POST-MARKET MONITORING REPORT

For the Cultivation of
Amylopectin Potato EH92-527-1
Variety Amflora in 2010

Submitted by

BASF Plant Science Company GmbH

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LIST OF CONTENTS

APPENDICES

1. GENERAL INFORMATION

1.1. Crop/trait(s)

The post-market monitoring report relates to amylopectin potato EH92-527-1, variety Amflora.

1.2. Decision authorization number pursuant to Directive 2001/18/EC, and number and date of consent pursuant to Directive 2001/18/EC

EH92-527-1 potato was approved for cultivation according to Directive 2001/18/EC based on Commission Decision 2010/135/EU and consent Dnr 22-3501/96 of 31 March 2010 by the Swedish Board of Agriculture.

1.3. Decision authorization number and date of authorization pursuant to Regulation (EC) No 1829/2003

EH92-527-1 was further approved for feed use according to Regulation (EC) No 1829/2003 based on Commission Decision 2010/136/EU.

1.4. Unique identifier

BPS-25271-9

1.5. Reporting period

31 March 2010 to 31 March 2011

1.6. Other monitoring reports have been submitted in respect of

Import and processing: No

Food/feed: No

2. EXECUTIVE SUMMARY

Post-market monitoring was conducted for amylopectin potato EH92-527-1, variety Amflora, according to the monitoring plan as contained in notification C/SE/96/3501 and addressing the conditions of monitoring as determined in Article 4 of Commission Decision 2010/135/EU and condition 9 of consent Dnr 22-3501/96 of 31 March 2010 by the Swedish Board of Agriculture. In 2010, the first year of its commercial cultivation, the starch potato variety Amflora was grown at a total of 26 locations (covering about 235 ha) for seed potato multiplication in Germany and Sweden, and starch potato production in the Czech Republic. Monitoring comprised general surveillance, case-specific monitoring and the Identity Preservation (IP) system. As part of general surveillance all growers contributed their observations in the format of an Amflora farm questionnaire. The evaluation of all 26 questionnaires indicated that Amflora overall performed as any other conventional potato or starch potato variety and that observed effects were due to environmental influences and no indication of potential adverse effects of Amflora on the environment. Third parties like seed certification authorities and other national authorities overseeing the cultivation of potato shared their observations with BASF Plant Science, and indicated that there were no findings pointing to any potential adverse effects of Amflora cultivation on the environment. The implementation and functioning of the IP system was documented via a list of training sessions, visits and audits performed throughout the growing period and the processing of the starch potatoes during the two starch campaigns. The results of the studies conducted as case-specific monitoring verified the assumptions made as part of the environmental risk assessment. The phenotypic and genetic stability of the amylopectin trait was confirmed, the open reading frame (ORF4) polypeptide is not expressed and the glycoalkaloid content in the tuber remained within the normal range for starch potatoes. In addition to the general surveillance as well as the case specific monitoring and the IP system implementation, a specific monitoring study was conducted addressing any potential adverse effects Amflora may have on potato-feeding organisms. Based on the results obtained there is no indication that Amflora potato exerts any adverse effects on organisms feeding on potato. Overall, the monitoring activities conducted in 2010 did not identify any adverse effects on human and animal health or the environment resulting form the cultivation of Amflora in the Czech Republic, Germany and Sweden. No adaptations relating to the Amflora monitoring plan are required.

3. MONITORING RESULTS

Post-market monitoring was conducted for amylopectin potato EH92-527-1, variety Amflora, according to the monitoring plan as presented by BASF Plant Science in notification C/SE/3501/96 and published by the European Food Safety Authority (EFSA) and the EU Commission (EU Register, 2010), as well as addressing the conditions of monitoring as determined in Article 4 of Commission Decision 2010/135/EU (EU Register, 2010) and Condition 9 of Consent Dnr 22-3501/96 of 31 March 2010 by the Swedish Board of Agriculture.

3.1. General surveillance

3.1.1. Description of general surveillance

BASF Plant Science monitoring plan (EU Register, 2010) describes in detail the approach to general surveillance for EH92-527-1 potato. The approach taken was specifically adapted to the cultivation of EH92-527-1 potato as well as its processing into starch and reflected the Guidance Notes in Council Decision 2002/811/EC and followed, as far as applicable to an amylopectin potato variety, the general principles as set out by an industry consensus plan dated 13 January 2003. Largely based on routine observations, general surveillance involves the collection, scientific evaluation and reporting of reliable scientific evidence, in order to be able to identify whether unanticipated, direct or indirect, immediate or delayed adverse effects have been caused by the placing on the market of the GM crop. For EH92-527-1 potato, general surveillance thereby comprised observations on the potato plants and their interactions with other organisms in the agricultural environment as well as information collected on the functioning of the IP system as applied to the cultivation of Amflora seed and starch potatoes, and included observations by third parties such as seed certification authorities and other official inspection bodies. All growers of Amflora potatoes as well as the participating starch companies were contractually bound to follow the requirements of the IP system thereby complying with the obligations of general surveillance. The IP system manual is presented in **Annex 1** and outlined in more detail in **Section 3.3**. As described in the monitoring plan, growers, as a standard practice, continually monitor crops for changes in plant characteristics that are significant to the performance of the crops. Because of their familiarity with specific crops, growers are the most qualified to observe changes in

the crop and the general growing environment. Within the IP system for EH92-527-1 potato, they assume an important role in observing and handling the potatoes. The baseline for observations was determined to be the previous experience obtained when growing EH92-527-1 potatoes in experimental field trials since 1993, including specific agronomic aspects that relate to the cultivation of seed and starch potato varieties in general in the member states of the European Union (EU). Observations by farmers cultivating Amflora seed and starch potatoes and relating to the growing area or location, the characteristics of the Amflora potato plants and their interaction with organisms in the agricultural environment are captured in the Form 5 of the Identity Preservation system (**Annex 1**). The results obtained are summarized in **Section 3.1.4.** and presented in **Annex 7**. Information documenting the functioning of the IP system is described in **Section 3.3.** and **Annex 12**. Observations by third parties as well as measures to communicate and collect information implemented by BASF Plant Science are summarized in the following sections.

3.1.2. Details of surveillance networks used to monitor environmental effects during general surveillance and description of other methodologies

BASF Plant Science is responsible for general surveillance and has defined the existing systems or networks contributing to the general surveillance efforts in the monitoring plan (EU Register, 2010). Those include official bodies that remain involved at the different stages of the cultivation of the potato variety Amflora, like seed certification officials that observe the seed potato productions each year and that verify if the material remains true to type. Starch companies provide additional information based on their routine checks relating to the overall performance of the material especially to the quality of the starch potato and the processed starch or pulp. As specified in the consent for cultivation of Amflora all growers were included in general surveillance in order to extend the existing networks. Growers and starch companies participating in the IP system received training on the system and were contractually required to contribute to general surveillance. The contractual obligations are described in **Annex 2**. Seed certification authorities and other national authorities overseeing the cultivation of Amflora potato have shared their observations with BASF Plant Science. A list of authority visits or inspections and general conclusions are provided in **Annex 3**.

3.1.3. Details of information and/or training provided to operators and users, etc.

In order to inform operators, users and other parties requiring background information on Amflora, the IP system, and the conditions of the cultivation approval including the monitoring obligations, BASF Plant Science developed a user guide. An example of the Amflora user guide in English is provided as **Annex 4**. Starting in April 2010 the user guide was shared in Czech, English, German and Swedish with all participants of the IP system, the involved national authorities or bodies, as well as relevant farmers, starch and trade organizations, and can be accessed on the BASF web (BASF, 2010a). At the start of the Amflora cultivation and the starch campaigns the growers and participating starch processors received training on the IP system. An example of a training presentation in English is provided as **Annex 5**. In Germany, the 2010 Amflora cultivation season was additionally accompanied by an internet platform informing and soliciting input from the general public (BASF, 2010b). BASF Plant Science representatives located in each of the three countries with Amflora cultivation offered training and advice as well as information and could be approached with questions or concerns by all operators, users and other parties.

3.1.4. Results of general surveillance

General surveillance accompanying the cultivation of Amflora seed and starch potatoes at a total of 26 locations (or fields) in 2010 in the Czech Republic, Germany and Sweden comprised the use of a farm questionnaire to collect observations by farmers, the implementation and integrity of the IP system as well as observations by existing networks like national seed certification authorities, inspection bodies, and participating starch processors. According to the quality ensuring IP system, all growers of Amflora potatoes were obliged to participate in the IP system, to operate according to the standard operating procedures and to complete the respective forms. Further, in order to meet the requirements of the consent to cultivate Amflora all growers are considered as members of the existing networks and engage in the general surveillance. To ensure the quality of the Amflora cultivation the field-plot card-index or Form 5 (**Annex 1**) as part of the IP system allows the recording of information that is relevant for a quality assurance system. A section of this Form 5 in addition serves to record general observations during the vegetation period as they relate to the climatic conditions, soil fertility, plant growth and development, disease

and pest susceptibility as well as observation on the occurrence of wildlife in the vicinity of Amflora fields. This corresponding information was collected from the growers using an interview-based farm questionnaire (**Annex 6**). A total of 26 Amflora farm questionnaires addressing the different monitoring characters were collected from the growers and analyzed. The results of the Amflora farm questionnaire are presented in **Annex 7**. An evaluation of the monitoring characters that were rated as usual or were deviating from what is in general observed for potato cultivation by the growers allowed the following conclusion. For most characters Amflora performed as any conventional potato variety (e.g. presence of wildlife, efficacy of pest or disease control measures, phenotype). Any deviations from what was considered *as usual* by the grower (e.g. earlier maturity, later harvest, slower development, lower yield) were clearly a consequence of adverse weather conditions and other factors influencing the growth and development of potato plants, and none of them were considered as potential adverse effects of Amflora on the environment. The implementation and integrity of the IP system as part of general surveillance is discussed in detail in **Section 3.3.** Visits, inspections and general observations by national authorities or other bodies are listed in **Annex 3**. All inspections by authorities confirmed compliance with the conditions stipulated by the consent for cultivation of Amflora potatoes. Furthermore, comments by authorities indicated that there were no findings pointing to any potential adverse effects of Amflora cultivation on the environment.

3.1.5. Additional information

No unanticipated or potentially adverse effects were observed during the cultivation of EH92-527-1 potato in 2010 as part of general surveillance, therefore no additional information is provided here. All observations were in line with the known characteristics and descriptions of Amflora potato throughout the experimental cultivation since 1993 or were within the range of variability as presented by the cultivation of conventional potato or starch potato varieties in the EU member states.

3.1.6. Review of peer-reviewed publications

The databases Web of Knowledge, Web of Science and Biosis were searched for peer-reviewed literature to cover the years 2009 and 2010. The search terms comprised Amflora, EH92-527-1, (potato or *Solanum tuberosum* or *S. tuberosum*)

and (amylopectin or waxy or granule bound starch synthase or GBSS) and (genetically modified or GM or GMO or transgenic or BASF), (nptII or antibiotic resistance or kanamycin resistance or neomycin phosphotransferase) and (potato or genetically modified or GM or GMO or transgenic or BASF). The search resulted in a list of 21 articles, out of which nine relate to the consent issued for Amflora, eight to detection methods for potato, one to plant biotechnology in Germany, two to starch functionality, and one article was identified that related to amylopectin potatoes and the environmental risk assessment, and therefore was considered to have some relevance to the cultivation of Amflora potato. No additional scientific studies, apart from those presented in **Section 3.2.**, were conducted by BASF Plant Science with Amflora potato in the years 2009 or 2010.

Publication: Geschwendtner, S., Reichmann, M., Moller, M., Radl, V., Munch, J.C., Schloter, M. (2010) Effects of genetically modified amylopectin-accumulating potato plants on the abundance of beneficial and pathogenic microorganisms in the rhizosphere. Plant and Soil 335:413-422

Abstract: **'***In this study, the potential effects of a genetically modified (GM) amylopectin-accumulating potato line (Solanum tuberosum L.) on plant beneficial bacteria and fungi as well as on phytopathogens in the rhizosphere were investigated in a greenhouse experiment and a field trial. For comparison, the non-transgenic parental cultivar of the GM line and a second non-transgenic cultivar were included in the study. Rhizospheres were sampled during young leaf development (EC30) and at florescence (EC60). The microbial community composition was analysed by real-time PCR to quantify the abundances of Pseudomonas spp., Clavibacter michiganensis, Trichoderma spp. and Phytophthora infestans. Additionally, total bacterial and fungal abundances were measured. None of the examined gene abundance patterns were affected by the genetic modification when wild type and GM line were compared. However, significant differences were observed between the two natural potato cultivars, especially during the early leaf development of the plants. Furthermore, gene abundance patterns were also influenced by the plant developmental stage. Interestingly, the impact of the cultivar and the plant vegetation stage on the microbial community structure was more pronounced in field than in greenhouse. Overall, field-grown plants showed a higher abundance of microorganisms in the rhizosphere than plants grown under greenhouse conditions'.*

Protection goal: Soil function

Observed parameter: Abundance and composition of the microbial community in the

rhizosphere of different potato varieties including one GM amylopectin potato (not Amflora) were observed.

Potential adverse effects identified: '*No effects caused by the genetic modification of the marker-free amylopectin accumulating potatoes on the investigated gene abundance patterns of plant beneficial microbes and phytopathogens were measured in this study'.*

Results of the study relating to the Amflora environmental risk assessment: No effects were identified that would trigger a need to revisit the original environmental risk assessment for EH92-527-1 potato. Furthermore, the study adds weight to previous evidence that differences in the interaction of crop plants (here potato) with organisms present in the agro-ecosystem are more pronounced when comparing different conventional varieties and between the same conventional varieties grown at different locations than between the GM variety and its genetically closely related comparator.

3.2. Case-specific monitoring

The consent Dnr 22-3501/96 for EH92-527-1 potato according to Directive 2001/18/EC and the Commission Decision 2010/135/EU require that the monitoring plan for Amflora includes case-specific monitoring. Case-specific monitoring should, when included in the monitoring plan, focus on potential effects arising from the placing on the market of a GMO that have been highlighted as a result of the conclusions and assumptions of the environmental risk assessment. The environmental risk assessment for EH92-527-1 potato did not identify any potential adverse effects on human and animal health or the environment and no particular concern was raised that would require a specific monitoring effort. Therefore, the case-specific monitoring as presented in the Amflora monitoring plan (EU Register, 2010) is strictly based on the verification of a set of assumptions that were made in the environmental risk assessment and their confirmation over a defined monitoring period. These main assumptions in the environmental risk assessment comprised the genetic and phenotypic stability of the trait, the absence of expression of an identified open reading frame (ORF4), and the stability of identified statistically significant compositional differences such as the reduction in glycoalkaloid levels in the Amflora potato tuber.

3.2.1. Description and results of case-specific monitoring (if applicable)

Following the Amflora monitoring plan four case-specific studies were conducted in 2010. The purpose of the first study was to demonstrate the presence of the EH92-527-1 insert, and thereby to confirm the identity and genetic stability of the EH92-527-1 event in Amflora potatoes grown for seed production at locations in Sweden and Germany. The monitoring plan required the collection of 80 pooled samples of seed tubers after harvest and their testing via an event-specific PCR assay. All samples, taken at random, covering a total of 18 locations in Sweden and one location in Germany tested positive for the presence of the EH92-527-1 insert. The results of the analysis are presented in **Annex 7** and confirm the identity of Amflora seed potatoes and consequently their genetic stability.

The same set of tuber samples collected from Amflora seed potato production locations were submitted to a second type of analysis. The aim of the study was to confirm the absence of expression of an open reading frame (ORF4) that is co-transcribed with the selectable marker gene neomycin phosphotransferase (*npt*II). A western blot method as described in the original notification with a limit of detection of 1 ng of the ORF4 polypeptide was applied to the protein extracts isolated from the pooled Amflora tuber samples. Based on the data presented in **Annex 8** it was concluded that none of Amflora samples analyzed showed any expression of the ORF 4 polypeptide at the limit of detection, and the study thereby confirmed the results and conclusions as described in Amflora notification C/SE/96/3501.

Due to the suppression of the amylose synthesis in Amflora tubers the amylopectin content in the tuber starch is increased to more than 98%. This amylopectin phenotype can easily be detected via iodine staining of the starch granules as described in Amflora notification C/SE/96/3501. In order to confirm the quality of the amylopectin potatoes as well as to monitor the stability of the trait according to the monitoring plan starch potatoes were collected after harvest from all seven starch production locations in the Czech Republic. As described in **Annex 9** starch was extracted from four replicates of pooled tuber samples per location and stained with Lugol's solution. All starch samples isolated from Amflora potato tubers stained reddish brown, which indicated the absence of amylose, whereas control starch samples from conventional potato tubers showed the dark blue staining which is

typical for the presence of amylose. The results of the analysis clearly confirmed phenotypic stability of the amylopectin trait in Amflora potatoes across all starch potato cultivation locations, and further documented the genetic stability of the event as determined by the PCR assay described above.

Finally a fourth study, a compositional analysis, was performed with pooled tuber samples collected in 4 replicates from all starch potato production locations to determine that the glycoalkaloid content in Amflora remains stable and within the ranges of conventional starch potato varieties. The results of the analysis are presented in **Annex 10** and confirm that the glycoalkaloid content of Amflora starch tubers is in the range of values as obtained in previous studies, and which were presented in notification C/SE/96/3501, and comparable to a conventional starch potato included in the analysis.

No further case-specific studies were conducted, since the pulp obtained as a by-product of the starch processing in 2010 was not used as animal feed.

In summary, the results of the studies conducted as case-specific monitoring verified the assumptions made as part of the environmental risk assessment. The phenotypic and genetic stability of the amylopectin trait was confirmed, the open reading frame (ORF4) polypeptide is not expressed and the glycoalkaloid content in the tuber is within the normal range for starch potato varieties.

3.2.2. Monitoring and reporting of adverse effects resulting from accidental spillage (if applicable)

The monitoring plan does not require the monitoring of adverse effects resulting from spillage, therefore this point is not applicable.

3.3. Integrity of the Identity Preservation system

General surveillance as described in the Amflora monitoring plan includes the integrity of the IP system, as well as the general observations of all growers throughout the growing season. The general observations of the growers as captured in the field-plot card-index (Form 5) of the IP system manual (**Annex 1**), and as recorded and analyzed with the help of the Amflora farm questionnaire are described

in **Section 3.1.4**. above and in **Annex 7**. The implementation and integrity of the IP system are essential elements of the Amflora monitoring plan as well as the Amflora product stewardship program. The IP system is a quality management tool and thus secures the quality and enables the traceability of Amflora products along the production chain from seed potato multiplication to starch production. In the 2010 season, the IP system manual, version 21 May 2003, including the field-plot card-index (Form 5) in its revised version from 2005, was used. In **Annex 12** the elements of the IP system, existing forms used, as well as complementary forms added in the 2010 season, are presented and their purpose in the context of addressing the Amflora monitoring plan as well as the monitoring conditions of the consent Dnr 22-3501/96 are described. The implementation and functioning of the system is further documented via the list of training sessions, visits and audits performed throughout the growing period and the two starch campaigns.

3.4. Monitoring study (Annex to Commission Decision 2010/135/EU)

According to Article 4.1(e) of Commission Decision 2010/135/EU and condition 9(e) of the consent Dnr 22-3501/96, BASF Plant Science is required '*to 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*'. The results of the study should '*be evaluated in view of the risk assessment contained in the notification'* C/SE/96/3501 according to Directive 2001/18/EC. These requirements were interpreted and implemented in the monitoring period of 2010 as follows. The type of study is interpreted to be a monitoring study in the field ('*to monitor potential adverse effects'*). Since the recital (18) of Commission Decision 2010/135/EU specifically states that monitoring measures relate to those fields '*where Solanum tuberosum L. line EH92-527-1 is commercially cultivated'*, the monitoring studies should focus on the commercial cultivation fields, and thus accompany the Amflora starch and seed potato production in 2010. Commercial cultivation implies further that management practices are applied to the growing of the potato crop that meet the purpose of the cultivation. More specifically it means that seed and starch potato cultivation is performed via applying the standard practice that is typical for the region or the purpose of the cultivation including the use of plant protection products as required to protect the crop against pests and diseases. The monitoring objects are those organisms that feed on potatoes ('*potato-feeding organisms'*), and therefore are likely to be present in sufficient abundance in

the Amflora fields. Potato-feeding organisms are typically those that inflict damage on the potato crop by chewing or sucking actions, and fall into the group of herbivores and thus are considered potato pests. According to the Consent, state-of-the-art protocols were to be used for the data collection, and standard statistical analysis methods to be applied to the data obtained. Therefore, the criteria to be met for the selection of the surveyed organisms can be summarized as: belonging to the functional group of herbivores (‘*key ecological function in the agricultural environment’*), prevalence and abundance of the species (*‘statistical analysis with standard methods’*), low mobility and close association with the potato plant (*‘potato-feeding’*), as well as availability of standardized data collection methods. In order to be able to further specify the organisms to be surveyed, a literature survey describing the arthropod fauna in central and northern European potato fields was prepared (**Annex 13**). Arthropods dwelling on potato foliage include pest species like aphids, the Colorado potato beetle, leafhoppers, and butterflies, as well as beneficial species like ladybird beetles, hoverflies, parasitic wasps, predatory flies, and some true bugs.

The following methodology was applied to the monitoring study in 2010 and is described in detail in **Annex 14**. The abundance of natural populations of Colorado potato beetles (*Leptinotarsa decemlineata*, Chrysomelidae), potato aphids (*Myzus persicae*, *Aphis nasturtii, Aphis frangulae, Aphis fabae, Aulacorthum solani, Macrosiphum euphorbiae*), and other common phytophagous arthropods (e.g. Collembola, Heteroptera, Auchenorrhyncha, Chrysomelidae) was investigated in seven starch potato production fields in the Czech Republic, and in a total of three seed potato multiplication fields in Sweden and Germany. Potato aphids were determined on species level and the other phytophagous arthropods were classified in main taxonomic groups. Ten transects, consisting of 10 potato plants each, were established per potato fields, eight within each potato field and two at the outer row of the potato field. The requirements for the monitoring study called for collection of data in the Amflora fields as well as in their vicinity. However, the vicinity of the Amflora cultivation area in the three member states was quite divergent, such that fields were either neighboured by agricultural land (other crops like maize or oilseed rape, grassland, potatoes in some instances at a distance), forest, shrubs or roads. Therefore, and in order to assure the presence of organisms feeding on potato in what could be considered representative of the vicinity, the outer rows of the potato fields were determined to be the area that should be monitored as vicinity of the

potato fields. Potato beetles and aphids were sampled in accordance with EPPO (European and Mediterranean Plant Protection Organisation) standards, and phytophagous arthropods were sucked of the potato plants using a suction sampler at one sampling time point, at peak insect abundance in July. In total, the abundance data comprised 10 plants per transect, 10 transects per location and 10 locations, and are presented for each transect including the mean value and standard deviation.

Details of the methodology and the results obtained by the monitoring study are presented in **Annex 14**. The results can be summarized as follows. Colorado potato beetles (*Leptinotarsa decemlineata*) were only found in very low abundances at three out of seven potato fields in the Czech Republic, and none were found in Germany. In Sweden Colorado potato beetles do not occur naturally. In the Czech Republic aphid abundance varied from 0.60 ± 1.07 to 6.90 ± 3.90 individuals per transect (n=10). In Sweden the abundance of potato aphids was nearly similar in both potato fields with approximately 4.00 individuals per transect (n=10). No potato aphids were found applying the EPPO Standard method at the potato field in Germany. The abundance of aphids sampled by the suction method spanned over a wide ranged from 4.90 ± 4.70 in Germany to 91.20 ± 24.48 individuals per transect (n=10) in the Czech Republic. In contrast to the results obtained by the EPPO Standard method, aphids were found at the German potato field in reasonable numbers. When applying either method, aphid abundances within the potato field (n=8) and the vicinity of the potato field (outer row of the field; n=2) did not differ significantly. The highest abundance of arthropods was determined applying the suction method at one potato field in the Czech Republic with 281.10 ± 81.67 arthropods per transect (n=10). In contrast, the lowest abundances of arthropods (42.70 ± 40.53 and 5.40 ± 22.10 individuals per transect) were found at the potato fields in Sweden. The abundance of other phytophagous arthropod groups, like Miridae, varied significantly between potato fields in the three geographic regions with the highest abundances found at potato fields in the Czech Republic, and the lowest at fields in Sweden.

In conclusion, the monitoring study provided field data on the abundances of phytophagous arthropods at ten commercially cultivated Amflora fields in the three member states, the Czech Republic, Germany and Sweden. The abundance of phytophagous arthropods (potato aphids, Colorado potato beetles, Collembola, Heteroptera, Auchenorhyncha, Chrysomelidae) in Amflora potato fields was variable

between the fields in the different commercial potato cultivation areas, with the highest abundances found at Amflora fields in the Czech Republic, and the lowest number of individuals counted in fields in Sweden. No significant differences were observed in the abundance of phytophagous arthropods sampled within or at the border rows of Amflora fields.

The purpose of the monitoring study was to monitor for potential adverse effects the commercial cultivation of Amflora potatoes might have on potato-feeding organisms. Since organisms feeding on potato plants and occurring in significant and measurable abundance are considered pest species, it is assumed that the following possible adverse effects were the rationale for requesting the monitoring study. It was hypothesized that unintended and unanticipated effects associated with the development of Amflora could make the potato more attractive for pest species, thereby exceeding the variability in pest susceptibility that is already present amongst the different potato varieties that are cultivated in the member states, and the diversity in potato cultivation measures that are taken by potato growers in the various regions to control potato pests. Such an effect could lead to a disproportionate multiplication of potato pests and a disproportionate use or failure of plant protection measures, or a loss of a biological control function, if applicable.

The results of the monitoring study demonstrate and document that the most important factors affecting arthropod abundance and diversity in potato fields are crop management, adjacent habitats and abiotic factors (**Annex 13**). The plant protection measures taken by the growers of Amflora potatoes were adapted to the different objectives for production of the Amflora crop. Whereas in Sweden and in Germany seed potato multiplication requires the intensive control of aphids in order to minimize any virus infection and to allow harvested seed tubers to pass national seed certification requirements, the cultivation of starch potatoes in the Czech Republic could accommodate a certain level of pest pressure. Overall, the lower abundances of the pest organisms in Germany or Sweden proved the success of the plant protection measures applied. The higher abundances of aphids and other phytophagous arthropods at the Amflora field locations in the Czech Republic might reflect the moderate use of plant protection measures. Both cases are supported by the results obtained via the interview-based Amflora farm questionnaire. The pest control measures used by farmers for Amflora potato production were the same used

in conventional potato production, and the efficacy of the control measures in Amflora was no different from the efficacy experienced by the farmers in the production of conventional potatoes (**Annex 7**). In addition, the variation in the aphid abundance in the Amflora cultivation regions might also be a reflection of the overall level of abundance of aphids in potato in 2010. As indicated in **Annex 14** member states like Germany or the Czech Republic (State Phytosanitary Administration, 2010) have installed aphid alert systems and thereby collect data on aphid abundance in potato fields from year to year. The information provided for the 2010 growing season showed that for example in the area of Amflora cultivation in Germany it was a year with overall very low occurrence of aphids. The aphid bulletin by the plant protection service of the Landesamt für Landwirtschaft, Lebensmittelsicherheit und Fischerei Mecklenburg-Vorpommern (LALLF, 2010) lists for the area of Amflora cultivation in Germany very low numbers of aphids on conventional potato varieties when using a method very similar to the EPPO Standard. Overall it can be concluded that based on the results obtained by the monitoring study there is no indication that Amflora potato exerts any adverse effects on organisms feeding on potato. Those results thereby support the conclusion of the environmental risk assessment presented in the notification for EH92-527-1 and by EFSA (EFSA, 2006), that there is no evidence to believe that the placing on the market of Amflora is likely to cause adverse effects on human and animal health or the environment in the context of its proposed uses.

3.5. Concluding remarks

Post-market monitoring was conducted for amylopectin potato EH92-527-1 according to the monitoring plan as contained in notification C/SE/3501/96 and addressing the requirements for monitoring as determined in Article 4 of Commission Decision 2010/135/EU and condition 9 of consent Dnr 22-3501/96 by the Swedish Board of Agriculture. As presented in this report the monitoring of Amflora cultivation in 2010 comprised general surveillance, case-specific monitoring as well as the IP system. The results relating to general surveillance are described in **Section 3.1.** and include observations collected from all growers using a farm questionnaire (**Annex 1**, **Annexes 6** and **7**), observations provided by authorities (**Annex 3**), a literature review (**Section 3.1.6.**) as well as information and training provided to growers and users of Amflora potatoes (**Annex 4** and **Annex 5**). The functioning of Amflora IP system is captured in **Section 3.3.** and further supported by **Annex 1**, **Annex 2** and

Annex 12. In addition, the monitoring plan provided for case-specific monitoring which is outlined in **Section 3.2.**, and a set of case-specific monitoring studies are attached in **Annexes 8** to **11**. As required by the consent condition 9(e) a specific monitoring study was performed, the results are discussed in **Section 3.4.** and the data are presented in **Annex 14**. All observations and results obtained via the various studies undertaken support the conclusion that any interaction of Amflora with the agro-ecosystem is comparable to that of conventional potatoes or starch potatoes cultivated in the member states Czech Republic, German and Sweden, and further demonstrate the absence of potential adverse effects of Amflora cultivation on human and animal health and the environment.

4. SUMMARY OF RESULTS AND CONCLUSIONS

The objective of the post-market monitoring accompanying the cultivation of amylopectin potato EH92-527-1 in the member states Czech Republic, Germany and Sweden in 2010 was:

- to confirm that any assumptions regarding the occurrence and impact of potential adverse effects of Amflora potato or its use in the environmental risk assessment presented in the notification for EH92-527-1 potato are correct and
- to identify any occurrence of adverse effects of Amflora potato or its use on human and animal health or the environment, which were not anticipated in the environmental risk assessment.

In 2010, the first year of its commercial cultivation, the starch potato variety Amflora was grown at a total of 26 locations (covering about 235 ha) for seed potato multiplication in Germany and Sweden, and starch potato production in the Czech Republic. Conventional agricultural practice was applied meeting the objectives of either seed or starch potato production, at the same time addressing national seed potato certification, and phytosanitary requirements. Amflora monitoring focused on those areas or processes where the exposure to Amflora potato was most likely to occur, and the opportunity to identify the occurrence of potential adverse effects was highest. There is very limited exposure to adjacent habitats since Amflora potato has a low tendency to produce flowers or mature seeds and due to the absence of nectar producing flowers in potatoes in general. All steps from Amflora potato multiplication to the production of starch are captured in the IP system which is under the control of

BASF Plant Science. Therefore the areas of monitoring comprised the agro-ecosystem and the observations by those handling or inspecting the potato within this system as well as the participating starch processors. As part of the IP system implementation growers were asked to record their observations in the format of a farm questionnaire. A total of 26 farm questionnaires addressing the different monitoring characters were collected and analyzed. An evaluation of the monitoring character rating allowed the conclusion that for most characters Amflora performed as any conventional potato variety, and for some deviations it was clearly a consequence of adverse weather conditions and other environmental factors influencing the growth and development of potato plants, and none of them were considered as potential adverse effects of Amflora potato on the environment. Third parties like seed certification authorities and other national authorities overseeing the cultivation of potato have shared their observations with BASF Plant Science, and indicated that there were no findings pointing to any potential adverse effects of Amflora cultivation on the environment. The implementation and functioning of the IP system was documented via a list of training sessions, visits and audits performed throughout the growing period and the two starch campaigns. The results of the studies conducted as case-specific monitoring verified the assumptions made as part of the environmental risk assessment. The phenotypic and genetic stability of the amylopectin trait was confirmed, the open reading frame (ORF4) polypeptide is not expressed and statistically significant compositional differences from the comparator variety Prevalent presented in the notification C/SE/96/3501, such as the glycoalkaloid content in the tuber, are stable and within acceptable range. In addition to the general surveillance, as well as the case specific monitoring and the IP system implementation described above, a specific monitoring study was conducted addressing the potential adverse effects by Amflora on potato-feeding organisms. Based on the results obtained there is no indication that Amflora potato exerts any adverse effects on organisms feeding on potato. Overall, the results of all monitoring activities in 2010 confirm that there is no evidence to believe that the cultivation of Amflora causes any adverse effects on human and animal health or the environment.

5. ADAPTATION OF THE MONITORING PLAN AND ASSOCIATED METHODOLOGY FOR FUTURE YEARS

There are no adaptations required relating to the Amflora monitoring plan and associated general surveillance methodologies. Nevertheless, it needs to be pointed out that as any quality management system, also the Amflora IP system including the farm questionnaire should not be a rigid system, but be developed further incorporating all previous experiences to improve its effectiveness.

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