



Environmental Risk Assessment of Insect Resistant Genetically Modified Maize MON810 for Cultivation, Seed Production, Import, Processing and Feed Uses under Directive 2001/18/EC (Notification C/F/95/12/02)

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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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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 Directorate for Nature Management to conduct final environmental risk assessments for all genetically modified

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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 Directorate requests VKM to consider whether updates or other changes to earlier submitted assessments are necessary.

MON810 notification C/F/95/12-02 is approved under Directive 90/220/EEC for cultivation, seed production, import and processing into feeding stuffs and industrial purposes since 22 April 1998 (Commission Decision 98/294/EC). In December 1997, food and food ingredients derived from the progeny of maize line MON810 were notified under Article 5 of Regulation (EC) No 258/97 on novel foods and novel food ingredients. In addition, existing food and feed products containing, consisting of or produced from MON810 were notified according to Articles 8 and 20 of Regulation (EC) No 1829/2003 and were placed in the Community Register in 2005.

Three applications for renewal of the authorisation for continued marketing of (1) existing food and food ingredients produced from MON810; (2) feed consisting of and/or containing maize MON810, and MON810 for feed use (including cultivation); and (3) food and feed additives, and feed materials produced from maize MON810 within the framework of Regulation (EC) No 1829/2003 were submitted in 2007.

Maize MON810 has previously been assessed by the VKM GMO Panel commissioned by the Norwegian Directorate for Nature Management in connection with the national finalisation of the procedure of the notification C/F/95/12/02 (VKM 2007a,b). In addition, MON810 has been evaluated by the VKM GMO Panel as a component of several stacked GM maize events (VKM 2005a,b,c, VKM 2007c, VKM 2008, VKM 2009, VKM 2012). Due to the publication of updated guidelines for environmental risk assessments of genetically modified plants and new scientific literature, the VKM GMO Panel has decided to deliver an updated environmental risk assessment of MON810.

The environmental risk assessment of the maize MON810 is based on information provided by the applicant in the notification C/F/95/12/02 and application EFSA/GMO/RX/MON810, 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 MON810 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 2006, 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 2006, 2011c).

The scientific risk assessment of maize MON810 include molecular characterisation of the inserted DNA and expression of the target protein, 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.

In line with its mandate, VKM emphasised that assessments of 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, shall not be carried out by the Panel on Genetically Modified Organisms.

The genetically modified maize MON810 was developed to provide protection against certain lepidopteran target pests, including European corn borer (*Ostrinia nubilalis*) and species belonging

to the genus *Sesamia*. Protection is achieved through expression in the plant of the insecticidal Cry protein, Cry1Ab, derived from *Bacillus thuringiensis* ssp. *kurstaki*, a common soil bacterium.

Molecular characterisation Appropriate analysis of the integration site including flanking sequences and bioinformatics analyses have been performed to analyse the construct integrated in the GM plant. Updated bioinformatics analyses revealed that one ORF shared sequence similarity to a putative HECT-ubiquitin ligase protein.

The VKM GMO Panel found no safety implications from the interruption of this gene sequence. Analyses of leaf, grains, whole plant tissue and pollen from the maize MON 810 demonstrated that the Cry1Ab protein is expressed at very low levels in all tissues tested and constitutes less than 0.001% of the fresh weight in each tissue. The cry1Ab gene is the only transgene expressed in line MON 810 and was expressed highest in the leaves. The stability of the genetic modification has been demonstrated over several generations.

Event MON810 and the physical, chemical and functional characteristics of the proteins have previously been evaluated by The VKM Panel on Genetically Modified Organisms, and considered satisfactory (VKM 2007a,b).

Comparative assessment:

Comparative analyses of data from field trials located at representative sites and environments in the USA and Europe indicate that maize MON810 is agronomically and phenotypically equivalent to the conventional counterpart and commercially available reference varieties, with the exception of the lepidopteran-protection trait, conferred by the expression of the Cry1Ab protein. The field evaluations support a conclusion of no phenotypic changes indicative of increased plant weed/pest potential of MON810 compared to conventional maize. Evaluations of ecological interactions between maize MON810 and the biotic and abiotic environment indicate no unintended effects of the introduced trait on agronomic and phenotypic characteristics.

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.

Published scientific studies show no or negligible adverse effects of Cry1Ab protein on non-target arthropods that live on or in the vicinity of maize plants. Cultivation of maize MON810 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 Cry1Ab 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.

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. 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 non-target 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.

In addition to the data presented by the applicant, the VKM GMO Panel is not aware of any scientific report of increased establishment and spread of maize MON810 and any change in survival (including over-wintering), persistence and invasiveness capacity. Because the general characteristics of maize MON810 are unchanged, insect resistance are not likely to provide a selective advantage outside cultivation in Norway.

Since MON810 has no altered agronomic and phenotypic characteristics, except for the specific target pest resistance, the VKM GMO Panel is of the opinion that the likelihood of unintended environmental effects due to the establishment and survival of maize MON810 will be no different to that of conventional maize varieties in Norway.

Overall conclusion:

The VKM GMO Panel concludes that cultivation of maize MON810 is unlikely to have any adverse effect on the environment in Norway.

Keywords: Maize; Zea mays L.; genetically modified maize MON810; C/F/9512/02; insect resistance; cry proteins; Cry1Ab; cultivation; environmental risk assessment; directive 2001/18/EC.

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NOTE:

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COMPETING INTERESTS

Authors have declared that no competing interests exist.

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