MINUTES OF THE 67TH MEETING OF THE SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS HELD ON 7-8 JULY 2011 IN PARMA, ITALY

(ADOPTED ON 7 SEPTEMBER 2011)

PARTICIPANTS

GMO Panel:
Hans Christer Andersson, Salvatore Arpaia, Detlef Bartsch, Josep Casacuberta, Howard Davies, Gerhard Flachowsky, Lieve Herman, Patrick du Jardin, Jozsef Kiss, Gijs Kleter, Harry Kuiper (Chair), Antoine Messéan, Kaare Nielsen, Joe Perry , Annette Pöting, Jeremy Sweet, Christoph Tebbe, Atte Von Wright and Jean-Michel Wal.

Hearing Experts:
Willem Seinen[1].

GMO Unit: Jaime Aguilera, Per Bergman, Anna Christodoulidou, Yann Devos, Zoltán Divéki, Christina Ehlert, Antonio Fernández, Karine Lheureux, Yi Liu, Irina Olaru, Claudia Paoletti, Nancy Podevin, Stefano Rodighiero, Reinhilde Schoonjans and Elisabeth Waigmann.
AHAW Unit: Per Have

European Commission:
Sabine Pelsser (DG SANCO).

APOLOGIES

GMO Panel:
Huw Jones and Sirpa Kärenlampi[2].

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1. WELCOME AND APOLOGIES FOR ABSENCE

The Chair opened the meeting and welcomed all. The Chair welcomed Irina Olaru, Seconded National Expert from Rumania, who will work with the GMM Team of the EFSA GMO Unit. Apologies for absences were received from the Panel members indicated above.

2. ADOPTION OF THE AGENDA

The agenda was adopted as proposed.

3. DECLARATION OF INTERESTS

In accordance with EFSA's Policy on Declarations of Interests, EFSA screened the Annual Declaration of interest (ADoI) and Specific Declaration of interest (SDoI) filled in by the experts invited to the present meeting.

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[1] Participated via tele-conference on 6 July for item 5.1 only.

[2] Technical reasons prevented EFSA to connect with Panel member via tele-conference.

With regard to this meeting no other interests than those already declared in the ADoI or in a previous SDoI and screened by EFSA in accordance with its Policy on Declarations of Interests and implementing documents thereof was declared by the experts. The following was declared:

In his specific declaration of interest (SDoI) and at the beginning of the meeting, the expert Detlef Bartsch declared an interest for item ~~5.2 (EFSA-GMO-UK-2007-43) and~~[1] 5.3 (EFSA-GMO-BE-2010-79), for which the expert's institution submitted comments in the MS table, and for item 5.4 (EFSA-Q-2010-01253), for which the expert's institution submitted comments during the public consultation.
At the beginning of the meeting and in line with his ADoI, the expert Christophe Tebbe expressed an interest for item 8.3.a (prohibition of the placing on the market of GM potato EH92-527-1 for cultivation purposes in Austria) and 8.3.b (request to assess Amflora PMEM report for the 2010 cultivation season).

For further details regarding the assessment of declared interests please refer to Annex 1 of these minutes.

4. ADOPTION OF THE MINUTES OF THE 66TH PLENARY MEETING HELD ON 25-26 MAY 2011

The minutes of the 66th Plenary meeting (25-26 May 2011) were adopted with minor editorial changes and will be published at: http://www.efsa.europa.eu/en/events/event/110525.htm

5. DISCUSSION AND POSSIBLE ADOPTION OF OPINIONS

5.1. Application for renewal of authorisation for continued marketing of food additives, feed materials and feed additives produced from cotton MON531 (EFSA-GMO-RX-MON531) (EFSA-Q-2007-151)

The GMO Panel discussed the draft scientific opinion and concluded that the issue of horizontal gene transfer of *npt*II, needs further discussion. The draft will be revised by the GMO Panel member experts and will be presented for adoption at the September Plenary meeting.

5.2. Application for authorisation of genetically modified Soybean 356043 and derived food and feed submitted under Regulation (EC) No 1829/2003 by Pioneer (EFSA-GMO-UK-2007-43) (EFSA-Q-2007-087)

Introduction

Following the submission of an application (EFSA-GMO-UK-2007-43) under Regulation (EC) No 1829/2003 from Pioneer, the EFSA Panel on Genetically Modified Organisms was asked to deliver a scientific opinion on the herbicide tolerant genetically modified (GM) soybean 356043 (Unique identifier DP-356Ø43-5) for food and feed uses, import and processing.

Discussion

In delivering its scientific opinion, the EFSA GMO Panel considered the application EFSA-GMO-UK-2007-43, additional information supplied by the applicant and scientific comments submitted by Member States. Furthermore, Pioneer provided additional toxicology studies to EFSA all of which were considered by EFSA in its opinion.

The scope of application EFSA-GMO-UK-2007-43 is for food and feed uses, import and processing of soybean 356043 and all derived products, but excludes cultivation in the EU. The EFSA GMO Panel assessed soybean 356043 with reference to the intended uses and appropriate principles described in the Guidance Document of the Scientific Panel on Genetically Modified Organisms for the risk assessment of genetically modified plants and derived food and feed (EFSA, 2006a). The scientific assessment included molecular characterisation of the inserted DNA and expression of target proteins. A comparative analysis of agronomic traits and composition was undertaken, and the safety of the new protein and the whole food/feed were evaluated with respect to potential toxicity, allergenicity and nutritional quality. An assessment of environmental impacts and of the post-market environmental monitoring plan was undertaken.

The 356043 soybean has been genetically modified for herbicide tolerance. This was achieved by the introduction of the *gat4601 (*an optimized form of the glyphosate acetyltransferase *(gat)* coding sequence from *Bacillus licheniformis* that confers tolerance to glyphosate- and glyphosate-ammonium based herbicides) and the *Glycine max-hra* (*gm-hra*, an optimized form of the endogenous acetolactate synthase (*als*) coding sequence from soybean (*Glycine max*), that confers tolerance to ALS-inhibiting herbicides, such as chlorimuron, thifensulfuron or sulfonylureas).

The molecular characterisation data establish that the genetically modified soybean 356043 contains one copy of an intact *gat4601* expression cassette and a *gm-hra* cassette in a single locus. No other parts of the plasmid used for transformation are present in the transformed plant. Bioinformatic analysis of the open reading frames spanning the junctions between the inserted DNA and soybean genomic DNA did not raise safety concerns. The stability of the inserted DNA and the herbicide tolerance trait were confirmed over several generations. Analyses of the levels of newly expressed proteins in various plant tissues collected from field trials performed in South- and North America did not raise safety concerns.

The GMO Panel concluded that no differences were identified between 356043 soybean and its conventional counterpart, except for the newly expressed proteins, for higher levels of the acetylated amino acids N-acetylaspartate (NAA) and N-acetylglutamate (NAG), and the odd-chain fatty acids heptadecanoic, heptadecenoic and heptadecadienoic acid in seed from 356043 soybean. The levels of these acetylated amino acids and odd chain fatty acids fall outside the natural ranges observed for other commercial non-GM soybean varieties. The overall level of NAA and NAG (taken together) in soybean 356043 was found to be less than 0.15 % of the total amino acids. The total level of odd chain fatty acids amounts to less than 1% of total fatty acids. No statistically significant differences in total amino acid contents in seed were observed between the 356043 soybean and its conventional counterpart. Levels of major fatty acids in 356043 soybean seed were found to be comparable to those observed in the conventional counterpart.

No toxicity of the GAT4601 and the *Glycine max*-HRA proteins was observed in repeated-dose (28 days) feeding studies using mice. The studies on *in vitro* digestibility of the proteins showed that most of the proteins were degraded. In bioinformatics studies the proteins showed no homology to known toxic proteins and allergens.

The odd-chain fatty acids heptadecanoic, heptadecenoic and heptadecadienoic acid are normal constituents of plants and animals and have also been identified in human tissues. There is no information indicating that the intake of small amounts of these fatty acids via food or feed causes adverse effects. The EFSA GMO Panel is of the opinion that the estimated increases in intake levels of heptadecanoic, heptadecenoic and heptadecadienoic acid resulting from replacement of conventional soybean oil with oil from soybean 356043 do not raise safety concerns.

NAA and NAG are normal constituents in the mammalian metabolism. They are also present in conventional foodstuffs and thus consumed as part of a normal diet. The available scientific

information indicates that under normal conditions NAA and NAG, like other N-acetylated amino acids, are deacetylated in the intestine to form the corresponding L-amino acids, which are further metabolised in the body. The oral toxicity of NAA and NAG has been tested in acute and subacute (28 days) studies using rats. In addition, NAA was tested in a subchronic (90 days) feeding study and in a study on reproductive and developmental toxicity (two generation study) using rats. Considering the outcome of a conservative intake assessment, the estimated increase in intake of NAA is more than 100 fold lower than the NOEL observed in the 90-day rat feeding study with NAA. Furthermore, in relation to the normal intake of L-aspartic acid and L-glutamic acid resulting from consumption of food protein, the estimated increases in the intake of NAA and NAG are considered low. Considering all the available information, the EFSA GMO Panel is of the opinion that the estimated increases in intake levels of NAA and NAG resulting from replacement of food products derived from conventional soybeans by the respective products derived from soybean 356043 do not raise safety concerns. The same conclusion applies to the use of feed materials derived from this genetically modified soybean.

Furthermore, a subchronic 92-day feeding study in rats using diets including meal and hulls derived from soybean 356043 provided no indications of adverse effects. Testing of extracts from soybeans 356043 with sera from patients allergic to soybean showed that the overall allergenicity of the whole plant had not been changed. A 42-day feeding study using broiler chickens demonstrated that soybean 356043 is nutritionally equivalent to its conventional counterpart and commercial non-GM soybean varieties included in this study. Therefore, the EFSA GMO Panel is of the opinion that soybean 356043 is as safe as its conventional counterpart with respect to potential effects on human and animal health in the context of its intended uses.

The application EFSA-GMO-UK-2007-43 is for food and feed uses, import and processing. Therefore, there is no requirement for scientific information on possible environmental effects associated with the cultivation of soybean 356043. There are no indications of an increased likelihood of establishment and spread of feral soybean plants in case of accidental release into the environment of viable seeds of soybean 356043 (e.g. during transportation and processing), except in the presence of glyphosate and ALS-inhibiting herbicides. Taking into account the scope of the application, the rare occurrence of feral soybean plants and the low levels of exposure through other routes, the risk to non-target organisms is extremely low. In the context of its intended uses, the theoretically possible transfer of the recombinant genes from soybean 356043 to gut or other environmental bacteria has not been identified to be a risk due to the lack of any selective advantage. The EFSA GMO Panel agrees with the reporting intervals proposed by the applicant in the general surveillance plan. The EFSA GMO Panel recommends that appropriate management systems should be in place to restrict seeds of soybean 356043 entering cultivation as the latter requires specific approval under Directive 2001/18/EC or Regulation (EC) No 1829/2003.

Conclusion

In conclusion, the EFSA GMO Panel considers that the information available for soybean 356043 addresses the scientific comments raised by the Member States and that the soybean 356043, as described in this application, is as safe as its conventional counterpart with respect to potential effects on human and animal health and the environment in the context of its intended uses.

Adoption

The opinion was adopted unanimously by the EFSA GMO Panel. The scientific opinion will be published on the following EFSA website: http://www.efsa.europa.eu/en/scdocs.htm.

The Panel notes that additional exposure to certain acetylated amino acids may occur from the consumption of non GM but also of other future GM crops expressing the GAT protein. Therefore

it recommends risk managers to consider the implementation of future horizontal measures monitoring the cumulative intake level of such compounds that might cause adverse health effect.

5.3. Application for authorisation of genetically modified Soybean MON87701 for food and feed uses, import and processing submitted under Regulation (EC) No 1829/2003 by Monsanto (EFSA-GMO-BE-2010-79) (EFSA-Q-2010-00867)

Introduction

Following the submission of an application (EFSA-GMO-BE-2010-79) under Regulation (EC) No 1829/2003 from Monsanto, the Panel on Genetically Modified Organisms of the European Food Safety Authority (EFSA GMO Panel) was asked to deliver a scientific opinion on the safety of insect resistant genetically modified (GM) soybean MON 87701 (Unique Identifier MON-877Ø1-2) for food and feed uses, import and processing.

Discussion

In delivering its scientific opinion, the EFSA GMO Panel considered the application EFSA-GMO-BE-2010-79, additional information supplied by the applicant, scientific comments submitted by the Member States, and relevant scientific publications. The scope of application EFSA-GMO-BE-2010-79 is for food and feed uses, import and processing of soybean MON 87701 within the European Union as any non-GM soybean but excludes cultivation in the EU. The EFSA GMO Panel evaluated soybean MON 87701 with reference to the intended uses and appropriate principles described in its Guidance Document of the Scientific Panel on Genetically Modified Organisms for the Risk Assessment of Genetically Modified Plants and Derived Food and Feed (EFSA, 2006a). The scientific evaluation of the risk assessment included molecular characterisation of the inserted DNA and expression of the corresponding proteins. An evaluation of the comparative analysis of composition, phenotypic and agronomic characteristics was undertaken, and the safety of the new proteins and the whole food/feed was evaluated with respect to potential toxicity, allergenicity and nutritional wholesomeness. An evaluation of the environmental impacts and of the post-market environmental monitoring plan was undertaken.

Soybean MON 87701 was transformed using *Agrobacterium tumefaciens*. Soybean MON 87701 expresses the *cry1Ac* gene leading to the production of the Cry1Ac insecticidal crystal protein (δ-endotoxin). The Cry1Ac protein provides protection from feeding damage caused by specific lepidopteran pests in the soybean.

The molecular characterisation data establish that the genetically modified soybean MON 87701 contains one copy of an intact *cry1Ac* expression cassette. No other parts of the plasmid used for transformation are present in the transformed plant. Results of the bioinformatic analysis of the 5' and 3' flanking sequences and open reading frames spanning the newly created DNA junctions did not indicate any safety concern. The stability of the inserted DNA was confirmed over several generations and a Mendelian inheritance pattern was demonstrated.

The EFSA GMO Panel compared the composition, phenotype and agronomic characteristics of soybean MON 87701 and its conventional counterpart (A5547), assessed all statistical differences identified, and came to the conclusion that soybean MON 87701 is compositionally not different from its conventional counterpart except for having an increased vitamin E content (still within the normal range of soybeans) and expressing the Cry1Ac protein. Except for expressing the Cry1Ac protein, soybean MON 87701 is also compositionally and agronomically equivalent to conventional soybean varieties. The risk assessment of the newly expressed protein and the whole crop included an analysis of data from analytical and bioinformatics studies, as well as in vitro and in vivo studies.

The EFSA GMO Panel concluded that the soybean MON 87701 is as safe as its commercial counterpart and that the overall allergenicity of the whole plant is not changed.

The application EFSA-GMO-BE-2010-79 concerns food and feed uses, import, and processing. Therefore, there is no requirement for scientific information on possible environmental effects associated with the cultivation of soybean MON 87701. There are no indications of an increased likelihood of establishment and spread of feral soybean plants in case of accidental release into the environment of viable soybean MON 87701 grains during transportation and processing for food and feed uses. Taking into account the scope of the application, both the rare occurrence of feral soybean plants and the low levels of exposure through other routes indicate that the risk to target and non-target organisms is extremely low. The unlikely but theoretically possible transfer of the recombinant gene from soybean MON 87701 to environmental bacteria does not raise concern due to the lack of a selective advantage in the context of its intended uses. The scope of the post-market environmental monitoring plan provided by the applicant is in line with the intended uses of soybean MON 87701. Furthermore, the EFSA GMO Panel agrees with the reporting intervals proposed by the applicant in the general surveillance plan.

Conclusion

In conclusion, the EFSA GMO Panel considers that the information available for soybean MON 87701 addresses the scientific issues indicated by the Guidance document of the EFSA GMO Panel and the scientific comments raised by the Member States, and that the soybean MON 87701 is as safe as its conventional counterparts with respect to potential effects on human and animal health or the environment. Therefore the GMO Panel concludes that soybean MON 87701 is unlikely to have any adverse effect on human and animal health or on the environment in the context of its intended uses.

Adoption

The opinion was adopted unanimously by the EFSA GMO Panel. The scientific opinion will be published on the following EFSA website: http://www.efsa.europa.eu/en/scdocs.htm.

5.4. Mandate to update the 2006 Opinion of the GMO Panel on the Post-Market Environmental Monitoring (PMEM) of GM plants (EFSA-Q-2010-01253)

Introduction

The Panel on Genetically Modified Organisms of the European Food Safety Authority (EFSA GMO Panel) was asked by the European Commission to update its 2006 scientific opinion on the Post-Market Environmental Monitoring (PMEM) of Genetically Modified Plants (GMPs).

The EFSA GMO Panel made use of the experience gained from its assessment of applications on GMPs for cultivation and considered different sources of information such as the PMEM reports on cultivated GMPs, relevant scientific literature and stakeholder comments. The Panel wishes to thank the EFSA Unit on Scientific Assessment Support (SAS) for their contribution to this work.

Discussion and conclusion

The EFSA GMO Panel firstly focused on the scientific rationale for PMEM. This scientific opinion shows how the overall conclusions and assumptions of the Environmental Risk Assessment (ERA), including the remaining uncertainties, determine the requirements for PMEM.

Secondly, the EFSA GMO Panel developed guidance to applicants on how to establish and implement their plans for Case-Specific Monitoring (CSM) in order to generate robust, scientifically-sound and statistically relevant data to further inform the ERA. Guidance on the statistical design and, when needed, the choice of appropriate non-GM comparators for CSM is provided. In addition, subject to the case-by-case character of CSM, examples of objectives for CSM are given in this scientific opinion.

Thirdly, the EFSA GMO Panel discussed the concept and principles of General Surveillance (GS). It was recognised that GS is not driven by specific hypothesis, as it targets unanticipated effects. A plan for GS should be designed to identify the aspects of the environment that need to be protected from harm. In this respect, the EFSA GMO Panel provides a non-exhaustive list of examples of protection goals, assessment endpoints and indicators as well as of possible approaches for GS. The EFSA GMO Panel refers to three main approaches for GS of GMPs, namely: (1) by monitoring the GMP and its cultivation sites (e.g. using a questionnaire to farmer), (2) by utilising the data collected by existing monitoring networks active in biodiversity surveys at local/regional/national scale and (3) by compiling and analysis of data from scientific literature. Whereas the EFSA GMO Panel highlights the advantages and limitations of these approaches for GS, it also provides detailed guidance on how to use and to improve them.

In the present opinion, the EFSA GMO Panel proposes a holistic and integrative approach for monitoring GM plants in the EU that considers GS within a framework of general environmental protection monitoring. In this context, the EFSA GMO Panel recognises that all parties (e.g. applicants, Member States) have to consider their roles in such an approach for environmental protection monitoring that embraces GS, both within countries and across the EU. In this wider context of monitoring GMPs as one component of the overall production system, the EFSA GMO Panel also suggests that standardised and centralised reporting centres for PMEM data be implemented. This would have the benefit of being able to harmonise and synchronise environmental monitoring, facilitate analysis and interpretation of PMEM reports.

Therefore, this scientific opinion revises and replaces the former 2006 scientific opinion of the EFSA GMO Panel on PMEM of GMPs.

Adoption

The opinion was adopted unanimously by the EFSA GMO Panel. The scientific opinion will be published on the following EFSA website: http://www.efsa.europa.eu/en/scdocs.htm.

6. DISCUSSION OF OPINIONS

6.1. Request for an opinion on the adequacy of EFSA guidelines to perform a risk assessment of plants developed through a number of new techniques: cisgenesis (EFSA-Q-2011-00152)

Following a request from the European Commission, the EFSA GMO Panel was asked to provide an opinion on (1) whether there is a need for new guidance or whether the existing guidance on risk assessment needs to be updated or further elaborated, in anticipation of the placing of products on the market through the application of these techniques and (2) whether or not these techniques pose risks in terms of impact on humans, animals and the environment, irrespective of whether or not they fall under the GMO legislation.

The draft opinion addressing cisgenesis and intragenesis was discussed. Comments made by the GMO Panel will be addressed by the Working Group on New Techniques at their next meeting. The European Commission clarified the mandate.

6.2. Application for authorisation of genetically modified maize MON87460 for food and feed uses, import and processing submitted under Regulation (EC) No. 1829/2003 by Monsanto (EFSA-GMO-NL-2009-70) (EFSA-Q-2009-00661)

A question to the applicant concerning this application was discussed by the standing Working Groups and finalised during the Plenary meeting.

6.3. Draft Guidance on the risk assessment of food and feed from genetically modified animals including animal health and welfare aspects

The draft opinion providing guidance on the risk assessment of genetically modified animal-derived food and feed including animal health and welfare aspects was discussed and reviewed. Following comments received during previous plenary meetings of the GMO and AHAW Panels, revisions were made to the part on animal health and welfare. It was clarified that the Guidance will address the food and feed risk assessment and the animal health and welfare assessment in separate chapters. However, the principles of the comparative approach that pertain to both assessments will be explained in a common introductory chapter while the post market monitoring will be addressed separately for all aspects.

The draft opinion on GM animals and derived food and feed was thus endorsed by the EFSA GMO Panel and will be placed at http://www.efsa.europa.eu/en/consultations/call/gmo110418.htm in August 2011 for public consultation.

6.4. Request for clarification on two recently published scientific opinions related to GMOs for food and feed uses EFSA-GMO-NL-2009-65 & EFSA-GMO-CZ-2008-62

The EC request (SANCO/E1/KK/mb Ares(2011)90387), in which EFSA was asked to complement the EFSA overall opinions, EFSA/GMO/CZ/2008/62 (maize MON89034 x 1507 x MON88017 x 59122) and EFSA/GMO/NL/2009/65 (maize MON89034 x 1507 x NK603) to cover all sub-combinations of their single events independently of their origin, was discussed.
A draft statement for EFSA-GMO-NL-2009-65 drafted by the Food/feed and Molecular Characterisation Working Groups was discussed while the Environment Working Group will discuss it at their next meeting in August. The draft statement on EFSA-GMO-NL-2009-65 will be considered for adoption at the next plenary meeting in September. With regards to application EFSA-GMO-CZ-2008-62, further discussions are needed and will be addressed at the next plenary meeting.

7. UPDATE ON APPLICATIONS RECEIVED UNDER REGULATION (EC) NO 1829/2003 AND REGULATION (EC) NO 1831/2003

7.1. Regulation (EC) No 1829/2003

None.

7.2. Regulation (EC) No 1831/2003

None.

8. NEW REQUESTS TO EFSA: DISCUSSION AND ADOPTION OF MANDATES

8.1. Applications under Regulation (EC) No 1829/2003

None.

8.2. Applications under Regulation (EC) No 1831/2003

None.

8.3. Other requests and Mandates

Two new mandates were received as follows:

a) Mandate for the assessment of the scientific elements supporting the prohibition of the placing on the market of GM potato EH92-527-1 for cultivation purposes in Austria. question nr.

b) Request to assess Amflora PMEM report for the 2010 cultivation season. (EFSA-Q-2011-0076).

9. UPDATE ON INTERNAL MANDATE ACTIVITIES AND GUIDANCE FOR GMO RISK ASSESSMENT

Administrative guidance to applicants on the preparation and presentation of applications for authorisation of genetically modified plants and derived food and feed under Regulation (EC) No 1829/2003

The Administrative Guidance has been reviewed and endorsed by three reviewers from the Panel. They are currently going through the sign-off procedure within EFSA. Publication of the Administrative Guidance is expected for end July 2011 after agreement with the EC on the formal format. A letter with an overview of applicable EFSA GMO guidance documents has been sent to EuropaBio.

Guidance on Environmental risk assessment of GM fish

Two meetings took place in June and the Working Group is making steady progress. The AHAW Panel is cooperating for the animal welfare part. A section on PMEM is to be developed. Harmonization of format and contents in line with the on-going documents for GM insects and for GM mammals & birds is envisaged and therefore the chairs of the respective Working Groups will attend the forthcoming meetings.

Guidance on Environmental risk assessment of GM insects

The Working Group held a first meeting on 6 June 2011 to which the contractor that had prepared the report was invited. A draft document is to be prepared for the next meeting that will take place in September. The Working Group is considering inviting additional external experts for specific sections.

Guidance on Environmental risk assessment of GM mammals and birds

The first meeting of the Working Group took place on 8 June 2011. Members were introduced to the mandate and to the recently adopted ERA Guidance. It was noted that collaboration with the AHAW Panel is a key element of this mandate. The Working Group will meet again in September.

Post-Market Environmental Monitoring of GMOs (PMEM)

Request from the European Commission to assess the monitoring (PMEM) report for the 2009 cultivation season of GM maize MON810: The GMO Panel was informed about the status and progress of the dedicated Working Group, supported by the EFSA SAS Unit. Three meetings took place during which the clarifications received from the applicant were addressed. The draft opinion is expected for discussion and possible adoption at the September Plenary meeting.

Software development in support of EFSA statistical requirements for GMO dossiers

The GMO Panel was informed about the status and progress of the development of software in support to the statistical requirements for GMO risk assessment. The prototype is expected to be ready by end of October. An initial test phase will take place early 2012.

Update on the negotiated procedure "Establishing a database of bio-ecological information on non-target arthropod species to support the environmental risk assessment of genetically modified crops in the EU"

The first interim report from the contractor was received end of June 2011 and was followed by a meeting of the Steering Committee. The contractor will now concentrate on collection of data, which seem to be more available from crop fields rather than from field margins. As announced at the GMO network meeting with Member States of 9-10 July, data input are expected from some Members States. The second interim report is expected for December 2011.

Update of the Environmental Risk Assessment of the GMO Panel on the GM maize 1507 for cultivation (Self-task)

The Working Group has now an advanced draft statement and the document is expected to be ready for preliminary discussion at the September Plenary meeting. The Panel was also informed that following a request from the European Commission to assess the PMEM plans of some applications (including that of maize 1507), the deadline of this mandate has been extended by two months.

EC request on complementary environmental risk assessment of GM maize Bt11

Following question from the GMO Panel, the answer received from the applicant was discussed during the May Plenary meeting. The Panel was also informed that following a request from the European Commission to assess the PMEM plans of some applications (including that of maize 1507), the deadline of this mandate has been extended by two months.

10. FEEDBACK FROM EFSA AND THE SCIENTIFIC COMMITTEE

GMO network meeting June 2011

The 2nd meeting of the GMO Network with Member States took place in Parma on 9-10 June. The meeting fostered high quality scientific discussion, on the basis of background documents and risk assessment questions focussed on topics where MS have a particularly relevant role, such as evaluation of new techniques, PMEM, risk assessment of applications and the collection of data on arthropods. The minutes of this meeting are in preparation. They will be circulated in July to the participants and subsequently published on the EFSA website. The next meeting of the GMO Network will take place in May-June 2012.

Scientific Committee meeting of 21 June 2011

The Chair of the GMO Panel reported on the endorsements of the EFSA Scientific Committee documents that are now published for public consultation:

- Draft EFSA guidance on repeated-dose 90-day oral toxicity study on whole food/feed in rodents
- Draft opinion on Threshold of Toxicological Concern
- Draft Guidance on default values
- Guidance on statistical significance and biological relevance was adopted.

11. FEEDBACK FROM THE COMMISSION

The representative from DG SANCO informed about the latest authorisations including: renewal of the authorisation of genetically modified maize 1507, authorisation of genetically modified cotton GHB614 and of genetically modified maize MON89034xMON88017.

DG SANCO set up a task force with some Member States with the objective to reflect on the feasibility and possible harmonisation of PMEM activities carried out by Member States taking into consideration the work delivered by the Monitoring Working Group set up under Directive 2001/18/EC from 2004 to 2008. EFSA GMO unit was invited to join this Working Group.

12. DATE AND PLACE OF FUTURE MEETINGS

Proposals for Plenary meeting dates for 2012 were presented to the EFSA GMO Panel at the Plenary meeting of December 2010.

Proposals for Plenary meeting dates for 2013 were presented to the EFSA GMO Panel:

23-24 January 2013

6- 7 March 2013

17-18 April 2013

29-30 May 2013

3-4 July 2013

11-12 September 2013

23-24 October 2013

4-5 December 2013

13. ANY OTHER BUSINESS

Panel members reporting on meetings and/or conference they attended for EFSA

Presentations were given at the AAB Conference on 28-29 June 2011, in Harpenden (United Kingdom) by GMO Panel members and EFSA GMO staff (http://www.aab.org.uk/images/110_contents.pdf).

Lectures were given at the e-biosafety masters of UNIVPM-UNIDO on 4 July 2011 in Ancona (Italy) by GMO Panel members and EFSA GMO Staff.

ANNEX 1

Interests and actions resulting from declared interests

Regarding interests declared by Detlef Bartsch
In this specific declaration of interest (SDOI) no conflict of interest is identified in relation to previously declared annual declaration of interest (ADOI) except under ~~item 5.2 Application for authorisation of genetically modified Soybean 356043 and derived food and feed submitted under Regulation (EC) No 1829/2003 by Pioneer (EFSA-GMO-UK-2007-43) (EFSA-Q-2007-087) and~~ [1] item 5.3 Application for authorisation of genetically modified Soybean MON87701 for food and feed uses, import and processing submitted under Regulation (EC) No 1829/2003 by Monsanto (EFSA-GMO-BE-2010-79) (EFSA-Q-2010-00867). These items are declared by the expert as an interest based on his ADOI: "As an EFSA GMO Panel member and WG member assessing applications and MS comments on applications I will declare through the specific declaration of interest prior of each meeting any involvement in commenting on applications I might have had as RA head of department of BVL." For item 5.4 Mandate to Update the 2006 Opinion of the GMO Panel on the Post-Market Environmental Monitoring (PMEM) of GM plants (EFSA-Q-2010-01253), EFSA has noted that the expert's institution has submitted comments during the public consultation. Related to his position as RA head of department of BVL expert will lead the MS commenting work on any new applications, agenda items 8.1 and 8.2. In accordance with EFSA's Policy on Declarations of Interests and Implementing documents thereof, and taking into account the specific matters discussed at the meeting in question, the interests above were deemed to represent a conflict of Interest (level C). Pursuant to EFSA's Procedure on Identifying and Handling Declarations of Interest point C.III.b[3], the said expert will be excluded from participating in EFSA activities concerned by the interest in question. In summary, the expert cannot participate in the discussion during agenda items 5.2, 5.3, 5.4, 8.1 and 8.2. For all other parts of the meeting no conflict of interest is identified in relation to previously declared ADOI.

Regarding interests declared by Christophe Tebbe
In line with his ADoI, Christoph Tebbe declared an interest for newly received mandates under item 8.3a) Mandate for the assessment of the scientific elements supporting the prohibition of the placing on the market of GM potato EH92-527-1 for cultivation purposes in Austria and 8.3b) Request to assess Amflora PMEM report for the 2010 cultivation season. (EFSA-Q-2011-0076). The interest arises from a past collaboration with an applicant, wherein potatoes and their effects on soil bacterial diversity were studied which therefore constitutes a conflict of interest.
In accordance with EFSA's Policy on Declarations of Interests and Implementing documents thereof, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a conflict of Interest (level C). Pursuant to EFSA's Procedure on Identifying and Handling Declarations of Interest point C.III.b[4], the said expert will be excluded from participating in EFSA activities concerned by the interest in question. In summary, the expert can not participate in the discussion during agenda items 8.3a) and 8.3b). For all other parts of the meeting no conflict of interest is identified in relation to previously declared ADOI.

[3] Implementing act to the policy on declaration of interests procedure for identifying and handling potential conflicts of interest. http://www.efsa.europa.eu/en/keydocs/docs/doiconflicts.pdf

[4] Implementing act to the policy on declaration of interests procedure for identifying and handling potential conflicts of interest. http://www.efsa.europa.eu/en/keydocs/docs/doiconflicts.pdf

[I] On 27 September 2011, the expert informed EFSA that the interest declared in relation to this item was declared by mistake.