

Information on handling the presence of another GM potato in Amflora

This report presents the main events of the admixture of GM potatoes discovered in fields cultivated with the GM potato called Amflora. The report is written from the perspective of the Swedish Board of Agriculture (SBA) and does not reflect measures taken by the European Commission or by the authorities in DE and CZ, which also had cultivation of Amflora in 2010.

Summary

Another GM-potato was discovered in five fields in Sweden, out of twenty, where the genetically modified starch potato Amflora was cultivated in 2010. This other potato was also a starch potato, which has been cultivated in field trials for six years in Sweden.

A thorough investigation on how, when and where this admixture could have occurred has been performed. The weight of evidence supports that the commingling occurred in a laboratory and a greenhouse. The SBA came to that conclusion after a thorough investigation of our own inspection protocols, interviews, inspection of laboratory, green house, and storage facilities and at the growers and a report from BASF.

The SBA decided soon after the notification of commingling that no lots of the Amflora in Sweden was to be used as feed, for starch production, as seed potatoes, sold or disposed of until further notice. The two lots with confirmed commingling has been destroyed. Further lots with suspected commingling has been, or will be, destroyed. After finalising the investigation we have reached the conclusion that further commingling is not likely. The Swedish Board of Agriculture has now decided to permit continued use and cultivation of remaining lots of Amflora in accordance with the decision of March 30th 2010.

The notification of commingling

The Swedish Board of Agriculture was informed by BASF through Plant Science Sweden AB on August 27th 2010 that a few plants of another GM potato had been found in fields cultivated with the GM potato Amflora.

After analyses it was concluded that the deviating potatoes belonged to the event AM04-1020 (hereon called Amadea). That event is authorised for field trials and has been cultivated in trials in Sweden since 2005. An application for release on the market was delivered to EFSA in October 2010.

The Amadea plants were detected because they have a different colour of flowers than Amflora (which seldom flowers). Control of morphologically deviating characters is part of the monitoring plan.

The admixture was found in two different seed lots¹. The first lot was grown in seven fields and 30 deviating plants were found in four of these fields. The second lot was grown in one field and there were 17 deviating plants. The admixture was thus 47 plants of about 640 000 (0.007%) in five fields in northern Sweden.

The first measures taken

On September 2nd 2010 the SBA decided on an injunction. Amongst the measures decided, BASF should continue to screen all fields with Amflora for deviating plants. The Amadea has permission to be cultivated (in trials) but under different conditions than Amflora. It was important that the seed lots of Amflora were not used as seed, for starch production, as feed or sold since Amadea is not licensed for such use. Therefore, the SBA decided that the lots with Amflora were not to be used as indicated above, until it could be established that there was no further admixture of Amadea.

BASF was also obliged to send in a report with an assessment on when, where and how the admixture could have occurred. The report was a thorough review of the handling of all the separate lots of Amflora year by year. Amadea was detected in cultivations from two seed lots. BASF reached the conclusion that commingling had occurred in two separate occasions, one in a greenhouse 2007 and another in a growth chamber 2009. Human mistake was given as the reason for the commingling. Amflora and Amadea had a few times been handled on the same premises which made it possible for someone to take wrong container. BASF has changed the routines to prevent this from happening again.

A joint mission to BASF premises in Germany was performed by representatives from the Commission and authorities from DE, CZ and SE.

Destruction of Amflora lots

The SBA decided on September 24th 2010 that three lots of Amflora should be destroyed. They were the two lots with confirmed admixture (99347 and 09_AMFLORA_f11_BP-1) and one lot with a suspected admixture (99341). Method of destruction in the north of Sweden was through freezing. The tubers were put in large containers with a thermometer to verify that it has been cold enough to destroy the potatoes. The SBA has sealed the locks on the containers. The tubers that were stored in the southern part of Sweden (lot no 99341) were destroyed through fermentation in a biogas plant. Part of a fourth lot (99348) will also be destroyed. Some of the potatoes from lot 99348 were cultivated in the same field as lot 99341. Those two were joined under the same field lot number during the summer. Therefore it was not possible for the SBA to verify that the correct seed lot had been destroyed and a decision was made to destroy tubers from lot 99348 that was grown in that field.

¹ In Sweden Amflora is cultivated for production of seed potato. Each lot is identified by a separate identification number given within the Swedish certification system, based on Council Directive 2002/56/EC of 13 June 2002 on the marketing of seed potatoes.

The tuber examination

The SBA decided in November 1st 2010 that 30 000 tubers from one of the lots that would be destroyed, should be examined before destruction. The examination was based on the colour of the tuber flesh. By choosing this method of examination the sample number could be increased in comparison to molecular analyses.

The purpose of this study was to determine how many Amadea plants that were not noticed in the field. That would indicate how good the method looking for white-flowering plants is to detect possible further commingling of Amadea.

The SBA and BASF had earlier performed a blind test on 100 tubers to establish the applicability of the method.

More than 30 000 potatoes were selected at random from the entire harvest of one field. These potatoes had been grown in a field that was small (0,6 ha) with a high relative admixture (8 plants) and with a variable emergence. The variable emergence could mean uncertain flowering. The field was thus selected to have a high probability for finding further Amadea tubers. The tubers were cut in half. By looking at the colour of the flesh, four tubers were deemed to have a deviating colour. This exercise was performed by BASF and monitored by the SBA. Those four potatoes were sent to the Swedish Food Administration for molecular analyses. One tuber was confirmed to be Amadea. The other three tubers were negative for tested gene sequences and therefore most likely not genetically modified.

That one tuber of Amadea was found in the study most likely means that the tuber came from a plant that had not been found to be morphologically distinct from Amflora. This was probably due to uneven emergence and that the plant not found did not bloom. It cannot be excluded, but not very likely, that the tuber could have belonged to one of the deviating plants detected but was left in the soil. If the tuber came from a plant that was not detected as Amadea in the field the level of commingling corresponds to one plant that went undetected in that field². Study of colour of flowers in fields with Amflora is thereby considered a good way to detect plants of Amadea.

Inspection of handling of Amflora relating to the admixture

The SBA inspection included visits at the two farms with confirmed commingling of Amadea in Amflora fields 2010. Two separate commercial potato storage facilities where Amflora and Amadea or Amflora alone have been stored previous years were also inspected. The purpose of the inspection was to control the documentation requirements of the Identity Preservation System (IPS) and was part of the investigation performed by the Swedish Board of Agriculture on the commingling at hand.

² The sample size was 115 kg per 500 kg box i.e. 1/5. One positive tuber should mean that there were 5 positive tubers in the harvest. There are at least 5 tubers per potato plant. Therefore 1 tuber tested positive in this test corresponds to 1 plant not detected in the field.

Results from inspection of handling of Amflora 2010 at the two farms

During the growing season the SBA visited the fields and no deviating plants were found. The reason that the SBA did not notice the deviating plants in 2008 to 2010³ is most likely that the timing of inspections did not coincide with time of flowering in all fields.

At the time for this inspection the potatoes were harvested and stored at facilities at the two growers' respective farms. The inspection included control that the relevant required documentation in the Identity Preservation System (IPS) was there. The documentation is comprised of activities during the growing season, storage, handling and transport. In addition, handling of Amflora not covered by the IP-system was discussed.

The documentation made by the growers for different activities required in the IPS was in accordance with the requirements. Both growers have cultivated seed lot 99347 (commingling confirmed). Growers confirmed that the seed lot arrived to the farm in pre-sprouting boxes labelled correctly.

The grower who received seed lot 09_AMFLORA_f11BP-1 (commingling confirmed) confirmed that the lot arrived in closed bags that had not been opened. These bags were opened on the field when and where they were planted.

Both growers had facilities in which they stored Amflora and other seed potatoes. All Amflora potatoes were stored in boxes, separated and labelled. In one facility Amflora was kept in a separate room. Lots with Amflora were labelled according to conditions in the decision for placing on the market.

Results from the inspection at the commercial storage facilities

The Amflora was approved for release on the market in March 31st 2010. Following that decision the IPS requirements started to apply.

Potato lot 09_AMFLORA_f11BP-1 was shipped from the greenhouse in Germany to a storage facility early in 2010. As mentioned above the bags were closed until they were opened in the field in time for planting. The SBA has ruled out the possibility of commingling at storage for this seed lot.

Potato lot 99347 was stored in the same facility 2008/2009 and a few months in 2009/2010. Amadea was stored in that facility in 2009/2010. According to the facility manager, the Amadea was stored in pre-sprouting boxes on one side of the sorting machine (but was not sorted). Amflora was in the last boxes of potatoes to be placed in the facility and was stored on the other side of the sorting machine, well separated from the Amadea lot. In the way that the handling at the storage was described there is a very low probability that commingling could have occurred at that facility.

The documentation in accordance to the IPS forms was controlled and there were no discrepancies. At the time for the inspection (autumn 2010) the facility had

³ The seed lot called 99347 has been cultivated in Sweden since 2008. Seed lot 09_AMFLORA_f11BP-1 was first grown in 2010.

Amadeus in storage. The Amadea were stored in a separate room where no other potatoes were stored. The staff could confirm the information in the BASF report on routines and handling. The general routines at this facility suggest that there is a low probability for commingling of different seed lots. All potato seed lots were stored separated and labelled.

There were no GM potatoes in a second storage at the time for inspection. Amflora lot 99347 had been stored and handled at this facility during the autumn 2009 until May 2010. Amadea was not handled at this storage at this time.

Based on information from BASF and the growers and staff at the storage facilities combined with our own inspections, the Swedish Board of Agriculture finds that it is not likely that commingling have occurred at storage or sorting. This accounts for both the lots with commingling as well as the other seed lots of Amflora. Amadea was found in four out of seven fields planted with Amflora lot 99347. This pattern also suggests that commingling could not have occurred in storage since Amadea must have been present in several boxes.

The decision to permit use of remaining lots

The Swedish Board of Agriculture has now lifted the ban on use of Amflora. The potatoes from 2010 years harvest with confirmed or suspected commingling have, or will be, destroyed. The Swedish Board of Agriculture finds the risk for further commingling in remaining harvested potato lots to be very low.

Reason for lifting ban on use

Five of the lots of Amflora have not been handled on the same premises, the same equipment has not been used and they have not grown in the vicinity of Amadea. Remaining lots of Amflora have at some point been stored in the same facility as Amadea. During storage though, potatoes are separated and kept in boxes or bags that are properly labelled. There are operational procedures for the separation. The same harvesting equipment has not been used and Amadea is not sorted in the sorting machines according to the BASF report. Cultivation of Amflora has not been placed near or on the same field as Amadea. There is a very low probability for commingling in these lots.

However, it is impossible to fully exclude the possibility that commingling has occurred without analysing every tuber. Nor can it be demonstrated that there is a commingling in these lots. However, the fact that Amadea plants were not detected in any other fields in 2010 than the five fields reported supports that there is no commingling in other lots. The performed examination of harvested tubers from a field with commingling further supports that. Thus, the SBA finds it reasonable to allow continued use of the remaining lots of Amflora.

Follow-up 2011

The purpose of the 30 000 tuber examination mentioned above was to determine the effectiveness of detecting Amadea in fields of Amflora through inspection of flowers. The fact that only one plant was undetected in the field in question

attests to the reliability of the method of field control during flowering time to detect Amadea in fields of Amflora.

The SBA has decided that during 2011, BASF shall increase the frequency of field inspection in 2011. Any plants with white flowers have to be analysed by a third party, using molecular methods. The extra inspection has a very good chance to detect any Amadea.

The fields where commingling was found

According to the permit for release on the market of Amflora, potatoes must not be cultivated again at the same fields where Amflora has grown until the fourth year. There is thus no risk that volunteers of Amadea would end up in the food chain or in other seed potato lots. In addition, there is a monitoring scheme for volunteers the year following Amflora cultivation. The SBA therefore considers that there is no reason to impose additional requirements on the handling of the fields where Amadea were found.