POST-MARKET MONITORING REPORT

for the cultivation and monitoring of amylopectin potato EH92-527-1 variety Amflora in 2011

submitted by

BASF Plant Science Company GmbH

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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 2011 to 31 March 2012

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 Amflora 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 2011, the second year of its commercial cultivation, the starch potato variety Amflora was grown at a total of five locations (covering about 20 ha) for seed potato multiplication in Germany and Sweden. Monitoring comprised general surveillance, case-specific monitoring, the Identity Preservation (IP) system, and volunteer monitoring. As part of general surveillance all growers contributed their observations in the format of an Amflora farm questionnaire. The evaluation of all five 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. The results of the studies conducted as case-specific monitoring verified the assumptions made as part of the environmental risk assessment. The genetic stability of the amylopectin trait was confirmed and the open reading frame (ORF4) polypeptide is not expressed. 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. Volunteer Monitoring has been performed according to the requirements set in the Amflora Identity Preservation System. 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 2011 did not identify any adverse effects on human and animal health or the environment resulting from the cultivation of Amflora in 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 Amflora 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

The 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 potatoes, and included observations by third parties such as seed certification authorities and other official inspection bodies. All growers of Amflora potatoes 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 persons to observe changes in the crop and the general growing environment. Within the IP system for EH92-527-1 potato, farmers assume an important role in observing and handling the

potatoes. The baseline for their observations was determined to be their general experience in cultivating potatoes. Observations by farmers cultivating Amflora seed 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 11. 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. As specified in the consent for cultivation of Amflora all growers were included in general surveillance in order to extend the existing networks. Growers 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 an Amflora User Guide. An example in English language is provided as Annex 4. Starting in April 2010 the User Guide was shared in the respective local language 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 website (BASF, 2010a). For the season 2011 the User Guide was handed over to all new partners, e. g. during the training session which took place for all growers cultivating Amflora prior to handling Amflora material. An example of a training presentation in English is provided as Annex 5. In Germany, the 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 two 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 potatoes at a total of five locations in 2011 in 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, and inspection bodies. 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 a farm questionnaire (Annex 6). A total of five 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 Annexes 7 and 8. 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 conclusion that for most characters Amflora performed as any conventional potato variety (e.g. sprouting, plant growth, time to emergence,

agronomic characteristics, success of weed, pest or disease control, presence of wildlife). The deviations from what was considered as usual by the grower (e.g. later harvest, 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 2011 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

A literature review was conducted in January 2012 based on searching 18 databases. Of main importance were the databases BIOSIS, Web of SCIENCE, Medline, Chemical Abstracts, CABA and PIRA. The search covered the publication period 2011. The search parameters were set as follows:

- Amflora or EH92-527-1 or potato in general in combination with a word profile for genetic engineering and in combination with the enzymes granule bound starch synthase or neomycin phosphotransferase.
- In addition Amflora or EH92-527-1 or potato in general in combination with a word profile for genetic engineering and in combination with amylopectin or waxy starch or antibiotic resistance or kanamycin resistance or BASF.

- The focus was on scientific literature or news, patents were not included.

All results were checked for intellectual relevance. The search resulted in a list of 29 articles (see Annex 14 for details including abstracts), out of which four publications deal with general starch applications and properties of starches derived from different sources, eight publications describe other research projects working with genetically modified potato lines without reference to Amflora, eight publications are about stable or transient plant transformation methods, different marker systems, and line selection methods, three publications describe PCR and multiplex PCR detection methods, one publication deals with GMO monitoring systems in Germany, one publication discusses the regulatory regime for genetically modified plant lines from a political and trader point of view, one publication contains an interview with the BASF Plant Science Potato Project Manager, and two publications deal with potato as food in general.

The following publication (PDF document available in Annex 15) identified in the literature review is related to amylopectin potatoes and the environmental risk assessment, and therefore is considered to have some relevance to the cultivation of Amflora potato:

Gschwendtner, Silvia; Esperschuetz, Juergen; Buegger, Franz; Reichmann, Michael; Mueller, Martin; Munch, Jean Charles and Schloter, Michael (2011) Effects of genetically modified starch metabolism in potato plants on photosynthate fluxes into the rhizosphere and on microbial degraders of root exudates. FEMS Microbiology Ecology 76(3): 564-575

Abstract: "*A high percentage of photosynthetically assimilated carbon is released into soil via root exudates, which are acknowledged as the most important factor for the development of microbial rhizosphere communities. As quality and quantity of root exudates are dependent on plant genotype, the genetic engineering of plants might also influence carbon partitioning within the plant and thus microbial rhizosphere community structure. In this study, the carbon allocation patterns within the plant-rhizosphere system of a genetically modified amylopectin-accumulating potato line (Solanum tuberosum L.) were linked to microbial degraders of root exudates under greenhouse conditions, using* ^{13}C-CO_2 *pulse-chase labeling in combination with phospholipid fatty acid (PLFA) anal. In addition, GM plants were compared with the parental cultivar as well as a second potato cultivar obtained by classical breeding. Rhizosphere samples were obtained during young leaf developmental and flowering*

stages. ^{13}C allocation in aboveground plant biomass, water-extractable organic carbon, microbial biomass carbon and PLFA as well as the microbial community structure in the rhizosphere varied significantly between the natural potato cultivars. However, no differences between the GM line and its parental cultivar were observed. Besides the considerable impact of plant cultivar, the plant developmental stage affected carbon partitioning via the plant into the rhizosphere and, subsequently, microbial communities involved in the transformation of root exudates."

In this study, the genetically modified potato line #1332 producing more than 99% amylopectin was used together with its parental cultivar Walli, and one additional nontransgenic potato variety Ponto to examine their influence on photosynthate allocation from plant to soil to microorganisms and on rhizosphere microbial community structure during their cultivation. The GM potato line #1332 was transformed with a *gbss* gene fragment in antisense orientation, very comparable to the genetic transformation leading to potato line EH92-527-1, variety Amflora. Potato plants of described lines #1332, Walli and Ponto were grown in pots from tubers in a greenhouse under very controlled conditions. Dried plant material from all lines and rhizosphere soil (soil attaching to the roots after vigorous shaking) was analyzed for changes in carbon metabolism. The result was that GM line #1332 and its non-transgenic parental variety Walli gave very similar results, but differing from the results gained for the control variety Ponto. After cultivation the rhizosphere in these pots was analyzed for changes in the soil microflora. Different parameter analyzed showed that GM line #1332 and Walli gave very similar results, but differing from the results gained for variety Ponto. All data generated gave no indication for GM-related differences and it was concluded that the genetic modification did not affect the microbial diversity in the rhizosphere.

Therefore, this publication presented no new arguments that potato line EH92-527-1 could cause harm on the environment, rather providing evidence that differences in the interaction of crop plants with other organisms present in the agro-ecosystem are more pronounced when comparing different conventional varieties than GM varieties with its genetically closely related parent variety.

No additional scientific studies, apart from those presented in Section 3.2., were conducted by BASF Plant Science with Amflora potato in the year 2011.

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. Several studies were required while cultivating Amflora for starch production purposes. However, in the season 2011 only seed multiplication was conducted and therefore only the respective studies described in the Amflora monitoring plan as required for seed multiplication were performed.

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

Following the Amflora monitoring plan three case-specific studies were conducted in 2011. 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 four locations in Sweden and one location in Germany were tested positive for the presence of the EH92-527-1 insert. The results of the analysis are presented in Annex 9 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 per 50 µg total protein was applied to the protein extracts isolated from the pooled Amflora tuber samples. Based on the data presented in Annex 10 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 the Amflora Notification C/SE/96/3501.

The third study conducted intented to evaluate the presence and persistence of Amflora volunteer plants and their frequency in the years following the Amflora cultivation for starch production. It should be analyzed if amylopectin potato EH92-527-1 does fit in the management scheme of conventional starch potatoes and if possible volunteer potatoes will be controlled effectively by the applied cultural practices. Monitoring for potato volunteer plants was performed at all fields which were cultivated for Amflora starch production in 2010. This comprised a total of seven fields in the Czech Republic. Out of these seven fields only at one field planted with maize in the season following the Amflora cultivation potato volunteer plants were detected. All potato volunteers were confirmed as being Amflora potato plants (Annex 13). The number of volunteer plants was reduced to zero within the field at the second monitoring time point. Therefore, the standard cultivation measures applied in the first year following the Amflora starch potato production were appropriate to control potato volunteers. It can be concluded that Amflora does not differ in its persistence from any other potato variety as described in the Amflora Notification C/SE/96/3501.

No further case-specific studies were conducted, since in the year 2011 Amflora was cultivated for seed multiplication purposes and not for starch production, therefore few studies conducted 2010 were not required in 2011.

In summary, the results of the studies conducted as case-specific monitoring verified the assumptions made as part of the environmental risk assessment. The genetic stability of the amylopectin trait was confirmed and the open reading frame (ORF4) polypeptide is not expressed.

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 11 the elements of the IP system, existing forms used, as well as complementary forms added in the 2010 and 2011 seasons, 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 (Annex 11).

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. 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 already prior to conducting the study in the year 2010 (Amflora PMEM, 2010). 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 2011 and is described in detail in Annex 12.

The abundance of natural populations of phytophagous arthropods such as 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 three

seed potato multiplication fields in Sweden and one seed potato multiplication in Germany by two different methods (hand sorting and suction sampling via D-Vac suction).

Potato aphids were determined on species level and the other phytophagous arthropods were classified in main taxonomic groups. Per potato field 12 transects were established, six within each potato field and six at the outer row of the potato field. Transects within the potato field consisted of three neighboring potato rows: one row for sampling of phytophagous arthropods (suction sampling) and one row for potato aphid sampling (hand sorting), separated by a buffer row. Within these rows insects were sampled from ten neighboring plants.

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 was quite divergent, such that fields were either neighboured by agricultural land (other crops like oat, wheat, barley, maize and 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 row of the potato fields was determined to be the area that should be monitored as vicinity of the potato fields. Potato 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, 12 transects per location and four locations, and are presented for each transect including the mean value and standard deviation. Colorado potato beetles were not investigated separately, because no Colorado potato beetles were found in the potato fields in Germany and Sweden during the sampling period of the Amflora monitoring study in 2010 (Amflora PMEM, 2010). However, the total abundance of phytophagous beetles was obtained in the present study.

Details of the methodology and the results obtained by the monitoring study are presented in Annex 12. The results can be summarized as follows.

The sampling of potato aphids by D-Vac suction was more successful than the sampling by hand sorting especially if very low abundances of aphids occurred at one region (e.g. Northern Sweden). Only one potato aphid species (*Myzus persicae*) was found in the German potato field, whereas two other potato aphid species (*Aphis*

nasturii and *Aphis frangulae*) were found in the Southern Swedish potato fields. The abundance of aphids sampled by D-Vac suction varied over a wide range from 2.42 ± 2.35 (SE03) to 85.42 ± 44.67 (SE01) individuals per transect (n=12), whereas the number of aphids sampled within the potato field (n=6) and in the vicinity of the potato field (outer row of the field, n=6) did not differ strongly, due to high variations between single transects.

The highest abundance of arthropods was sampled by D-Vac suction at the German potato field DE01 with 193.17 ± 69.96 arthropods per transect (n=12). In contrast the lowest abundances of arthropods (33.58 ± 16.95 individuals per transect, n=12) were found at one of the potato fields in Southern Sweden (SE02). However, only 48% of all arthropods sampled by suction sampling at the potato field in Germany (DE01) were phytophagous. In contrast, 70% of all arthropods sampled by this method at the other potato field in Southern Sweden (SE01) were phytophagous.

The abundances of most other phytophagous arthropod groups (e.g. Miridae, Heteroptera, Auchenorrhyncha and Collembola) were very low at all potato fields. In contrast, the abundance of Thysanoptera varied strongly between the potato fields in the two geographic regions (Germany and Sweden). The highest abundances were found at the potato field in Germany. Furthermore, the abundance of Thysanoptera were higher in the vicinity of the German potato field (94.20 ± 27.80 individuals per transect; n=6) than in transects within the potato field (48.80 ± 16.70 individuals per transect; n=6).

In conclusion, the monitoring study provided field data on the abundances of phytophagous arthropods at four commercially cultivated Amflora fields in Sweden and Germany. The abundance of phytophagous arthropods in Amflora potato fields differed strongly between the different commercial potato cultivation areas in Germany and Sweden. The highest abundances were found at potato fields in Germany. The lowest number of individuals was mostly counted at the potato field in Northern Sweden. Furthermore, differences were found between abundances of phytophagous arthropods sampled within the Amflora fields and in the vicinity of the Amflora fields. However, the abundance of phytophagous arthropods in Amflora potato fields varied strongly between transects and therefore differences are not significant.

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 12). The plant protection measures taken by the growers of Amflora potatoes were adapted to the regional requirements.

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 Amflora 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 2011 comprised general surveillance, case-specific monitoring as well as the Identity Preservation 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 to 8), observations provided by authorities (Annex 3), a literature review (Section 3.1.6. and Annex 14) as well as information and

training provided to growers and users of Amflora potatoes (Annexes 4 and 5). The functioning of Amflora IP system is captured in Section 3.3. and further supported by Annexes 1, 2 and 11. In addition, the monitoring plan provided for case-specific monitoring which is outlined in Section 3.2., and three case-specific monitoring studies are attached in Annexes 9, 10 and 13. 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 12. 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 Sweden and German, 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 Germany and Sweden in 2011 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,
- 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 2011, the second year of its commercial cultivation, the starch potato variety Amflora was grown at a total of five locations (covering about 20 ha) for seed potato multiplication in Sweden and Germany. Conventional agricultural practice was applied meeting the objectives of seed multiplication, 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 part of the IP system implementation growers were asked to record their observations in the format of a farm questionnaire. A total of five 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 genetic stability of the amylopectin trait was confirmed, and the open reading frame (ORF4) polypeptide is not expressed. 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 2011 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 since Amflora will not be cultivated in the upcoming years in the EU.

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