

Amflora cultivation

The application for cultivation of Amflora as starch potato for industrial was filed under regulation 1829/2003. Amflora has been genetically modified so that one of the two starch fractions in the potato tubers is not produced - or only to very small amounts. A second genetic modification confers an antibiotic resistance (nptII) against a number of antibiotics such as kanamycin and neomycins. For details on this check [GM potato event Amflora](#) [1].

Cultivation of Amflora was authorized in March 2010 as one of the first deeds of the EU Health Commissioner Dalli. A draft decision by EU Environmental Commissioner Dimas in 2007 had not reached a qualified majority. The cultivation authorisation contradicts the EFSA opinion with regard to case specific monitoring.

Lack of environmental studies

The original application contained next to no information on the interactions of the GM potato with the biotic and abiotic environment. Instead it was simply stated that "a detailed investigation of effects on the micro-flora before placing on the market or in a monitoring program would not be proportional to the possible risk from the putative detection of a minor difference in micro-flora composition."

The EFSA requested further information on the impact of the GM potato on plant-associated organisms (e.g. invertebrates). According to the EFSA opinions the applicant then provided data from field studies suggesting that there is no greater susceptibility nor greater resistance to pests and diseases, nor is there a change in sensitivity to a number of potato associated viruses.

"5.2.4 Interactions with the GM plant with non-target organisms

From the field studies carried out in Sweden, Germany and The Netherlands, the applicant provided data on the impact of the modified crops on plant-associated organisms. The result of field studies suggest neither greater susceptibility nor greater resistance to pests (e.g. aphids, leafhoppers, potato cyst nematodes (sp Globodera)) and diseases (e.g. late blight (*Phytophthora infestans*), potato early blight (*Alternaria solani*), Erwinia rots) than non-GM potato. There was no evidence of changes in sensitivity to the plant associated viruses PVY, PLRV, PMTV, and TRV. In view of this and of the equivalent composition of the GM potato plant, it is considered that no adverse effects on plant-associated organisms would be expected from cultivation of the potato EH92-527-1."

These studies were obviously performed to study the performance of the new GM potatoes. They only recorded the susceptibility of the GM potato to pests and diseases, but they give no information about the effects of the potato on these organisms, and they don't give any information at all about possible effects of the GM potato on other organisms that are not considered pest, like beneficiary insects, earthworms or other wild animals. There are no studies about possible impacts on the biodiversity on or around the field.

The starch has by intent a different starch composition than the non-modified potato, and it has higher sugar levels - possible a result from the changed metabolism of the plant. There are also indications that other compositions (e.g. vitamin C levels) are different. These changes could make the GM plants more or less attractive to animals as food source.

This different starch composition could also result in a different decomposition. EFSA states in its opinions that "GM tubers have a different starch composition, and therefore may be decomposed by a changed microbial community [...]" These effects are not studied at all, but need to be studied as part of an e.r.a.

EFSA acknowledges, that "some different interactions with plant associated organisms may occur in Southern regions" but conclude that "there is no indication that plant-associated organisms would be adversely affected." Such conclusion cannot be drawn, on the basis of so little information.

There also is no environmental risk assessment of the intended use of GM potato juice (a by-product from starch production) as fertilizer.

Antibiotic resistance

The GM starch potato contains the antibiotic marker nptII as selection marker. It provides resistance not only for kanamycin, but also for neomycin, paromomycin, ribostamycin, butirosin, gentamicin B and geneticin (G418).

According to Directive 2001/18/EC Article 4, Member States and the Commission shall ensure that antibiotic markers shall be phased out for GMOs regulated under Part C by 31 December 2004. Nevertheless, the EFSA gave a positive opinion about the use of this antibiotic resistance marker in the GM potato. In contrast to EFSA's opinion that kanamycin resistance was already widely spread in bacteria anyway, Other national and international authorities come to different conclusions about the importance of kanamycin.

Kanamycin is listed in the WHO Essential Medicines Library as a drug against multi-drug resistant tuberculosis. This kind of tuberculosis is a growing problem worldwide and the potential need to use kanamycin should therefore be taken seriously.

The EFSA however simply states that "any additional contribution from potential transfer to soil organism is considered to be insignificant."

Comments on the opinion of the GMO Panel:

Even though the GMO Panel initially recognized the lack of studies for the environmental risk assessment, it then considered as sufficient a study that clearly does not answer the questions raised, and where only a summary of the study was provided.

On this thin basis, the EFSA found it could not identify any potential risks, and also considered the monitoring plan to be sufficient

Further EU procedure:

In 2007, the EU Environmental Commissioner Dimas drafted a decision to authorize the cultivation of Amflora. This decision contradicts EFSA's assessment that no case specific monitoring would be needed and that the general post-market monitoring plan was sufficient.

In an unprecedented act, the decision states additional requirements for studies to be conducted as part of the monitoring. These requirements concern issues that the GMO Panel had not mentioned in its opinion.

Article 4.1(e)

the consent holder shall carry out specific field studies to monitor potential adverse effects on potato-feeding organisms in the fields and their vicinity where *Solanum tuberosum* L. line EH92-527-1 is cultivated in accordance with the requirements laid down in Annex. [...]

Annex

Monitoring of potato-feeding organisms in the fields where *Solanum tuberosum* L. line EH92-527-1 is cultivated and in their vicinity.

1. The consent holder shall undertake field studies to monitor the potential adverse effects on potato-feeding organisms in the fields where *Solanum tuberosum* L. line EH92-527-1 is cultivated and in their vicinity.
2. The monitoring study shall focus on model potato-feeding organisms in the potato fields and in their vicinity, representative of key ecological functions in the agricultural environment.
3. The monitoring study shall take into account the latest scientific findings and use state-of-the-art protocols including statistical analysis of the data in accordance with standard methods.
4. The results of these studies shall be evaluated in view of the risk assessment contained in the notification and reported as provided for in Article 4(2).
5. Where appropriate, the results of these studies shall be used to review and modify the monitoring plan proposed in the notification as provided for in Article 4(3).

Related events: [Amflora potato](#) [2]

Related application(s): [Amflora as feed and food](#) [3]

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Question number: EFSA-Q-2005-023**Application number:** C/SE/96/3501**Application date:** 10.02.2005**Type:** new application**Application accepted:** 08.04.2005**Status:** finished**Deadline:** 31.12.2005**Links & resources:** [Comments by A. Lorch on EFSA's Amflora cultivation opinion](#) [4][EFSA registration](#) [5]**Applicant/Requester:** European Commission - DG ENV**Opinion number:** ON-323**Opinion adopted:** 07.12.2005**Opinion published:** 24.02.2006[Opinion of the GMO Panel](#) [6]**Application status at EU level:** authorized[EU authorization status](#) [7]**Authorisation date:** 02.03.2010[Impressum](#) | [Datenschutzerklärung](#)

Quellen-URL:<https://www.testbiotech.org/content/amflora-cultivation-0>**Links**[\[1\] https://www.testbiotech.org/en/node/338](#) [\[2\] https://www.testbiotech.org/content/amflora-potato](#)[\[3\] https://www.testbiotech.org/content/amflora-feed-and-food](#) [\[4\] http://ifrik.org/comments-efsa-](#)[opinion-allow-cultivation-basfs-starch-potato-amflora](#) [\[5\]](#)<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2005-023>[\[6\] http://www.efsa.europa.eu/en/scdocs/scdoc/323.htm](#) [\[7\] http://eur-lex.europa.eu/LexUriServ/LexU](#)[riServ.do?uri=OJ%3AL%3A2010%3A053%3A0011%3A0014%3AEN%3APDF](http://eur-lex.europa.eu/LexUriServ.do?uri=OJ%3AL%3A2010%3A053%3A0011%3A0014%3AEN%3APDF)