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Updated scientific arguments supporting
the import ban of *Solanum tuberosum*
L. line EH92-527-1

AutorInnen:

Michael Eckerstorfer
Andreas Heissenberger

Umweltbundesamt GmbH, Abteilung Landnutzung &
Biologische Sicherheit, Spittelauer Lände 5, 1090 Wien

Update of SCIENTIFIC ARGUMENTS supporting the existing BAN ON CULTIVATION OF GENETICALLY MODIFIED POTATO (*Solanum tuberosum* L. line EH92-527-1, NOTIFICATION C/SE/96/3501) IN AUSTRIA

MONITORING OF CULTIVATION OF GM POTATO EH92-527-1

1. General remarks concerning monitoring of cultivation of GM potato EH92-527-1

1.1. Background for introduction of the Austrian safeguard measure

Austria submitted reasoned objections against this notification on 25th June 2004 and again on 26th January 2005, with regard to concerns about the environmental risk assessment and monitoring. The objection was upheld taking into account the discussions and clarifications provided by the notifier on 11th January 2005. Several other Member States also upheld their objections concerning aspects related to monitoring of GM potato EH92-527-1 after discussions at a meeting on 11th January 2005.

On 2nd March 2010 Decisions were published by the European Commission to grant authorisation of the proposed use of GM potato EH92-527-1 according to the notifications under Directive 2001/18/EC and Regulation (EC) No 1829/2003 (It has to be remarked that the notification submitted according to Regulation (EC) No 1829/2003 in 2005 is also referring to the monitoring plan submitted in the framework of the notification according to Directive 2001/18/EC).

The Swedish Board of Agriculture has taken a decision on 31st March 2010 to place GM potato EH92-527-1 on the market for cultivation and industrial use, in compliance with the European Commission Decision under Directive 2001/18/EC (2010/135/EU) of 2nd March 2010.

The Swedish Board of Agriculture is currently discussing with the consent holder, BASF Plant Science how to implement the monitoring as laid out in the annex of the decision of the European Commission. At the same time a decision to add GM potato EH92-527-1 to the Swedish National variety list was taken. On 10th April 2010 this product was registered in the Common Catalogue of Varieties of Agricultural Plant Science.

The COM Decision (2010/135/EU) of 2nd March 2010 in its Annex only provides a very general obligation to undertake field studies to monitor for potential adverse effects on potato-feeding organisms in the fields where GM potato EH92-527-1 is cultivated and reconfirms the proposed monitoring with a view to discussions between the consent holder and the competent authorities of the Member States.

1.2. Background for extension of the Austrian safeguard measure in October 2012

In October 2012 the existing Austrian safeguard measure banning the cultivation of GM potato EH92-527-1 in Austria was extended until 2015. The reasoning supporting this decision takes into account new information as regards post-market environmental monitoring (PMEM). Among others it considers the reports by the consent holder on implementation of the existing monitoring plan submitted in 2011 and 2012, as well as the reviews on these reports conducted by EFSA and Member States like Austria. Of specific interest in this respect is the opinion of the EFSA GMO panel on the PMEM report submitted by the consent holder in 2011 reviewing the PMEM measures conducted during the cultivation year 2010 (EFSA 2012a).

2. Flaws in the risk assessment with relevance for monitoring

Previously Austria issued concerns related to the notified changes in composition of GM potato EH92-527-1 based on the environmental risk assessment (ERA) conducted by the Swedish competent authority: “A change in these parameters (note: mono- and disaccharides, vitamin C, glycoalkaloid level) could indicate that next to the insertion of the genes of interest other changes have occurred. They may be a direct consequence of the modification or result from epigenetic changes or somaclonal variation. These deviations may remain unnoticed and, if deleterious, could affect other organisms” (SBA 2004).

However some of the concerns (see BMG 2010) are not considered adequately in the implemented monitoring plan. No additional specific requirements to address these uncertainties were set forth in the decision for authorisation by the European Commission according to Directive 2001/18/EC, except for the requirement for CSM-monitoring measures for effects of GM potato EH92-527-1 on organisms present in and around the cultivation fields.

In our opinion relevant aspects of the ERA conducted for GM potato EH92-527-1 are lacking adequate strength and are associated with significant uncertainties. According to Directive 2001/18/EC post-marketing monitoring needs to be implemented in accordance with Annex VII to address any identified risks and to confirm assumptions taken during the risk assessment as well as to identify the occurrence of adverse effects of the GMO or its use on human health or the environment, which were not anticipated in the risk assessment. Appropriate monitoring is thus an important instrument to implement the precautionary approach in GMO regulation in a case specific manner (Züghart et al. 2011).

3. Shortcomings of the monitoring of cultivation of GM potato EH92-527-1

3.1. General shortcomings

As criticised previously (BMG 2010) the monitoring plan provided by the notifier is not deemed comprehensive enough and is not elaborated in adequate detail. Among other issues the current monitoring plan lacks a number of necessary elements: e.g. reference to standardised methods adequate to address the pending issues, appropriate setting of the scope of investigations, as well as application of methods for analysing data, which can be considered state of the art.

We note that in this respect the recommendations for monitoring issues, methods and location & timing of monitoring measures as outlined in the comprehensive monitoring checklist for GM potatoes with altered starch content (MWG 2008c) established by the Monitoring working group of the Commission and the Competent Authorities under Directive 2001/18/EC (MWG 2008a) were not adequately considered by the consent holder to conceptionally implement the legal framework for monitoring (Züghart et al. 2008).

Additionally the representativeness of the implemented monitoring with regard to a potential large-scale application of GM potato EH92-527-1 needs to be explained further.

Furthermore Austria noted that PMEM needs to address all potential routes of environmental exposition for cultivation and import of GM potato EH92-527-1, including accidental spillage or release of tubers during transport and handling. As indicated by BMG (2010) the survival of viable transgenic potato tubers over winters cannot be excluded and should be subject to monitoring. A study by the consent holder on the occurrence of volunteers from the cultivation of GM potato EH92-527-1 in 2010 indicates that a substantial number of volunteer plants were detected next to one of the seven fields monitored. At this location some volunteer plants could still be detected at the second time-point (Annex 13, Table 2). This seems to indicate a potential of GM potato EH92-527-1 for persistence and should be further addressed in the light of our previously noted concerns (see BMG 2010).

The general conclusions by the EFSA GMO panel also indicate that the current approach by the consent holder should be improved as regards adequate monitoring of all exposure pathways (EFSA 2012b). EFSA recommends in this respect that the currently used Identity Preservation System should be supplemented by further measures to better address the use of material derived from GM potato EH92-527-1 for animal feed.

The review by Member States, among them Austria, of the PMEM measures implemented by the consent holder in the years 2010 and 2011 indicates that PMEM conducted by the consent holder is deficient in a number of ways. This conclusion is supported by the substantial number of recommendations for improvement of monitoring as described in a recent EFSA opinion on the annual PMEM report on the cultivation of genetically modified potato EH92-527-1 in 2010 (EFSA 2012a).

We also note that the consent holder in 2011 did not take into account the recommendations for improvement outlined by several Member States, among them Austria, submitted in response to the PMEM report on monitoring in 2010. Since the EFSA opinion on PMEM reported for the year 2010 supports many of the concerns notified previously by Member States, we cannot accept the general conclusion by the consent holder that the monitoring is adequately addressing the conditions required by Commission Decision 2010/135/EU and consent Dnr 22-3501/96 by the Swedish Board of Agriculture and that no adaptations concerning the monitoring of GM potato EH92-527-1 are required.

The results of the EFSA review (EFSA 2012a) support the Austrian opinion that the monitoring activities need substantial improvement to meet the objectives defined in Annex VII of Directive 2001/18/EC and to sufficiently address uncertainties associated with the ERA (BMG 2010). We are concerned that the design of the current PMEM is not suited to conclusively assess adverse effects by GM potato EH92-527-1 in a meaningful way. Since some monitoring measures are not appropriately addressing the issues that are subject to monitoring and do not meet the respective requirements, we cannot support the overall conclusion by the consent holder that the reported results could demonstrate that GM potato EH92-527-1 exerts no adverse effects on human and animal health and the environment.

On the contrary the monitoring approach needs to be urgently revised by the consent holder taking into account the following issues and the many recommendations by the EFSA GMO panel (EFSA 2012a).

3.2 Flaws in the Case-Specific Monitoring (CSM)

The review of the current PMEM which was implemented for two consecutive years (2010 & 2011) shows that the CSM approach needs to be substantially revised to provide appropriate monitoring (see e.g. EFSA 2012a, 2012b).

Many concerns by Austria (BMG 2010) were not adequately addressed by the implemented PMEM measures, e.g.

- The stability of the transgenic traits and the composition of GM potato EH92-527-1, specifically as regards the compositional differences identified during ERA regarding mono- and disaccharides as well as vitamin C.
- The consideration of additional potential routes of environmental exposition, e.g. accidental spillage or release of tubers during transport and handling.
- The impact of material from GM potato EH92-527-1 on decomposition processes in the soil.
- The possibility of horizontal gene transfer of antibiotic resistance marker genes from GM potato EH92-527-1 to soil microorganisms.
- Appropriate investigation of effects of GM potato EH92-527-1 cultivation on biodiversity and specific organisms associated with potato crops.

- Potential unanticipated effects on human and animal health.

The monitoring therefore needs to specifically address whether the significant differences identified during ERA for some compounds present in GM potato EH92-527-1 (increase of mono- and disaccharide content and decrease of solanin and chaconin content) have consequences for the susceptibility of the GM potato cultures to all relevant potato pests and diseases (see BMG 2010). The monitoring needs to take into consideration any single or combined effects of these compositional changes since the different pest species react differently to increased sugar and/or decreased glycoalkaloid contents. The indirect effects of any changes in susceptibility to pests need to be taken in consideration as well, since consequently a higher amount of pesticides may be needed for cultivation management.

The current PMEM addresses some issues concerning stability and composition of GM potato EH92-527-1. However the comments of Member States, including Austria, concerning these monitoring measures demonstrate, that the approach for monitoring and the methods used for monitoring by the consent holder are not fully appropriate. E.g. for the composition the consent holder did not establish the representativeness of trial sites, different methods were used in different years which limits comparability, an adequate statistical analysis of results is missing, and the influence of location and varieties are not discussed by the consent holder. Furthermore the conducted studies do not seem to be fully adequate to implement the monitoring plan submitted by the consent holder or to sufficiently implement a comparative approach.

As requested previously (BMG 2010) the PMEM approach should address effects of the GM potato EH92-527-1 on the microorganism-flora of the soil. The monitoring needs also to address any impacts on decomposition processes in the soil, to substantiate assumption taken by the consent holder during ERA. Furthermore the possibility of horizontal gene transfer of antibiotic resistance marker genes to soil microorganisms should be taken into account.

The monitoring also needs to better address issues which may be associated with the identified compositional changes in GM potato EH92-527-1 (as noted by BMG 2010). A specific point in question which is not sufficiently addressed by the current monitoring is the issue whether the modified starch content and the increase in mono- and disaccharide content is influencing frost tolerance of the tubers of GM potato EH92-527-1. The currently implemented monitoring of GM potato volunteers is not sufficient to comprehensively address this issue. Any PMEM for larger scale-cultivation of GM potato EH92-527-1 therefore needs to specifically assess the following factors in order to establish an estimate of the potential for contamination of potato-products produced for the food- and feed-supply:

- winter temperatures and snow covering periods in the cultivation areas,
- relevant crop rotation factors, specifically with respect to subsequent potato cultivation,

- cultivated potato varieties, specifically the use of nematode resistant potato-varieties which allow shorter rotation schemes for potato cultivation,
- methods of harvest and tillage procedures,
- management of subsequent crops.

In addition to the above concerns, the PMEM implemented by the consent holder in 2010 and 2011 failed to meet the requirements by Commission Decision 2010/135/EU as regards implementation of a study to monitor potato feeding organisms, which occur naturally on potato fields and in their vicinity.

The study implemented in 2010 and 2011 was poorly designed and executed and did not generate conclusive data. The EFSA GMO panel (EFSA 2012a, 2012c) identified crucial shortcomings and “relevant flaws” echoing our concerns.

In conclusion EFSA recommended improvements to be made concerning e.g.

- the range of organisms addressed by the study, e.g. to include pollinators,
- the sampling approach, e.g. as regards the timing and frequency of sampling
- that the study did not investigate the “vicinity” of the fields, but only the outer rows of the fields,
- the fact that insecticide treatments of the used management regime have a substantial impact on the study results,
- the way the data were analysed (i.e. lack of appropriate statistical analysis).

Most importantly the study was not designed as a comparative assessment: “A major drawback of the field study performed by the applicant is the lack of a meaningful comparator” (EFSA 2012a). Additionally “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” (EFSA 2012a). The results of the study therefore cannot be extrapolated to different management systems for starch potato cropping and are thus of limited overall significance.

In summary EFSA concluded 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 ...” (EFSA 2012a).

EFSA also noted that the study did not assess the vicinity of GM potato fields but only the outer rows of the GM crop and requested that the applicant “revises his definition of vicinity” (EFSA 2012a, 2012b). Thus the study failed to meet the requirements stated by Commission Decision 2010/135/EU.

We note that similar shortcomings were apparent for the study included in the monitoring report submitted in 2012. Thus the results reported by the consent holder cannot be considered adequate as regards the objectives of the study and the requirements of Commission Decision 2010/135/EU.

3.3 General surveillance (GS) of unforeseen and long-term effects

The general surveillance implemented by the consent holder in 2011 consisted of several measures, e.g. feedback from growers by farmers questionnaires, observations by third parties, implementation of an IP system and the assessment of relevant literature. However it is not sufficient to allow the detection of potential (unanticipated) adverse effects upon cultivation of GM potato EH92-527-1. Thus the current GS does not meet the requirements set out in Annex VII of Directive 2001/18/EC.

The current GS does not apply scientific methods for the investigation of effects of biodiversity, except the organisms investigated during the CSM. Instead the proposed GS focuses on feedback from the growers by farmer questionnaires. Again Member States and EFSA (EFSA 2012a) identified weaknesses in the implemented methodology for conducting the surveys:

- The methodology of interviews needs to be revised to ensure an impartial and standardised conduct of interviews, to support the necessary quality assurance and auditing. Among other issues more detailed questions are necessary to better address environmental effects (e.g. effects on wild living animals should be specified for the different groups of animals exposed to Amflora potatoes).
- Data analysis needs to be revised and the power of the results needs to be discussed adequately (for respective guidance see EFSA 2010b). It appears that too few interviews were conducted to provide evidence for absence of effects. Furthermore the monitored characteristics were surveyed using a very coarse, qualitative scale, which limits the significance of the results.
- The monitoring of environmental parameters needs to be based on scientific measurements involving expert knowledge rather than on the individual knowledge of farmers.
- 40% of interviewees report lower yield and a delayed harvest time for GM potato EH92-527-1 potatoes in comparison to non-GM starch potatoes for 2011. Such apparent differences should be further addressed by the consent holder.

In addition the recent general suggestions for an improved use of farmer questionnaires (e.g. EFSA 2011b) should be taken into account, as well as the recommendations directed to the specific application itself: “The EFSA GMO Panel has noted a number of shortcomings in the methodology and, therefore, has given specific recommendations to the applicant for improvement of the methodology (e.g., farmers survey) for GS of potato EH92-527-1” (EFSA 2012c).

In our opinion the monitoring by farmer questionnaires as conducted by the consent holder is not suitable for the early detection of adverse effects to human health and the environment as required by Directive 2001/18/EC.

The monitoring plan proposed for GM potato EH92-527-1 describes the implication of key existing networks other than potato growers and industrial processors, among them non-agronomical experts for the surveillance of the receiving environments and human

and veterinary health institutions. However – as noted by EFSA - the consent holder did not provide any details on implication of existing environmental networks active in biodiversity survey (EFSA 2012a). Again Austria on this account supports the notion by EFSA that the implemented methodology should be revised (e.g. EFSA 2012b).

In summary the current approach to GS does not address Austrian concerns regarding the need to involve appropriate monitoring networks in GS, the expertise of the institutions and persons involved in monitoring, the methodology used for monitoring, and the location and frequency of monitoring activities. Furthermore an evaluation as required by Commission Decision 2009/770/EC to assess “whether the information gained from general surveillance is adequate and of relevance for the monitoring/detection of direct, indirect, delayed and/or cumulative effects is lacking.”

4. Conclusion

The currently monitoring approach for GM potato EH92-527-1 is not sufficient to meet either the general requirements of Annex VII of Directive 2001/18/EC or the obligations according to COM decision 2010/135/EU.

The PMEM approach therefore needs to be significantly improved in the following ways:

- in general terms as outlined in chapter 3.1.,
- with regard to Case-Specific Monitoring (see chapter 3.2.) taking into account the relevant guidance for ERA and PMEM (EFSA 2010a, 2011a) and suggestions for improvement derived from the review of monitoring conducted in 2010 and 2011 (e.g. EFSA 2012a)
- with regard to General Surveillance (see Chapter 3.3.) taking into account the recommendations of the Monitoring Working Group concerning PMEM of GM potato crops (MWG 2008b) and general recommendations for GS of GM crops derived from the review of existing PMEM approaches (EFSA 2011b, 2012a).

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