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 2010[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 2010 cultivation season of GM potato EH92-527-1 (variety Amflora) provided by BASF. The EFSA GMO Panel assessed, in close collaboration with the EFSA Unit for Scientific Assessment Support, the methodology applied by the applicant for the four case-specific studies, the General Surveillance (GS) of potato EH92-527-1 and the field study to monitor potential adverse effects on potato-feeding organisms. From the overall dataset submitted by the applicant in its 2010 Amflora monitoring report, the EFSA GMO Panel does not identify adverse effects on the environment, human and animal health due to potato EH92-527-1 cultivation during the 2010 growing season. The outcomes of the 2010 Amflora monitoring report do not invalidate the previous EFSA GMO Panel's risk assessment conclusions on potato EH92-527-1. Nevertheless, the EFSA GMO Panel notes a number of weaknesses in the methodology for GS and therefore gives specific recommendations for improvement of the strategy, methodology and reporting for GS of potato EH92-527-1. Concerning the field study on potato-feeding organisms as required in the related Commission Decision, the EFSA GMO Panel makes recommendations in order to improve the study. However, the EFSA GMO Panel considers the GS framework as a more proportionate alternative for collecting relevant information on potato-feeding organisms.

KEY WORDS

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

[1] On request from European Commission, Question No EFSA-Q-2011-00761, adopted on 26 January 2012.

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SUMMARY

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 2010 cultivation season of GM potato EH92-527-1 (variety Amflora) provided by BASF. The EFSA GMO Panel assessed, in close collaboration with the EFSA Unit for Scientific Assessment Support, the methodology applied by the applicant for the Case-Specific Monitoring (CSM), the General Surveillance (GS) of potato EH92-527-1 and the study on potato-feeding organisms as requested in the related Commission Decision (EC, 2010).

Firstly, although the EFSA GMO Panel did not recommend CSM (EFSA, 2006a,b), the EFSA GMO Panel assessed the four case-specific studies submitted by the applicant in order to *verify a set of assumptions that were made during the Environmental Risk Assessment and their confirmation over a defined monitoring period.* The EFSA GMO Panel concludes that these four case-specific studies do not provide scientific evidence that would invalidate the previous safety evaluations of potato EH92-527-1 (EFSA, 2006a,b).

In response to this mandate from the European Commission, the EFSA GMO Panel assessed the appropriateness of the applicant's approach 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 concludes that the hypothesis set by the applicant in response to the request in the related Commission Decision cannot be answered by the study design and method used by the applicant. Hence, to test the hypothesis as set-up by the applicant, the EFSA GMO Panel makes comments and recommendations in order to improve the study. Alternatively, the EFSA GMO Panel considers that the GS framework is a more proportionate way to collect relevant information on potato-feeding organisms and therefore recommends the applicant to further elaborate the farmer questionnaire.

Concerning GS, the EFSA GMO Panel paid particular attention to the design and analysis of the farmer questionnaires and gives recommendations to the applicant in order to improve the design and reporting of the farmers survey. In addition, the EFSA GMO Panel considered the information collected by national surveillance authorities, the literature review as well as the identity preservation system set up by the applicant. The EFSA GMO Panel concludes that the 2010 analysis of the farmer questionnaires on potato EH92-527-1, the observations by national surveillance authorities and the literature review do not indicate any adverse environmental impacts associated with the cultivation of potato EH92-527-1. However, the EFSA GMO Panel notes a number of shortcomings in the methodology for GS. Hence, this Scientific Opinion gives specific recommendations to the applicant for improvement of the strategy, methodology and reporting for GS of potato EH92-527-1. The applicant should also take into consideration the guidance provided by the EFSA GMO Panel in its 2011 Scientific Opinion on Post-Market Environmental Monitoring of Genetically Modified (GM) plants (EFSA, 2011a).

From the overall dataset submitted by the applicant in its 2010 Amflora report, the EFSA GMO Panel does not identify adverse effects on the environment, human and animal health due to potato EH92-527-1 cultivation during the 2010 growing season. The outcomes of the 2010 Amflora report do not invalidate the previous EFSA GMO Panel's risk assessment conclusions on potato EH92-527-1 (EFSA, 2006a,b).

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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) 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 risk that required 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).

Hence, potato EH92-527-1 (variety Amflora) 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. Commission Decision 2010/135/EU requires 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 (EC, 2010). 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.

Consequently, BASF Plant Science submitted to the European Commission its first Post-Market Environmental Monitoring (PMEM) report for the 2010 growing season 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 (variety Amflora) in 2010. The EFSA 'Standing Working Group on the annual PMEM reports' was commissioned to assess the Amflora monitoring report for the 2010 growing season. On 28 September 2011, the aforementioned Working Group required additional information which was received on 24 November and 15 December 2011.

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION AND EFSA

On 10 May 2011, the EFSA GMO Panel received a request from the European Commission "*to assess the Amflora monitoring report for the 2010 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 indicate 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 2011*."

Aiming at a comprehensive assessment of the monitoring report, EFSA asked the European Commission and the applicant to provide missing information such as the comments raised by Member States on the report and clarifications on the methodology, respectively. The EFSA GMO Panel committed to complete its evaluation of the report within a period of time of five months, starting from the reception date of the missing information.

On 5 July 2011, the EFSA GMO Panel received a complementary request from the European Commission to consider the Amflora monitoring report for the 2010 cultivation season in light of its 2011 Scientific Opinion providing guidance on PMEM of GM plants.

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 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. A gene conferring kanamycin resistance (*npt*II) 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 and was cultivated for starch production in the Czech Republic, and for seed potato production in Germany and Sweden in 2010. Hence, 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 of the cultivation of potato EH92-527-1.

Against this background, the EFSA GMO Panel was asked by the European Commission to assess the annual PMEM report submitted by the applicant on the cultivation of potato EH92-527-1 in 2010 (hereafter referred to as '2010 Amflora report'). During the 2010 growing season, the applicant monitored the potato EH92-527-1, including

(1) **Case-Specific Monitoring** (CSM) based on the verification of a set of assumptions that were made during the ERA,

(2) 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) **General Surveillance** (GS) including the analysis of the questionnaires answered by farmers in the EU Member States where potato EH92-527-1 was cultivated in 2010,

(4) **Identity Preservation (IP) system** in order to assure the quality of the potato EH92-527-1 through a system of tracking and records.

In preparing the present Scientific Opinion, the EFSA GMO Panel took into consideration various sources of information such as the comments from Member States on the 2010 Amflora report, previous work by the Monitoring Working Group[4] set up by the European Commission, most recent scientific data and relevant peer-reviewed publications.

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., statistical analysis of the farmer questionnaires).

During its assessment of the 2010 Amflora report, the EFSA GMO Panel identified shortcomings, including the lack of information (e.g., raw data, reports from national surveillance authorities). Upon request of the EFSA GMO Panel, the applicant provided clarifications and additional data on 24 November and 15 December 2011.

In the present Scientific Opinion, the EFSA GMO Panel assesses the 2010 Amflora report (see chapters 2.2, 3.2, 4.2 and 5.2), with particular emphasis on the methodology suggested by the

[4] Available at http://ec.europa.eu/food/food/biotechnology/index_en.htm

applicant (see Appendices 1&2). The EFSA GMO Panel also considers the relevance and implications of the 2010 PMEM results on the previous safety assessment of potato EH92-527-1 (EFSA, 2006a,b).

Finally, based on its evaluation of the 2010 Amflora report, the EFSA GMO Panel makes specific recommendations to the applicant on the strategy, methodology and reporting for PMEM (see chapters 3.3, 4.3 and 5.3) that supplement the guidance provided in its 2011 Scientific Opinion on PMEM of GM plants (EFSA, 2011a).

2. Case-Specific Monitoring

2.1. Summary of the information provided by the applicant

In the initial notification[5] C/SE/96/3501 and application EFSA-GMO-UK-2005-14, the applicant submitted a 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*[6]*'*. 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 the potato EH92-527-1 tuber. The applicant considered post-market monitoring as an opportunity to confirm these assumptions under different environmental and agronomic conditions and/or over a longer period in time.

In its 2010 Amflora report, the applicant therefore provided four case-specific studies and concluded that

(1) An event-specific PCR assay of potato EH92-527-1 seed tubers confirms the presence of the EH92-527-1 insert, hence the identity of potato EH92-527-1 seed potatoes and their genetic stability[7];

(2) The phenotypic stability of the amylopectin trait in potatoes EH92-527-1 was confirmed via iodine staining of the starch granules[8];

(3) The absence of expression of the identified ORF4 is confirmed via Western blot analysis[9];

(4) A compositional analysis[10] confirms that the glycoalkaloid content of potato EH92-527-1 tubers is in the range of values as obtained in previous studies.

2.2. Assessment by the EFSA GMO Panel

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 risk nor 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 which have been identified in the ERA.

[5] Notification C/SE/96/3501, Appendix 43
[6] 2010 Amflora report, Section 3.2, page 11
[7] 2010 Amflora report, Appendix 8
[8] 2010 Amflora report, Appendix 10
[9] 2010 Amflora report, Appendix 9
[10] 2010 Amflora report, Appendix 11

However, in response to this request by the European Commission (see Terms of Reference), the EFSA GMO Panel assessed the four case-specific monitoring studies as provided by the applicant.

2.2.1. Confirmation of identity of seed potatoes EH92-527-1 grown in 2010 via PRC analysis[11]

The aim of the confirmation of identity of seed potatoes EH92-527-1 was to check the presence of the EH92-527-1 insert in the potato EH92-527-1 seed tubers grown in a total of 18 locations in Sweden and one location in Germany. Therefore DNA was extracted from a total of 82 potato EH92-527-1 pooled tuber samples, consisting of a total of 800 individual potato tubers. An EH92-527-1 event-specific quantitative real time PCR (qPCR) was used to confirm the identity of the tubers.

The EFSA GMO Panel finds this method adequate for the confirmation of identity of seed potatoes EH92-527-1.

2.2.2. Expression[12] of open reading frame 4 (ORF4) in tubers of seed potatoes EH92-527-1 grown in 2010

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 2010 Amflora 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 2010. A total of 82 pooled potato EH92-527-1 samples were analysed by western analysis using ORF4-specific antibodies raised against bacterial recombinant ORF4 protein. The limit of detection was 0.1 ng of the protein.

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

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

2.2.3. Stability[13] of the amylopectin trait in tubers of starch potatoes EH92-527-1 grown in 2010

Potato EH92-527-1 tubers have over 96% amylopectin content in the tuber starch fraction, due to the reduction of amylose synthesis. The purpose of the analysis was to confirm that starch potato EH92-527-1 tubers maintained the intended amylopectin trait. A total of 28 pooled potato EH92-527-1 samples and 8 pooled conventional potato tubers, each consisting of 10 individual tubers, were analysed by starch extraction and staining with Lugol's iodine solution. The phenotypic stability was proven.

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. The EFSA GMO Panel is also of the opinion that the loss of the high amylopectin trait would not represent a safety issue.

2.2.4. Compositional analysis

The most important natural toxins in potatoes are the glycoalkaloids. Their total level in table potatoes should not exceed 200 mg/kg fresh weight (Slanina, 1990). The glycoalkaloids are compounds composed of a common aglycone and a branched trisaccharide. Not more than a few percent of the glycoalkaloids in table potatoes are other compounds than α-solanine and α-chaconine. The latter two usually occurring in a ratio of approximately 1:1.5-2. In α-chaconine the trisaccharide is β-chacotriose (bis-α-L-rhamnopyranosyl-β-D-glucopyranose) attached to the 3-OH group of the aglycone solanidine, whereas in α-solanine it is β-solatriose (α-L-rhamnopyranosyl-β-D-glucopyranosyl-β-

[11] 2010 Amflora report, Appendix 8
[12] 2010 Amflora report, Appendix 9
[13] 2010 Amflora report, Appendix 10

galactopyranose) attached to the 3-OH group of solanidine. Thus both types of glycoalkaloids contain the same aglycone but different sugar moieties. In addition to the two main glycoalkaloids α-chaconine and α-solanine, potatoes may contain small amounts of β_1-chaconine, β_2-chaconine, γ-chaconine, β_1-solanine, β_2-solanine, γ-solanine and solanidine. All of these may be formed by acid and enzymatic hydrolysis of α-chaconine and α-solanine. As enzymes catalysing the step-wise degradation of the trisaccharide moieties on the glycoalkaloids are available in the potato tuber, it is important to handle the tuber material properly during sample preparation before chemical analysis in order to get a correct picture of the glycoalkaloid composition of the tuber.

The chemical analysis for glycoalkaloid content in the potato varieties EH92-527-1 and Bonanza was performed using a standard HPLC technique (Houben and Brunt, 1994). Although the limit of detection for the glycoalkaloids (20 mg/kg fresh weight) was somewhat high, the EFSA GMO Panel finds the analytical RP-HPLC method adequate. In practise the applicant had no problem analysing down to 3 mg/kg fresh weight β-chaconine.

During the assessment of notification C/SE/96/3501 and application EFSA-GMO-UK-2005-14 and when giving its Scientific Opinions in 2006 (EFSA, 2006a,b), the EFSA GMO Panel carefully considered the glycoalkaloid level in tubers of the GM potato EH92-527-1 and its conventional counterpart Prevalent. Compositional data were available from tuber materials harvested the seasons 1996, 1997 and 1998, guaranteeing that potato tubers were produced under different environmental conditions. As the glycoalkaloids are inducible it came as no surprise that the level varied between season, possibly due to different stress conditions. However, glycoalkaloid levels varied in the same manner for potato EH92-527-1 and Prevalent tubers. The mean level of total glycoalkaloids in potato EH92-527-1 was 83 mg/kg fresh weight in 1996, 209 mg/kg in 1997 and 154 mg/kg in 1998.

Tuber material for the post-market monitoring of glycoalkaloid content of potato EH92-527-1 were obtained from seven fields in the Czech Republic where the potato EH92-527-1 was cultivated in 2010. Four samples were taken at each site, each sample made up of ten tubers. In addition to the samples of potato EH92-527-1, four samples (each constituted by 10 tubers) of the conventional starch potato variety Bonanza grown in Kristianstad in Southern Sweden or in Baalberge in Germany were included in the monitoring study. These control samples were a substitute for the Prevalent control samples used in the 1990's (not available in 2010). Whereas the parental variety Prevalent, which is no longer cultivated in the EU, had a genetic background very similar to potato EH92-527-1, this was not the case for Bonanza.

The mean of total glycoalkaloids in potato EH92-527-1 harvested from the seven sites in the Czech Republic was 128 mg/kg fresh weight, the range in mean values from the various sites being 116.8-134.3 mg/kg fresh weight. This small variation indirectly indicates a low stress on the potato plants. The variation in glycoalkaloid content between the four samples taken at each site was low. The total glycoalkaloid content in the conventional starch potato Bonanza was 92.8 mg/kg fresh weight in the material from Sweden and 142.0 mg/kg fresh weight in the material from Germany. Thus, the total glycoalkaloid content of the potato EH92-527-1 tuber material harvested the growing season 2010 were within the range in total glycoalkaloid level demonstrated for these varieties earlier. In addition to α-chaconine and α-solanine, the potato EH92-527-1 tubers contained 2.0-12.8% β-chaconine. Some of the samples contained relatively high β-chaconine levels.

The analytical RP-HPLC method was considered appropriate to assess the total glycoalkaloid content. Although a comparative analysis with the variety Bonanza as such is not relevant, the results demonstrate that the glycoalkaloid content of potato EH92-527-1 tubers is in the range established in previous studies and has not changed over time. Due to the absence of evidence for any safety concern, routine monitoring of the glycoalkaloid content in potato EH92-527-1 is not considered needed.

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 inserts and phenotypic expression during cultivation of potato EH92-527-1.

In response to this request of the European Commission (see Terms of Reference), the EFSA GMO Panel assessed the aforementioned four case-specific studies provided by the applicant in its 2010 Amflora report as well as evaluated the appropriateness of the methods used by the applicant.

The EFSA GMO Panel concludes that these four 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 field study[14] '*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'*.

In absence of a clear risk hypothesis set by risk managers, the applicant built the study on the following rationale: "*Unintended and unanticipated effects associated with the development of Amflora could make the potato more attractive for pest species, thereby exceeding the variability in pest susceptibility that is already present amongst the different potato varieties that are cultivated in the member states, and the diversity in potato cultivation measures that are taken by potato growers in the various regions to control potato pests. Such an effect could lead to a disproportionate multiplication of potato pests and a disproportionate use or failure of plant protection measures, or a loss of a biological control function, if applicable. The purpose of the monitoring study was to monitor for potential adverse effects the commercial cultivation of Amflora potatoes might have on potato-feeding organisms. Since organisms feeding on potato plants and occurring in significant and measurable abundance are considered pest species, it is assumed that the following possible adverse effects were the rationale for requesting the monitoring study*[15]".

Based on a literature search[16], the applicant identified organisms to monitor. By screening different databases and using various keyword combinations, the applicant referred to 33 relevant publications on arthropods in potato fields of Northern and Central Europe. However, the number of publications available varied between the different groups of arthropods. The applicant argued that arthropod diversity in potato fields is generally low as compared to other crops (e.g., cereals) and depends upon different factors (e.g., crop management practices, adjacent habitats, abiotic factors).

Hence, the applicant monitored the abundance of selected potato-feeding arthropods in inner and outer rows[17] of ten potato EH92-527-1 fields in three different countries (namely, seven fields in Czech Republic for starch potato production, and one in Germany and two in Sweden for seed potato production). Local agronomic practices were applied in each potato field. Within each field, ten transects were identified (eight within the field and two in the outermost rows on both sides of the fields). Each transect included 10 potato plants (or 30 leaves in case of aphids) and for each transect the applicant sampled common arthropods in potato fields by two methods: (1) Colorado potato beetle and potato aphids by visual counting and (2) other arthropods (e.g., Thysanoptera, Aphididae, Miridae, Auchenorrhynacha, Coccinellidae, Neuroptera, Araneae) collected by sucking device. Individuals

[14] 2010 Amflora report, Appendix 14
[15] 2010 Amflora report, page 17
[16] 2010 Amflora report, Appendix 13
[17] Outer rows are defined by the applicant as the 2-3 border rows.

surveyed by visual counting were determined to species level. All samplings were conducted according to the European and Mediterranean Plant Protection Organization (EPPO) standards. Where available, the applicant compared field data with data from other sources (i.e., aphid numbers from plant protection bulletins in Germany and Czech Republic).

The applicant concluded that '*No strong differences were found between abundances of phytophagous arthropods sampled within the Amflora fields and in the vicinity of the Amflora fields. The abundance of phytophagous arthropods in Amflora potato fields varied strongly between the fields in the different commercial potato cultivation areas in the Czech Republic, Germany and Sweden. The highest abundances were found at potato fields in the Czech Republic. The lowest number of individuals was mostly counted at the potato fields in Sweden*[18]*'*.

3.2. Assessment by the EFSA GMO Panel

In its Scientific Opinions on potato EH92-527-1 (EFSA, 2006a,b), the EFSA GMO Panel did not identify risks to non-target organisms or any scientific reason to support the hypothesis of a potential increase in herbivore pressure on potato EH92-527-1 fields. Therefore, the EFSA GMO Panel did not recommend that any CSM studies were required. However, in response to this request from the European Commission (see Terms of Reference), the EFSA GMO Panel assessed the appropriateness of the applicant's approach for the field study to monitor potential adverse effects on potato-feeding organisms in the potato EH92-527-1 fields and in their vicinity. This study was conducted by the applicant in response to the conditions for the placing on the market of potato EH92-527-1 as in the Commission Decision 2010/135/EU (EC, 2010).

(1) On the hypothesis built by the applicant

The Commission Decision concerning the placing on the market of potato EH92-527-1 does not specify any hypothesis to be tested (EC, 2010). Moreover, the 2006 Scientific Opinions of the EFSA GMO Panel on potato EH92-527-1 (EFSA, 2006a,b) did not identify a hypothesis for monitoring of potential effects of the GM potato on potato-feeding organisms. The EFSA GMO Panel notes that the (null) hypothesis set by the applicant is that cultivation of potato EH92-527-1 does not cause increases in abundance of insect pests and thus the applicant proposes monitoring of foliar herbivorous insects.

The EFSA GMO Panel agrees with the applicant that the selected pest species (i.e., the Colorado potato beetles and aphids) are representative of the main foliar herbivore guilds for potato fields, since they occur at many locations. However, the EFSA GMO Panel is aware that the infestation levels of foliar herbivores may differ from one region to another[19] and that local pest management practices (e.g., use of insecticides) have implications for herbivore abundance at each starch and seed production potato site. Indeed, seed production potato fields are isolated from other potato fields and are treated with insecticides (tuber and foliar applications) to minimize virus transmission by aphids and to reduce pest damage. These considerations should have been better taken into account when designing the experimental set-up as they greatly affect the relevance of the results.

(2) On the observations

A total of 80 (Colorado potato beetles) and 240 (potato aphids) visual samplings[20] were conducted within the field at a single time point during the growing season. However, the applicant presented in its report the data pooled by transect; this reduced the total number to 8 samples/field for Colorado potato beetle. Even though the mean abundance of sampled individuals was very small and therefore pooling would not greatly affect the results, pooling greatly reduced the ability of the analysis to

[18] 2010 Amflora report, Appendix 14
[19] For example, Colorado potato beetle does not occur naturally in Sweden.
[20] 2010 Amflora report, Appendix 14

estimate within-field variability. Information on such variability is essential to plan efficient future sampling schemes.

In addition to visual data from samplings on the density of Colorado potato beetle and aphids on potato plant, the applicant provided detailed data on arthropod assemblages collected with suction (D-Vac) method on potato fields. This method allows the collection of arthropods (any developmental stage except eggs and pupae) that are present and active in the foliage of potato plants. These data therefore give details on densities of phytophagous species (aphids, thrips, mirids and other Heteropteran species, leafhoppers, coleopterans), predatory species (coccinellids, Neuroptera) and decomposers (Collembola).

Both visual and D-Vac samplings were timed to the expected relatively high abundance level of pests based on regional historical data. The EFSA GMO Panel considers that the choice of sampling for these herbivore species only once during the growing season is a questionable approach as their population dynamics are generally characterised by seasonal fluctuations which might not be detected by single sampling.

(3) On the comparator

A major drawback of the field study performed by the applicant is the lack of a meaningful comparator. In the 2010 Amflora report, neither an historical baseline (to monitor if potato pest pressure changes after the introduction of potato EH92-527-1), nor a non-GM comparator cultivated under similar conditions is presented. In some cases, aphid numbers retrieved from plant protection bulletins are presented. However, the data collection methods are not completely comparable with those presented by the applicant. Therefore, the EFSA GMO Panel does not consider that appropriate comparators were chosen.

(4) On the vicinity

The applicant stated that '*the vicinity of the Amflora cultivation area in the three member states was quite divergent, such that fields were either neighboured by agricultural land (other crops like maize or oilseed rape, grassland, potatoes in some instances at a distance), forest, shrubs or roads. Therefore, and in order to assure the presence of organisms feeding on potato in what could be considered representative of the vicinity, the outer rows of the potato fields were determined to be the area that should be monitored as vicinity of the potato fields*'.

The EFSA GMO Panel acknowledges that the vicinity of potato fields might not be easy to define but considers that outer rows cannot be '*the area that should be monitored as vicinity of the potato fields'*. Indeed, outer rows are part of the potato crops and by no means can be used as representative of the vicinity of the potato fields or as a comparator.

The EFSA GMO Panel also considers that it is not appropriate to compare insect abundance on outer rows and within crop rows. The first reason is that the outer rows are also cultivated with potatoes EH92-527-1 and therefore no variety effect can be detected. Moreover, it is well known that "edge effects" might occur so that it is normal practice to exclude outer rows from data generation in field experiments. In addition, several insect pests, including Colorado potato beetle, immigrate into field from overwintering habitats and from other potato fields and may result in pest density differences in outer rows compared to inner rows.

Finally, there is no consideration in the 2010 Amflora report of the differences in management practices (e.g., use of insecticides) for each field and for starch or seed production, and their likely impact on insect abundance in sampled potato fields. Local pest management practices (e.g., use of insecticides) will differ at each starch and seed production potato site and have different impacts on herbivore abundance at each site.

3.3. Conclusions of the study & Recommendations

The EFSA GMO Panel concludes that the hypothesis set by the applicant in response to the request by the European Commission cannot be answered by the study design and method used by the applicant[21]. The reasons for this are listed in the hereabove chapter 3.2 and include the lack of appropriate comparators, the sampling method, and also the need to conduct this study over several seasons in order to detect consistent effects. However, the EFSA GMO Panel considers the request for a field study as in the related Commission Decision (EC, 2010) to have not been detailed (see also chapter 3.2).

Therefore, the EFSA GMO Panel considers that the current study of foliar herbivores is unlikely to produce data of environmental significance or relevance and that alternative approaches are needed for the design, conduct and analysis of field study in order to determine whether cultivation of potato EH92-527-1 is likely to have adverse environmental effects through its associations with phytophagous arthropods.

To test the hypothesis as set-up by the applicant, the EFSA GMO Panel makes the following comments and recommendations:

- In the design of the study, consideration should be given to pest management and 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 receiving similar management;

- It will be necessary to improve the quantitative sampling plan in order to allow an analysis with a desired 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. Then, a prospective power analysis would define the number of location sites to monitor. It would also be necessary to increase the number of sampling dates in order to better reflect insects' 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);

- The literature review[22] preceding the study on abundance of potato-feeding organisms should be improved. For example, key functional groups such as pollinators should be considered in the forthcoming PMEM reports on potato EH92-527-1.

Alternatively, the EFSA GMO Panel considers that the GS framework is a more proportionate way to collect relevant information on potato-feeding organisms. In this case, the EFSA GMO Panel recommends the applicant, in close collaboration with risk managers, to further elaborate the farmer questionnaire on the two following aspects:

[21] 2010 Amflora report, Appendix 14
[22] 2010 Amflora report, Appendix 13

(1) Monitoring potato-feeding organisms over time

Adapted farmer questionnaires and existing surveillance authorities (such as national services already involved in the PMEM of potato EH92-527-1, see chapter 4.2.2) could provide relevant data on changes in abundance of potato-feeding organisms over time. Farmer questionnaires should include more detailed questions on potato-feeding organisms observed in potato EH92-527-1 crops as compared with conventional potato crops, conducted under similar management practices, if available (for further details, see chapters 4.2.1 and 4.3). Such an approach would only be able to detect significant changes in potato-feeding organisms abundance. Specific guidance should be given to farmers, or such monitoring could be carried out by external observers.

(2) Monitoring changes in pest management practices

As the applicant hypothesis states that the purpose of their monitoring is to assess if changes in abundance are high enough to trigger changes in pest management practices, farmer questionnaires should specifically request information on pest management practices and any changes noted by farmers. However, they will also need to provide information on pest management practices of nearby conventional potato crops; if significant changes or differences were reported, further specific studies would be required to determine causes and effects.

Farmer questionnaires should clearly identify the selected comparator and the EFSA GMO Panel considers that non-GM starch-potato crops or conventional potato crops, grown nearby with similar cultivation conditions and pest management practices, are the most appropriate. If these are not available, then an historical baseline could be considered (EFSA, 2011a).

According to the EFSA GMO Panel Scientific Opinion providing guidance on PMEM of GM plants (EFSA, 2011a), the design of the GS plan will influence the quality and usefulness of resulting data, hence efforts should be made to ensure that data from monitoring can be statistically analysed (Wilhelm *et al.*, 2003, 2004a,b, 2009; Graef *et al*., 2008). A scientific methodology shall be applied, wherever possible, in order to collect empirical data and establish certain baselines. This especially refers to defining sample sizes, sampling and recording methods, in order to produce statistically valid data for detecting any unanticipated adverse effects (EFSA, 2011a).

4. General Surveillance

4.1. Summary of the information provided by the applicant

For the 2010 growing season of potato EH92-527-1, the applicant reported the results of its GS plan which consists in (1) the farmer survey in the three EU Member States where potato EH92-527-1 was cultivated in 2010, (2) a review of peer-reviewed publications, (3) visits and inspections by national authorities and other existing networks, (4) stewardship programme and (5) training & information to operators and users.

Furthermore, GS includes an Identity Preservation (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[23] that supplements the observations gathered from farmer questionnaires[24].

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

(1) All farmers planting potato EH92-527-1 in 2010 were asked to record and report their observations and assessment in potato EH92-527-1 fields in comparison to a potato variety, if available, used as comparator. In 2010, a total of 26 questionnaires were received from all

[23] 2010 Amflora report, Appendix 1, form 5
[24] 2010 Amflora report, Appendix 6

farmers participating to the IP system in the three European countries (18 in Sweden, 1 in Germany, 7 in Czech Republic) where potato EH92-527-1 was grown. The farmers were interviewed by representatives of BioMath, contractor of BASF which also processed the data from farmer questionnaires. From the 2010 statistical analysis[25] of the 26 questionnaires, the applicant concluded that "*for most characters Amflora performed as any conventional potato variety (e.g., presence of wildlife, success of pest or disease control, phenotype). Other deviations (e.g., earlier maturity, later harvest, slower development, 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 and Biosis), the applicant found 26 hits from which only 21 referred to scientific literature likely to be relevant for the ERA of potato EH92-527-1. Out of the 21 publications, the applicant identified one single article by Geschwendtner *et al.* (2010) of relevance as it was related to amylopectin potatoes and the ERA. The applicant concluded that the peer-reviewed literature does not raise safety concern for potato EH92-527-1.

(3) The applicant provided a list of visits and inspections by national authorities (i.e., services from Ministry of Agriculture in Czech Republic, regional authority in Germany, Seed Certification Unit in Sweden) during the potato EH92-527-1 growing season 2010[26].

4.2. Assessment by the EFSA GMO Panel

On 28 September 2011, the EFSA GMO Panel asked the applicant to provide additional data (e.g., raw data of farmer questionnaires, publications identified from the literature search, details from visits & inspections by national authorities) and, where needed, to clarify some topics (e.g., statistical analysis of farmer questionnaires). The requested data were received on 24 November and 15 December 2011.

4.2.1. Farmer questionnaires

The EFSA GMO Panel is of the opinion that questionnaires, directed at farms or production systems where GM plants are grown, are considered a useful method for collecting first hand data on the management and performance of a GM plant and its cultivation in order to determine impacts on the environment in comparison with conventional plant cultivation. The EFSA GMO Panel is of the opinion that farmer questionnaire can be used as an early-warning tool which would trigger additional studies, should unanticipated changes occur which might lead to adverse environmental effects. However, it is recognised that the information supplied by farmers will be limited to observations they can make within their areas of experience, related mostly to the areas on their farms cultivated with the GM and non-GM crop and their historical experience (EFSA, 2011a). In its recent Scientific Opinion on PMEM (EFSA, 2011a), the EFSA GMO Panel provides guidance to applicants on how to supplement and analyse the farmer questionnaires for an optimised monitoring of the GM plant and of its cultivation sites.

According to the terms of reference of the present mandate from the European Commission, the EFSA GMO Panel also assessed the methodology followed by the applicant to analyse the farmer questionnaires. The EFSA GMO Panel was assisted by the EFSA Unit for Scientific Assessment Support (EFSA SAS Unit) which provides a methodological guidance for a systematic evaluation of the farmer questionnaires (see Appendix 1). Appendix 1 sets a list of evaluation criteria (e.g., sample size, survey response rate, statistical analysis) that can be applied to farmer surveys in the context of GS of GM plants.

Results on the appropriateness of the farmer questionnaire for potato EH92-527-1, its design, it use and analysis are given in Appendix 1. Appendix 1 also includes recommendations to the applicant to improve the study design and reporting (for further details, see chapter 4.3).

[25] 2010 Amflora report, Appendix 7
[26] 2010 Amflora report, Appendix 3

Furthermore, according to chapter 3.3, the EFSA GMO Panel considers that the GS framework is a more proportionate way to collect relevant information on potato-feeding organisms. In this case, the EFSA GMO Panel recommends the applicant, in close collaboration with risk managers, to further elaborate the farmer questionnaires on the two following aspects: (1) monitoring potato-feeding organisms over time and (2) monitoring changes in pest management practices (for further details, see chapter 3.3). The applicant should consider more detailed questions on biodiversity abundance and, in particular, on potato-feeding organisms observed (e.g., aphids, Colorado potato beetles and other relevant potato pests) in potato EH92-527-1 fields as compared with conventional potato crops, conducted under similar management practices, if available. Information on pest management practices might also be indicative of change in the abundance of potato-feeding organisms; more detailed questions on pest treatment should also be considered for both the GM potato crops and the appropriate comparator. In this respect, farmer questionnaires should clearly identify the selected comparator and the EFSA GMO Panel considers that non-GM starch-potato crops or conventional potato crops grown nearby with similar cultivation conditions and pest management practices, are the most appropriate. If these are not available then an historical baseline could be considered (EFSA, 2011a).

From the 2010 analysis of the farmer questionnaires on potato EH92-527-1, the EFSA GMO Panel concludes that no unanticipated adverse effect was identified based on the available data. However, the EFSA GMO Panel, assisted by the EFSA SAS Unit, identified weaknesses in the methodology and gives recommendations to the applicant (see chapter 4.3).

4.2.2. Existing Monitoring Networks

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

The EFSA GMO Panel notes that, in the 2010 Amflora report, the applicant did not provide details on the existing environmental networks of the aforementioned type 2 which are active in biodiversity surveys. However, the applicant referred to reports from visits and inspections by national authorities. On 28 September 2011, the EFSA GMO Panel requested those reports. On 15 December 2011, the applicant provided letters summarising the observations from the Swedish, Czech and German surveillance authorities, including the protocols from the German surveillance authority. The EFSA GMO Panel assessed the reports from visits and inspections by national authorities and considered them as a valuable information source for GS. The EFSA GMO Panel recognised the difficulty to gather 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 26 fields) of potato EH92-527-1 in 2010, existing environmental networks would have been unlikely to detect changes in environmental impacts due to the cultivation of potato EH92-527-1 in 2010. However, the EFSA GMO Panel recalls that existing surveillance networks may detect potential changes on the environment which 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 (EFSA, 2011a), the applicant is invited to identify relevant environmental networks when the potato EH92-527-1 cultivation in the EU will become more significant.

4.2.3. Literature review

From the literature review (2009-2010), the applicant found 26 hits from which only 21 referred to scientific literature likely to be relevant for the ERA of potato EH92-527-1. Out of the 21 publications, only one publication (i.e., Geschwendtner *et al*., 2010) was discussed as describing potential effects of

cultivating potato EH92-527-1 or other potato varieties on the abundance of different soil microorganims.

Considering the large number of databases used by the applicant for the literature search, the EFSA GMO Panel notes that most of the identified publications are about the general context of marketing GM potatoes in the EU and the detection tools for GM potatoes, which are out of the remit of the EFSA GMO Panel. According to the EFSA Guidance Document (http://www.efsa.europa.eu/en/efsajournal/pub/1637.htm) on systematic literature review methodology, 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). The EFSA GMO Panel expects the selected papers to be put into context and considered in the light of the overall ERA of potato EH92-527-1 (see EFSA, 2011a). These publications should be listed and summarised according to the Appendix of Commission Decision 2009/770/EC (EC, 2009).

The EFSA GMO Panel considered the publication by Geschwendtner *et al*. (2010) on the potential effects of a GM amylopectin-accumulating potato line on plant beneficial bacteria and fungi as well as on phytopathogens in the rhizosphere in a greenhouse experiment and a field trial. For the investigated GM potato line, its non-GM parent and an other non-GM line cultivated in greenhouse and in field, the rhizospheres were sampled and analysed by real-time PCR for abundance of bacteria (e.g., *Pseudomonas*) and fungi (e.g., *Phytophthora*). Geschwendtner *et al*. (2010) concluded that no difference in abundance between the GM line and and its non-GM parent was observed and that no effects caused by the genetic modification on the plant beneficial microbes and phytopathogens abundance were measured. Therefore, the EFSA GMO Panel concludes that the publication by Geschwendtner *et al*. (2010) does not identify an environmental safety concern that would invalidate its 2006 Scientific Opinions on potato EH92-527-1 (EFSA, 2006a,b).

4.2.4. Additional consideration by the EFSA GMO Panel

Considering the possible use of potato EH92-527-1 pulp as animal feed, the EFSA GMO Panel notes that possible effects of potato EH92-527-1 and its by-products on animals (e.g., pulp, fertilisers) were considered by the applicant in its initial GS plan. In its initial GS plan[27], the applicant stated that, "*in the absence of a national general surveillance system, to detect potential adverse effects of starch processing by-products used as animal feed, a questionnaire will be developed. The questionnaire will accompany the receipt of potato pulp for use as animal feed and will be addressed to the contract farmer*".

The EFSA GMO Panel acknowledges that this is not relevant for the 2010 growing season as the potato EH92-527-1 pulp was not used as animal feed but was sent to biogas facilities.

In the case where potato EH92-527-1 pulp is used as animal feed in the coming years, the EFSA GMO Panel recommends that the aforementioned questionnaire is developed. This would supplement the Identity Preservation System which already traces and records information on potato EH92-527-1 by-products[28].

4.3. Conclusions & Recommendations on GS

The EFSA GMO Panel considers that the 2010 analysis of the farmer questionnaires on potato EH92-527-1, the observations by national surveillance authorities and the literature review do not indicate any adverse environmental impacts associated with the cultivation of potato EH92-527-1. However, the EFSA GMO Panel identifies weaknesses in the methodology of the GS plan.

Therefore, the EFSA GMO Panel recommends the applicant to consider the following points in order to improve the methodology related to

[27] See Part VII of notification with reference C/SE/96/3501 and the application with reference EFSA-GMO-UK-2005-14)
[28] 2010 Amflora report, Appendix 5

(1) The farmers survey

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

- to carry out impartial and standardised interviews by independent parties to reduce the interviewers bias and to implement effective quality assurance and auditing (EFSA, 2011a);

- to consider alignment of the field-plot card-index (Form 5) with the farmer questionnaire for an appropriate cross-checking of the data (see chapter 5);

- to revise the method to calculate the confidence intervals (see Appendix 1) ;

- due to the limited number of locations where potato EH92-527-1 was grown in 2010, the farmers 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 future farmer surveys. This would require a consistent survey methodology and questionnaire format.

  In addition, the selected comparator should be clearly identified in the farmer questionnaires (e.g., exact location of comparator fields). The EFSA GMO Panel considers that non-GM starch-potato crops or conventional potato crops, grown nearby with similar cultivation conditions and pest management practices, are the most appropriate. If these are not available then an 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 to collect relevant information on potato-feeding organisms. The EFSA GMO Panel recommends to further elaborate the farmer questionnaire and, in particular to consider more detailed questions (e.g., on abundance of potato-feeding organisms like aphids, 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 of 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

According to the EFSA Guidance Document (http://www.efsa.europa.eu/en/efsajournal/pub/1637.htm) on systematic literature review methodology, 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). The EFSA GMO Panel expects the selected papers to be put into context and considered in the light of the overall ERA of potato EH92-527-1 (see EFSA, 2011a).

Finally, the EFSA GMO Panel recommends that, in the case where potato EH92-527-1 pulp is used as animal feed in the coming years, a questionnaire on the use of such by-product is developed. Finally, the EFSA GMO Panel reminds the applicant to provide raw data to Member States and European Commission and this according to its 2011 Scientific Opinion providing guidance on PMEM of GM plants (EFSA, 2011a).

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 Identity Preservation (IP) system set up by the applicant in order to assure the quality of the potato EH92-527-1 through a system of tracking and records[29]. The potatoes EH92-527-1 were cultivated under contracts between the applicant and farmers who supplied them 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 the levels of the production according to strict standard operation procedures (SOP). 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 Identity Preservation system.

The applicant reported on the implementation and integrity of the Amflora IP system[30]. During field visits and audits by the applicant, *off-type* potatoes were identified in the potato EH92-527-1 fields in Sweden. After analysis, the applicant further reported to the authorities on the presence of *Amadea potato plants (AM04-1020 Amylopectin Potato, BPS-A1Ø2Ø-5) in field sites for seed propagation of Amflora potatoes (EH92-527-1 Amylopectin Potato, BPS-25271-9) in Northern Sweden.*

5.2. Assessment by the EFSA GMO Panel

Potatoes EH92-527-1 are marketed within a closed loop system: they are cultivated under contracts with the applicant who will then supply them directly to the processors for starch extraction. The cultivation and handling of potatoes EH92-527-1 are governed under an IP system, controlled and supervised through manuals, instructions, checklists and report forms at all the levels of the production (EFSA, 2006a,b). The purpose of the IP system is to ensure the quality of potatoes EH92-527-1 by keeping other potato cultivars separated from them. In this respect, the EFSA GMO Panel reminds that the issue of accidental admixtures (like the adventitious presence of Amadea potatoes) falls outside its remit. However, the EFSA GMO Panel notes that the IP system enabled the applicant to detect accidental presence of Amadea potatoes in potato EH92-527-1 fields in Sweden. The EFSA GMO Panel considers that the field-plot card-index (Form 5) of the manual for IP system is a relevant source of information on the management of the potato EH92-527-1 in addition to the farmer questionnaires (see chapter 4.3). The EFSA GMO Panel recommends that raw data of Forms 5 are provided in order to ensure a cross-checking of results between Forms 5 and the farmer questionnaires. The EFSA GMO Panel also recommends the applicant to improve Form 5 (i.e., by including reference to a comparator).

5.3. Conclusions & recommendations on the IP system

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

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

[29] 2010 Amflora report, Appendix 1
[30] 2010 Amflora report, Appendix 12

OVERALL CONCLUSIONS AND RECOMMENDATIONS

Following a request from the European Commission, the EFSA GMO Panel assessed the monitoring report for the 2010 cultivation season of the GM potato EH92-527-1 (variety Amflora) provided by BASF.

The EFSA GMO Panel assessed, in close collaboration with the EFSA Unit for Scientific Assessment Support, the methodology applied by the applicant for the CSM, the GS of potato EH92-527-1 and the study on potato-feeding organisms as requested in the related Commission Decision (EC, 2010).

Firstly, although the EFSA GMO Panel did not recommend CSM (EFSA, 2006a,b), the EFSA GMO Panel assessed the four case-specific studies submitted by the applicant in order to *verify a set of assumptions that were made during the Environmental Risk Assessment and their confirmation over a defined monitoring period.* The EFSA GMO Panel concludes that these four case-specific studies do not provide scientific evidence that would invalidate the previous safety evaluations of potato EH92-527-1 (EFSA, 2006a,b).

In response to this mandate from the European Commission, the EFSA GMO Panel assessed the appropriateness of the applicant's approach for the field study to monitor potential adverse effects on potato-feeding organisms in the potato EH92-527-1 fields and in their vicinity (see chapter 3.2). The EFSA GMO Panel concludes that the hypothesis set by the applicant in response to the request in the related Commission Decision cannot be answered by the study design and method used by the applicant. Hence, to test the hypothesis as set-up by the applicant, the EFSA GMO Panel makes comments and recommendations in order to improve the study. Alternatively, the EFSA GMO Panel considers that the GS framework is a more proportionate way to collect relevant information on potato-feeding organisms and therefore recommends the applicant to further elaborate the farmer questionnaire.

Concerning GS, the EFSA GMO Panel paid particular attention to the design and analysis of the farmer questionnaires and gives recommendations to the applicant in order to improve the design and reporting of the farmers survey (see chapter 4.3 and Appendix 1). In addition, the EFSA GMO Panel considered the information collected by national surveillance authorities, the literature review as well as the identity preservation system set up by the applicant. The EFSA GMO Panel concludes that the 2010 analysis of the farmer questionnaires on potato EH92-527-1, the observations by national surveillance authorities and the literature review do not indicate any adverse environmental impacts associated with the cultivation of potato EH92-527-1. However, the EFSA GMO Panel notes a number of shortcomings in the methodology for GS. Hence, this Scientific Opinion gives specific recommendations to the applicant for improvement of the strategy, methodology and reporting for GS of potato EH92-527-1. The applicant should also take into consideration the guidance provided by the EFSA GMO Panel in its 2011 Scientific Opinion on Post-Market Environmental Monitoring of GM plants (EFSA, 2011a).

From the overall dataset submitted by the applicant in its 2010 Amflora report, the EFSA GMO Panel does not identify adverse effects on the environment, human and animal health due to potato EH92-527-1 cultivation during the 2010 growing season. The outcomes of the 2010 Amflora report do not invalidate the previous EFSA GMO Panel's risk assessment conclusions on potato EH92-527-1 (EFSA, 2006a,b).

DOCUMENTATION PROVIDED TO EFSA

1. Letter from the European Commission, dated 3 May 2011, to the EFSA Executive Director requesting the assessment of Amflora monitoring report related to the 2010 cultivation season provided by BASF.

2. Acknowledgement letter, dated 30 May 2011, from the EFSA Executive Director to the European Commission.

3. Letter from the European Commission, dated 5 July 2011, to the EFSA Executive Director concerning the Scientific Opinion providing guidance on post-market environmental monitoring of GM plants.

4. Letter from EFSA to the applicant, dated 28 September 2011, requesting additional information.

5. Letter from the applicant to EFSA, dated 24 November 2011, providing the additional information requested by EFSA.

6. Letter from the applicant to EFSA, dated 15 December 2011, providing the additional information requested by EFSA.

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APPENDICES

A. APPENDIX 1 – SAS[31] TECHNICAL REPORT[32] ON THE EVALUATION OF FARMER QUESTIONNAIRES SUBMITTED IN THE 2010 AMFLORA REPORT

Method

The evaluation uses criteria developed according to the principles of design for cross-sectional studies, in particular surveys, and was 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.

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
Survey response rate (non response bias)	1) Follow-up method for non-responders is described and appropriate 2) Response rate is specified

[31] Correspondence: SAS@efsa.europa.eu
[32] On request from EFSA, Question No EFSA-Q-2011-00230, Assistance to GMO EFSA-Q-2010-01254.

	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 2010, potato EH92-527-1 was grown in 26 locations in the European Union. The distribution of farms and fields extracted from the farmer questionnaire raw data provided by BASF on the 24 November is shown in Table 1.

Table 1: Countries, farms and fields surveyed in 2010

Country	*Number of farms*	*Number of fields*
Czech Republic	3	3,2,2
Germany	1	1
Sweden	5	3,2,2,7,4

All potato EH92-527-1 growers for the 26 EH92-527-1 locations in the European Union were interviewed in order to complete the farmer questionnaire. Since this is a census, the sampling frame assessment criterion is not relevant.

Sampling method

All potato EH92-527-1 growers for the 26 EH92-527-1 locations in the European Union were interviewed in order to complete the farmer questionnaire. Since this is a census, the sampling method assessment criterion is not relevant.

Sample size

All potato EH92-527-1 growers for the 26 EH92-527-1 locations in the European Union were interviewed in order to complete the farmer questionnaire. Since this is a census, the sample size assessment criterion is not relevant.

Survey response rate

Since all potato EH92-527-1 growers for the 26 EH92-527-1 locations in the European Union were interviewed, this criterion should not be relevant. However, it is noted that the field-plot card indices (Forms 5) for only 24 locations were completed. The report states that *"for 24 cases (in two cases one farmer in Sweden completed one field-plot card-index to cover two neighbouring fields)"*. Ideally field-plot card-indices and the farmer questionnaires should be completed for each location included in the survey.

Instrument design

1) Interviewer bias

All growers were required to participate in the IP system and trained in the IP system procedures. The IP system procedures included the requirement to complete documentation throughout the starch potato production process, in particular the field-plot card-indices (Forms 5) were to be completed recording the agricultural management of the crop, agronomic parameters and general observations during the growing season. This Form 5 was used to support the interview process and completion of the farmer questionnaire. All information necessary to complete the farmer questionnaire should be included in the field-plot card-indices and the information recorded in the farmer questionnaire should directly correspond with the information previously recorded in the field-plot card-indices. This would reduce the effects of interviewer bias.

2) Interviewer training

The growers were interviewed face-to-face by representatives from BioMath, the company that prepared the farmer questionnaire and performed analysis on the completed questionnaires.

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 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 interview which results in 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 allows the starch potato variety used as the comparator to be recorded and asks if the cultivation conditions are the same for potato EH92-527-1 and the comparator variety. The farmer questionnaire raw data provided by BASF on the 24 November 2011 indicates for all locations "no starch potato variety comparator" was available. In section 3.2.1 of Appendix 7 of the 2010 Amflora report, it is stated that only one farm cultivated conventional starch potatoes in 2010 and for 3 farms (6 locations) no conventional potato varieties were grown in 2010. Consequently the comparator was conventional potato production and for 6 locations this comparison relied on recollections from previous growing seasons. Potato EH92-527-1 Form 5 of the IP system documents does not make any specific reference to a comparator variety and simply requires the farmer to record whether farm conditions and management practices were "as usual" or "different". It would be of value to be more explicit in the training for growers and IP documents about the importance of comparing the performance and experiences with potato EH92-527-1 against a comparator variety, ideally a non-GM starch potato variety or conventional potato grown in the same year, as this comparison is at the core of the GS analysis presented in Appendix 7 of the 2010 Amflora report.

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 2001-2009 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.

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. In the analysis section of Appendix 7 of the 2010 Amflora report, results for changes in weed management practice and *Phytophthora infestans* treatment are presented using information obtained from Form 5 of the IP documents. 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 production (see chapter 4.3).

- 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; in 2010, this was not assessed since this was the first season of commercial production of potato EH92-527-1. Monitoring of volunteers is part of the IP system and this information will be presented in the 2011 Amflora monitoring report. 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

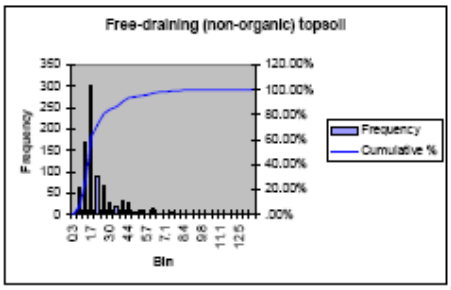
In the Scientific Opinions of the EFSA GMO Panel on potato EH92-527-1 (EFSA 2006a,b), the section of comparative analysis states the following *"In addition to the intended alterations in starch composition of the GM potato, some statistically significant differences between the GM potato and its control 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 farmer 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[33] 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 farmer 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 with reports for accelerated maturity from 6 locations and delayed maturity from 4 locations in the farmers survey.

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 2.0 and 4.0 with a mean of 3.3 however this information was only available for 9 locations. It can be seen that this range falls within that of the SPADE-2 range for organic carbon content. Soil pH was reported for 17 locations, with values between 4.90 and 6.40 with a mean of 5.7. 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 and pests to which the potato EH92-527-1 was more or less susceptible that could be used to check for external consistency. In Table 2 the reported pests and diseases from the farmer questionnaire are compared with the known distribution of these pests and diseases in Europe as reported in the Crop Protection Compendium (CABI, 2011a,b). For the reported pests and diseases in the survey there is a correspondence between the pests and diseases reported and the known distribution of the pests and diseases according to the Crop Protection Compendium.

[33] Note: the parental variety Prevalent is no longer cultivated in the EU.

Table 2: Reported diseases and known distribution

Reported pests and diseases	*Known Distribution*	*Locations where disease was reported*
Blackleg	Present in CZ, DE, SE	DE, SE
Potato virus Y	Present in CZ, DE, SE	CZ, DE, SE
Rhizoctonia solani (*Thanatephorus cucumeris*)	Present in CZ, DE, SE	SE
Potato leaf roll virus	Present in CZ, DE	CZ
Potato beetle	Widespread CZ, DE Eradicated SE	CZ, DE

The report states that in Form 5 (field-plot card-index) for seven locations the average annual rainfall was between 600 and 700 with a mean of 657.14 mm per year. At four locations the farmers categorised rainfall as average and 20 as above or below average. From the farmer questionnaire for 25 locations the farmers reported average annual rainfall between 500 and 700 with a mean of 574 mm per year, and for 25 locations the farmers categorised rainfall as above average rainfall and for one location as below average. 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). It is noted that there is some discrepancy between the assessment of rainfall by the farmers when comparing the results from Form 5 and the farmer questionnaire.

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 3). The sequence of events indicates the dates are plausible.

Table 3: Earliest and latest dates for management of potatoes EH92-527-1 in 2010

Event	*Earliest date*	*Latest date*
Planting	April 19	June 24
Application mineral fertilisers	April 20	August 21
Ridge formation	May 5	June 28
Disease control	May 15	August 3
Emergence	May 25	July 16
Application herbicides	May 27	July 29
Application insecticides	June 2	August 16
Late blight control	June 23	September 20
Harvest	August 31	October 27

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 *"deviations from this baseline pattern are observable for the characters maturity, date of harvest and yield"*. For 18 locations the farmers reported a lower yield, for 15 locations the farmers reported delayed harvest, for 6 locations the farmers reported accelerated maturity and for 4 locations the farmers reported delayed maturity. It could be predicted that a slower growing crop would result in a later harvest date, however for 6 locations the farmers report accelerated maturity and delayed harvest. It is possible that the modification to starch biosynthesis could result in a slower growing crop and reduced yield. Consistency and agreement between outcome variables is not shown, however these characteristics would also be affected by local conditions and management practices in addition to the genetic modification.

Data validation

1) Validation procedures

Section 2.7 of Appendix 7 of the 2010 Amflora 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 file 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. It is noted that when describing temperature during the growing season the information collected in Form 5 indicated the temperature was as usual for all locations, in the farmer questionnaire seven locations are classified as temperatures below average. The responses in the farmer questionnaire should be correlated with the information recorded during the growing season through the IP system.

2) Exclusion of results

All completed questionnaires (26) were included in the analysis.

3) Missing values

In the analysis of each of the monitoring characteristics the number of responses for each value is shown in the table including the missing values where they occur. Missing values occur only for the monitoring characteristic "Presence of wild animals". The report states "*at 7 fields (26.9%) the farmers did not observe wild animals"*. The farmer questionnaire raw data provided by BASF on the 24 November 2011 indicates the response was "*do not know*" for seven locations. The question in the farmer questionnaire is not formulated to obtain information on the absence of wild animals but to detect differences in animal occurrence compared to the comparator variety. This question should be phrased in the same way as the other monitoring characteristics and the "*don't know*" option should be removed.

Longitudinal aspects

1) Sampling over multiple years

2010 is the first year of commercial production for potato EH92-527-1. For the following years it would be of value to record if farm and field/s have been previously surveyed and to have information on the history of potato EH92-527-1 cultivation at the site. It is noted that the IP system specifies a

four year crop rotation for the cultivation of potatoes in fields where potato EH92-527-1 has been grown and this should be respected in any longitudinal analysis plan.

Statistical analysis

1) Objective and hypotheses

Appendix 7 of the 2010 Amflora 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 2.5 of Appendix 7 of the 2010 Amflora 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 fields surveyed in 2010. There was no analysis of country level data. Given the number of farms surveyed in some countries analyses of country level sub-group may not have been statistically valid, however consideration should be given to the fact that Member States may require country level results. It would be of interest to know if monitoring characteristics described as not "As usual" were identified by the farmers using previous experience with conventional potatoes as the comparator.

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. In response to a request for additional information, BASF provided the formula for the confidence intervals (shown below).

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

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

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

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 and "valid percentages" (the proportion of answers excluding missing values) 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, rainfall and temperature, 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

In the tables two percentages are presented the "Percent" which included missing values and the "Valid percentages" where the missing data or the "Don't know" responses were excluded. No missing values are reported with the exception of "Presence of wild animals".

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. 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 2010 Amflora report contains the following conclusions:

"The summary shows - considering the small sample size of 26 - mainly balanced distributions with a predominant part of the farmers assessing the situation to be as usual for most monitoring characters. Evident deviations from this baseline pattern are observable for the characters maturity, 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). Also other slight deviations (time to emergence, plant growth) must be explained by these environmental influences.

Other deviations like success of weed control indicate a positive effect contrary to an adverse one.

The occurrence of diseases and pest and disease susceptibility show increased frequencies of Plus answers. This can be explained by variety characteristics, which do not exceed conventional varieties' variation and do not indicate an adverse effect of the genetic modification."

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%. However, the farmer questionnaire raw data provided by BASF on the 24 November 2011 indicates that for all locations "no starch potato variety comparator" was available. As a consequence the comparison with the EH92-527-1 crop of 2010 is being made with conventional potato production and for six locations this is based on historical knowledge. This means that the assessment of difference in monitoring characteristics may be subject to recall bias for six locations. 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 2010 were interviewed in order to complete the farmer questionnaire, in total 26 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 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 future farmer surveys.

3) Substantiation of results

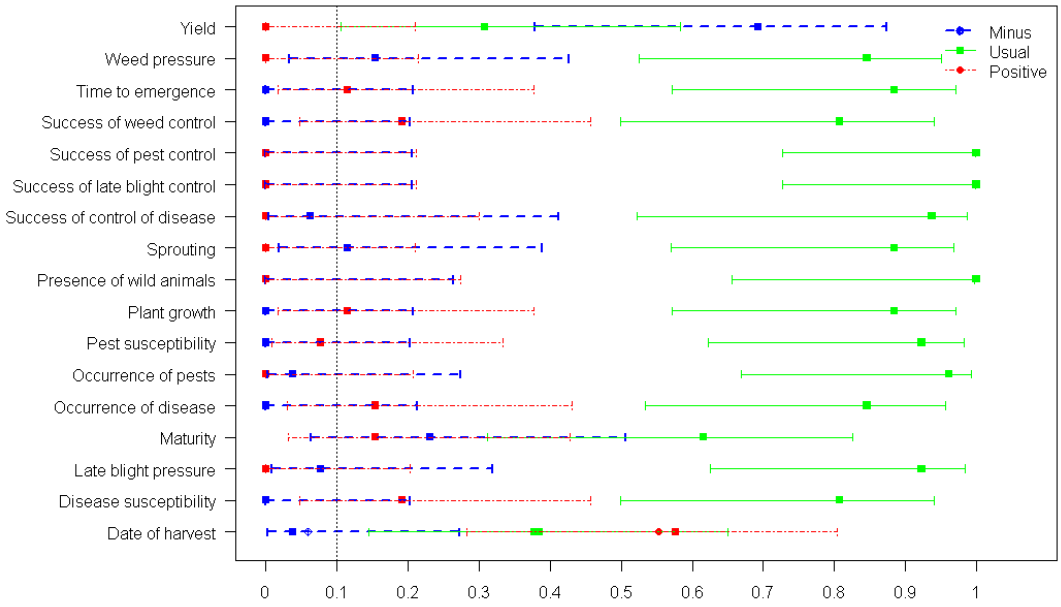
Due to the small number of farmers available for inclusion in the survey and large number of monitoring characteristics with "Plus" or "Minus" responses equal to zero, the multinomial model to estimate the confidence intervals used when assessing the farmer questionnaire for maize MON 810 was considered not appropriate for this survey (EFSA, 2011b). In order to deal with this issue (monitoring characteristics without "Plus" or "Minus" responses), the Bayesian paradigm was used. The Bayesian modelling approach assumed an uninformative Dirichlet prior distribution (continuous multivariate probability distribution bounded between 0 and 1) for the probabilities of the multinomial model to estimate the credible intervals. The 95% credible interval describes the uncertainty about the result based on the observations obtained from the survey combined with the prior information, which in this case was an uninformative prior, hence all uncertainty is related to the data. The method for deriving the credible intervals is provided in Appendix 2 and the results are shown in Figure 4.

In Figure 4 the lower bound of the credible interval for lower yield and delayed harvest is greater the 10% threshold indicating a difference between potato EH92-527-1 and the comparator varieties. Lower yield was reported for 18 locations (9 farms) from the raw data it can be seen that for locations reporting "As usual" the yield was from 12-22 t/ha and for lower yield the range was between 3-28.74 t/ha. Delayed harvest was reported for 15 locations (6 farms) from the raw data it can be seen that for locations reporting harvest as usual harvest dates ranged between 31/8/2010 – 24/09/2010 whereas for locations with delayed harvest dates ranged between 11/09/2011 – 27/10/2010. The report states that this can be explained by unfavourable weather conditions. 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.

However a proportion of responses greater than 10% are reported for increased disease occurrence and increased disease susceptibility. From the raw data it can be seen that increased disease susceptibility was reported in 5 locations (2 farms) and in one of the farms (four locations) the occurrence of disease was classified as higher than in conventional potatoes. For the 5 locations blackleg and potato virus Y were reported and control measures were applied, the success of the control measures was classified

"As usual". It would be of value to include in the monitoring report information on the diseases the increased occurrence and increased susceptibility related to when not classified "As usual". Responses above 10% for poorer sprouting, delayed time to emergence, delayed plant growth, less weeds and better weed control were also reported. However due the small number of locations growing potato EH92-527-1 in 2010 the upper credible interval exceeded 10% for all monitoring characteristics, even for those characteristics where "Plus" or "Minus" responses were zero hence the presence or absence of these effects cannot be assessed.

Figure 3: Credible Intervals (95%) for the Monitoring Characteristics reported in the potato EH92-527-1 farmer questionnaire for the 2010 growing season



Recommendations and Conclusions

From the data provided in the 2010 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 requirement of record keeping for plant performance, management practices and observations during the growing season (field-plot card-indices) as part the IP system which can be used as a basis during the interview process for the farmer questionnaire is to be commended. All information necessary to complete the farmer questionnaire should be included in the field-plot card-indices and the information recorded in the farmer questionnaire should directly correspond with the information previously recorded in the field-plot card-indices;

- The design of the farmer questionnaire relies on a comparison between potato EH92-527-1 and a comparator variety to detect unanticipated effects. It would be of value to be more explicit in the training for growers and IP documents about the importance of comparing the performance and experiences with potato EH92-527-1 against a comparator variety. The EFSA GMO Panel considers that non-GM starch-potato crops or conventional potato crops,

grown nearby with similar cultivation conditions 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 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;

- It is recommended to use independent trained interviewers to reduce interviewer bias;

- 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 2010 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 2010. To improve the assessment of possible effects the number of locations surveyed could be increased by pooling with the results of future farmer surveys. 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 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")
```