

SCIENTIFIC OPINION

Scientific Opinion on the annual Post-Market Environmental Monitoring (PMEM) report from BASF Plant Science Company GmbH on genetically modified potato EH92-527-1 in 2012¹

EFSA Panel on Genetically Modified Organisms (GMO)^{2, 3}

European Food Safety Authority (EFSA), Parma, Italy

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, provided by BASF, on the genetically modified (GM) potato EH92-527-1 (variety Amflora) for the 2012 growing season. Because of the discontinuation of the GM potato cultivation in the European Union in 2012, the 2012 monitoring report contained a limited information package, mainly the results of the 2012 monitoring study for volunteers within and around the fields cropped with the GM potato in 2010. The EFSA GMO Panel concludes that GM potato volunteers can be controlled by the applied weed control practices but cannot conclude on the absence of enhanced fitness of the GM potato due to data limitations and flaws in the study design. Hence, the EFSA GMO Panel makes appropriate recommendations. Accounting for the biology of the crop, the GM trait and the common management practices in potato cropping, the EFSA GMO Panel considers it is unlikely that a potential change in fitness or persistence would significantly alter the ability of GM volunteers to establish. Moreover, the EFSA GMO Panel does not consider the occurrence of potato volunteers as an environmental concern but rather as a crop management issue. Therefore, the EFSA GMO Panel concludes that the information provided in the 2012 monitoring report does not indicate any adverse effects of potato EH92-527-1 on the environment or human and animal health. Therefore, the outcomes of the 2012 monitoring report do not invalidate the conclusions of the EFSA GMO Panel's previous opinions on potato EH92-527-1.

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KEY WORDS

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

¹ On request from the European Commission, Question No EFSA-Q-2013-00439, adopted on 23 October 2013.

² Panel members: Salvatore Arpaia, Nicholas Birch, Andrew Chesson, Patrick du Jardin, Achim Gathmann, Jürgen Gropp, Lieve Herman, Hilde-Gunn Hoen-Sorteberg, Huw Jones, Jozsef Kiss, Gijs Kleter, Martinus Lovik, Antoine Messéan, Hanspeter Naegeli, Kaare M. Nielsen, Jaroslava Ovesná, Joe Perry, Nils Rostoks, Christoph Tebbe. One member of the Panel did not participate in the discussion on the subject referred to above because of potential conflicts of interest identified in accordance with the EFSA policy on declarations of interests.

Correspondence: gmo@efsa.europa.eu

³ Acknowledgement: The Panel wishes to thank the members of the Standing Working Group on annual PMEM reports: Salvatore Arpaia, Achim Gathmann, Jozsef Kiss, Antoine Messéan, Joe Perry for the preparation of this scientific opinion, and EFSA staff: Sylvie Mestdagh and Jane Richardson, for the support provided to this scientific opinion.

Suggested citation: EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2013. Scientific Opinion on the annual Post-Market Environmental Monitoring (PMEM) report from BASF Plant Science Company GmbH on genetically modified potato EH92-527-1 in 2012. EFSA Journal 2013;11(10):3445, 10 pp. doi:10.2903/j.efsa.2013.3445

Available online: www.efsa.europa.eu/efsajournal

SUMMARY

On 26 January and 6 December 2012, in response to the requests from the European Commission, the Panel on Genetically Modified Organisms of the European Food Safety Authority (EFSA GMO Panel) adopted a scientific opinion on the monitoring report on the genetically modified (GM) potato EH92-527-1 (variety Amflora) for the 2010 and 2011 growing seasons, respectively. During its assessment of these monitoring reports, the EFSA GMO Panel had identified shortcomings and made recommendations for the improvement of the methodology for both general surveillance (GS) and case-specific monitoring (CSM) for potato EH92-527-1.

Genetically modified (GM) potato EH92-527-1 cultivation was discontinued in the European Union in 2012. Consequently, the 2012 monitoring report contained a limited information package, including reports from visits by growers of fields cropped with potato EH92-527-1 in 2010 and 2011 under the identity preservation system, a review of peer-reviewed publications on the safety of potato EH92-527-1 and the outcomes of the 2012 monitoring study for volunteers within and around the fields in which potato EH92-527-1 was grown for starch production in 2010.

The EFSA GMO Panel notes similar shortcomings in the methodology of the specific study monitoring GM volunteers as were found in the monitoring report for the 2011 growing season. Hence, the EFSA GMO Panel makes recommendations for improvement of the study design and e.g. to gather additional data from seed tuber production fields. Nevertheless, based on the information provided by the applicant in its report, the EFSA GMO Panel concludes that the potato EH92-527-1 volunteers can be controlled by common agricultural practices in accordance with its previous environmental risk assessments of the GM potato.

Considering the data limitations (e.g. lack of data for seed tuber production fields) as well as the flaws (e.g. no baseline data for proper comparison) identified in the design of the specific monitoring study for volunteers, the EFSA GMO Panel cannot conclude on the absence of enhanced fitness of the GM potato. However, accounting for the biology of the crop, the GM trait and the common management practices in potato cropping, the EFSA GMO Panel considers it is unlikely that a potential change in fitness or persistence would significantly alter the ability of GM volunteers to establish. Moreover, the EFSA GMO Panel does not consider the occurrence of potato volunteers as an environmental concern but rather as a crop management issue.

In general, the EFSA GMO Panel concludes that the information provided in the 2012 monitoring report does not indicate any adverse effects of potato EH92-527-1 on the environment or human and animal health. The outcomes of the 2012 monitoring report do not invalidate the conclusions of the EFSA GMO Panel's previous opinions on potato EH92-527-1.

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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; unique identifier BPS-25271-9) with altered starch composition, for cultivation and production of starch from BASF Plant Science (EFSA, 2006a,b). The EFSA GMO Panel was of the opinion that the weight of evidence indicates that potato EH92-527-1 and derived products are no more likely to cause adverse effects on human and animal health or the environment than conventional potato, in the context of the proposed uses. The EFSA GMO Panel concluded that the environmental risk assessment (ERA) did not identify a risk that required Case-Specific Monitoring (CSM). However, the EFSA GMO Panel welcomed the proposals by the applicant to monitor the stability of the inserts and phenotypic expression during cultivation of the potato EH92-527-1 (EFSA, 2006a,b).

Subsequently, potato EH92-527-1 was approved under Directive 2001/18/EC (EC, 2001) for cultivation and industrial use in the EU and under Regulation 1829/2003 (EC, 2003) for production of starch and food and feed uses (EC, 2010). Commission Decision 2010/135/EU (EC, 2010) required the consent holder to carry out a specific field study to monitor potential adverse effects on potato-feeding organisms in the potato EH92-527-1 fields and their vicinity. A final consent was granted to the applicant by Sweden on 31 March 2010. Potato EH92-527-1 was cultivated in the European Union in 2010 and 2011. Hence the applicant submitted to the European Commission a monitoring report on the cultivation of the GM potato over the 2010 and 2011 growing seasons.

Consequently, upon requests from the European Commission, the EFSA GMO Panel adopted a scientific opinion on the 2010 and 2011 monitoring reports on GM potato EH92-527-1, respectively on 26 January and 6 December 2012. During its assessment of these monitoring reports, the EFSA GMO Panel had identified shortcomings in the methodology for both general surveillance (GS) and, in particular, the case-specific studies as required in the related Commission Decision. Hence the EFSA GMO Panel provided recommendations for the improvement of the Post-Market Environmental Monitoring (PMEM) of potato EH92-527-1 (for further details, see EFSA, 2012a,b). However, from the overall dataset submitted by the applicant, the EFSA GMO Panel did not identify adverse effects on the environment and to human and animal health due to potato EH92-527-1 cultivation in 2010 and 2011.

Genetically modified (GM) potato EH92-527-1 cultivation was discontinued in the European Union in 2012. However, in accordance with the Commission Decision (EC, 2010), the applicant submitted to European Commission the 2012 monitoring report.

On 21 May 2013, the EFSA GMO Panel received from the European Commission a request to assess the monitoring report submitted by BASF on potato EH92-527-1 in 2012. All the comments of the Member States on this report were received early July 2013.

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION AND EFSA

On 21 May 2013, the EFSA GMO Panel received a request from the European Commission to assess the Amflora 2012 monitoring report provided by BASF. This assessment should be reported through the adoption of a scientific opinion by October 2013.

ASSESSMENT

1. INTRODUCTION

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

The potato transformation event EH92-527-1 with the variety name Amflora was approved for commercial cultivation in the European Union in March 2010. Whilst GM potato EH92-527-1 was cultivated in the European Union (EU) in 2010 and 2011, the commercial cultivation was discontinued in 2012.

Nevertheless, in accordance with the EU legislative framework and the Commission Decision for the authorisation of GM potato EH92-527-1 (EC, 2010), the applicant reported to the European Commission and to Member States the results of its monitoring activities on potato EH92-527-1 in 2012. Due to the discontinuation of the GM potato cultivation, the 2012 monitoring report did not contain data from the case-specific studies, farmer questionnaires or study on potato-feeding organisms. However, the 2012 monitoring report contained a limited information package, including: (1) reports from visits by growers of fields cropped with potato EH92-527-1 in 2010 and 2011 under the identity preservation (IP) system, (2) a review of peer-reviewed publications on the safety of potato EH92-527-1, and (3) the outcomes of the 2012 monitoring of volunteers within and around the fields in which potato EH92-527-1 was grown for starch production in 2010.

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

In the following chapters of this Scientific Opinion, the EFSA GMO Panel describes its assessment of the 2012 monitoring report on potato EH92-527-1.

2. CASE-SPECIFIC MONITORING

2.1. Summary of the information provided by the applicant

Because of the discontinuation of the commercial cultivation of potato EH92-527-1 in the EU in 2012, the applicant did not monitor (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 GM potato tubers.

Under case-specific monitoring (CSM), the applicant monitored⁴ the seven fields in Czech Republic that were cropped with potato EH92-527-1 for starch production in 2010 in order

- (1) “to evaluate presence and persistence of Amflora volunteers and their frequency in the years following Amflora cultivation for starch production”, and

⁴ 2012 Monitoring report, Annex 4

- (2) “to demonstrate that Amflora is comparable to conventional potatoes with regard to its competitive behavior and the capacity to survive or tolerate environmental conditions like frost”, and
- (3) “to demonstrate that possible volunteer potatoes will be controlled effectively by the applied cultural practices”.

The applicant explained that there was no systematic monitoring of volunteers in and around the fields cropped with the GM potato in 2011 as all of the 2011 fields were for seed tuber production only. However, these fields were monitored for volunteers by growers within the IP system.

The applicant monitored twice within and on the perimeter of the fields (i.e., June and August 2012). The applicant recorded volunteer numbers within 20 plots (of 1 m²/each) per field and also surveyed a 2 m wide margin all around the field. In August 2012, the applicant detected two volunteers within one out of the seven monitored fields. That field was cultivated with maize. Leaf samples from potato volunteers were analysed by polymerase chain reaction (PCR), using primers specific to potato EH92-527-1. The PCR analysis showed that the two volunteers were derived from potato EH92-527-1.

The applicant acknowledged the decrease of volunteers compared to the outcome of the 2011 study as well as the fact that a maize crop seems to offer more favourable conditions for volunteers to emerge than other crops used in rotation like oilseed rape, spring barley, etc. Finally, the applicant concluded that the standard cultivation measures applied following starch potato EH92-527-1 production were appropriate to control potato volunteers, and that potato EH92-527-1 does not differ in its persistence from other potato varieties.

The applicant also reported the outcome of the monitoring of volunteers performed by growers under the IP system⁵ (for further details, see chapter 5 of EFSA, 2012b). In 2012, growers did not observe volunteers on their fields, cropped with potato EH92-527-1 in 2011. However, they still observed volunteers on 6 out of the 7 fields cropped with potato EH92-527-1 (i.e. for seed tuber production) in Sweden over 2010.

2.2. Assessment by the EFSA GMO Panel

Considering the timeline, the EFSA GMO Panel acknowledges that the applicant could not have fully implemented the Panel’s recommendations (e.g. to monitor some seed tuber production fields) on PMEM, as referred to in its scientific opinion on the 2011 monitoring report on potato EH92-527-1, in the 2012 monitoring scheme for the GM potato (EFSA, 2012b).

The results of the case-specific monitoring study on volunteers show that GM potato volunteers were present in very low numbers or not detected in these studies. The small number of volunteers observed (i.e. two volunteers) at only one out of the seven fields monitored confirmed that the sporadic occurrence of volunteers does not constitute an environmental concern but rather an agronomic and crop management issue (i.e. to be handled with appropriate weed control regimes). Accounting for the unchanged methodology for PMEM of potato EH92-527-1 in 2012, the EFSA GMO Panel reiterates its previous recommendations for the improvement of the field study to monitor for volunteers in GM potato fields for starch production in 2010. For further details, please consult sections 2.2.3 and 2.3 of EFSA (2012b).

Furthermore, the EFSA GMO Panel also considered the monitoring for presence or absence of volunteers by growers under the IP system. The occurrence of volunteers on most of the Swedish fields of 2010 (i.e. for seed tuber production) in the second year after cultivation might be an indication for a non optimal volunteer control of potatoes in the fields in Sweden. However, the monitoring under the IP system (i.e. presence/absence of volunteers) does not provide any indication,

⁵ 2012 Monitoring report, Annex 1

neither of their abundance, nor of the potential relationship to the field characteristics. A qualitative estimation of volunteer densities should be possible under the IP system.

Taking into consideration the results of the volunteer monitoring by growers of seed tuber production fields in Sweden, the EFSA GMO Panel reiterates its previous recommendation that seed production fields should be considered in the aforementioned case-specific study for monitoring volunteers (EFSA, 2012b).

2.3. Conclusions & Recommendations on CSM

Concerning the monitoring study of GM potato volunteers in 2012, the EFSA GMO Panel concludes that the null hypothesis was not clearly set by the applicant and also identifies weaknesses in the study (e.g., missing information on weed control practices, sampling methodology). In the absence of a clear rationale and risk hypothesis, the EFSA GMO Panel evaluated the methodology of the study aiming to test the hypothesis that the applied weed control practices controlled GM potato volunteers (i.e. maintain the incidence of volunteers close or equal to zero).

To test the null hypothesis as put forward by the EFSA GMO Panel (see Section 2.2.3 of EFSA, 2012b), the applicant should consider the following comments and recommendations:

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

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

- to describe the crop management practices in the fields monitored, paying particular attention to those techniques (e.g. cultivation management and harvesting methods, especially soil tillage, herbicide treatments) which may affect the survival of tubers in the soil and subsequent potato volunteers;
- to record weather conditions; as this monitoring study is aimed to last four years after potato EH92-527-1 cultivation, such data should be collected over this period;
- to better identify the observer collecting the data and to describe the protocol. For instance, raw data and quality control documents relating to the monitoring should be provided.

The EFSA GMO Panel also recommends that the applicant considers monitoring a proportion of seed tuber production fields each year in addition to starch production fields. The EFSA GMO Panel also recommends that, under the IP system, the monitoring of volunteers by growers is not restricted to qualitative observations but that rough estimates of volunteer densities are provided.

Based on the information provided by the applicant in its report, the EFSA GMO Panel confirms the aforementioned hypothesis that the applied weed control practices controlled GM potato volunteers (for further details, please see EFSA, 2006a,b; 2012a,b). Even though unusual observations indicating an increased fitness or persistence were not made, an increased fitness or persistence can not be completely excluded due to lack of data and an incomplete study design. However, accounting for the biology of the crop, the GM trait and the common management practices in potato cropping, the EFSA GMO Panel considers it is unlikely that a potential change in fitness or persistence would significantly

alter the ability of GM volunteers to establish. Moreover, the EFSA GMO Panel does not consider the occurrence of potato volunteers as an environmental concern but rather as a crop management issue.

3. GENERAL SURVEILLANCE

3.1. Summary of the information provided by the applicant

Considering the discontinuation of the commercial cultivation of potato EH92-527-1 in the EU in 2012, the general surveillance (GS) of the GM potato in 2012 was restricted to (1) the review⁶ of peer-reviewed publications on the safety of potato EH92-527-1 and (2) the visits⁷ by growers of 2010 and 2011 potato EH92-527-1 fields for presence of volunteers under the IP system.

From the literature search, the applicant found 16 hits, of which only two articles⁸, by Hannula et al. (2012a,b), are of relevance for the ERA of potato EH92-527-1. The applicant concluded that the peer-reviewed literature does not raise any safety concerns for potato EH92-527-1.

3.2. Assessment by the EFSA GMO Panel

The EFSA GMO Panel agreed with the overall approach followed by the applicant for the literature review. The EFSA GMO Panel agrees with the applicant that most of the identified publications (i.e. 16 hits) are not directly related to the cultivation of potato EH92-527-1 nor they are pertinent to the food and feed risk assessment of potato EH92-527-1.

Therefore, the EFSA GMO Panel considered the two articles⁹ by Hannula et al (2012a,b) that are of relevance for the ERA of potato EH92-527-1.

In their first study, Hannula et al. (2012a) analysed in a greenhouse study the potential effects of the GM potato Modena with increased levels of amylopectin, compared to parental variety Karnico¹⁰, on photosynthetic assimilation of CO₂, exudation of assimilated carbonaceous compounds in the rhizosphere and potential alterations in the soil fungal communities. According to the authors, the fungal microbial biomass differed between the GM and non GM potato rhizosphere mainly due to the speed of carbon flow to fungal communities. The authors also pointed the need to repeat the experiments under representative field conditions.

In their second study, Hannula et al. (2012b) compared the effects of growth stage of GM and non GM potato grown in field, soil type and year on the fungal communities. Only a few punctual differences were observed between the GM and parental variety. The authors concluded that the growth stage of the plant and the year were the two major factors influencing the diversity and function of soil fungal communities regardless whether the plant was GM or not.

The results underline the fact that variability in carbon flow and consequently in fungal community structures can occur in response to the growth stage of the potato and cultivar and indicate effect of the genetic modification of the GM potato on the selected parameters. The results support previous conclusions drawn by e.g. Geschwendtner et al. (2011) (for further details, see EFSA, 2012b). Considering the lack of significant difference between the GM event and the parental cultivar and the natural variability of carbonaceous compound distribution within the plant, depending on its developmental stage, the EFSA GMO Panel concludes that the publications by Hannula et al. (2012a,b) does not identify an environmental safety concern that would invalidate its 2006 Scientific Opinions on potato EH92-527-1 (EFSA, 2006a,b; EFSA, 2012a,b).

⁶ 2012 Monitoring report, Section 3.2.3 and Annex 5

⁷ 2012 Monitoring report, Annex 3

⁸ 2012 Monitoring report, Annex 6

⁹ 2012 Monitoring report, Annex 6

¹⁰ Karnico is the parental variety of GM potato Amflora.

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

3.3. Conclusions & Recommendations on GS

The EFSA GMO Panel acknowledges that the literature review submitted by the applicant was balanced and set in the context of the overall ERA of potato EH92-527-1. From the literature review provided by the applicant over 2012, no adverse effect due to potato EH92-527-1 can be identified. To conclude, no new data from the GS of potato EH92-527-1 in 2012 were provided that would invalidate previous evaluations of potato EH92-527-1 (EFSA, 2006a,b; 2012a,b).

OVERALL CONCLUSIONS AND RECOMMENDATIONS

The EFSA GMO Panel notes similar shortcomings in the methodology of the 2012 monitoring study for volunteers as were found in the monitoring report for the 2011 growing season. Hence, the EFSA GMO Panel makes recommendations for improvement of the study design and e.g. to gather additional data from seed tuber production fields. Nevertheless, based on the information provided by the applicant in its report, the EFSA GMO Panel concludes that the potato EH92-527-1 volunteers can be controlled by common agricultural practices in accordance with its previous environmental risk assessments (EFSA, 2006a,b; 2012a,b).

Considering the data limitations (e.g. lack of data for seed tuber production fields) as well as the flaws (e.g. no baseline data for proper comparison) identified in the design of the specific monitoring study for volunteers, the EFSA GMO Panel cannot conclude on the absence of enhanced fitness of the GM potato. However, accounting for the biology of the crop, the GM trait and the common management practices in potato cropping, the EFSA GMO Panel considers it is unlikely that a potential change in fitness or persistence would significantly alter the ability of GM volunteers to establish. Moreover, the EFSA GMO Panel does not consider the occurrence of potato volunteers as an environmental concern but rather as a crop management issue.

In general, the EFSA GMO Panel concludes that the information provided in the 2012 monitoring report does not indicate any adverse effects of potato EH92-527-1 on the environment or human and animal health. The outcomes of the 2012 monitoring report do not invalidate the conclusions of the EFSA GMO Panel’s previous opinions on potato EH92-527-1.

DOCUMENTATION PROVIDED TO EFSA

1. Letter from the European Commission, dated 7 May 2013, to the EFSA Executive Director requesting the assessment of Amflora monitoring report for the 2012 cultivation season provided by BASF.
2. Acknowledgement letter, dated 7 June 2013, from the EFSA Executive Director to the European Commission.

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