Amflora as feed and food

Initially, BASF and their Swedish partners only sought authorisation for Amflora cultivation, because the potato is modified for a different starch composition, making it more suitable for industrial processing. However, leftovers from the starch factories are used as animal feed, so an application Amflora as feed was added later, extended as food and feed use.
Amflora is not supposed to be eaten, but it was acknowledged that contamination cannot be avoided. The feed application therefore seem to be more born from legal reasons: contamination of a food product with an authorized GMO would need to be labelled but could still be sold, while products that are contaminated with an un-authorized GMO cannot be sold and usually have to be destroyed.
In Amrch 2010, the EU Commission authorized Amflora as animal feed, and in an unprecedented move authorized it also as a food for quantities less then 0.9%. This amount seems to be set arbitrary because none of the studies about food and feed safety make any distinction between the safety of different amounts of Amflora in the human diet.
The GMO Panel had given a positive opinion on the food and feed safety of Amflora, despite member states criticizing the two feeding studies as not sufficient.
The GMO panel also repeatedly came to the conclusion that the antibiotic resistance gene in Amflora would not have negative effects. (See GM potato Amflora [1] for more details.

Comments on the opinion of the GMO Panel:
The positive opinion about Amflora's food and feed safety is based on two simple feeding studies which both have been criticized as not sufficient for an safety assessment. In addition, where one study showed significant differences between modified and unmodified potatoes, these were not followed up but simply disregarded. None of the two studies were conducted with the actual fresh potatoes.

In a 90-day feeding study, rats were fed with diets containing 5% freeze-dried potatoes. This is low compared to other studies that feed concentrations up to 30%. Significant differences were recorded in female rats for white blood cells and spleen weight. In male rats, the number of cysts in thyroids were increase. None of these findings were followed up. Even as the potatoes are freeze-dried, this is the only feeding study with the starch potato itself, even though next to no experience exists about GM crops with changed composition.

In the second study2 2x16 cows were fed on GM pulp for periods of 8 weeks to measure weight gain as an indicator for the nutritional value. The study was not set up to assess any toxicological parameters. For example blood or urine were not not studied, nor where any physiological factors recorded to assess animal health. This study has been criticised in detail by the Finnish Plant Production Inspection Centre. They conclude that:

"The animal feeding trial does not answer, unambitiously, the question on the potential impact of feed GM-starch by-products on feed intake, digestibility or weight gains. Nor is it possible to draw any conclusions about the effects of the product on milk production. In the rumen the microbes metabolise the side products to volatile fatty acids. Whilst one might not expect to see any effects on the activity of rumen microbes caused by the different potato pulps this question has not been addressed."

The starch potato has been modified with the goal of a change metabolism and a changed composition and besides the intended change other changes in composition have been recorded, but the application only provides two animals studies, only one of which actually uses the GM crop (and even then only freeze dried) and the second uses a production by-product. One of the study only measures weight gain in a study set up with fundamental flaws that could mask possible effects. In the other study significant differences in physiological parameters were found and not followed up. There is no digestion study, even though the complex digestive system of cows who are supposed to feed on the GM potato are known. Also, the information provided is not sufficient to exclude allergic risks.

Nevertheless the EFSA disregarded questions about animal and human health and just looked "from a nutritional point of view" and declared that there were "no outstanding safety issues." In addition, the EFSA does not consider any post-market monitor of the GM potato as food or feed necessary.

Further EU procedure:
Two draft decisions to authorize Amflora for cultivation and as food/feed did not a qualified majority in 2007, but in March 2010 the new EU Commission authorized both.
In an unprecedented move the EU Commission introduced a maximum amount of 0.9% up to which Amflora is authorized as food. Authorization as feed is without restriction. There are no studies concerning Amflora safety at different levels, or no reasoning why the animal feeding studies that in other cases are also seen as sufficient for human health do not do so in this case. It therefore has to be assumed that the "0.9% food authorization" is a political, not a scientific decision, and that it mainly serves the purpose to avoid liability issues in case of Amflora contamination of food.
The 0.9% appear to be set arbitrary, based on the 0.9% level under which accidental contamination with an authorized GMO does not have to be labelled.

Related events: Amflora potato [2]
Related application(s): Amflora cultivation [3]
Question number: EFSA-Q-2005-070
Type: new application
Application date: 25/04/2005
Aplication accepted: 12/07/2005
Status: finished
Deadline: 31/05/2006
Links & resources: Comments by A. Lorch on EFSA's Amflora cultivation opinion [4]
EFSA registration [5]
Petitioner: BASF Plant Science
Applicant/Requester: United Kingdom
Opinion number: ON-324
Opinion adopted: 10/11/2006
Opinion published: 10/11/2006
Opinion of the GMO Panel [6]
Application status at EU level: authorized
EU authorization status [7]
Authorisation date: 02/03/2010

Source URL: https://www.testbiotech.org/en/content/amflora-feed-and-food

Links
[1] https://en/node/338
[2] https://www.testbiotech.org/en/content/amflora-potato
[3] https://www.testbiotech.org/en/content/amflora-cultivation-0
[4] http://ifrik.org/comments-efsa-opinion-allow-cultivation-basfs-starch-potato-amflora
[5] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2005-070
[6] http://www.efsa.europa.eu/en/scdocs/scdoc/324.htm
[7] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ%3AL%3A2010%3A053%3A0015%3A0018%3AEN%3APDF