



Press release

The Norwegian Directorate for Nature Management considers that the cultivation and use of the genetically modified potato Amflora in feed and food should be prohibited in Norway.

The EEA Agreement obliges Norway to make a national decision on all genetically modified organisms that are approved in the EU. Amflora was given a green light by the EU on 2 March 2010 and therefore the Norwegian authorities have considered whether to allow Amflora in Norway.

DN has evaluated the available information regarding the product's risk to health and the environment, social benefit, contribution to sustainable development and ethical issues in accordance with the Norwegian Gene Technology Act and Nature Diversity Act. DN has concluded that the potato should not be cultivated, nor used for industry purposes or in animal feed in Norway. DN has also recommended against allowing unintended mixing of the potato in food and feed products up to 0.9%.

The evaluation report has been forwarded to the Norwegian Ministry of the Environment who will make a final decision regarding the cultivation and use of the GMO potato Amflora in Norway.

Resistance to antibiotics

The presence of the antibiotic resistance marker gene *nptII* in the potato is the main reason for DN's recommendation to ban it in Norway. Senior Adviser Bjarte Heide elaborates:

- Norway has a ban on feed and food products that contain genes which confer resistance to antibiotics. Furthermore, Norway has a general restrictive attitude towards the use of such genes in GMOs, for any purpose. Norway has previously laid down prohibitions against the use of other genetically modified organisms based on the presence of antibiotic resistance marker genes, says Heide.

No need for the product

Other reasons for the recommendation are that the applicant has not sufficiently assessed the risk to the environment, in particular with regards to effects on certain groups of non-target organisms. In addition, DN believes that the use of Amflora is of no benefit to the Norwegian society, as there is no need for the product in Norway and that the potato can result in increased costs for manufacturers and thereby has a negative impact. In Norway, it will not be possible to use waste products from the industry for feed due to the Norwegian ban on the content of antibiotic resistance genes in feed.

The recommendation is based on the DN's own assessments, as well as the Norwegian Food Safety Authority's assessments of health, agriculture-related environmental risk and coexistence. The Norwegian Scientific Committee for Food Safety has been the Food Safety Authority's advisory body. The Norwegian Biotechnology Advisory Board has assessed risk to health and environment, sustainability, benefit to society and ethics. In addition, relevant information from the public consultation is taken into account.

Visiting address:

Tungasletta 2

Postal address:

Postboks 5672 Sluppen
N-7485 Trondheim

Phone:

+47 73 580 500

Telefaks:

+47 73 580 501

Videoconf:

+47 73 905 140

Internett:

www.dirnat.no

E-mail:

Postmottak@dirnat.no



Summary of the impact assessment

Application (C/SE/96/3501) under Directive 2001/18/EC (the Directive) covers the use of the genetically modified potato line EH92-527-1 (Amflora) for cultivation and industrial purposes. Application (EFSA/GMO/UK/2005/14) under Regulation (EC) No 1829/2003 (the Regulation) covers the use of the same potato line for feed and unintentional mixing in food and feed products up to 0.9%.

Amflora has increased content of the starch component amylopectin and reduced content of amylose. The purpose of the genetic modification is to make the potato more suitable for various industrial processes, particularly the paper industry. This is achieved by inhibiting expression of an enzyme (GBSS), which is important for the formation of amylose. In addition, Amflora contains the *nptII* gene that causes resistance to certain antibiotics, including kanamycin and neomycin.

The application under the Directive and the application under the Regulation were approved in the EU 2 March 2010, and the approvals are valid for a period of 10 years from the date of approval. The approval under the Directive applies only to the cultivation and industrial use, and the European Commission emphasizes that Amflora is to be kept separate from other potatoes at every stage of production from farm to delivery at specialized processing units. The approval under the Regulation allows the use of the by-products of the starch production for feed. The approval also allows unintended admixture of the potato in other food and feed up to 0.9%. The monitoring plan includes requirements for the case specific monitoring of potato-eating organisms in the area where Amflora is grown. Amflora has the identification number BPS 2527-9 and the name "amylopectin potato starch" is to be used for labeling.

The Regulation is presently not implemented in Norway, therefore, only the application for cultivation and industrial use will be applicable in Norway. The Norwegian Directorate for Nature Management (DN) has been commissioned by the Norwegian Ministry of the Environment (MoE) to finalize both the application under Regulation and the application under the Directive. Because the two applications concern the same product, DN has chosen to summarize the reviews in a joint conclusion.

DN has evaluated the available information regarding health and environmental risk, benefit to society, the product's contribution to sustainable development and ethical issues in accordance with the Gene Technology Act and the Nature Diversity Act.

DN requested the Norwegian Food Safety Authority (MT) to conduct a risk assessment of Amflora within their own areas of responsibility, which involves an assessment of health risks, agriculture-related environmental risks and coexistence. MT has requested VKM to undertake a scientific risk assessment of Amflora in these areas. MT concludes, on the basis of VKMs statements, that it is unlikely that the intended use of the potato as animal feed and unintended admixture of the potato in food and feed up to 0.9% will result in altered risks for animal health or human health in relation to conventional starch potatoes. Furthermore, MT states: "*By-products from starch production used as feed and unintended presence of the potato in certain food and feed, will be covered by the Norwegian total ban on such in food and feed*". In its assessment of the application under the Regulation MT points out that since the Regulation is not implemented in Norway, they assume Norway will make a final decision at a later date when/if the regulation is implemented in Norway. MT concludes in their assessment of the application under the Directive that there will be minimal agriculture-related environmental risk resulting from the cultivation of Amflora compared to conventional potato varieties. MT believes it will be possible with co-existence of genetically modified potatoes and conventional and organic crops, but points out that Amflora is not very relevant in Norwegian agriculture.



The Norwegian Biotechnology Advisory Board (NBAB) was requested by DN to consider the potato's contribution to sustainable development and benefit to society, and to make an ethical assessment of the marketing of the potato. The NBAB concluded that the marketing of genetically modified plants containing genes for antibiotic resistance should not be approved and that more environmentally friendly alternatives should be promoted.

The Norwegian Gene Technology Act does not prohibit cultivation of organisms containing antibiotic resistance marker genes (ARMG). However, the Norwegian Parliament has stated that permission to use ARMG should only be given if the risk is negligible and the products are of use to the society.

In DN's opinion, the greatest risk of the presence of ARMG in the potato is the possibility of transfer of antibiotic resistance to pathogenic bacteria. Although there may be a low probability of such an event the consequences can be very serious. Furthermore, equivalent products, which do not contain ARMG, exist. As Norwegian producers do not want to use Amflora, DN is of the opinion that the cultivation of Amflora may have an overall negative benefit to the Norwegian community.

In DN's opinion the potential effects on non-target organisms that come into indirect contact with Amflora is not adequately assessed. There is a need for further knowledge about the effects of cultivation of potato with modified starch contents on microbial organisms in soil and biogeochemical processes in the cultivation area.

Furthermore, DN is of the opinion that the Notifier has given an inadequate description of the mechanism for down-regulation of the GBSS enzyme in Amflora, making it difficult to assess whether non-target genes may have been affected.

VKM points out that it would be useful to have more information about the natural distribution, dynamics and prevalence of the *nptII* gene in Norway, the extent of overwintering potato tubers and the potential for insect dispersal of pollen from potato.

In light of the foregoing, especially given the risks of ARMG, insufficient information and because DN has concluded that the potato can be of negative benefit to the community, our recommendation is to prohibit marketing of potato line EH92-527-1 under Directive 2001/18/EC.

Information from the Notifier has shown that small amounts of *nptII* protein may be found in tubers, leaves and pulp (waste products) from Amflora. Also, it cannot be excluded that traces of *nptII* will be found in the feed. Due to these facts and based on the prohibition of ARMG in the Norwegian Regulation on feed products, § 5, DN recommends to prohibit the use of potato line EH92-527-1 for feed and unintentional admixture in food and feed under Regulation 1829/2003.