

**MINUTES OF THE 72ND MEETING OF THE
SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS
HELD ON 7 AND 8 MARCH 2012 IN PARMA, ITALY
(ADOPTED ON 18 APRIL 2012)**

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PARTICIPANTS

GMO Panel:

Hans Christer Andersson, Salvatore Arpaia, Detlef Bartsch, Howard Davies, Lieve Herman, Patrick du Jardin, Huw Jones¹, Sirpa Kärenlampi, 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 Seinen² (for item 5.1 of the agenda).

GMO Unit: Jaime Aguilera, Andrea Gennaro, Andrea Germini, Ana Gomes, Yi Liu, Sylvie Mestdagh, Irina Olaru, Claudia Paoletti, Nancy Podevin, Stefano Rodighiero and Elisabeth Waigmann.

European Commission:

Kaja Kantorska (DG SANCO).

APOLOGIES

GMO Panel:

Josep Casacuberta and Gerhard Flachowsky.

1. WELCOME AND APOLOGIES FOR ABSENCE

The Chair of the GMO Panel opened the meeting and welcomed all. Apologies for absences were received from two Panel members as 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.

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 were declared by the experts. The following was declared:

¹ Participated via tele conference.

² Member of the EFSA Applications – Food and Feed Working Group.

In his specific declaration of interest (SDoI), the expert Detlef Bartsch declared an interest for item 5.4 Request to assess MON 810 monitoring report for the 2010 cultivation season (EFSA-Q-2011-01161).

In his specific declaration of interest (SDoI), the expert Christoph Tebbe declared an interest for item 5.3 Statement on a request from the European Commission for the assessment of the scientific elements supporting the prohibition for the placing on the market of GM potato EH92-527-1 for cultivation purposes in Austria (EFSA-Q-2011-00797).

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

4. ADOPTION OF THE MINUTES OF THE 71ST PLENARY MEETING HELD ON 25 - 26 JANUARY 2012

The minutes of the 71st Plenary meeting (25 and 26 January 2012) were adopted with minor editorial changes and will be published at: <http://www.efsa.europa.eu/en/events/event/120125b.htm>

5. DISCUSSION AND POSSIBLE ADOPTION OF OPINIONS

5.1. Scientific Opinion on applications EFSA-GMO-UK-2005-09 and EFSA-GMO-RX-MON531×MON1445 for the placing on the market of food and feed produced from or containing ingredients produced from insect-resistant and herbicide-tolerant genetically modified cotton MON 531 × MON 1445 (EFSA-Q-2005-012); and for the renewal of authorisation of existing products produced from cotton MON 531 × MON 1445 (EFSA-Q-2007-152), both under Regulation (EC) No 1829/2003 from Monsanto.

Introduction

This scientific opinion evaluates the risk assessment for the authorisation for (continued) marketing of genetically modified insect-resistant and herbicide-tolerant cotton MON 531 × MON 1445 for food and feed produced from it.

Discussion and conclusion

Cotton MON 531 × MON 1445 was produced by conventional crossing methods and the stack is homozygous for the newly introduced traits. The integrity and the stable co-inheritance of the parental events were demonstrated in the stack. Molecular characterisation did not reveal safety issues. No biologically relevant differences were identified in the compositional, phenotypic and agronomic characteristics of cotton MON 531 × MON 1445 in comparison with its conventional counterpart and its composition fell within the range of non-GM cotton varieties, except for the Cry1Ac, CP4 EPSPS and NPTII proteins. No safety issues were identified with regard to toxicity and allergenicity of food and feed produced from cotton MON 531 × MON 1445. A feeding study in catfish confirmed that toasted cottonseed meal from MON 531 × MON 1445 is as nutritious as toasted cottonseed meal from its conventional counterpart and four commercial non-GM cotton varieties. Products from cotton MON 531 × MON 1445 do not contain viable plant parts. The insert structure in cotton MON 531 × MON 1445 may facilitate the stabilisation of the nptII gene in plasmids of environmental bacteria through double homologous recombination. However, considering the overall limited occurrence of horizontal transfer of DNA in plant material to bacteria, and the very low exposure to DNA from cotton MON 531 × MON 1445, the EFSA GMO

Panel concludes that it is highly unlikely that cotton MON 531 × MON 1445 will contribute to the environmental prevalence of *nptII* genes. Potential interactions of cotton MON 531 × MON 1445 with non-target organisms and the abiotic environment were not considered to be an issue because of low exposure levels. A post-market environmental monitoring plan is not required.

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>.

5.2. Statement on a request from the European Commission for the assessment of the scientific elements supporting the prohibition for the placing on the market of GM potato EH92-527-1 for cultivation purposes in Austria (EFSA-Q-2011-00797).

Introduction

Austria notified to the European Commission its ordinance implementing a national safeguard measure prohibiting the placing on the market of GM potato EH92-527-1 for cultivation purposes in Austria, after which the European Commission asked the European Food Safety Authority to assess the scientific elements supporting the prohibition.

Discussion and conclusion

Having considered the information package provided by Austria and all relevant scientific publications, the GMO and BIOHAZ Panels concluded that: i) no new data specific to the safety of the *nptII* gene have been provided; ii) the risk posed by the formation of mosaic structures of aminoglycoside phosphotransferase genes could not be assessed without data documenting the existence of such structures among the existing gene variants and such data were not provided; iii) the therapeutic relevance of kanamycin and neomycin was already addressed in the EFSA's opinion on antibiotic resistance marker (ARM) genes and as of yet there is no evidence to indicate that resistance to these antibiotics in clinically-relevant bacteria has developed as a result of acquisition of the *nptII* gene; iv) the knowledge gaps and uncertainties highlighted in the Austrian document have already been considered in the EFSA's opinion on ARM genes. Austria did not provide any new or additional information on the molecular characterisation or PMEM of potato EH92-527-1 after the date of consent for this GM event that would require the reassessment of existing information. The EFSA GMO Panel reiterates its scientific opinion on the 2010 monitoring report of GM potato EH92-527-1 in which it provides specific recommendations to improve the methodology of the PMEM of the GM potato. Further, the EFSA GMO Panel concludes that no grounds exist to date that would lead to reconsideration of its opinion on GM potato EH92-527-1.

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>.

5.3. Request to assess MON 810 monitoring report for the 2010 cultivation season (EFSA-Q-2011-01161).

Introduction

Following the 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 growing season of maize MON810 provided by Monsanto Europe S.A.

Discussion and conclusion

On 7 September 2011, the EFSA GMO Panel already adopted a scientific opinion on the 2009 monitoring report of maize MON 810. The EFSA GMO Panel followed the same approach as for the assessment of the 2009 monitoring report and assessed, in close collaboration with the EFSA Unit for Scientific Assessment Support, the methodology applied by the applicant for the Case-Specific Monitoring and General Surveillance of maize MON 810 in 2010. Concerning the Case-Specific Monitoring (CSM), the EFSA GMO Panel considered the plan for Insect-Resistant Management mainly based on the “high dose/refuge strategy”, monitoring of target pest resistance and education of farmers. Concerning General Surveillance (GS), the EFSA GMO Panel paid particular attention to the design and analysis of the farmer questionnaires. The EFSA GMO Panel notes similar shortcomings in the methodology for CSM and GS as in the 2009 monitoring report. Hence, the EFSA GMO Panel reiterates the same recommendations for improvement of the methodology for the post-market environmental monitoring of maize MON 810 as in its scientific opinion on the 2009 monitoring report of maize MON 810. However, from the data submitted by the applicant in its 2010 monitoring report, the EFSA GMO Panel does not identify adverse effects on the environment, human and animal health due to maize MON810 cultivation during the 2010 growing season. The outcomes of the 2010 monitoring report do not invalidate the previous EFSA GMO Panel’s scientific opinions on maize MON 810.

Adoption

The Scientific 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

None.

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

One application was received as follows:

- Application for authorisation of genetically modified soybean DAS-44406-6 for all food and feed uses submitted under Regulation (EC) N° 1829/2003 by Dow AgroSciences LLC (EFSA-GMO-NL-2012-106) (EFSA-Q-2012-000368).

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

Two applications were received as follows:

- L-Arginine for all animal species (EFSA-Q-2012-000291);

- L-threonine // L-Threonine, technically pure (ThreAMINO®) for all animal species (EFSA-Q-2012-000290).

8.3. Annual Post-market environmental monitoring reports of GM plants

None

8.4. Other requests and Mandates.

One new mandate was received as follows:

- Mandate for the assessment of the scientific elements supporting the prohibition by France of the placing on the market of GM maize MON 810 for cultivation purposes (EFSA-Q-2012-00345).

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

Guidance on Environmental risk assessment of GM fish

The Chair of the GM fish Working Group indicated that a joint meeting of WG GM mammals and birds, WG GM fish and WG GM insects took place on 7-8 February 2012 and that specific sections of the Guidance document had been completed. The current discussions are aiming for a harmonisation of general issues between the three Working Groups (GM mammals and birds, GM fish and GM insects).

Guidance on Environmental risk assessment of GM insects

In addition to the above, the Chair of the GM insects Working Group indicated that several sections of the document, related to specific risks had been finalised. Issues to be discussed during the following meeting include impact of GM insects on human health, management and control systems and vertical gene transfer.

Guidance on Environmental risk assessment of GM mammals and birds

The Chair of the GM mammals and birds Working Group indicated that the joint meeting was successful. The proportionality of the whole document is still to be addressed. During the following meetings, discussions will be held on: choice of comparators when there is no conventional counterpart in the receiving environment, impact of vertical gene transfer on genetic diversity, non-target organisms, persistence, invasiveness and pathogens.

Related to this subject, the GMO Panel was informed that the Dutch Commission for Genetic Modification (COGEM) had published a topic report on GM animals.

Allergens and compositional analysis workshop

The GMO Panel discussed the agenda of the EFSA-Austria-Norway workshop “Key allergens and compositional analysis in the allergenicity assessment of genetically modified plants”.

PMEM Workshop. Panel and EFSA involvement

The workshop organised by the European Commission, DG SANCO will take place on 29 March 2012, in Brussels. There are 4 sessions scheduled: practical experience in the EU; practical experience of companies, Member States and 3rd countries; surveillance networks of biodiversity and agricultural practices in EU; and potential use of existing programmes.

10. FEEDBACK FROM EFSA AND THE SCIENTIFIC COMMITTEE

Multi-sectorial issues: case of co-adoptions

The GMO Panel was informed that multi-sectorial issues should be addressed by the Scientific Committee, according to the general framework established by [Regulation EC/178/2002](#). Practical details regarding each Panel's involvement are still to be decided.

Feedback from the Scientific Committee

The GMO Panel was updated on topics dealt by the EFSA Scientific Committee at its [53rd Plenary meeting](#), such as the Draft opinion on risk assessment terminology and the Draft opinion on Threshold of Toxicological Concern. Regarding the latter, revisions were made after the public consultation. Further discussion is needed with the non-food Scientific Committees of the European Commission, which are finalising an opinion on the same subject.

Food Feed Draft Regulation

The EFSA and the GMO Panel discussed the Draft Regulation and provided comments to be sent to the Commission.

11. FEEDBACK FROM THE COMMISSION

New authorisations

The representative of the European Commission informed the GMO Panel that four soybean events had been authorised for commercialisation in the EU: MON40-3-2 (renewal), and MON87701 from Monsanto, event 356043 from Pioneer and event A5547-127 from Bayer CropScience ([Link](#) to authorised products).

Generic mandates

The GMO Panel was also informed that the Commission will send new mandates on food-feed and cultivation safeguard clauses and emergency measures, and on the EC's interest in New techniques regarding Zinc finger nucleases.

12. ANY OTHER BUSINESS

Update on Panel renewal

The GMO Acting Head of Unit informed that the proposal for the members of the GMO Panel for 2012-2015 would be presented for approval of the EFSA Management Board in March. Upon endorsement, selected members will be contacted by EFSA and asked to confirm their involvement.

Update on recent publication on EFSA statistical approach

The SAS and GMO Units are testing the software with the datasets provided by industry. The results will be presented in an internal report.

EFSA 10th Anniversary

With the occasion of its 10th anniversary, EFSA is organising a conference on the 7-8 November 2012. A special issue of the EFSA Journal will feature contributions of the Panels on their accomplishments.

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 5.4 Request to assess MON 810 monitoring report for the 2010 cultivation season (EFSA-Q-2011-01161). This item is 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, the expert’s institution has submitted comments on the MON810 PMEM report for the 2010 season. A conflict level C is assigned to this agenda item. To avoid the occurrence of a potential conflict of interest with his activities at BVL, EFSA excluded the expert from any discussion or voting regarding agenda item 5.4. The CoI was therefore prevented.

Regarding interests declared by Christoph Tebbe

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 5.3 Statement on a request from the European Commission for the assessment of the scientific elements supporting the prohibition for the placing on the market of GM potato EH92-527-1 for cultivation purposes in Austria (EFSA-Q-2011-00797). The applicant company for the Amflora potato, BASF, has previously commissioned a study on potato to the institute of the expert in which the expert participated. Consequently, as stated in the experts ADOI, he will declare a conflict of interest for all potato and for all BASF applications. Therefore, for the safeguard clause on the Amflora potato a conflict of interest is judged to be existent and is assigned indicative level C. To avoid the occurrence of this potential conflict, EFSA excluded the expert from any discussion or voting regarding agenda item 5.3. The CoI was therefore prevented.