SCIENTIFIC OPINION

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[1]

EFSA Panel on Genetically Modified Organisms (GMO)[2, 3]

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ABSTRACT

Following a request from the European Commission, the Panel on Genetically Modified Organisms of the European Food Safety Authority (EFSA GMO Panel) assessed the monitoring report for the 2011 growing season, provided by BASF, on the genetically modified (GM) potato EH92-527-1 (variety Amflora). On 26 January 2012, the EFSA GMO Panel had adopted a scientific opinion on the 2010 monitoring report on potato EH92-527-1. The EFSA GMO Panel followed the same approach as for the assessment of the 2010 monitoring report and assessed, in close collaboration with the EFSA Unit for Scientific Assessment Support, the methodology used by the applicant in 2011 for the case-specific studies, the general surveillance of potato EH92-527-1 and the field study to monitor potential adverse effects on potato-feeding organisms as required in the related Commission Decision. The EFSA GMO Panel notes similar shortcomings in the methodology for general surveillance and for the specific field study on potato-feeding organisms as were found in the 2010 monitoring report. Hence, the EFSA GMO Panel reiterates the same recommendations for improvement of the methodology for the post-market environmental monitoring of potato EH92-527-1 as it did in its scientific opinion on the 2010 monitoring report. The EFSA GMO Panel also assessed the methodology of a new study monitoring GM volunteers within and around fields cropped with potato EH92-527-1 in 2010. The EFSA GMO Panel identified flaws in that study and therefore makes recommendations to the applicant to improve the study design. However, from the overall dataset submitted by the applicant, the EFSA GMO Panel did not identify adverse effects on the environment or human and animal health due to potato EH92-527-1 cultivation. The outcomes of the 2011 monitoring report do not invalidate the conclusions of the EFSA GMO Panel's previous opinions on potato EH92-527-1.

KEY WORDS

GMO, potato, PMEM, annual report, cultivation, case-specific monitoring, general surveillance

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SUMMARY

On 26 January 2012, in response to a request from the European Commission, the Panel on Genetically Modified Organisms of the European Food Safety Authority (EFSA GMO Panel) adopted a scientific opinion on the monitoring report for the 2010 growing season, provided by BASF, on genetically modified (GM) potato EH92-527-1 (variety Amflora). During its assessment of the 2010 monitoring report, the EFSA GMO Panel had identified shortcomings in the methodology for both general surveillance and the specific field study on potato-feeding organisms as required in the related Commission Decision, and hence provided recommendations for the improvement of the Post-Market Environmental Monitoring (PMEM) of potato EH92-527-1.

Following a similar request from the European Commission to assess the monitoring report of the same potato EH92-527-1 for the 2011 growing season, the EFSA GMO Panel assessed, in close collaboration with the EFSA Unit for Scientific Assessment Support, the methodology used by the applicant in the case-specific studies, the general surveillance of potato EH92-527-1 and the specific field study to monitor potential adverse effects on potato-feeding organisms as required in the related Commission Decision. The methodology used for the monitoring of potato EH92-527-1 in 2011 is similar to that used in 2010. Therefore, the EFSA GMO Panel mostly focused on the new 2011 datasets, i.e., data from farmer questionnaires, monitoring of potato-feeding organisms and monitoring of volunteers in fields in which potato EH92-527-1 was grown for starch production in 2010.

The EFSA GMO Panel notes similar shortcomings in the methodology for general surveillance and the specific field study to monitor potential adverse effects on potato-feeding organisms as were found in the 2010 monitoring report. Hence, the EFSA GMO Panel reiterates the same recommendations for improvement of the methodology used in the PMEM of potato EH92-527-1 as it did in its scientific opinion on the 2010 monitoring report.

The EFSA GMO Panel also assessed the methodology of a new study monitoring GM volunteers within and around fields cropped with potato EH92-527-1 in 2010. The EFSA GMO Panel identified flaws in the study and therefore makes recommendations to the applicant to improve the study design.

However, from the overall dataset submitted by the applicant in its 2011 monitoring report, the EFSA GMO Panel did not identify any adverse effects on the environment or human and animal health due to potato EH92-527-1 cultivation. The outcomes of this 2011 monitoring report do not invalidate the conclusions of the EFSA GMO Panel's previous opinions on potato EH92-527-1.

TABLE OF CONTENTS

BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION AND EFSA

In 2006, the EFSA GMO Panel adopted two Scientific Opinions on the notification (Reference C/SE/96/3501) and the application (Reference EFSA-GMO-UK-2005-14) for the placing on the market of genetically modified (GM) potato EH92-527-1 (variety Amflora; unique identifier BPS-25271-9) with altered starch composition, for cultivation and production of starch from BASF Plant Science (EFSA, 2006a,b). The EFSA GMO Panel was of the opinion that the weight of evidence indicates that potato EH92-527-1 and derived products are no more likely to cause adverse effects on human and animal health or the environment than conventional potato, in the context of the proposed uses. The EFSA GMO Panel concluded that the environmental risk assessment (ERA) did not identify a risk that required Case-Specific Monitoring (CSM). However, the EFSA GMO Panel welcomed the proposals by the applicant to monitor the stability of the inserts and phenotypic expression during cultivation of the potato EH92-527-1 (EFSA, 2006a,b).

Subsequently, potato EH92-527-1 was approved under Directive 2001/18/EC (EC, 2001) for cultivation and industrial use in the EU and under Regulation 1829/2003 (EC, 2003) for production of starch and food and feed uses (EC, 2010). Commission Decision 2010/135/EU required the consent holder to carry out a specific field study to monitor potential adverse effects on potato-feeding organisms in the potato EH92-527-1 fields and their vicinity. A final consent was granted to the applicant by Sweden on 31 March 2010. Potato EH92-527-1 was cultivated for starch production in the Czech Republic, and for seed potato production in Germany and Sweden in 2010.

In 2010, BASF Plant Science submitted to the European Commission the first annual Post-Market Environmental Monitoring (PMEM) report on the cultivation of potato EH92-527-1 according to Directive 2001/18/EC (EC, 2001).

On 10 May 2011, the EFSA GMO Panel received a request from the European Commission to assess the PMEM report submitted by BASF Plant Science on the cultivation of potato EH92-527-1 in 2010. The EFSA 'Standing Working Group on the annual PMEM reports' was commissioned to assess that monitoring report for the 2010 growing season. Consequently, on 26 January 2012, the EFSA GMO Panel adopted a Scientific Opinion on the 2010 monitoring report on potato EH92-527-1 (EFSA, 2012). In the 2010 monitoring report, the EFSA GMO Panel noted shortcomings in the methodology for general surveillance (GS) as well as in the specific field study to monitor potential adverse effects on potato-feeding organisms and hence made recommendations for the improvement of the PMEM of potato EH92-527-1. However, from the overall dataset submitted by the applicant, the EFSA GMO Panel did not identify adverse effects on the environment and to human and animal health due to potato EH92-527-1 cultivation in 2010.

On 25 May 2012, the EFSA GMO Panel received from the European Commission a request to assess the second monitoring report submitted by BASF on the cultivation of potato EH92-527-1 in 2011. A copy of the CD-ROM containing the full report as well as the comments of the Member States on this report were received mid-June 2012.

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION AND EFSA

On 25 May 2012, the EFSA GMO Panel received a request from the European Commission to assess the Amflora monitoring report for the 2011 cultivation season provided by BASF. This assessment should be reported through the adoption of an Opinion including the analysis of the appropriateness of the methodology of implementation and also clearly indicating the potential consequences of this assessment on the safety of the GMO in question. The European Commission asked the EFSA GMO Panel to adopt a Scientific Opinion by September 2012.

ASSESSMENT

1. INTRODUCTION

The potato transformation event EH92-527-1 was developed by the applicant, BASF Plant Science Company GmbH. Potato leaf discs from the cultivar Prevalent were transformed by *Agrobacterium*-mediated gene transfer technology. The modification involves the introduction of two gene sequences, one of which results in the inhibition of the expression of granule bound starch synthase protein (GBSS), responsible for amylose biosynthesis. As a result, the starch produced has little or no amylose and consists of amylopectin (branched starch), which modifies the physical properties of the starch. The other gene sequence confers kanamycin resistance (*npt*II) and was used as a selectable marker (for further details, see EFSA, 2006a,b).

The potato transformation event EH92-527-1 with the variety name Amflora was approved for commercial cultivation in the European Union in March 2010. While potato EH92-527-1 was cultivated for starch production in the Czech Republic, and for seed potato production in Germany and Sweden in 2010, the GM potato was grown for seed production in Sweden (at four locations) and Germany (at one location) in 2011. In accordance with the EU legislative framework, the applicant reports to the European Commission and to Member States on an annual basis the results of its monitoring activities on the cultivation of potato EH92-527-1.

As was the case for the 2010 monitoring report, the EFSA GMO Panel was asked by the European Commission to assess the monitoring report[4] of potato EH92-527-1 for the second growing season (hereafter referred to as the '2011 monitoring report'). The applicant adopted a similar PMEM approach as it had in its 2010 report and:

(1) reported the results of two case-specific studies based on the verification of a set of assumptions that were made during the ERA and in accordance with the Identity Preservation (IP) system;

(2) reported the results of the field study to monitor potential adverse effects on potato-feeding organisms in the fields where potato EH92-527-1 was cultivated and in their vicinity (EC, 2010);

(3) reported the results of its GS monitoring programme, including the analysis of the questionnaires answered by all farmers in the EU Member States where potato EH92-527-1 was cultivated in 2011 and a review of peer-reviewed publications on the safety of potato EH92-527-1.

In its 2011 monitoring report, the applicant did not provide case-specific studies related to the phenotypic stability of the amylopectin trait in potatoes EH92-527-1 and to the glycoalkaloid content of potato EH92-527-1 tubers (see Section 2 of EFSA, 2012) as none of the potato EH92-527-1 fields in 2011 were for starch production.

However, in 2011, the applicant carried out a new study[5] monitoring GM volunteers within and around fields cropped with potato EH92-527-1 for starch production in the Czech Republic in 2010 (EFSA, 2012).

In preparing the present Scientific Opinion, the EFSA GMO Panel considered its previous experience of the 2010 monitoring report on potato EH92-527-1 as well as various sources of information such as comments from Member States on both the 2010 and the 2011 monitoring reports, the most recent scientific data and relevant peer-reviewed publications.

[4] The 2011 Monitoring report submitted by BASF is publicly available on the webpage of the EC Directorate General for Health and Consumers, at http://ec.europa.eu/food/food/biotechnology/index_en.htm

[5] 2011 Monitoring report, Appendix 13

In response to this mandate of the European Commission, the EFSA GMO Panel, in close collaboration with the EFSA Unit for Scientific Assessment Support (SAS Unit), assessed the appropriateness of the methodology (e.g., the statistical analysis of the farmer questionnaires).

Considering the timeline, the EFSA GMO Panel acknowledges that the applicant could not have introduced all the Panel's recommendations on PMEM, as referred to in its scientific opinion on the 2010 monitoring report, in the 2011 monitoring scheme for potato EH92-527-1 (EFSA, 2012).

Considering the unchanged methodology for PMEM of potato EH92-527-1 in 2011, the EFSA GMO Panel mostly focused its assessment on the new 2011 datasets (i.e. farmer responses to questionnaires, monitoring of potato-feeding organisms and monitoring of volunteers in fields in which potato EH92-527-1 fields was grown for starch production in 2010). Hence, for forthcoming monitoring reports, the EFSA GMO Panel invites the applicant to highlight the parts of the reports that contain additional datasets and novel methodology, if any, compared with the report for the previous year.

Considering that potato EH92-527-1 cultivation was restricted to seed production in 2011, the EFSA GMO Panel acknowledges and agrees that monitoring of potato EH92-527-1 by-products is not addressed in the present PMEM report. In case in which potato EH92-527-1 pulp is to be used as animal feed in the future, the EFSA GMO Panel reiterates its previous recommendation that a questionnaire should be developed on the use of such by-products (for further details, see Sections 4.2.4 and 4.3 of EFSA (2012)).

In the following chapters of this Scientific Opinion, the EFSA GMO Panel describes its assessment of the 2011 monitoring report on potato EH92-527-1.

2. CASE-SPECIFIC MONITORING

2.1. Summary of the information provided by the applicant

In the initial notification[6] C/SE/96/3501 and application EFSA-GMO-UK-2005-14, the applicant submitted a Case-Specific Monitoring (CSM) plan '*strictly based on the verification of a set of assumptions that were made during the Environmental Risk Assessment (ERA) and their confirmation over a defined monitoring period*[7]'. The applicant listed the main assumptions in the ERA: (1) the genetic stability of the trait; (2) the phenotypic stability of the trait; (3) the absence of expression of the identified open reading frame (ORF4) and (4) the stability of identified statistically significant compositional differences such as the reduction in glycoalkaloid levels in potato EH92-527-1 tubers. The applicant considered PMEM as an opportunity to confirm these assumptions under different environmental and agronomic conditions and/or over a longer period in time.

In its 2011 monitoring report, the applicant did not provide case-specific studies related to the phenotypic stability of the amylopectin trait in potatoes EH92-527-1 and to the glycoalkaloid content of potato EH92-527-1 tubers (see Section 2 of EFSA, 2012) as none of the potato EH92-527-1 fields in 2011 was for starch production.

However, in 2011, the applicant monitored seven fields in the Czech Republic that were cropped with potato EH92-527-1 during the 2010 growing season[8] for the presence of potato volunteers. The applicant monitored within and on the perimeter of these fields at two times (i.e., June and August 2011). The applicant recorded volunteer numbers within 20 plots (of 1 m²/each) per field and also surveyed a 2 m wide margin all around the field. The applicant detected volunteers within (i.e., three volunteers) and on (i.e., 61 volunteers) the perimeter of one out of the seven fields monitored in 2011. That field was cultivated with maize whereas the other fields were cultivated either with spring barley or with spring wheat. Leaf samples from potato volunteers were analysed by polymerase chain

[6] Notification C/SE/96/3501, Appendix 43
[7] 2011 Monitoring report, Section 3.2, page 12
[8] The 2010 growing season was the first year that potato EH92-527-1 was cultivated in the EU.

reaction (PCR), using primers specific to potato EH92-527-1. The PCR analysis showed that all volunteers were derived from potato EH92-527-1. All volunteers were removed or destroyed according to the requirements of the IP system (see Section 5).

In its 2011 monitoring report, the applicant concluded from the three case-specific studies that:

(1) An event-specific PCR assay of potato EH92-527-1 seed tubers confirmed the presence of the EH92-527-1 insert, and hence the identity of potato EH92-527-1 seed potatoes and their genetic stability[9];

(2) The absence of expression of the identified ORF4 was confirmed via Western blot analysis[10];

(3) The standard cultivation measures applied in the first year following starch potato EH92-527-1 production were appropriate to control potato volunteers, and that potato EH92-527-1 does not differ in its persistence from other potato varieties.

2.2. Assessment by the EFSA GMO Panel

As in its previous Scientific Opinion on the 2010 monitoring report on potato EH92-527-1 (EFSA, 2012), the EFSA GMO Panel recalls that, according to Directive 2001/18/EC (EC, 2001) and its Scientific Opinion providing guidance on PMEM of GM plants (EFSA, 2011a), CSM should be carried out when risks or important gaps in scientific information or significant levels of critical uncertainty linked to the GM plant and its management have been identified in the ERA. In its Scientific Opinions on potato EH92-527-1 (EFSA, 2006a,b), the EFSA GMO Panel did not identify a risk or critical uncertainty and therefore concluded that no CSM was needed. Against this background, the EFSA GMO Panel notes that the CSM submitted by the applicant is '*strictly based on the verification of a set of assumptions that were made during the ERA and their confirmation over a defined monitoring period*' and not directly related to risks, important gaps in scientific information or significant levels of critical uncertainty linked to the GM plant and its management that were identified in the ERA.

However, in response to the request from the European Commission (see Terms of Reference), the EFSA GMO Panel assessed the methodology used to the CSM studies as provided by the applicant.

2.2.1. Confirmation of the presence and stability of the event in seed potatoes EH92-527-1 growing in 2011 by PCR analysis[11]

The aim of the study was to check the presence of the EH92-527-1 insert in the potato EH92-527-1 seed tubers grown at four locations in Sweden and one location in Germany. Therefore DNA was extracted from a total of 80 pooled tuber samples, yielding a total of 800 individual potato tubers. An EH92-527-1 event-specific quantitative real-time PCR (qPCR) was used to confirm the presence and stability of the event in the tubers and did not indicate loss of the insert.

The EFSA GMO Panel is of the opinion that simple staining of tuber slices with Lugol's iodine solution would be sufficient to show stability of the high amylopectin trait on a tuber to tuber basis. The EFSA GMO Panel is also of the opinion that the loss of the high amylopectin trait would not represent a safety issue.

[9] 2011 Monitoring report, Appendix 9
[10] 2011 Monitoring report, Appendix 10
[11] 2011 Monitoring report, Appendix 9

2.2.2. Expression[12] of open reading frame 4 (ORF4) in tubers of seed potatoes EH92-527-1 grown in 2011

Bioinformatic analysis identified 18 ORFs in the insert sequence of the potato EH92-527-1. ORF4 transcript was detected in the potato. Studies evaluated by the EFSA GMO Panel (EFSA, 2006a,b) showed that the transcript would not be translated into a protein. The purpose of the study included in the 2011 monitoring report was to confirm the lack of ORF4 protein in seed potato EH92-527-1 tubers grown at field locations in Sweden and Germany in 2011. A total of 80 pooled tuber samples were analysed by western analysis using ORF4-specific antibodies raised against bacterial recombinant ORF4 protein. The limit of detection was 1 ng per 50 µg of protein extract.

The method is appropriate and showed no indication of the presence of the protein.

The EFSA GMO Panel considers that, in absence of any evidence for concern over safety, monitoring the presence of this hypothetical protein will not be needed.

2.2.3. Monitoring of GM potato volunteers[13] at 2010 starch potato production fields

In response to the request from the European Commission (see Terms of Reference), the EFSA GMO Panel assessed the appropriateness of the applicant's approach in the field study to monitor for volunteers in fields in which potato EH92-527-1 was grown for starch production in 2010.

The EFSA GMO Panel makes the following comments on this monitoring study:

(1) The null hypothesis for the study is unclear as different hypotheses are referred to in the 2011 monitoring report[14] such as (a) to estimate the abundance of volunteers, (b) to monitor the incidence (presence or absence) of volunteers or (c) to test the efficacy of the weed control practices in maintaining the incidence of volunteers close or equal to zero. In the absence of a clear rationale and risk hypothesis being set by the applicant, the EFSA GMO Panel evaluated whether the study tested the hypothesis that the applied weed control practices controlled GM potato volunteers (see (c) above).

However in order to address this, information on the field management practices (e.g., herbicide treatments, soil tillage) at and after the GM potato harvest and during the subsequent season should have been provided in order to assess the efficacy of the different weed control practices on GM volunteer abundance. In addition, information on the usual management practices in crop rotations including potatoes was also needed to serve as a baseline for comparative purposes.

(2) The applicant did not document the weather conditions following the harvest of potato EH92-527-1 in 2010. For instance, soil temperature and moisture conditions influence the survival of tubers and the soil treatments applied and hence the number of volunteers in the following crop.

(3) The sampling protocol followed by the applicant (Roberts-Pichette and Gillespie, 1999) was inappropriate. These authors developed a methodology for diversity measurements (i.e., species accumulation curves) but not for incidence estimation. In order to select an appropriate sampling scheme (in terms of the size, number and location of quadrats), the applicant should state the goal(s) of the study more explicitly (see point (1) above). It is paramount to clarify whether the null hypothesis of the study is (a) abundance estimation, (b) incidence estimation (i.e., presence or absence) or (c) the efficacy of the weed control practices in maintaining the incidence of GM potato volunteers close or equal to zero.

[12] 2011 Monitoring report, Appendix 10
[13] 2011 Monitoring report, Appendix 13
[14] 2011 Monitoring report, Appendix 13

(4) Twenty plots were sampled per field regardless of the field size or the expected mean density of volunteers and variance.

Volunteers were assessed in June and August 2011, independently of the timing of weed control practices, and the volunteers observed in June were removed or destroyed by specific herbicide applications, meaning that their subsequent growth and survival could not be assessed in that season. This could jeopardize the assessment of the null hypothesis that the 'current weed control management practices do control volunteers'.

In addition to this specific study on Czech fields for starch production in 2010, and in accordance with the IP System, farmers who cultivated potato EH92-527-1 in 2010 were requested to monitor their fields in 2011 for the presence or absence of volunteers. All fields (both for seed and for starch production) were monitored; volunteers were reported in several locations in which seed was produced in 2010. The EFSA GMO Panel therefore recommends to consider monitoring a proportion of seed production fields in addition to starch production fields.

Even in the absence of data on the agricultural practices, the EFSA GMO Panel acknowledges that the occurrence of volunteers may have been influenced by differing management practices in spring barley, spring wheat and maize fields. This difference in practices (e.g., sowing dates) may explain the occurrence of volunteers in the maize field only.

2.3. Conclusions & Recommendations on CSM

In its Scientific Opinions on potato EH92-527-1 (EFSA, 2006a,b), the EFSA GMO Panel agreed that no CSM was needed. However, the EFSA GMO Panel welcomed the proposals by the applicant to monitor the stability of the insert during the cultivation of potato EH92-527-1.

In response to the request from the European Commission (see Terms of Reference), the EFSA GMO Panel assessed the aforementioned case-specific studies provided by the applicant in its 2011 monitoring report, as well as evaluating the appropriateness of the methods used by the applicant.

Concerning the novel monitoring study of GM potato volunteers in 2011, the EFSA GMO Panel concludes that the null hypothesis was not clearly set by the applicant and also identifies weaknesses in the study (e.g., missing information on weed control practices, sampling methodology). In the absence of a clear rationale and risk hypothesis, the EFSA GMO Panel evaluated the methodology of the study aiming to test the hypothesis that the applied weed control practices controlled GM potato volunteers.

To test the null hypothesis as put forward by the EFSA GMO Panel (see Section 2.2.3 above), the applicant should consider the following comments and recommendations:

- to use a protocol more appropriate than that of Roberts-Pichette and Gillespie (1999). The applicant could tailor protocols to potato volunteers (Hughes et al., 1996; Madden et al., 1996). The applicant should state what level of precision is required. The applicant could use datasets from the literature if any or those collected throughout the ERA to fix sampling size, according to that desired level of precision.

  If the goal of the study was to estimate (a) volunteer abundance or (b) volunteer incidence in order to support the assessment of the efficacy of the weed control practices, then an important first step for the applicant would be to state explicitly what level of precision the study is designed to achieve. The applicant is strongly advised to consider whether the variances and means recorded in the nine years of data collected thus far could be of use in fixing the precision levels. For further information, see Perry (1994);

- to describe the crop management practices in the fields monitored, paying particular attention to those techniques (e.g., harvesting methods and weed control, especially soil tillage,

herbicide treatments) which may affect the survival of tubers in the soil and subsequent potato volunteers;

- to record weather conditions; as this monitoring study is aimed to last four years after potato EH92-527-1 cultivation, such data should be collected over this period;

- to better identify the observer collecting the data and to describe the protocol. For instance, raw data and quality control documents relating to the monitoring should be provided.

The results of this study show that GM potato volunteers were present in very low numbers or not detected in these studies. Therefore, the EFSA GMO Panel concludes that there is no safety concern for the environment and reiterates its previous conclusions that potato EH92-527-1 volunteers can be controlled by common agricultural practices (EFSA, 2006a,b).

The EFSA GMO Panel recommends that the applicant considers monitoring a proportion of seed production fields each year in addition to starch production fields.

The EFSA GMO Panel concludes that these case-specific studies do not provide scientific evidence that would invalidate the previous safety evaluations of potato EH92-527-1 (EFSA, 2006a,b).

3. FIELD STUDY ON POTATO-FEEDING ORGANISMS

3.1. Summary of the information provided by the applicant

In accordance with the provisions set by the European Commission for the placing on the market of potato EH92-527-1 (see the Annex of EC, 2010), the applicant carried out a field study[15] '*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 applicant monitored the abundance of aphids and other common phytophagous arthropods in inner and outer rows[16] of four potato EH92-527-1 fields in Germany and Sweden (all fields for seed potato production). The applicant pointed out that Colorado potato beetles (CPB) were not investigated separately, as in 2010, but the total abundance of phytophagous beetles was reported. Local agronomic practices were applied in each potato field. Within each field, 12 transects were identified (six within the field and six in the outermost rows on both sides of the fields). Each transect included 10 potato plants (or 30 leaves in the case of aphids) and for each transect the applicant sampled common arthropods in potato fields by two methods: (1) potato aphids by visual counting and (2) other arthropods (e.g., Thysanoptera, Aphididae, Miridae, Auchenorrhyncha, Coccinellidae, Neuroptera, Araneae) collected by sucking device. Individuals surveyed by visual counting were determined to species level. All samplings were conducted according to European and Mediterranean Plant Protection Organization (EPPO) standards.

The applicant concluded that *'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 the potato field 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*[17]*'*.

Similar field studies were conducted by the applicant on potato EH92-527-1 fields during the 2010 growing season and reported in the previous PMEM report (for further details, see EFSA, 2012).

[15] 2011 Monitoring report, Appendix 12
[16] Outer rows are defined by the applicant as the two or three border rows.
[17] 2011 Monitoring report, Appendix 12

3.2. Assessment by the EFSA GMO Panel

In its Scientific Opinion on the 2010 PMEM report of potato EH92-527-1 (EFSA, 2012), the EFSA GMO Panel already assessed the appropriateness of the applicant's approach and methodology used by the applicant for the field study to monitor potential adverse effects on potato-feeding organisms in the potato EH92-527-1 fields and in their vicinity.

The EFSA GMO Panel previously identified weaknesses in the study, namely the relevance of the hypothesis set by the applicant, the sampling strategy, the lack of an appropriate comparator and the definition of 'vicinity' (for further details, see EFSA, 2012).

The EFSA GMO Panel notes shortcomings in the methodology used for the field study reported in the 2011 monitoring report similar to those identified in the 2010 monitoring report. The EFSA GMO Panel also acknowledges that, owing to time constraints, the applicant could not have introduced all of its recommendations on PMEM, made in its scientific opinion on the 2010 monitoring report, in the 2011 monitoring scheme (EFSA, 2012). Hence, the EFSA GMO Panel reiterates the same recommendations for improvements in the methodology (see Section 3.3).

During the 2011 growing season, the EFSA GMO Panel acknowledges that frequent applications of insecticides on potato fields for seed production are in line with common practice. These frequent insecticide treatments hindered the establishment and build-up of phytophagous arthropod populations in the field and impacted non-phytophagous (e.g., predator, decomposer.) arthropod densities as well. Such situations are not appropriate to address the hypothesis[18] set by the applicant (see Section 3 of EFSA (2012)). Therefore, the EFSA GMO Panel concludes that the outcomes of this study cannot be extrapolated to the same study under typical cultivation practices of potatoes for starch production.

3.3. Conclusions of the study & Recommendations

The EFSA GMO Panel acknowledges that, owing to time constraints, the applicant could not have introduced all of its recommendations on PMEM, made in its scientific opinion on the 2010 monitoring report, into the 2011 monitoring scheme for potato EH92-527-1 (EFSA, 2012).

Considering the absence of change in the methodology used for the 2011 field study, the EFSA GMO Panel reiterates the following recommendations, made in its Scientific opinion on the 2010 monitoring report (EFSA, 2012):

- In the design of the study, consideration should be given to pest management and the fact that large shifts in pest populations are required to trigger changes in pest control that might have environmental consequences as potatoes (especially seed crops) already receive intensive inputs of pesticides;

- These changes in pest populations should be detected at several sites or occur consistently in several seasons at some sites. Thus such field studies would need to be conducted over years taking account of local pest management practices and other factors influencing pest infestations;

- In order to generate appropriate scientific data, the study needs to be conducted on the basis of comparing potato EH92-527-1 with appropriate comparators within the same fields or as close as possible and preferably under similar management practices;

- It will be necessary to improve the quantitative sampling plan in order to allow an analysis with the required power to detect differences. First, the applicant would need to select and justify the threshold level(s) above which changes in pest management are likely to occur.

[18] That is 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.

Then, a prospective power analysis would define the number of sites to monitor. It would also be necessary to increase the number of sampling dates in order to better reflect insect population dynamics and at the same time increase the number of samples needed to test the statistical hypothesis of the design;

- The applicant should revise its definition of '*vicinity*' as referred to in the Commission Decision 2010/135/EU (EC, 2010).

Furthermore, the EFSA GMO Panel considers that monitoring phytophagous arthropods in potato seed production fields is inappropriate, considering the large number of insecticide treatments required on seed production crops in order to maintain seed quality.

The EFSA GMO Panel remains of the opinion that the GS framework is a more proportionate way to collect relevant information on potato-feeding organisms. In its Scientific Opinion on the 2010 monitoring report on potato EH92-527-1 (EFSA, 2012), the EFSA GMO Panel previously recommended that the applicant, in close collaboration with risk managers, modifies the farmer questionnaire in relation to collecting data on changes in the abundance of potato-feeding organisms over time and monitoring changes in pest management practices.

4. GENERAL SURVEILLANCE

4.1. Summary of the information provided by the applicant

For the 2011 growing season of potato EH92-527-1, the applicant reported the results of its GS plan which consisted of: (1) the farmers' survey in the two EU Member States where potato EH92-527-1 was cultivated in 2011; (2) a review of peer-reviewed publications; (3) visits and inspections by national authorities and other existing networks; (4) stewardship programme; and (5) training and information for operators and users.

Furthermore, GS includes an IP system (see chapter 5) which ensures the traceability and quality of potato EH92-527-1. The IP manual includes a field-plot card-index[19] that supplements the observations gathered from farmer questionnaires[20].

More details on some of the elements of the GS plan are given hereunder:

(1) All farmers planting potato EH92-527-1 in 2011 were asked to record and report their observations and assessments in potato EH92-527-1 fields in comparison with a potato variety, if available, used as comparator. In 2011, a total of five questionnaires were received from all farmers participating in the IP system in the two European countries (four in Sweden, one in Germany) where potato EH92-527-1 was grown. The farmers were interviewed by representatives of BioMath, BASF's contractor, which also processed the data from the farmer questionnaires. From the 2011 statistical analysis[21] of the five questionnaires, the applicant concluded 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 (later harvest, lower yield) were clearly a consequence of adverse weather conditions and other influencing factors, and none of them were considered as adverse effects*".

(2) From a literature search in 18 databases (including, Web of Science), the applicant found 21 hits, of which only one single article, by Geschwendtner et al. (2011), is of relevance for the ERA of potato EH92-527-1. The applicant concluded that the peer-reviewed literature does not raise any safety concerns for potato EH92-527-1.

[19] 2011 Monitoring report, Appendix 1, Form 5
[20] 2011 Monitoring report, Appendix 6
[21] 2011 Monitoring report, Appendix 7

(3) The applicant provided a list of visits and inspections by national authorities (i.e., regional authority in Germany, Seed Certification Unit in Sweden) during the potato EH92-527-1 growing season 2011[22].

4.2. Assessment by the EFSA GMO Panel

4.2.1. Farmer questionnaires

The EFSA GMO Panel noted that the farmer questionnaire used in 2011 was identical to the one used in 2010. Considering the timeline, the EFSA GMO Panel acknowledges that the applicant could not have introduced its previous recommendations on PMEM, made to in the Panel's scientific opinion on the 2010 monitoring report (see Section 4.3 of EFSA, 2012), into the 2011 monitoring scheme for potato EH92-527-1.

According to the EFSA GMO Panel's Scientific Opinion providing guidance on PMEM of GM plants (EFSA, 2011a), raw data[23] from the farmers' survey were provided by the applicant.

According to the terms of reference of the mandate from the European Commission, the EFSA GMO Panel assessed the methodology used by the applicant to analyse the farmer questionnaires. As for the assessment of the 2010 monitoring report, the EFSA GMO Panel was assisted by the EFSA SAS Unit which provided methodological guidance for a systematic evaluation of the farmer questionnaires (see Appendices 1 and 2). Appendix 1 sets out a list of evaluation criteria (e.g., sample size, survey response rate, statistical analysis) that can be applied to farmers' surveys in the context of GS of GM plants. The findings on the appropriateness of the farmer questionnaire for potato EH92-527-1, its design, it use and analysis are given in Appendix 1. The EFSA GMO Panel, assisted by the EFSA SAS Unit, identified weaknesses in the methodology and makes recommendations to the applicant (see Section 4.3). However, from the 2011 analysis of the farmer questionnaires on potato EH92-527-1, the EFSA GMO Panel concludes that no unanticipated adverse effect can be identified (see Appendix 1).

4.2.2. Existing Monitoring Networks

According to its Scientific Opinion providing guidance on PMEM (EFSA, 2011a), the EFSA GMO Panel identified two types of existing monitoring networks: (1) regional or national organisations/services collecting data on, for example, use of pesticides, varieties registration and (2) voluntary organisations monitoring various aspects of the environment (e.g., fauna, flora).

As for the 2010 growing season, the EFSA GMO Panel notes that, in the 2011 Monitoring report, the applicant did not provide details on the existing environmental networks of the aforementioned type 2 that are active in biodiversity surveys. However, the applicant provided reports[24] of visits and inspections by national authorities. The EFSA GMO Panel considered the reports arising from visits and inspections by national authorities as a valuable source of information for GS. The EFSA GMO Panel recognised the difficulty of gathering a sufficient dataset from those national surveillance authorities on an annual basis. A detailed analysis of the data gathered by this type of existing networks (e.g., plant protection services) could be carried out over time (e.g., pooled data analysis) and could be provided periodically (e.g., every three years).

Considering the small-scale release (only five fields) of potato EH92-527-1 in 2011, existing environmental networks would have been unlikely to detect changes in environmental impacts due to the cultivation of potato EH92-527-1 in 2011. However, the EFSA GMO Panel recalls that existing surveillance networks may detect potential changes in the environment that would trigger additional studies to assess to what extent such changes might be related to a larger scale cultivation of potato EH92-527-1. According to the EFSA GMO Panel Scientific Opinion providing guidance on PMEM

[22] 2011 Monitoring report, Appendix 3
[23] 2011 Monitoring report, Appendix 8
[24] 2011 Monitoring report, Appendix 16 (CBI)

(EFSA, 2011a), the applicant is invited to identify relevant environmental networks when potato EH92-527-1 cultivation in the EU becomes more significant.

4.2.3. Literature review

The EFSA GMO Panel agreed with the overall approach followed by the applicant for the literature review. However, the EFSA GMO Panel recommends the applicant to detail further how the search was conducted (i.e., to list the keywords used for the search). According to the EFSA Guidance Document (EFSA, 2010) on the methodology for systematic literature reviews, an explanation of the criteria used to select the relevant papers should be provided and finally a discussion of the publications (e.g., assessment endpoints, exposure, effects). Against this background, the EFSA GMO Panel highlighted a paper by Kim et al. (2010) on the persistence of GM potatoes in the fields which was not reported and discussed by the applicant.

From the literature review carried out over 2011, the applicant found 29 hits from which only one paper (i.e., Geschwendtner et al., 2011) was likely to be relevant for the ERA of potato EH92-527-1. Considering the large number of databases used by the applicant for the literature search, the EFSA GMO Panel agrees with the applicant that most of the identified publications are not directly related to the cultivation of potato EH92-527-1 nor they are pertinent to the food and feed risk assessment of potato EH92-527-1.

Therefore, the EFSA GMO Panel considered the study by Geschwendtner et al. (2011), which analysed in a greenhouse study the potential effects of a GM potato with increased levels of amylopectin in its tubers on photosynthetic assimilation of CO2, exudation of assimilated carbonaceous compounds in the rhizosphere and potential alterations in the soil microbial biomass and diversity inhabiting this soil compartment. Although comparisons of two growth stages of the potatoes revealed significant responses in some of these parameters, no differences were found between the GM potato and its unmodified parental cultivar. Interestingly, significant differences were found in the efficiency of carbon assimilation and root exudation when both the GM potato and its parental line were compared to another conventionally bred cultivar. The results underline the fact that variability can occur in response to the growth stage of the potato and cultivar and thus indicates that the GM potato with increased levels of amylopectin had no effect on the selected parameters. Considering the lack of difference between the GM event and the parental cultivar and the natural variability of carbonaceous compound distribution within the plant, depending on its developmental stage, the EFSA GMO Panel concludes that the publication by Geschwendtner et al. (2011) does not identify an environmental safety concern that would invalidate its 2006 Scientific Opinions on potato EH92-527-1 (EFSA, 2006a,b).

The new information available on potato EH92-527-1 confirms the previous evaluation of the risk assessment performed by the EFSA GMO Panel, which stated that '*there is no evidence to indicate that the placing on the market of potato EH92-527-1, for use in cultivation and starch production, is likely to cause adverse effects on human and animal health or the environment'* (EFSA, 2006a,b).

4.3. Conclusions & Recommendations on GS

From the data provided by the analysis of the 2011 farmer questionnaires on potato EH92-527-1, the observations by national surveillance authorities and the literature review, no adverse effect of the cultivation of potato EH92-527-1 in 2011 can be identified. However, the EFSA GMO Panel identified shortcomings similar to those found in its evaluation of the GS results for the 2010 growing season, and therefore makes the same following recommendations to the applicant to reconsider the GS as it did in its Scientific Opinion on the 2010 monitoring report (for further details, see Appendices 1 and 2):

(1) The farmers' survey

Recommendations to the applicant to improve the study design and reporting are given in Appendices 1 and 2. In particular, the applicant is invited:

- to report in the farmer questionnaire changes in volumes of inputs (pesticides, fertilisers, etc) in order to assess whether the cultivation of potato EH92-527-1 results in a change in inputs to the production system compared with conventional starch potato for seed production;

- to compare existing accessible data sources with the responses to the farmer questionnaires for appropriate cross-checking of the data;

- to revise the method to calculate the confidence intervals;

- due to the limited number of locations where potato EH92-527-1 was grown in 2011, the farmers' survey cannot provide evidence for the absence of an effect. To improve the assessment of unanticipated effects, pooling the results of past and future farmers' surveys should be considered and suitable analysis techniques selected. This would require a consistent survey methodology and questionnaire format.

The design of the farmer questionnaire relies on a comparison between potato EH92-527-1 and a comparator variety to detect unanticipated effects. In 2011, for the five locations, the comparison was based on general experience in potato. The EFSA GMO Panel considers that non-GM starch-potato crops or conventional potato crops, grown nearby under similar cultivation conditions (i.e., seed production) and pest management practices, are the most appropriate comparators. If these are not available, then a historical baseline could be considered (EFSA, 2011a).

In its assessment of the specific study on potato-feeding organisms (see chapter 3), the EFSA GMO Panel suggests that the GS framework is a more proportionate way of collecting relevant information on potato-feeding organisms. The EFSA GMO Panel recommends that the applicant further elaborate the farmer questionnaire and, in particular, consider more detailed questions (e.g., on the abundance of potato-feeding organisms such as aphids, and Colorado potato beetles and/or on changes in pest management practices).

(2) The use of existing monitoring networks

A detailed analysis of the data gathered by the national surveillance authorities could be carried out over time (e.g., pooled data analysis) and could be provided periodically (e.g., every three years). In the future, subject to a significant increase in potato EH92-527-1 cultivation in the EU, the applicant is invited to identify existing environmental networks that could be relevant for GS.

(3) The literature review

The EFSA GMO Panel acknowledges that the literature review submitted by the applicant was balanced and set in the context of the overall ERA of potato EH92-527-1. However, the EFSA GMO Panel invites the applicant to improve its search of the literature (i.e., keywords used) according to the EFSA Guidance Document on the methodology for systematic literature reviews (EFSA, 2010).

To conclude, no new data from the GS of potato EH92-527-1 grown in 2011 were provided that would invalidate previous evaluations of potato EH92-527-1 (EFSA, 2006a,b).

5. IDENTITY PRESERVATION SYSTEM

5.1. Summary of the information provided by the applicant

The cultivation and handling of potato EH92-527-1 was governed under an IP system set up by the applicant in order to ensure the quality of potato EH92-527-1 through a system of tracking and records[25]. Potato EH92-527-1 was cultivated under contracts between the applicant and farmers who supplied the potatoes directly to the processors for starch extraction. This IP system mostly relies on manuals, forms (i.e., for packaging and transport of seeds, for receipt of shipment of potatoes) and report forms at all levels of the production process according to strict standard operating procedures (SOPs). An internal audit of the procedure is also foreseen. The applicant also provided a template of the field-plot card-index (Form 5) of the manual for the IP system. Potato EH92-527-1 fields are audited by BASF representatives three times a year.

In 2011, according to the IP system requirements, the applicant also monitored the presence and persistence of potato EH92-527-1 volunteers[26] in all fields cropped with potato EH92-527-1 in 2010 for starch production in the Czech Republic (see Section 2.2.3).

5.2. Assessment by the EFSA GMO Panel

Potato EH92-527-1 is marketed within a closed-loop system: it is cultivated under contract with the applicant who will then supply harvested tubers directly to the processors for starch extraction. The cultivation and handling of potato EH92-527-1 is governed under an IP system, controlled and supervised through manuals, instructions, checklists and report forms at all levels of the production process (EFSA, 2006a,b). The purpose of the IP system is to ensure the quality of potato EH92-527-1 by keeping other potato cultivars separated from it. The EFSA GMO Panel considers that the field-plot card-index (Form 5) of the manual for the IP system is a relevant source of information on the management of potato EH92-527-1 in addition to the farmer questionnaires (see chapter 4.3). The EFSA GMO Panel recommends that the raw data from Form 5 are provided in order to ensure cross-checking with the farmer questionnaires. The EFSA GMO Panel also recommends that the applicant improves Form 5 (i.e., by including reference to a comparator).

5.3. Conclusions and recommendations on the IP system

The EFSA GMO Panel welcomes the IP system as part of the applicant's quality control system. The EFSA GMO Panel is of the opinion that this management system will facilitate GS of potato EH92-527-1.

The EFSA GMO Panel recommends that the raw data from Form 5 are provided in order to ensure cross-checking with the farmer questionnaires (see Appendix 1). The EFSA GMO Panel also recommends that the applicant improves Form 5 (i.e., by including reference to a comparator).

[25] 2011 Monitoring report, Appendix 1
[26] 2011 Monitoring report, Appendix 13

OVERALL CONCLUSIONS AND RECOMMENDATIONS

Following a request from the European Commission to assess the monitoring report of potato EH92-527-1 for the 2011 growing season, the EFSA GMO Panel assessed, in close collaboration with the EFSA SAS Unit, the methodology used by the applicant for the case-specific studies, the GS of potato EH92-527-1 and the specific field study to monitor potential adverse effects on potato-feeding organisms as required in the related Commission Decision. The methodology used for the monitoring of potato EH92-527-1 in 2011 is similar to that used in 2010. Therefore, the EFSA GMO Panel mainly focused on the new 2011 datasets, i.e., data from farmer questionnaires, monitoring of potato-feeding organisms and the new monitoring study for volunteers in fields in which potato EH92-527-1 was grown for starch production in 2010.

The EFSA GMO Panel notes shortcomings in the methodology for GS and the specific field study to monitor potential adverse effects on potato-feeding organisms similar to those identified in the 2010 monitoring report. Hence, the EFSA GMO Panel reiterates the same recommendations for improvement of the methodology used in the PMEM of potato EH92-527-1 as it did in its scientific opinion on the 2010 monitoring report of potato EH92-527-1.

The EFSA GMO Panel also assessed the methodology of a new study monitoring GM volunteers within and around fields cropped with potato EH92-527-1 in 2010. The EFSA GMO Panel identified flaws in the study and therefore makes recommendations to the applicant to improve the study design.

However, from the overall dataset submitted by the applicant in its 2011 monitoring report, the EFSA GMO Panel did not identify any adverse effects on the environment or human and animal health due to potato EH92-527-1 cultivation. The outcomes of this 2011 monitoring report do not invalidate the conclusions of the EFSA GMO Panel's previous opinions on potato EH92-527-1.

DOCUMENTATION PROVIDED TO EFSA

1. Letter from the European Commission, dated 22 May 2012, to the EFSA Executive Director requesting the assessment of Amflora monitoring report, provided by BASF, relating to the 2011 cultivation season.

2. Acknowledgement letter, dated 4 July 2012, from the EFSA Executive Director to the European Commission.

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APPENDICES

A. APPENDIX 1 – SAS[27] TECHNICAL REPORT[28] ON THE EVALUATION OF FARMER QUESTIONNAIRES SUBMITTED IN THE 2011 MONITORING REPORT

METHOD

The evaluation uses criteria developed according to the principles of design for cross-sectional studies, in particular surveys, and that were firstly used for the assessment of the 2009 monitoring report of maize MON 810 (see Appendix 1 of EFSA, 2011b). In July 2011, the EFSA GMO Panel adopted a Scientific Opinion providing guidance on the PMEM of GM plants. The criteria have been updated to reflect the recommendations in this Guidance Document resulting in changes to the instrument design and validity criteria.

These criteria were already used to assess the PMEM report from BASF Plant Science Company GmbH on the cultivation of GM potato EH92-527-1 in 2010 (EFSA, 2012).

Study design principle	Criteria
Sampling frame	1) The sampling frame used is specified 2) The total population included the sampling frame is specified 3) The characteristics of the population included in the sampling frame are described, including region, agricultural practices, GM cultivation 4) The sampling frame coverage is appropriate for GM cultivation in the EU
Sampling method (sample bias)	1) The sampling method to select sample units from the sampling frame is described 2) The sampling method ensures sampling units from representative environments, reflecting the range and distribution of plant production systems and environments exposed to the GM plants and its cultivation are sampled 3) A list of sample units selected from the sample frame is provided 4) The sampling method minimises selection bias
Sample size (sample precision)	1) The size of the adverse effect to be measured is specified and scientifically justified and is within an acceptable limit of change. 2) The significance level is specified and the chosen level is scientifically justified (Type I error rate) 3) The power is specified and the chosen level is scientifically justified (Type II error rate) 4) A literature reference for the sample size method is provided 5) The sample size calculation method is appropriate for a proportion in a cross-sectional study 6) The sample size is sufficient to detect an adverse effect related to GM cultivation

[27] Correspondence: SAS@efsa.europa.eu
[28] On request from EFSA, SAS assistance to Question No EFSA-Q-2012-00643.

Survey response rate (non response bias)	1) Follow-up method for non-responders is described and appropriate 2) Response rate is specified 3) Details of losses in sampling are described 4) The number of partial responses and reasons for non-completion are specified 5) Comparison is made between characteristics of responder group and non-responder group 6) Comparison is made between characteristics of responder group and independent sources of information about the target population 7) The effects of non response bias have been minimised
Instrument design	1) The study design includes considerations to avoid interviewer bias 2) Where interviewers are used the interviewer training is described 3) The selection of open and closed questions is appropriate for the question type 4) The questions are clearly phrased and not open to misinterpretation 5) The questions encourage independent and objective responses 6) The comparator used in the study is described and appropriate for GS 7) The instrument has been previously tested and validated
Instrument validity	1) Content validity – the survey includes questions relevant to assess • Background data Identifier of location of monitoring site and comparator site, surrounding landscape, type of field margins, proximity to conservation areas, cultivation and management of the GM field including recent history and previous cropping, soil (type, structure, quality), nutrient status, fertilization, irrigation. • Data informing on possible change in behaviour and performance of GMP Other GMPs cultivated, number of years of cultivation of GMP, cultivation and tillage from the removal of the previous crop to seed sowing, crop husbandry including sowing/planting date, post planting management, crop emergence, growth (vigour, height), pest, disease and weed management, flowering, standing ability, harvesting date and methods, yield, post-harvest management and subsequent cropping of the site, post-harvest storage, handling, processing, feeding • Data informing on possible ecological/environmental impacts of GMP on the protection goals and measurement Weed and pest populations, observations of other flora and fauna such as insects, birds and mammals, pollination

	and presence of pollinators, health of humans and performance of livestock. • Implementation of specific management requirements Implementation of risk management measures, coexistence segregation measures, stewardship recommendations, specific management due to regional environmental requirements 2) Criterion validity – agronomy parameters reported in the survey are compared with field trial data to test for concurrency 3) External consistency - results from survey are compared to and conform with independent external data sources (for example pest/weed occurrence reports, soil characteristics from geological surveys, authorisations and use reports for plant protection products) 4) Plausibility of responses – results for cultivation methods, agronomy parameters and weed/pest management practices reported in the survey conform to European agricultural practices 5) Construct validity – consistency and agreement between outcome variables is examined
Data validation	1) Data validation procedure are documented 2) Results excluded from the statistical analysis during validation are reported 3) Missing values are reported
Longitudinal aspects	Comparison with survey results from previous years 1) The survey is applied to the sample unit for multiple years in order to assess residual effects
Statistical analysis	1) Objective and hypotheses for analysis are clearly stated 2) A statistical analysis plan is provided 3) Statistical analysis includes analysis of pre-defined sub-groups according to the Guidance Document on PMEM (EFSA, 2011a) - E.g., country 4) Statistical analysis is appropriate for the data types 5) Results are clearly and consistently presented 6) The report should include descriptive statistics for the outcome variables 7) The issue of multiplicity is addressed 8) Method for handing missing values are described 9) Where appropriate confidence intervals should be provided 10) The results of post-hoc analysis should be identifiable
Report conclusions	1) The report conclusions are clearly stated 2) The study design is appropriate to assess the conclusions 3) The data presented supports the conclusions presented in the report

RESULTS

Sampling frame

In 2011, potato EH92-527-1 was grown in five locations: four locations in Sweden and one Germany.

All potato EH92-527-1 growers for the five locations in the European Union completed the farmer questionnaire. Since this is a census, the sampling frame assessment criteria is not relevant.

Sampling method

All potato EH92-527-1 growers for the five locations in the European Union completed the farmer questionnaire. Since this is a census, the sampling method assessment criteria is not relevant.

Sample size

All potato EH92-527-1 growers for the five locations in the European Union completed the farmer questionnaire. Since this is a census, the sample size assessment criteria is not relevant.

Survey response rate

All potato EH92-527-1 growers for the five locations in the European Union completed the farmer questionnaire, the response rate is 100%.

Instrument design

1) Interviewer bias

It is not clear in the Annex 7 of the 2011 monitoring report if interviewers were used for this survey of not. The report states that "*The farm questionnaires were completed by the farmers throughout the growing season*". The method of completion of the questionnaires should be explicit in the annual monitoring report. However all growers were required to participate in the Identity Preservation (IP) system and trained in the IP system procedures. The IP system exists to "*assure the quality of the subject product through a system of tracking and records*". The IP system procedures included the requirement to complete documentation throughout the starch potato production process, in particular the field-plot card-indices (Form 5[29]) were to be completed recording the agricultural management of the crop, agronomic parameters and general observations during the growing season. This document is used to support the completion of the farmer questionnaire and should ensure that the responses accurately reflect the events during the growing season.

2) Interviewer training

If no interviewers were used, the requirement for interviewer training is not relevant.

3) Question type

The questionnaire contains 18 closed questions which require a comparison between the potato EH92-527-1 variety and similar varieties and represent the monitoring characteristics analysed in the report. For these questions the response options are "As usual" or "Plus" or "Minus". Where the response is not "as usual" there is an option to provide more details as free text. There is also a mix of closed and open questions to gather additional information about the agricultural practices on the farm. The combination of open and closed questions allows quantitative analysis of the 18

[29] 2011 Monitoring report, Appendix 1

monitoring characteristics, plus where the result is not "As usual" explanatory analysis can be performed using the information from the free text questions.

4) Phrasing of questions

The questionnaire uses questions based on farm records and should be understood by a grower. As part of the IP system the growers complete Form 5 to record information on the management of the potato EH92-527-1, this is then used as a basis for the completion of the farmer questionnaire. It would be of value to align Form 5 with the farmer questionnaire and ensure information relating to disease susceptibility and the general farm environment are recorded.

5) Independent and objective responses

Overall the questionnaire seeks to obtain an objective set of responses to summarise the results and experiences during the growing season for starch potatoes.

6) Comparator

The questionnaire records the conventional varieties and number of starch potato varieties planted in 2011. A modification to the questionnaire used in 2011 (compared with the questionnaire used in 2010), allows the farmer to specify if the comparator is the Amflora variety description or general experience in potato cultivation when no starch potatoes are grown. Annex 7 states "*At two farms no conventional potato variety was planted. No other starch potatoes were cultivated at all farms. During this survey the Amflora potato cultivation was compared with general experience in potato cultivation at all farms*." This is in alignment with Form 5 of the IP system documents which requires only "*General observations during the vegetation period*". The EFSA GMO Panel considers that non-GM starch-potato crops or conventional potato crops, grown nearby with similar cultivation conditions (i.e. seeds production) and pest management practices, are the most appropriate comparators. If these are not available then an historical baseline could be considered (EFSA, 2011a).

7) Validation of the instrument

The original farmer questionnaire was developed by the German Federal Biological Research Centre and Forestry, maize breeders and statisticians in Germany and the results of the pilot of this questionnaire were published in 2004 (Wilhelm et al., 2004a,b). A version of the questionnaire has been used in annual monitoring reports 2001-2010 for maize MON 810 and the design principles of GM maize questionnaire are described in the report by Schmidt et al. (2008). The questionnaire used for monitoring of potato EH92-527-1 in 2010 is based on the GM maize questionnaire but adapted for the production of starch potatoes (EFSA, 2012).

Instrument validity

1) Content validity

- Background data

Background data relating to geographical location in local land registry, soil type and composition, weather during the growing season, fertiliser treatments and irrigation is collected by the questionnaire.

- Data informing on possible change in behaviour and performance of GMP

The monitoring characteristics Sprouting, Time to emergence, Plant growth, Phenotype, Success of weed control, Pest susceptibility, Success of pest control, Disease susceptibility, Success of late

blight control, Success of disease control, Maturity, Date of harvest and Yield seek to obtain data on change in behaviour and performance of potato EH92-527-1. There are no questions relating to changes in agricultural practices as a result of growing potato EH92-527-1 compared to conventional starch potato production. Changes in volumes of inputs (e.g., pesticides[30], fertilisers) would be an indication of changes in the sustainability of the production system, it may be of value to expand the questionnaire to assess if the cultivation of potato EH92-527-1 results in a change in inputs to the production system compared to conventional starch potato production.

- Data informing on possible ecological/environmental impacts of GMP on the protection goals and measurement

The monitoring characteristics Weed pressure, Occurrence of pests, Occurrence of disease, Late blight pressure and Presence of wild animals seek to obtain information on possible ecological/environmental impacts of potato EH92-527-1 on protection goals. Occurrence of volunteers is an important monitoring characteristic, the results of the 2011 Monitoring for Volunteer potatoes is presented as a separate study[31] with on-field observations. There are no questions to obtain information on the health of people handling potato EH92-527-1 plants and tubers during the production process. Consideration should be given to the inclusion of a question relating to health effects in particular allergenicity. For a potato crop it may be of value to include a question relating to occurrence of soil biota.

- Implementation of specific management requirements

There are no questions relating to this topic in the farmer questionnaire but information relating to adherence to good agricultural practices is captured by the IP system.

2) Criterion validity

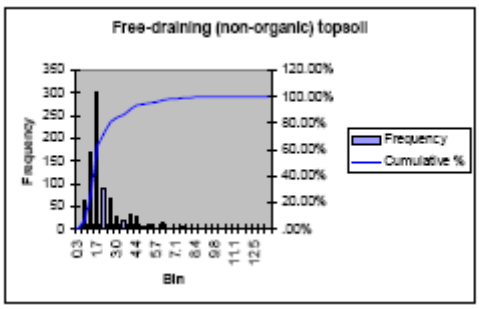
In the Scientific Opinions of the EFSA GMO Panel on potato EH92-527-1 (EFSA, 2006a,b), the section of comparative analysis states the following *"In addition to the intended alterations in starch composition of the GM potato, some statistically significant differences between the GM potato and its control were observed each year, including a decrease in yield and dry matter and an increase in sucrose content (1.7g/100g in the GM potato versus 1.2g/100g in parental cultivar) and vitamin C content (67 mg/100g in the GM potato versus 49 mg/100g in parental cultivar). With regard to yield, additional data on potato EH92-527-1 tested during starch production trials in 1998-2000 shows similar values for yield compared with equivalent potato cultivars."* For the field trials the parent cultivar Prevalent was used as a comparator. The plant variety registration documents (Community Plant Variety Office 2003) record that in the Swedish field trials the potato EH92-527-1 variety was classified as late (grading 7) for time at which the plant matures. Comparing field trial data with the farmers' survey data provides an opportunity to check the validity of the farmer's responses. Discrepancies between field trial data and the questionnaire could also be explained by the fact that the conventional crops grown on the farms differ[32] from the comparator variety used in the field trials or the GM crop is performing differently in farm scale cultivation. A reduction in yield was observed in the field trials and in the results of the farmers' survey indicating concurrency between the farmer's responses and the field trial data presented for the authorisation process. However for plant maturity concurrency with the variety registration trials is not demonstrated as maturity was classified as "as usual" for all locations in the 2011 farm survey.

[30] http://ec.europa.eu/sanco_pesticides/public/index.cfm?event=activesubstance.selection
[31] 2011 Monitoring report, Appendix 13
[32] Note: the parental variety Prevalent is no longer cultivated in the EU.

3) External consistency

Comparison of the data reported in the survey with information from independent data sources provides a further opportunity to test the validity of the responses.

The information on soil quality offers the opportunity to compare with the information held in the European Soil Portal. Figure 1 shows the information on top soil organic carbon contained in The Soil Profile Analytical Database for Europe (SPADE-2) (Hollis et al 2006). The potato EH92-527-1 survey reports humus content values between 2.5 and 7.8 for four of the locations. It can be seen that this range falls within that of the SPADE-2 range for organic carbon content. Soil pH was reported in all locations, with values between 5.6 and 6.6. This is comparable with the estimated values of pHCaCl2 for the EU27 MS and some adjacent countries presented in Soil pH in Europe map (JRC). It should be noted that the European Soil Portal provides a useful datasets for European soil properties but that the values are derived from a limited set of soil samples for each EU country.



Mean	1.983665
Standard Error	0.051215
Median	1.5
Mode	1.5
Standard Deviation	1.494919
Sample Variance	2.234783
Kurtosis	9.998333
Skewness	2.648682
Range	13.1
Minimum	0.3
Maximum	13.4
Sum	1690.082
Count	852
Confidence Level(95.0%)	0.100523

Figure 1: Distribution and descriptive statistics of topsoil organic carbon contents in SPADE-2 for free draining non-organic soils

The report includes a list of diseases other than late potato blight that were observed in 2011 and could be used to check for external consistency. In Table 1 the reported diseases from the farm questionnaire are compared with the known distribution of these diseases in Europe as reported in the Crop Protection Compendium (CABI, 2011a,b). For the reported diseases in the survey there is a correspondence between the diseases reported and the known distribution of the diseases according to the Crop Protection Compendium.

Table 1: Reported diseases and known distribution

Reported diseases	*Known Distribution*	*Locations were disease was reported*
Blackleg	Present in DE, SE	DE, SE
Potato virus Y	Present in DE, SE	DE, SE
Rhizoctonia solani (Thanatephorus cucumeris)	Present in DE, SE	DE, SE
Potato leaf roll virus	Present in DE	DE

The report records the average annual rainfall for 1961-1990 to be between 550 and 580 mm per year in the five locations. The average annual rainfall values are comparable with the averaged values 1940-1995 published in the Average annual precipitation in the EEA area map (EEA, 2003). The annual rainfall in 2011 is not requested, but could have been used as additional evidence for the assessment in four locations for the characterisation of the rainfall during the growing season as "above average – damp".

Overall there is good agreement between the farmers' responses in the survey and information from external data sources for soil properties, weather and disease distribution and this provides evidence for external consistency for the potato EH92-527-1 survey. It would be of value to include external consistency checks in the report to provide evidence of the validity of the survey responses.

4) Plausibility of responses

The dates of key events in the management of the potato EH92-527-1 crop were collected through the farmer questionnaire (Table 2). The sequence of events indicates the dates are plausible.

Table 2: Earliest and latest dates for management of potatoes EH92-527-1 in 2011

Event	*Earliest date*	*Latest date*
Application mineral fertilisers	March 2	June 22
Planting	May 7	June 15
Ridge formation	May 7	July 5
Disease control	May 7	July 29
Application herbicides	May 25	August 4
Application insecticides	May 29	August 24
Emergence	May 30	July 15
Late blight control	June 20	August 24
Harvest	August 31	October 2

5) Construct validity

The genetic modification results in the inhibition of the granule bound starch synthase protein (GBSS) and results in an increase in the amylopectin/amylose ratio. The report states that "*Evident deviations from this baseline pattern are observable for the characters date of harvest and yield. This clearly can be explained by weather conditions, as it was specified in the farmers' explanations or in the influencing factors (rain fall, temperature)*". It is possible that the modification to starch biosynthesis could result in a slower growing crop and reduced yield, however these characteristics would also be affected by local conditions and management. Farmers in four locations reported above average rainfall. The survey responses indicate consistency and agreement among outcome variables.

Data validation

1) Validation procedures

Section 2.5 of Appendix 7 of the 2011 monitoring report describes the data management and quality control procedures. It states that "*For not readable entries in the questionnaires, queries were formulated and the field representatives or farmers were asked for explanation. These entries*

in the database were corrected". The number of questionnaires which require further clarification with the farmers should be included in the report, including a classification by error types.

Cross-checking of results between Form 5 and the farmer questionnaire should also be performed and presented. The responses in the farmer questionnaire should correlate with the information recorded during the growing season through the IP system.

2) Exclusion of results

All completed questionnaires (5) were included in the analysis.

3) Missing values

For each of the 18 monitoring characteristics there were no missing values.

Longitudinal aspects

1) Sampling over multiple years

The 2011 monitoring report does not indicate whether potato EH92-527-1 cultivation occurred in the same farms in 2010 and 2011. The IP system specifies a four year crop rotation for the cultivation of potatoes in fields where potato EH92-527-1 has been grown, therefore potato EH92-527-1 cultivation should not have occurred in the same field in 2010 and 2011.

Statistical analysis

1) Objective and hypotheses

Appendix 7 of the 2011 monitoring report states

"Questions on monitoring characters are formulated in such a way that farmers give their assessment on the behaviour of the GM potato compared to conventional (starch) potatoes, and therefore with three possible answers (Plus/ As usual/ Minus). The Plus and Minus answers indicate a deviation from experiences in cultivation of conventional (starch) potatoes. Each Plus or Minus assessment must be provided with an explanation for this assessment. High frequencies (> 10% of answers from all farmers for respective question) of Plus or Minus answers would indicate possible effects."

2) Statistical analysis plan

Section 2.4 of Appendix 7 of the 2011 monitoring report describes the statistical analysis plan. For each of the monitoring characteristics there are three possible responses "As usual", "Plus" or "Minus". The proportion of responses and the 99% upper confidence intervals are calculated. If the upper confidence bound does not exceed the 10% threshold then no effect is assumed, if the upper confidence bound exceeds 10% an effect is possible and should be further examined. It would be expedient to provide scientific references to support the selection of the 10% threshold.

3) Pre-defined sub-groups

The analysis was performed for all five locations surveyed in 2011.

4) Statistical analysis

The report states that the confidence intervals were calculated using the methodology published in Rasch D, Herrendörfer G, Bock J, Victor N, Guiard V (2007) - Verfahrensbibliothek Versuchsplanung und auswertung, Oldenbourg Verlag München. This method was also used in the

2010 monitoring survey. In that context, in response to a request for additional information, the applicant provided the formula for the confidence intervals (shown below) (see EFSA, 2012).

$$p'_{upper} = \frac{(k-1)F[2(k+1); 2(n-k); 1-\alpha]}{n-k+(k-1)F[2(k+1); 2(n-k); 1-\alpha]}$$

where:
n = sum of all answers
k = frequency of Plus or Minus answers
α = 0,01
F = quantile of F distribution

Figure 2: Formula for Estimate of a probability (Binomial Distribution)

This method assumes a binomial distribution, however there are three possible responses ("As usual", "Minus" or "Plus"), therefore confidence intervals should be estimated based on a multinomial distribution. In addition for the F distribution the degrees of freedom are strictly greater than zero and therefore using this binomial method the lower bound is set to zero for categories with no responses.

5) Results presentation

For each monitoring characteristic measured by the survey a table of the responses is provided with percent plus a bar chart of the frequency of responses.

6) Descriptive statistics

Descriptive statistics are provided for the continuous outcome values size of farm, area of potatoes, area of potato EH92-527-1, size of field, soil properties, planting, ridge formation and emergence dates. The analysis of the categorical monitoring characteristics is provided in frequency tables.

7) Multiplicity

The analysis calculated 99% upper bound confidence intervals for eighteen monitoring characteristics. No adjustment for multiplicity of testing is specified.

8) Handing missing values

Not applicable since for the 18 monitoring characteristics as there were no missing values.

9) Confidence intervals

Upper 99% confidence intervals were calculated for the "Minus" and "Plus" responses. Upper and lower confidence intervals should be calculated for all three possible responses using a multinomial distribution. If the lower confidence interval exceeds the biologically relevant threshold this indicates an effect that should be further examined.

10) Post-hoc analysis

Post-hoc analysis has only been performed when an effect has been identified and further explanatory analysis is possible using less structured information (e.g., free text collected in the questionnaire).

Report conclusions

1) Report conclusions

Appendix 7 of the 2011 monitoring report contains the following conclusions:

"A total of five farm questionnaires addressing the different monitoring characters were collected from all growers participating in the IP system for cultivation of Amflora potato, and analyzed. An evaluation of the monitoring characters that were rated as usual or were deviating from what is in general observed for potato cultivation by the growers allowed the following conclusions. 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 (later harvest, lower yield) were clearly a consequence of adverse weather conditions and other influencing factors, and none of them were considered as adverse effects."

2) Study design

The survey seeks to evaluate a set of monitoring characteristics relating to plant performance and management practices to determine whether potato EH92-527-1 differs from conventional varieties by a threshold of 10%. The report states that *"During this survey the Amflora potato cultivation was compared with general experience in potato cultivation at all farms."* This means that the assessment as to whether the potato EH92-527-1 in 2011 growing season is "As usual" may be subject to recall bias and assessments relating to season specific characteristics may be invalid. In addition the comparison is being made between different potato production systems (conventional versus starch production) which may vary in terms of agricultural inputs and management practices. All growers of potato EH92-527-1 in 2011 completed the farmer questionnaire, in total five locations were sampled. For all monitoring characteristics the upper confidence intervals exceeded the 10% threshold, therefore an effect could not be excluded for any of the monitoring characteristics. Due to the very limited number of locations growing potato EH92-527-1, the survey cannot provide evidence for the absence of an effect. To improve the assessment of possible effects the number of locations surveyed could be increased by pooling with the results of past and future farmers' surveys.

3) Substantiation of results

The previous assessment of the 2010 monitoring report (EFSA, 2012) recommended pooling of results since the number of locations in the survey was small. An analysis of the pooled results is presented. The method to estimate upper and lower credible intervals is the same as that used for the assessment of the 2010 monitoring report (EFSA, 2012), using the Bayesian multinomial model due to the large number of monitoring characteristics with "Plus" or "Minus" responses equal to zero. The 95% credible interval describes the uncertainty about the result based on the observations obtained from the survey. The results from the 2010 and 2011 farmers' survey were simply combined and an uninformative Dirichlet prior distribution (continuous multivariate probability distribution bounded between 0 and 1) was used (see Figure 3). Since the 2011 survey contains scarce information (only 5 locations), the estimated posterior likelihood is largely defined by the data obtained from the 26 locations in 2010. The uncertainty about the results is large due to the limited number of locations available for the survey and consequently the results cannot provide evidence for the absence of an effect.

Both lower yield and delayed harvest clearly exceed the 10% threshold indicating a difference between potato EH92-527-1 and general experience in potato cultivation. In locations reporting "As usual" the yield was from 12-31.02 t/ha and for lower yield the range was between 3-28.74 t/ha. In locations reporting "as usual" for date of harvest the reported dates ranged from 31/08/2011-25/09/2011 and for locations reporting delayed harvest the reported dates ranged from 27/09/2011-02/10/2011. The report states that this can be explained by unfavourable weather

conditions, however comparisons of this type are difficult to substantiate when the comparator is not a conventional crop grown in the same year. Lower yield was also observed in the field trials performed during the authorisation process and late maturity is a property recorded for the potato EH92-527-1 variety. Since the genetic modification changes starch biosynthesis, it is possible that lower yield and slower plant development is a property of the potato EH92-527-1. Lower yield and delayed harvest do not represent an adverse effect for the environment.

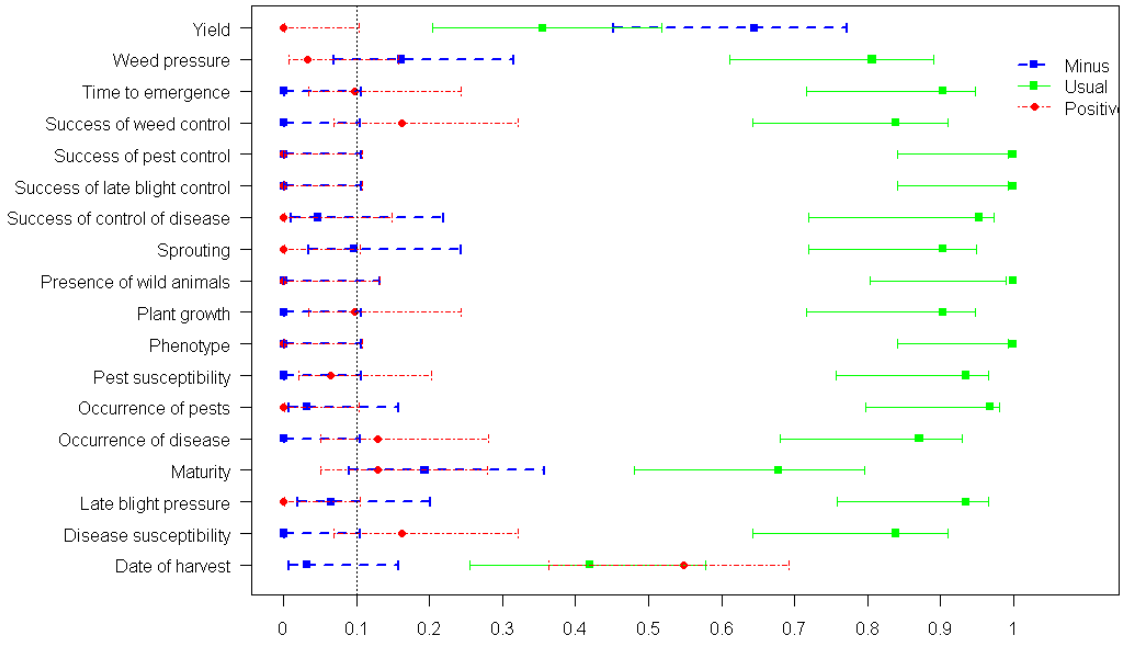


Figure 3: Proportions and Credible Intervals (95%) for the Monitoring Characteristics reported in the 2010 and 2011 farmer questionnaires on potato EH92-527-1 with an uninformative prior

RECOMMENDATIONS AND CONCLUSIONS

From the data provided in the 2011 farmers' survey to monitor adverse unanticipated effects associated with the cultivation of potato EH92-527-1, no adverse effect can be identified. However a number of improvements to the survey design and reporting have been identified and are listed in the recommendations below:

- The design of the farmer questionnaire relies on a comparison between potato EH92-527-1 and a comparator variety to detect unanticipated effects. In 2011 for the five locations, the comparison was based on general experience in potato. The EFSA GMO Panel considers that non-GM starch-potato crops or conventional potato crops, grown nearby with similar cultivation conditions (i.e. seed production) and pest management practices, are the most appropriate comparators. If these are not available then an historical baseline could be considered (EFSA, 2011a);

- Changes in volumes of inputs (pesticides, fertilisers, etc) would be an indication of changes in the sustainability of the production system, it may be of value to expand the questionnaire to assess if the cultivation of potato EH92-527-1 results in a change in inputs to the production system compared to conventional starch potato for seed production;

- Where accessible data sources exist the responses in the survey should be compared with alternative data sources to check the validity of the farmer's responses. The results of criterion validity and external consistency checks should be included in the report;

- Upper and lower confidence intervals or credible intervals for each of the responses for the monitoring characteristics should be included in the statistical report. The estimate of these intervals should be based on a multinomial distribution since there are three possible responses for each monitoring characteristic;

- The 2011 farmers' survey cannot provide evidence for the absence of an effect due to the limited number of locations where potato EH92-527-1 was grown in 2011. To improve the assessment of unanticipated effects, pooling the results of past and future farmers' surveys should be considered and suitable analysis techniques selected. This would require a consistent survey methodology and questionnaire format.

B. APPENDIX 2 – R CODE FOR THE ESTIMATION OF CREDIBLE INTERVALS FOR THE MONITORING CHARACTERISTICS OBTAINED IN THE POTATO EH92-527-1 2010 AND 2011 SURVEY

```
multiEH92-527-1<-function(input,a,nt){

## Setting the working directory ##

setwd("H:/R/EH92-527-1")

## Installing a package that is needed to run the model##

## install.packages("BRugs_0.5-3.zip",repos=NULL,dependecies=TRUE)

library(BRugs)

### Writing the Bayesian multinomial model ###

modelEH92-527-1<-function(){

        y[1:k]~dmulti(theta[1:k],n)

        theta[1:k] ~ddirch(alpha[1:k])

        }


filename <- file.path("modelEH92-527-1.txt")

## write model file:

writeModel(modelEH92-527-1, filename)


### Bayesian Approach for multinomial model ###

### The input data is                ###

mydata <- pairlist(k=length(input),alpha=rep(1,length(input)),y=input,n=sum(input))


namedat<-paste("simdat.txt",sep="")


### Creating a txt file with the data ###

dput(mydata, namedat, control=NULL)


## some usual steps (like clicking in WinBUGS):
```

```
modelCheck("modelEH92-527-1.txt") # check model file

modelData(namedat) # read data file

modelCompile(numChains=2) # compile model with 2 chains

modelGenInits()

modelUpdate(5000) # burn in

samplesSet(c("theta")) # parameters to be monitored

modelUpdate(10000,thin=20) # 10000 more iterations ....

out<-as.matrix(buildMCMC("theta"))

corrci<-apply(out,2,function(x) {quantile(x,prob=c((a/(2*nt)),0.025,0.5,0.975,(1-(a/(2*nt)))))})

EH92-527-1stat<-samplesStats("*") # the summarized results

return(list(EH92-527-1stat[,c(1,4:6)],corrci))

}


multiEH92-527-1(as.numeric(input[1,2:4]),a=0.05,nt=dim(input)[1])


## Calculating the lower and upper bounds  ##

setwd("H:/R/EH92-527-1")

input<-na.omit(read.table("EH92-527-1Results.txt",sep="\t",header=T))

out<-hout<-list()

for (i in 1:dim(input)[1]) {

                        out[[i]]<-multiEH92-527-1(as.numeric(input[i,2:4]),a=0.05,nt=dim(input)[1])

                        }

names(out)<-input[,1]


prop<- matrix(c(input$Minus/(input$Minus + input$Usual + input$Plus), input$Usual/(input$Minus +
input$Usual + input$Plus), input$Plus/(input$Minus + input$Usual + input$Plus)), ncol = 3)

prop
```

```
## Ploting  credible intervals with Bonferroni type of corrections ##

par(mar=c(3,12,4,4),las=2)

plot(out[[1]][[2]][3,],rep(1,3),type="p",pch=c(10,15,19),xlab="probability",ylab="",xlim=c(0,1.07),yli
m=c(0.75,17),xaxt="n",yaxt="n",col=c("blue","green","red"))

for (i in 1:dim(input)[1]){

        points(prop[i,1],i, pch=15,col="blue")

        points(prop[i,2],i, pch=15,col="green")

        points(prop[i,3],i, pch=15,col="red")

        ##points(out[[i]][[2]][3,],rep(i,3),pch=c(10,15,19),col=c("blue","green","red"))##

        arrows(out[[i]][[2]][1,1],i,out[[i]][[2]][5,1],i,lty=2,col="blue",angle=90,length=0.04,code=3,l
wd=2)

        arrows(out[[i]][[2]][1,2],i,out[[i]][[2]][5,2],i,lty=1,col="green",angle=90,length=0.04,code=3,l
wd=1)

        arrows(out[[i]][[2]][1,3],i,out[[i]][[2]][5,3],i,lty=4,col="red",angle=90,length=0.04,code=3,lw
d=1)

}

abline(v=0.1,lty=3)

axis(2,1:dim(input)[1],input[,1])

axis(1,(0:10)/10,(0:10)/10,las=1)

legend(0.95,17.5,c("Minus","Usual","Positive"),lty=c(2,1,4),lwd=c(2,1,1),col=c("blue","green","red"),
pch=c(10,15,19),bty="n")
```