



Environmental Risk Assessment of Glufosinate-Tolerant Genetically Modified Oilseed Rape T45 for Food and Feed Uses, Import and Processing under Regulation (EC) No 1829/2003 (Application EFSA/GMO/UK/2005/25)

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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 assignment includes a scientific environmental risk assessment of oilseed rape T45 (Reference EFSA/GMO/UK/2005/25) from Bayer CropScience for food and feed uses, import and processing. Oilseed rape T45 has previously been risk assessed by the VKM Panel on Genetically Modified Organisms (GMO), commissioned by the Norwegian Food Safety Authority related to the EFSA's public hearing in 2007 (VKM 2007a).

Food additives produced from T45 oilseed rape were notified in the EU as existing food additives within the meaning of Article 8 (1)(b) of Regulation 1829/2003, authorized under Directive 89/10/EEC (Community Register 2005). Feed materials produced from T45 were also notified as existing feed products containing, consisting of or produced from T45 according to Articles 8 and 20 of Regulation (EC) No 1829/2003 in 2003.

A notification for placing on the market of T45 according to the Directive 2001/18/EC was submitted in March 2004 (C/GB/04/M5/4), covering import and processing of T45 into food and feed. The application was further transferred into Regulation (EC) No 1829/2003 in November 2005 (EFSA/GMO/UK/2005/25). An application for renewal of authorisation for continued marketing of food additives and feed materials produced from T45 oilseed rape was submitted under Regulation (EC) No 1829/2003 in 2007 (EFSA/GMO/RX/T45). The EFSA GMO Panel performed one single comprehensive risk assessment for all intended uses of genetically modified oilseed rape T45, and issued a comprehensive scientific opinion for both applications submitted under Regulation (EC) No 1829/2003. The scientific opinion was published in January 30 2008 (EFSA 2008), and food and feed products containing or produced from oilseed rape T45 was approved by Commission Decision 26 March 2009 (Commission Decision 2009/184/EC).

The oilseed rape T45 is however currently being phased out (EU-COM 2009). The commercialisation of T45 oilseed rape seeds in third countries was stopped after the 2005 planting season and stocks of all oilseed rape T45 lines have been recalled from distribution and destroyed. The applicant commits not to commercialize the event in the future and the import will therefore be restricted to adventitious levels in oilseed rape commodity. Thus the incidence of oilseed rape T45 in the EU is expected to be limited.

The environmental risk assessment of the oilseed rape T45 is based on information provided by the notifier in the application EFSA/GMO/UK/2005/25 and EFSA/GMO/RX/T45, 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 T45 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 T45 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 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 glufosinate ammonium-tolerant oilseed rape transformation event T45 (Unique Identifier ACSBNØØ8-2) was developed by Agrobacterium-mediated transformation of protoplast from the conventional oilseed rape cultivar "AC Excel". T45 contains a synthetic version of the native pat gene isolated from the bacteria *Streptomyces viridochromogenes*, strain Tü 494. The inserted gene encodes the enzyme phosphinothricin acetyltransferase (PAT), which confers tolerance to the herbical active substance glufosinate ammonium. The PAT enzyme detoxifies glufosinate-ammonium by acetylation of the L-isomer into N-acetyl-L-glufosinate ammonium (NAG) which does not inhibit glutamine synthetase and therefore confers tolerance to the herbicide.

Glufosinate ammonium-tolerant oilseed rape transformation event T45 has been conventionally bred into an array of spring-type oilseed rape varieties.

Molecular characterization:

The molecular characterisation data established that only one copy of the gene cassette is integrated in the oilseed rape genomic DNA. Appropriate analysis of the integration site including sequence determination of the inserted DNA and flanking regions and bioinformatics analysis have been performed. Bioinformatics analyses of junction regions demonstrated the absence of any potential new ORFs coding for known toxins or allergens. The genetic stability of transformation event T45 was demonstrated at the genomic level over multiple generations by Southern analysis. Segregation analysis shows that event T45 is inherited as dominant, single locus trait. Phenotypic stability has been confirmed by stable tolerance to the herbicide for T45 lines and varieties derived from the event grown in Canada since 1993.

Oilseed rape transformation event T45 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).

Comparative assessment:

Based on results from comparative analyses of data from field trials located at representative sites and environments in Canada in 1995-1997, it is concluded that oilseed rape T45 is agronomically and phenotypically equivalent to the conventional counterpart and commercial available reference varieties, with the exception of maturity and the herbicide tolerance conferred by the PAT protein. The field evaluations support a conclusion of no phenotypic changes indicative of increased plant weed/pest potential of event T45 compared to conventional oilseed rape. Furthermore, the results demonstrate that in-crop applications of glufosinate herbicide do not alter the phenotypic and agronomic characteristics of event T45 compared to conventional oilseed rape.

Environmental risk:

According to the applicant, the event T45 has been phased out, and stocks of all oilseed rape T45 lines have been recalled from distribution and destroyed since 2005. However, since future cultivation and import of oilseed rape T45 into the EU/EEA area cannot be entirely ruled out, the environmental risk assessment consider exposure of viable seeds of T45 through accidental spillage 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 T45, or hybridizing wild relatives, compared to conventional oilseed rape varieties, unless the plants are exposed to herbicides with the active substance glufosinate ammonium. Glufosinate ammonium-containing herbicides have been withdrawn from the Norwegian market since 2008, and the substance will be phased out in the EU in 2017 for reasons of reproductive toxicity.

Accidental spillage and loss of viable seeds of T45 during transport, storage, handling in the environment and processing into derived products is, however, likely to take place over time, and the establishment of small populations of oilseed rape T45 cannot be excluded. Feral oilseed rape T45 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 glufosinate 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 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 in Norway.

Overall conclusion:

Taking into account the expected limited import of oilseed rape T45 (EU COM 2009), the VKM GMO Panel considers that the routes of gene flow from T45 would not introduce significant numbers of transgenic plants into agricultural areas or result in any environmental consequences in Norway.

The VKM GMO Panel concludes that oilseed rape T45 is unlikely to have any adverse effect on the environment in Norway in the context of its intended usage.

Keywords: *Oilseed rape; Brassica napus ssp. oleifera (DC.) Metzg.; genetically modified oilseed rape T45; EFSA/GMO/2005/25; glufosinate-tolerant; pat gene; PAT protein; ACS-BNØØ8-2; environmental risk assessment; import; processing; regulation (EC) No 1829/2003; 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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