



Preliminary Environmental Risk Assessment of Genetically Modified Oilseed Rape MON 88302 for Food and Feed Uses, Import and Processing under Regulation (EC) No 1829/2003 (Application EFSA/GMO/BE/2011/101)

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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

The environmental risk assessment of the herbicide tolerant genetically modified oilseed rape MON 88302 (Reference EFSA/GMO/BE/2011/101) has been performed by the Panel on Genetically Modified Organisms (GMO) of the Norwegian Scientific Committee for Food Safety (VKM). VKM has been requested by the Norwegian Directorate for Nature Management and the

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Norwegian Food Safety Authority to issue a preliminary scientific opinion on the safety of the genetically modified oilseed rape MON 88302 (Unique identifier MON-88Ø2-9) for food and feed uses, import and processing, and submit relevant scientific comments or questions to EFSA on the application EFSA/GMOBE/2011/101.

The environmental risk assessment of the MON 88302 is based on information provided by the applicant in the application EFSA/GMO/BE/2011/101, and scientific comments from EFSA and other member states made available on the EFSA website GMO Extranet. The risk assessment also considered peer-reviewed scientific literature as relevant.

The VKM GMO Panel has evaluated MON 88302 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 oilseed rape MON 88302 include molecular characterisation of the inserted DNA and expression of target proteins, comparative assessment of agronomic and phenotypic characteristics, unintended effects on plant fitness, potential for horizontal and vertical gene transfer, and evaluations of the post-market environmental plan.

In line with its mandate, VKM emphasized 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 GMO Panel has therefore not considered possible health and environmental effects of cultivation and processing of oilseed rape MON 88302 outside the EU/EEA area.

The genetically modified oilseed rape MON 88302 was developed to provide tolerance to the herbical active substance glyphosate by the introduction of a gene coding for the enzyme 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) from *Agrobacterium tumefaciens*, strain CP4 (CP4 EPSPS). Glyphosate is a non-selective herbicide and is normally phytotoxic to a broad range of plants. Its mode of action occurs by binding to and inactivating the EPSPS protein, which is a key enzyme in the shikimate pathway that leads to the biosynthesis of the aromatic amino acids tyrosine, tryptophan and phenylalanine. The disruption of this pathway and the resulting inability to produce key amino acids prevents growth and ultimately leads to plant death.

Molecular characterization:

The VKM Panel on Genetically Modified Organisms find the conclusion that no major section of the T-DNA plasmid backbone is inserted in MON88302 oilseed rape justified. We also find it justified that there is only one major T-DNA insert in MON88302.

Comparative assessment:

Based on results from comparative analyses of data from field trials located at representative sites and environments in the USA, Canada and Chile, it is concluded that oilseed rape MON 88302 is agronomically and phenotypically equivalent to the conventional counterpart and commercial available reference varieties, with the exception of the herbicide tolerance conferred by the CP4 EPSPS protein. The field evaluations support a conclusion of no phenotypic changes indicative of increased plant weed/pest potential of MON 88302 compared to conventional oilseed rape. Furthermore, the results demonstrate that in-crop applications of glyphosate herbicide do not alter

the phenotypic and agronomic characteristics of MON 88302 compared to conventional oilseed rape.

Evaluations of environmental interactions between genetically modified oilseed rape MON 88302 and the biotic and abiotic environment, and studies of seed dormancy, seed germination, pollen morphology and viability indicates no unintended effects of the introduced trait on these characteristics in MON 88302 oilseed rape.

Environmental risk:

Considering the scope of the application EFSA/GMO/BE/2011/101, excluding cultivation purposes, the environmental risk assessment is limited to exposure through accidental spillage of viable seeds of MON 88302 into the environment during transportation, storage, handling, processing and use of derived products.

Oilseed rape is mainly a self-pollinating species, but has entomophilous flowers capable of both self- and cross-pollinating. Normally the level of outcrossing is about 30 %, but outcrossing frequencies up to 55 % are reported.

Several plant species related to oilseed rape that are either cultivated, occurs as weeds of cultivated and disturbed lands, or grow outside cultivation areas to which gene introgression from oilseed rape could be of concern. These are found both in the Brassica species complex and in related genera. A series of controlled crosses between oilseed rape and related taxa have been reported in the scientific literature. Because of a mismatch in the chromosome numbers most hybrids have a severely reduced fertility. Exceptions are hybrids obtained from crosses between oilseed rape and wild turnip (*B. rapa* ssp. *campestris*) and to a lesser extent, mustard greens (*B.juncea*), where spontaneously hybridising and transgene introgression under field conditions have been confirmed. Wild turnip is native to Norway and a common weed in arable lowlands.

There is no evidence that the herbicide tolerant trait results in enhanced fitness, persistence or invasiveness of oilseed rape MON 88302, or hybridizing wild relatives, compared to conventional oilseed rape varieties, unless the plants are exposed to glyphosate-containing herbicides.

However, accidental spillage and loss of viable seeds of MON 88302 during transport, storage, handling in the environment and processing into derived products is likely to take place over time, and the establishment of small populations of oilseed rape MON 88302 on locations where glyphosate is frequently applied to control weeds e.g. on railway tracks, cannot be excluded. Feral oilseed rape MON 88302 arising from spilled seed could theoretically pollinate conventional crop plants if the escaped populations are immediately adjacent to field crops, and shed seeds from cross-pollinated crop plants could emerge as GM volunteers in subsequent crops. However, both the occurrence of feral oilseed rape resulting from seed import spills and the introgression of genetic material from feral oilseed rape populations to wild populations are likely to be low in an import scenario. Apart from the glyphosate tolerance trait, the resulting progeny will not possess a higher fitness and will not be different from progeny arising from cross-fertilisation with conventional oilseed rape varieties.

The VKM GMO Panel concludes that this route of gene flow would not introduce significant numbers of transgenic plants into agricultural areas or result in any environmental consequences in Norway.

The environmental risk assessment will be completed and finalized by the VKM Panel on Genetically Modified Organisms when requested additional information from the applicant is available.

Keywords: Oilseed rape; *Brassica napus* ssp. *oleifera* (DC.) Metzg.; genetically modified oilseed rape MON 88302; EFSA/GMO/BE/2011/101; herbicide tolerance; glyphosate; CP4 EPSPS protein; environmental risk; Regulation (EC) No 1829/2003; Directive 2001/18/EC.

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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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