

POST-MARKET MONITORING REPORT

**for the monitoring of
amylopectin potato EH92-527-1
variety Amflora in 2012**

submitted by

BASF Plant Science Company GmbH

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LIST OF CONTENTS

1.	General information	4
1.1.	Crop/trait(s)	4
1.2.	Decision authorization number pursuant to Directive 2001/18/EC, and number and date of consent pursuant to Directive 2001/18/EC	4
1.3.	Decision authorization number and date of authorization pursuant to Regulation (EC) No 1829/2003	4
1.4.	Unique identifier	4
1.5.	Reporting period	4
1.6.	Other monitoring reports have been submitted in respect of	4
2.	executive summary	5
3.	monitoring results	5
3.1.	General surveillance	6
3.1.1.	Description of general surveillance	6
3.1.2.	Results of general surveillance	7
3.1.3.	Review of peer-reviewed publications	8
3.1.4.	Additional information	12
3.2.	Case-specific monitoring	12
3.2.1.	Description and results of case-specific monitoring (if applicable)	14
3.2.2.	Monitoring and reporting of adverse effects resulting from accidental spillage (if applicable)	16
3.3.	Integrity of the Identity Preservation system	17
3.4.	Concluding remarks	17
4.	Summary of results and conclusions	18
5.	Adaptation of the monitoring plan and associated methodology for future years	18
	References	19

APPENDICES

1	Identity Preservation system manual	20
2	Contractual obligations.....	93
3	Integrity of the Amflora Identity Preservation system.....	95
4	2012 monitoring for volunteer potatoes at 2010 starch potato production fields.	103
5	Literature review.....	133
6	Publications	144

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 2012 to 31 March 2013

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 2012, the commercial cultivation of starch potato variety Amflora was stopped. The 2012 Post-Market Monitoring Report presents the results of monitoring the fields cultivated with potato variety Amflora in 2010 and 2011 comprising general surveillance, case-specific monitoring, and the Identity Preservation (IP) system.

Monitoring for volunteer potatoes was performed according to the requirements set in the Amflora Identity Preservation System. The adherence to the IP system requirements was documented via a list of visits and audits performed to manage the volunteer monitoring in 2012. In addition, a volunteer monitoring study was conducted as an element of case-specific monitoring and verified the assumptions made as part of the environmental risk assessment. The evaluation of all data indicated that Amflora overall performed as any other conventional potato variety.

Overall, the monitoring activities conducted in 2012 did not identify any adverse effects on human and animal health or the environment resulting from the cultivation of Amflora potato in 2010 and 2011 in Sweden, Germany and the Czech Republic.

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 and Condition 9 of Consent Dnr 22-3501/96 of 31 March 2010 by the Swedish Board of Agriculture.

Commercial cultivation of Amflora took place in 2010 in Sweden, Germany and the Czech Republic and in 2011 in Sweden and Germany. The only cultivation for starch production purposes was conducted in the year 2010 in the Czech Republic on an acreage of about 140 ha. The commercial cultivation for Amflora was discontinued in 2012. The commercialization and further development of this project has been completely stopped and there is no intention to resume cultivation in the future (BASF, 2012).

Since 2010, two post-market environmental monitoring reports on the cultivation seasons 2010 and 2011, respectively, were submitted by BASF Plant Science (Amflora PMEM, 2010 and Amflora PMEM, 2011) and evaluated by the EFSA GMO Panel. Corresponding EFSA opinions were published on February 23, 2012 (EFSA, 2012a) and December 17, 2012, respectively (EFSA, 2012b).

The publication of the EFSA opinion on the Amflora 2010 PMEM Report in February 2012 coincided with the submission of the Amflora 2011 PMEM Report by BASF Plant Science in March 2012. Due to this circumstance and since all studies required as part of the 2011 report were already completed it was impossible for the consent holder to apply the recommendations of the EFSA GMO Panel retroactively for the cultivation period 2011. In the EFSA opinion on the Amflora 2011 PMEM Report which was published December 17, 2012 (EFSA, 2012b), the GMO panel reiterates several of the recommendations from the previous EFSA opinion on the Amflora 2010 PMEM report. Since in 2012 no cultivation of Amflora was conducted most of the recommendations from the EFSA opinion on the Amflora 2010 or 2011 PMEM reports could not be implemented in the 2012 season either (see also Sections 3.1.1. and 3.2. for details).

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

- Information collected on the functioning of the Identity Preservation system as applied to the cultivation of Amflora potatoes,
- Observations by farmers cultivating Amflora on the potato plants and their interactions with other organisms in the agricultural environment (field-plot card-index of the Identity Preservation system [Form 5] and the farmer questionnaire),
- Observations by surveillance networks and third parties, like seed certification authorities and other official inspection bodies overseeing the cultivation of Amflora potato
- Review of peer-reviewed publications

In 2012, the IP system was followed to document the monitoring on volunteer plants (Section 3.3.). 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 contractual obligations are described in Annex 2. The other element of general surveillance applicable to season 2012 was the review of peer-reviewed publications (Section 3.1.3.). Due to the discontinuation of Amflora cultivation in 2012 no observations performed by either farmers or by authorities are available for the 2012 season.

3.1.2. Results of general surveillance

In 2012 no cultivation of amylopectin potato EH92-527-1 took place and there is no intention to resume cultivation in the future. For this reason seed tubers of EH92-527-1 potato were destroyed via steaming or burning. After steaming the potato tubers were transferred in a biogas plant. In consequence, the 2012 general surveillance only comprised the following elements: (i) adherence to the IP system and operating procedures as applicable to crop rotation after cultivation, the monitoring of volunteer potatoes and the destruction of EH92-527-1 potato material (section 3.3.) and (ii) the review of peer-reviewed publications (section 3.1.3.).

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. The IP system manual is presented

in Annex 1. In 2012 the duty of the growers was to conduct the volunteer monitoring on all Amflora cultivation fields from 2011 and on all those fields where Amflora was cultivated in 2010 and where potato volunteer plants were observed in 2011.

The adherence to the IP system as part of general surveillance is discussed in detail in Section 3.3. Visits and inspections are listed in Annex 3.

BASF Plant Science representatives located in each of the three countries where Amflora was cultivated in 2010 and 2011 offered training and advice and could be approached with questions or concerns by all operators, users and other parties.

3.1.3. Review of peer-reviewed publications

A literature review was conducted in January 2013 based on searching relevant STN databases covering the publication year 2012. Executing the search profile given below 16 hits were found in the traditional bibliographic databases Chemical Abstracts, Biosis, Caba, CBNB, Compendex, Embase and Medline (see Annex 5 for details on the databases).

The search profil was set as follows:

- Amflora
or
- EH92-527-1 or "EH92 527 1" or eh925271
or
- gbss or qbssi or "granule bound starch synthase"
or
- (nptII or kanamycin resistance or neomycin phosphotransferase) and (potato or solanum)
or
- (potato or solanum) and (amylopectin* or "amylo pectin*" or waxy starch or basf) and (gmo or transgen* or "genet* engine*)

The focus of the review was on scientific literature or news, patents were not included. All results were intellectually checked for relevance.

The search resulted in a list of 16 articles (see Annex 5 for details including abstracts), out of which three publications (papers 5, 6 and 10 in Annex 5) deal with stable potato transformation methods testing several potato cultivars for transformation efficiency, testing more suitable potato tissue for transformation or optimizing transformation parameters respectively. One publication (paper 7 in Annex 5) describes phylogenetic analyses on the Solanum section using the granule-bound starch synthase gene for sequence comparison. Two publications (papers 8 and 13) describe other research

projects working with genetically modified potato lines without reference to Amflora or safety impacts of genetically modified potatoes. One publication (paper 11) is about a different high-amylopectin potato describing the cloning approach and construction of a RNAi vector for transformation. One review publication (paper 16) summarizes the various methods of starch modification and presents the applications of the modified starches. One hit (paper 1) contains the press release of BASF Plant Science announcing the stop of the development and commercialization of all products targeted solely at the European market. And five publications (papers 2, 9, 12, 14 and 15) are Scientific Opinions and statements from the European Food Safety Authority (EFSA) referring to assessments of the monitoring reports for the 2010 and 2011 cultivation season of EH92-527-1 potato or to the notifications from the Member States Austria, Luxembourg and Hungary to prohibit the placing on the market of EH92-527-1 potato. In these documents EFSA confirmed that the placing on the market does not pose adverse effects on the environment, human and animal health. Overall EFSA confirmed that the monitoring results did not invalidate its 2006 Scientific Opinions on potato EH92-527-1 (EFSA, 2006). In the Scientific Opinions on the monitoring reports the EFSA GMO Panel recommends to detail further how the search was conducted. Following the recommendations a detailed list of keywords used for the survey is given above and the databases are described in Annex 5.

The only publications resulting from the literature review conducted as described above having some relevance for the cultivation of EH92-527-1 potato are the publications from Hannula et al., 2012a and Hannula et al., 2012b. Both publications are discussed below and the PDF documents are included in Annex 6.

Hannula et al., 2012a

Hannula, S. E.; Boschker, H. T. S.; Boer, W. de; Veen, J. A. van; de Boer, W.; van Veen, J. A. (2012). ¹³C pulse-labeling assessment of the community structure of active fungi in the rhizosphere of a genetically starch-modified potato (*Solanum tuberosum*) cultivar and its parental isolate. *New Phytologist* 194 (3): 784-799

Abstract: "The aim of this study was to gain understanding of the carbon flow from the roots of a genetically modified (GM) amylopectin-accumulating potato (Solanum tuberosum) cultivar and its parental isolate to the soil fungal community using stable isotope probing (SIP). The microbes receiving ¹³C from the plant were assessed through RNA/phospholipid fatty acid analysis with stable isotope probing (PLFA-SIP)"

at three time-points (1, 5 and 12 d after the start of labeling). The communities of Ascomycota, Basidiomycota and Glomeromycota were analysed separately with RT-qPCR and terminal restriction fragment length polymorphism (T-RFLP). Ascomycetes and glomeromycetes received carbon from the plant as early as 1 and 5 d after labeling, while basidiomycetes were slower in accumulating the labeled carbon. The rate of carbon allocation in the GM variety differed from that in its parental variety, thereby affecting soil fungal communities. We conclude that both saprotrophic and mycorrhizal fungi rapidly metabolize organic substrates flowing from the root into the rhizosphere, that there are large differences in utilization of root-derived compounds at a lower phylogenetic level within investigated fungal phyla, and that active communities in the rhizosphere differ between the GM plant and its parental cultivar through effects of differential carbon flow from the plant.”

In this study, a method is being described measuring effects exerted by crop plantings on soil microorganisms. For this purpose the genetically modified potato line Modena with an altered starch composition and its parental isolate Karnico was compared with regard to potential effects on soil fungal communities. As it is known that a high percentage of the carbon produced by the plant is transferred via the roots to the soil it is reasonable to compare plant lines with a different carbon composition to detect effects on soil microorganisms. The experiments described in this publication were conducted under glasshouse conditions. Potato plants were cultivated in pots filled with soil collected from an agricultural field until the stage of senescence. $^{13}\text{CO}_2$ labelling was conducted prior to harvest. The soil was brushed off from the roots and analyzed for the carbon composition and fungal communities of three different fungal divisions. T-RFLP was used as a fingerprinting method to assess the abundance of the three different fungal divisions analyzed. The outcome of these small-scale experiments was that differences between the two potato varieties could be detected in the speed of carbon flow to fungal communities which might be the reason for the differences shown mainly in the diversity of arbuscular mycorrhizal fungi between the potato varieties Modena and Karnico. The authors state that caution must be exercised extrapolating these results to field conditions, especially as previous studies conducted by this research group did not reveal significant differences in bacterial and fungal communities between the same potato varieties analyzed.

Therefore, this publication presents a sensitive method which might be applied to analyze potential effects caused by crop plantings on soil communities as part of the environmental risk assessment. This study does not provide any evidence that

cultivation of potato line EH92-527-1 could potentially cause harm on the environment but rather shows that the abundance of fungal communities largely depend on the plant developmental stage. The authors recommend that experiments similar to those described in this publication should be repeated under field conditions and analyzing several potato varieties to determine if the differences detected in this research study are linked to the modification of the starch composition. In case the differences in the fungal communities could be verified under field conditions, it also needs to be analyzed if these effects are in the same range as those effects caused by other influencing factors like fertilization, management practices, crop rotation as it is usual in common agricultural practice.

Hannula et al, 2012b

Hannula, S. E.; Boer, W. de; Veen, J. van; de Boer, W.; van Veen, J. (2012). A 3-year study reveals that plant growth stage, season and field site affect soil fungal communities while cultivar and GM-trait have minor effects. PLoS ONE 7 (4): 1-13

Abstract: "In this three year field study the impact of different potato (Solanum tuberosum L.) cultivars including a genetically modified (GM) amylopectin-accumulating potato line on rhizosphere fungal communities are investigated using molecular microbiological methods. The effects of growth stage of a plant, soil type and year on the rhizosphere fungi were included in this study. To compare the effects, one GM cultivar, the parental isolate, and four non-related cultivars were planted in the fields and analysed using T-RFLP on the basis of fungal phylum specific primers combined with multivariate statistical methods. Additionally, fungal biomass and some extracellular fungal enzymes (laccases, Mn-peroxidases and cellulases) were quantified in order to gain insight into the function of the fungal communities. Plant growth stage and year (and agricultural management) had the strongest effect on both diversity and function of the fungal communities while the GM-trait studied was the least explanatory factor. The impact of cultivar and soil type was intermediate. Occasional differences between cultivars, the amylopectin-accumulating potato line, and its parental variety were detected, but these differences were mostly transient in nature and detected either only in one soil, one growth stage or one year."

In this study, the fungal community structure in two fields in the Netherlands cultivated with six potato cultivars during a period of three years of field trials was analyzed. The six potato cultivars were chosen to include varieties with high and low starch content

as well as the genetically modified starch potato Modena and its parental isolate Karnico. The fungal communities of three fungal divisions were compared between the two fields, across the three years, various potato growth stages and soil properties. In this study the potato variety Modena was not significantly different in any measured parameter like community structure of the three fungal divisions or total fungi content from its parental isolate Karnico in pairwise comparisons. The only significant difference between these two varieties was in the abundance of fungi during senescence, however differences between potato varieties have been detected in several parameters. In general, the genetically modified starch potato Modena was in the middle range of the cultivars tested. The most influencing factors of the measured parameters were the potato growth stage, followed by year and the soil type. Overall this study showed that the composition and function of fungal communities in the rhizosphere are highly dynamic and only to a small extent influenced by the potato cultivar.

Overall, the publications from this literature review on the publication year 2012 did not provide any indication on potential adverse effects which would invalidate the risk assessment of EH92-527-1 potato.

3.1.4. Additional information

No unanticipated or potentially adverse effects were observed during the volunteer monitoring of EH92-527-1 potato in 2012 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.

3.2. 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.

Several case-specific studies according to the Amflora monitoring plan were required during the cultivation of Amflora comprising

- Verification of 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,
- Confirmation that Amflora starch potato tubers grown at field locations maintain the intended amylopectin trait via an amylopectin-specific staining assay,
- Study to confirm the absence of expression of an open reading frame (ORF4) that is co-transcribed with the selectable marker gene neomycin phosphotransferase (*nptII*) during Amflora seed potato production,
- Determination of the levels of glycoalkaloids in Amflora starch potatoes
- Monitoring study on potato-feeding organisms

In the season 2012 no cultivation of Amflora was conducted and therefore only the volunteer monitoring study as described in the Amflora monitoring plan was performed in 2012 (section 3.2.1.). Consequently the suggestions by EFSA to optimize or slightly modify the study layout of studies to be conducted during the cultivation or on the Amflora harvest material could not be implemented. Shortcomings were e. g. identified by the EFSA GMO Panel for the potato-feeding organism study to improve the quantitative sampling plan, sampling scheme in the vicinity of the Amflora fields and the applications of insecticides on the sampling fields. BASF would have appreciated a detailed discussion on these points to increase the scientific value of the study but due to not being able to apply the learnings in the field in 2012 the value of such an exchange for either EFSA or BASF was viewed as very limited. Other recommendations refer to the simplifications relating to the study that confirms the identity and genetic stability of EH92-527-1 event.

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

Following the Amflora monitoring plan one case-specific study was conducted in 2012. The intention of this study was 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 agricultural 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. In 2011 and 2012, no Amflora cultivation for starch production purposes was conducted. Out of these seven fields only at one field planted with maize in the second season following the Amflora cultivation two potato volunteer plants were detected. These two potato volunteers were confirmed by PCR analysis as being Amflora potato plants (Annex 4). In the first year of volunteer monitoring after Amflora cultivation the number of volunteers was slightly higher (Table 2). The small number of potato volunteers detected during the first and second year of volunteer monitoring (66 volunteer plants in 2011 and two volunteer plants in 2012), as well as the decline from the first to the second year of monitoring clearly demonstrate that the cultivation measures applied 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.

In its opinion on the cultivation season 2011 (EFSA, 2012b) the EFSA GMO Panel identified some shortcomings in the methodology of the volunteer monitoring study. To evaluate the efficacy of the different soil treatment and weed control practices more details should have been collected together with data on the soil temperature and moisture. In addition to the collection of more data EFSA suggested to modify the methodology. As pointed out in Section 3. of this report it was not possible for the consent holder to implement the recommendations because the opinion was only published after the experimental conclusion of the study in 2012. In case Amflora cultivation would have been continued the consent holder would have initiated a discussion on which parameters could be optimized to increase the scientific value of this study.

For the continuation of this volunteer monitoring study the consent holder suggests to complete the study over the period of the four years (2011, 2012, 2013 and 2014) following commercial starch potato cultivation according to the Amflora monitoring plan and as described in the study report (Annex 4). Due to the very low number of potato volunteers detected and the decline in numbers from 2011 to 2012 it is not expected that a significant number of volunteer plants can be found in 2013 and 2014. Hence it is not considered reasonable to modify the way the study is conducted, especially since the volunteer monitoring study only relates to one single year of Amflora cultivation in 2010 and is a continuation of monitoring activities in 2011 and 2012. Following the monitoring plan, in 2013 and 2014, the volunteer monitoring study will focus on monitoring plots within the fields. According to the monitoring plan a monitoring of the field surroundings is not required. In addition and because in 2011 at one field border 61 Amflora volunteers were detected this area will be monitored in 2013 although in 2012 at this region no potato plants were found.

No further case-specific studies were conducted, since in the year 2012 Amflora was not cultivated, neither for seed multiplication purposes nor for starch production.

Table 1. Amflora starch potato production fields 2010

Field code	Region	Size [ha]	Harvesting period [dd.mm.yyyy]
CZ01	Olešná	33.6	16.10. – 21.10.2010
CZ02	Olešná	1.0	21.10.2010
CZ03	Olešná	11.5	21.10. – 23.10.2010
CZ04	Bohdalec	18.4	01.10. – 27.10.2010
CZ05	Bohdalec	28.4	05.10. – 24.10.2010
CZ06	Nové Dvory	2.0	23.10.2010
CZ07	Nové Dvory	44.1	18.10. – 23.10.2010

Table 2. Number of potato volunteers found 2011 and 2012 at all fields which were cultivated for Amflora starch production in 2010

Field code	2011					2012				
	Crop planted in 2011	Number of volunteers observed June 2011		Number of volunteers observed August 2011		Crop planted in 2012	Number of volunteers observed June 2012		Number of volunteers observed August 2012	
		within the field	outside the field	within the field	outside the field		within the field	outside the field	within the field	outside the field
CZ01	spring barley	0	0	0	0	peas and other feed crops	0	0	0	0
CZ02	spring barley	0	0	0	0	maize	0	0	2	0
CZ03	spring barley	0	0	0	0	peas and other feed crops	0	0	0	0
CZ04	maize	3	61	0	2	spring barley	0	0	0	0
CZ05	spring wheat	0	0	0	0	maize	0	0	0	0
CZ06	spring barley	0	0	0	0	oilseed rape	0	0	0	0
CZ07	spring barley	0	0	0	0	oilseed rape	0	0	0	0

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 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 2012 season, the IP system manual, version 21 May 2003 was used. In Annex 1 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 visits and audits performed throughout the volunteer monitoring period in 2012 (Annex 3).

3.4. 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 handling in 2012 comprised general surveillance, case-specific monitoring as well as the Identity Preservation system (IP system). The results relating to general surveillance are described in Section 3.1. and include a literature review (Section 3.1.3. and Annexes 5 and 6). The adherence to the Amflora IP system is captured in Section 3.3. and further supported by Annex 3. In addition, the monitoring plan provided for case-specific monitoring which is outlined in Section 3.2. describes the volunteer monitoring study conducted in the Czech Republic (Annex 4).

All observations and results obtained support the conclusion that any interaction of Amflora with the agro-ecosystem is comparable to that of conventional potatoes or starch potatoes cultivated, 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 volunteer monitoring of amylopectin potato EH92-527-1 in the member states Sweden, Germany and the Czech Republic after cultivation in 2011 and 2012 was:

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

In 2012, the third year of its commercial handling, the starch potato variety Amflora was not cultivated in Europe.

The adherence to the Identity Preservation system was documented via a list visits and audits performed throughout the volunteer monitoring period. The results of the volunteer monitoring study conducted as case-specific monitoring verified the assumptions made as part of the environmental risk assessment.

The literature review conducted for the publication year 2012 resulted in 16 publications from which two publications were seen as potentially relevant for the cultivation of amylopectin potato EH92-527-1. These publications however did not provide any indication on potential adverse effects which would invalidate the risk assessment of EH92-527-1 potato.

Overall, the results of all monitoring activities in 2012 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 potato will not be cultivated any longer.

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