen produced under flowering is also limited. The potential exposure of Cry1F-containing maize pollen on non-target lepidopteran species in Norway is therefore negligible.

Cultivation of maize 1507 is not considered to represent a threat to the prevalence of red-listed species in Norway.

Exposure of non-target organisms to Cry proteins in aquatic ecosystems is likely to be very low, and potential exposure of Cry proteins to non-target organisms in aquatic ecosystems in Norway is considered to be negligible.

VKM 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. Despite limited number of studies, 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.

#### **Coexistence:**

VKM concludes that separation distances of 200 meters most likely will ensure coexistence between genetically modified maize and conventional and organic maize varieties in Norway.

#### **Overall Conclusion:**

Based on current knowledge, VKM concludes that maize 1507 is nutritionally equivalent to conventional maize varieties. It is unlikely that the Cry1F and PAT proteins will introduce a toxic or allergenic potential in food or feed derived from maize 1507. VKM likewise concludes that cultivation of maize 1507 is unlikely to have any adverse effect on the environment or 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; glufosinate ammonium; cultivation; food/feed risk assessment; environmental risk assessment; Directive 2001/18; Regulation (EC) No 1829/2003.

Available: <https://vkm.no/download/18.4fdace2015eceedf2143f44c/1507028536027/Risk%20assessment%20of%20maize%201507%20for%20cultivation.pdf>

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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 Organism of VKM. All authors read and approved the final manuscript.

Competence of VKM experts: Persons working for VKM, either as appointed members of the Committee or as external experts, do this by virtue of their scientific expertise, not as representatives for their employers or third party interests. The Civil Services Act instructions on legal competence apply for all work prepared by VKM.

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## **COMPETING INTERESTS**

Authors have declared that no competing interests exist.

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