

# **POST-MARKET MONITORING REPORT**

**for the monitoring of  
amylopectin potato EH92-527-1  
variety Amflora in 2013**

**submitted by**

**BASF Plant Science Company GmbH**

**March 2014**

**© 2014 BASF Plant Science Company GmbH. All Rights Reserved.**

This document is protected under copyright law. This document and the information contained herein are for use only by the regulatory authority to which it has been submitted by BASF Plant Science Company GmbH ("BPS"), and only in support of actions requested by BPS. Any other use of this document and the information contained herein requires the prior written consent of BPS. The submission of this document by BPS shall not be construed as granting of any rights or licenses.

## 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.	Review of peer-reviewed publications .....	7
3.2.	Case-specific monitoring .....	10
3.2.1.	Description and results of case-specific monitoring (if applicable) .....	10
4.	Summary of results and conclusions .....	13
5.	Adaptation of the monitoring plan and associated methodology for future years .....	13
	References.....	14

## LIST OF TABLES

Table 1.	Amflora starch potato production fields 2010 .....	12
Table 2.	Number of potato volunteers in 2011, 2012 and 2013 at all fields which were cultivated for Amflora starch production in 2010 .....	12

## APPENDICES

- 1 2013 Monitoring for volunteer potatoes at 2010 starch potato production fields.....
- 2 Literature review .....
- 3 Publication .....

## **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 2013 to 31 March 2014

### **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 2013 Post-Market Monitoring Report presents the results of monitoring the fields cultivated with potato variety Amflora in 2010 and 2011 comprising general surveillance and case-specific monitoring. 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 2013 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, 2013).

Since 2010, three post-market environmental monitoring reports on the cultivation seasons 2010, 2011 and 2012 respectively, were submitted by BASF Plant Science (Amflora PMEM, 2010; Amflora PMEM, 2011 and Amflora PMEM, 2012) and evaluated by the EFSA GMO Panel. Corresponding EFSA opinions were published on February 23, 2012 (EFSA, 2012a), December 17, 2012 (EFSA, 2012b) and October 25, 2013 respectively (EFSA, 2013).

### **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 2013, and as consequence of the discontinuation of Amflora cultivation in 2012, the information related to the functioning of the IP system was not collected and hence the monitoring for volunteer plants was not conducted. The only remaining element of general surveillance applicable to the 2013 season therefore was the review of peer-reviewed publications (Section 3.1.2.).

### 3.1.2. Review of peer-reviewed publications

A literature review was conducted in January 2014 based on searching relevant STN databases covering the publication year 2013. Executing the search profile given below 38 hits were found in the traditional bibliographic databases Chemical Abstracts, Biosis, Caba, and Medline (see Annex 2 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 gbssi 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 38 articles (see Annex 2 for details including abstracts), out of which four publications (papers 1, 2, 14, 15 in Annex 2) deal with established policies and laws in regard to the introduction of genetically modified organisms into the environment while 13 publications (paper 5, 9, 10, 11, 12, 13, 16, 17, 19, 21, 22, 26, 27 in Annex 2) discuss risk assessment and decision making including controversies and public concern surrounding GM foods and crops. Six publications (paper 3, 4, 6, 7, 8, 23 in Annex 2) describe various molecular detection methods for the identification of genetically modified organisms. Four publications (paper 18, 20, 24, 25 in Annex 2) deal with developing potato transformation methods using molecular genetic techniques. Nine publications (paper 28, 29, 30, 31, 32, 33, 35, 37, 38 in Annex 2) are about other research projects working with starch synthase

modified crops without reference to Amflora or potential safety impacts of genetically modified potatoes. And one publication (paper 36) is a Scientific Opinion from the European Food Safety Authority (EFSA) referring to the assessment of the monitoring report for the 2012 cultivation season of EH92-527-1 potato. In the document 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).

The only one publication resulting from the literature review conducted as described above having some relevance for the cultivation of EH92-527-1 potato is the publication by Hannula et al., 2013. The publication is discussed below and the PDF document is included in Annex 3.

#### Hannula et al., 2013

Hannula, S. E., Boer, W. de, Baldrian, P., Veen, J. A. van. (2013). Effect of genetic modification of potato starch on decomposition of leaves and tubers and on fungal decomposer communities. *Soil Biol Biochem* 58: 88-98, 74 refs.

*Abstract: As part of a risk evaluation of growing genetically modified crops, we investigated the effects of a genetic modification of starch quality (increased level of amylopectin) in potato tubers (Solanum tuberosum L.) on the decomposition of tissues (tubers and leaves) as well as on the associated fungal functional and phylogenetic diversity. The weight loss of both leaves and tubers in litterbags was analysed after 1, 3 and 6 months of incubation in soils and combined with measurements of fungal extracellular enzyme activities (laccases, Mn-peroxidases and cellulases) as well as molecular analyses of the fungal community (ITS regions and cellobiohydrolase I (cbhl) genes). The study revealed that initial (after one month) decomposition of both tubers and leaves of the parental isolate was significantly faster than that of the genetically modified (GM)-variety. This coincided with differences in fungal community composition. After this initial difference, no significant differences in any of the parameters measured could be detected after 3 and 6 months of decomposition illustrating the transient nature of the initial difference between the cultivars. Thus, it can be concluded that the starch modified tubers are not harmful to the fungal decomposer community and that despite initial differences in decomposition, the final decomposition rate of tissues from the GM-variety was similar to that of tissues from the parental variety. Furthermore, interesting dynamics of fungal phyla and species*



*during decomposition were observed; the basidiomycetal yeasts and ascomycetes were primary colonizers of the potato tissue while basidiomycetes were dominant in the more decomposed and lignin-rich litter.*

In this study, a method is being described measuring effects exerted by crop plantings on the decomposition rates of both tubers and leaves of GM-variety and its non modified isoline Karnico, activities of some of the key enzymes involved, and the abundance and diversity of *cbhl* gene. Furthermore, to complement the functional measurements the ITS copy numbers of Basidiomycota and Ascomycota were quantified and the community composition and diversity of these phyla were estimated.

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. The litterbags containing tissues from the GM potato or its isoline were placed in the soil in which the same cultivar of potato has been grown. The residue sphere soil, collected by brushing the litterbag was used for enzyme activity measurement. T-RFLP was used as a fingerprinting method to assess the diversity and community development of the *Ascomycota* and *Basidiomycota*. The outcome of these experiments was that the initial decomposition of both tubers and leaves of parental isoline was significantly faster compared to the genetically modified variety. This reflected to the differences in any of the parameters measured could be detected after 3 and 6 months of decomposition illustrating the transient nature of the initial difference between the cultivars. 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 using a wider range of modifications and crop species. Overall, the publications from this literature review relating to the publication year 2013 did not provide any indication on potential adverse effects which would invalidate the risk assessment of EH92-527-1 potato.

### 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 requires 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 2013, no cultivation of Amflora was conducted and therefore only the volunteer monitoring study as described in the Amflora monitoring plan was performed in 2013 (section 3.2.1.).

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

Following the Amflora monitoring plan one case-specific study was conducted in 2013. The intention of this study was to evaluate the presence and persistence of Amflora volunteer plants and their frequency within the field 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, 2012, and 2013 no Amflora cultivation for starch production purposes was conducted. Out of these seven fields (Table 1) only at one field planted with maize following the Amflora cultivation potato volunteer plants were detected (Table 2). These potato volunteers were confirmed by PCR analysis as being Amflora potato plants (Annex 1).

### **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.

### **3.4. 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 2013 comprised general surveillance as well as case-specific. The results relating to general surveillance are described in Section 3.1. and include a literature review (Section 3.1.2. and Annexes 2). In addition, the monitoring plan provided for case-specific monitoring which is outlined in Section 3.2. and describes the volunteer monitoring study conducted in the Czech Republic (Annex 1).

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.

**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 in 2011, 2012 and 2013 at all fields which were cultivated for Amflora starch production in 2010

Field Code	Number of volunteers observed								
	Crop	2011		Crop	2012		Crop	2013	
		Jun	Aug		Jun	Aug		Jun	Aug
CZ01	spring barley	0	0	peas & other feed crops	0	0	mix of Trifolium & other crops	0	0
CZ02	spring barley	0	0	maize	0	2	maize	68	133
CZ03	spring barley	0	0	peas & other feed crops	0	0	mix of Trifolium & other crops	0	0
CZ04	maize	3	0	spring barley	0	0	spring barley	0	0
CZ05	spring wheat	0	0	maize	0	0	maize	0	0
CZ06	spring barley	0	0	oilseed rape	0	0	winter wheat	0	0
CZ07	spring barley	0	0	oilseed rape	0	0	winter wheat	0	0

#### **4. SUMMARY OF RESULTS AND CONCLUSIONS**

The objective of the post-market monitoring of amylopectin potato EH92-527-1 in the member states Sweden, Germany and the Czech Republic after cultivation in 2010 and 2011 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 2013, and as in 2012, the starch potato variety Amflora was not cultivated in Europe. 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 2013 resulted in 38 publications from which one publication was seen as potentially relevant for the cultivation of amylopectin potato EH92-527-1. This publication 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 the monitoring activities in 2013 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 cultivation of Amflora potato was discontinued in 2012.

## REFERENCES

- Amflora PMEM (2010) Post-market monitoring report for the cultivation of amylopectin potato EH92-527-1, variety Amflora in 2010, available online:  
[http://ec.europa.eu/food/food/biotechnology/index\\_en.htm](http://ec.europa.eu/food/food/biotechnology/index_en.htm)
- Amflora PMEM (2011) Post-market monitoring report for the cultivation of amylopectin potato EH92-527-1, variety Amflora in 2011, available online:  
[http://ec.europa.eu/food/food/biotechnology/index\\_en.htm](http://ec.europa.eu/food/food/biotechnology/index_en.htm)
- Amflora PMEM (2012) Post-market monitoring report for the cultivation of amylopectin potato EH92-527-1, variety Amflora in 2012, available online:  
[http://ec.europa.eu/food/food/biotechnology/index\\_en.htm](http://ec.europa.eu/food/food/biotechnology/index_en.htm)
- BASF (2013) Letter to European Commission Health and Consumers Directorate General Safety of the Food Chain Biotechnology. 10 April 2013. TS.
- EFSA (2006) Opinion of the Scientific Panel on Genetically Modified Organisms on an application (Reference EFSA-GMO-UK-2005-14) for the placing on the market of genetically modified potato EH92-527-1 with altered starch composition, for production of starch and food/feed uses under Regulation (EC) No 1829/2003 from BASF Plant Science. EFSA Journal 324, 1-20. Available online:  
<http://www.efsa.europa.eu/de/efsajournal/pub/324.htm>
- EFSA (2012a) Scientific Opinion on the annual Post-Market Environmental Monitoring (PMEM) report from BASF Plant Science Company GmbH on the cultivation of genetically modified potato EH92-527-1 in 2010. EFSA Journal 10(2):2558. [38 pp.] doi:10.2903/j.efsa.2012.2558. Available online:  
[www.efsa.europa.eu/efsajournal](http://www.efsa.europa.eu/efsajournal)
- EFSA (2012b) Scientific Opinion on the annual Post-Market Environmental Monitoring (PMEM) report from BASF Plant Science Company GmbH on the cultivation of genetically modified potato EH92-527-1 in 2011. EFSA Journal 10(12):3015. [35 pp.] doi:10.2903/j.efsa.2012.3015. Available online:  
[www.efsa.europa.eu/efsajournal](http://www.efsa.europa.eu/efsajournal)
- EFSA (2013) Scientific Opinion on the annual Post-Market Environmental Monitoring (PMEM) report from BASF Plant Science Company GmbH on the cultivation of genetically modified potato EH92-527-1 in 2012. EFSA Journal 11(10):3445. [10 pp.] doi:10.2903/j.efsa.2013.3445. Available online  
<http://www.efsa.europa.eu/en/efsajournal/doc/3445.pdf>
- EU Register (2010) Post-market monitoring plan for Notification C/SE/96/3501. Available at:  
[http://ec.europa.eu/food/dyna/gm\\_register/monitoringplan\\_eh92-527-1.pdf](http://ec.europa.eu/food/dyna/gm_register/monitoringplan_eh92-527-1.pdf)