

**MINUTES OF THE 63RD MEETING OF THE
SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS
HELD ON 26-27 JANUARY 2011 IN PARMA, ITALY**

(ADOPTED ON 8 MARCH 2011)

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PARTICIPANTS

GMO Panel:

Salvatore Arpaia, Detlef Bartsch¹, Josep Casacuberta, Lieve Herman, Patrick du Jardin, Huw Jones, Jozsef Kiss, Gijs Kleter, Harry Kuiper (Chair), Antoine Messéan, Kaare Nielsen, Joe Perry, Annette Pötting, Jeremy Sweet, Christoph Tebbe, Atte Von Wright and Jean-Michel Wal.

GMO Unit: Jaime Aguilera, Per Bergman, Anna Christodoulidou Zoltan Diveki, Antonio Fernández, Andrea Germini, Ana Gomes, Karine Lheureux, Yi Liu, Sylvie Mestdagh, Claudia Paoletti, and Reinhilde Schoonjans.

Ad hoc expert²:

Esther Kok (RIKILT Institute of Food Safety, Wageningen)

German Competent Authority under Directive 2001/18/EC³:

Ulrike Middelhoff, Ulrich Ehlers and Werner Schenkel (BVL Federal Office of Consumer Protection and Food Safety, Berlin)

External Contractor for GM Mammals & Birds report⁴

Christine Henry and Graham Smith (FERA Food and Environment Research Agency, York)

European Commission:

Sébastien Goux and Giuseppina Luvarà (DG SANCO).

APOLOGIES

GMO Panel:

Hans Christer Andersson, Howard Davies, Gerhard Flachowsky and Sirpa Kärenlampi.

1. WELCOME AND APOLOGIES FOR ABSENCE

The Chair opened the meeting and welcomed all. Apologies for absence were received from the four Panel members listed above.

2. ADOPTION OF THE AGENDA

The agenda was adopted as proposed.

¹ Participated on 26 January only.

² For agenda item 6.b) only.

³ For agenda item 7.1 only.

⁴ For agenda item 9.d) only.

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 for 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 was declared by the experts. The following was declared:

In line with his ADoI, Detlef Bartsch declared an interest for update on applications received under Regulation (EC) No 1829/2003, item 7.1: Application EFSA-GMO-DE-2008-63 H7-1 and for newly received applications announced under item 8.1.a): EFSA-GMO-BE-2010-90. For further details regarding the assessment of declared interests please refer to Annex 1 of these minutes.

4. ADOPTION OF THE MINUTES OF THE 62ND PLENARY MEETING HELD ON 1 DECEMBER 2010

The minutes of the 62nd Plenary meeting (1 December 2010) were adopted with minor editorial changes and will be published at: <http://www.efsa.europa.eu/en/events/event/gmo101201.htm>

5. DISCUSSION AND POSSIBLE ADOPTION OF OPINIONS ON:

None

6. DISCUSSION OF OPINIONS

Two **cotton applications** have been analysed by the standing Working Groups and finalisation of the Question to applicant was discussed.

Human health safety assessment of GM animals: The co-rapporteur of the Working Group, Ester Kok, presented the draft Guidance Document on Food/Feed Safety assessment of GM animals to the GMO Panel. The document was further amended together with the Panel and will now be finalized for submission to the EFSA AHAW Panel for comments. The AHAW document is expected to be ready for consultation by May 2011. The GMO Panel thanked the Working Group and the invited expert for presenting the work.

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

7.1. Regulation (EC) No 1829/2003

Application - presentation of ERA report from Germany: The Competent Authority of Germany under Directive 2001/18/EC has carried out the environmental risk assessment (ERA) of application EFSA-GMO-DE-2008-63 (Sugar beet H7-1 for cultivation) in accordance with articles 6.3(c) and 19.3(c) of Regulation (EC) No 1829/2003. Representatives of the Competent Authority of the Germany presented their ERA report of application EFSA-GMO-DE-2008-63 to the GMO Panel. The members of the EFSA GMO Panel thanked the German experts for their work and presentation.

The EFSA GMO Panel discussed the report and will consider this report when assessing sugar beet H7-1, and the report will be included as an annex to the final EFSA overall opinion.

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

Two new applications were received:

- Application for authorization of genetically modified maize MON89034 for cultivation, submitted under Regulation (EC) No 1829/2003 by Monsanto (EFSA-GMO-BE-2010-90) (EFSA-Q-2011-00014).
- Application for renewal of the authorisation for genetically modified oilseed rape GT73 for food and feed use (excluding cultivation) and feed containing and consisting of GT73 oilseed rape, submitted under Regulation (EC) No 1829/2003 by Monsanto (EFSA-GMO-RX-GT73(2)) (EFSA-Q-2011-01088).

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

Two new applications were received:

- Vitamin B2 (riboflavin and riboflavin 5'-phosphate ester monosodium salt) (Riboflavin Universal; ROVIMIX® B2 80-SD; Riboflavin 5'- Phosphate Sodium) for all animal species (EFSA-Q-2011-00018).
- Belfeed B MP/ML (endo-1,4-beta-xylanase) for chickens for fattening, chickens reared for laying, laying hens, turkeys for fattening, turkeys for breeding purposes, turkeys reared for breeding, ducks, piglets (weaned), pigs for fattening, minor poultry species for fattening and laying (EFSA-Q-2011-00020).

8.3. Other requests and Mandates

- EFSA Self-task mandate on an update of the Environmental Risk Assessment of the GM maize 1507 for cultivation (EFSA-Q-2010-01470). In the frame of the ERA insect-resistant GM maize, the EFSA GMO Panel developed and used a new mathematical model to simulate and assess potential adverse effects resulting from the exposure of non-target Lepidoptera to GM maize. In the light of such a new methodology, the EFSA GMO Panel will review its 2005 safety assessment of GM maize 1507 for cultivation by applying the mathematical model and studying information from the scientific literature that has appeared recently. A first discussion within the Environmental Working Groups took place on 15 December 2010 and the next meeting is scheduled on 14 and 15 February 2011. Additional information has been requested from the applicant and will be provided by March 2011.
- EC mandate to perform a complementary environmental risk assessment of GM maize Bt11 for cultivation (EFSA-Q-2011-00005). The EFSA acceptance letter to EC and a request to the applicant, for additional information, were sent on 6 January 2011.

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

Food/Feed and MC Guidance Document. EFSA proceeds with the finalisation and publication of its updated FF/MC Guidance Document for the risk assessment of GM plants. Meetings took place on 2 December 2010 and 16 December 2010 to discuss the draft EFSA Guidance Document. The

next meeting will take place on 28 January 2011 and subsequent discussions are expected to take place in the frame of the standing Working Groups on FF and MC. Also advancements in the Guidance on the selection of comparators are awaited before the adoption of the final document by the EFSA GMO Panel in spring 2011.

Administrative Guidance. On 11 September 2009, the GMO Unit received a mandate from EFSA, to develop an administrative guidance to applicants as supplement to the food/feed (FF) and environmental Guidance documents. The unit has made progress to optimise and finalise the core document of the guidance. The completeness check list and other annexes of the document will be finalised after the Commission Regulation has been adopted and after EFSA has published its finalized FF Guidance Document. Two GMO Panel experts have volunteered to act as reviewers. Subsequently, the document will be presented to the EFSA GMO Panel for information and submitted for approval by the EFSA Executive Director. The unit has a deadline of two months following the adoption of the FF Guidance Document to publish this Administrative Guidance on the EFSA Journal.

Environmental risk assessment of GM animals. EFSA launched an information website on its mandate and work plan for GM animals <http://www.efsa.europa.eu/en/gmotopics/topic/gmanimals.htm>. Some timelines are likely to be reconsidered in view of the high priority given by the European Commission to other unrelated work involving a review of post-market environmental monitoring activities.

- GM Fish: The Working Group held a meeting on 2 December 2010 to discuss the draft Guidance Document prepared on the basis of the GM fish report delivered by the external contractors. The draft Guidance Document describes a step-wise approach, cross-cutting issues and specific areas of potential risk. The next meeting will take place on 16-17 February 2011. New members with complementary expertise in the relevant fields have been identified in the EFSA expert database.
- GM Insects: After publication of the report from the external contractor on 10 September 2010, the start of EFSA Working Group on GM insects is being postponed in view of the priority given to PMEM mandates. The EFSA GMO Panel was informed about GM mosquito releases in Malaysia to diminish deadly diseases.
- GM mammals and birds. The final report of the external contractor was received on 11 November 2010, revised by EFSA and approved for publication in December 2010. The contractors, Christine Henry and Graham Smith from FERA (Food and Environment Research Agency, York) have kindly accepted the invitation to this Plenary meeting and presented their work to the GMO Panel. The presentation showed the issues that could be considered during the assessment and provided a state-of-play of GM mammals and birds under development (e.g. the Atryn goat and the Enviropig being closest to commercialisation). After an exchange of views on a number of questions from the Panel, the chair of the Working Group on mammals and birds thanked the contractors for their work delivered.
The EFSA Working Group on GM mammals and birds (using the external report as input for information) is to be set-up to develop draft Guidance. Initiation of this WG will begin as soon as possible, but will acknowledge the priority given by the EC to PMEM mandates.

Mandates on Post Market Environmental Monitoring (PMEM).

- Update of PMEM Guidance. A Working Group has been established following a mandate from the European Commission to update the EFSA Guidance document on PMEM monitoring dealing with Case Specific Monitoring and General Surveillance. The first meetings took place on 14 December 2010 and 27-28 January 2011 while a third meeting will be held on 10-11 February 2011.
- Annual PMEM report on maize MON810: The data in the monitoring reports on MON810 are being analysed by the Working Group with the support of the statistical experts of EFSA Assessment Methodology Unit (AMU). The findings and discussions will be informative for the updating of the PMEM Guidance Document.

Software development in support of EFSA statistical requirements for GMO dossiers. A first meeting with the contractor was held on 19 November 2010 where the software and its implementation were discussed. The contractor delivered the implementation plan of the software on 13 January 2011 and feedback from the GMO unit was provided on 27 January 2011. The final implementation plan is expected by mid February 2011 and a meeting will be scheduled after the reception of such plan.

Update on the negotiated procedure “Faunistic baseline data on NTOs to support the environmental risk assessment of GM plants”. Following the EFSA open call for tender, the contract for “Establishing a database of bio-ecological information on non-target arthropod species to support the environmental risk assessment of GM crops in the EU” was signed on 6 December 2010 with ART-Agroscope, Switzerland. The work started with a first meeting (kick off) held on 14 January 2011. During this meeting open questions were discussed and clarified. Agreement was reached on: database entries; controlled terminology; literature searches and screening; geographical zoning concepts; crop species; field margins; case studies; timelines and deliverable deadlines; payments; and on contact points. It was also agreed that EFSA would request feedback from EU Member States on available arthropod data collected on their territory, as this type of data could support the literature searches and screening performed by the Contractor. This may facilitate the identification of published data from regional studies in national languages. The interim report from the contractor is expected by 6 June 2011 and the next meeting is planned for 29 June 2011.

90-day feeding study protocol. The document is advanced and will be further discussed on 4 February 2011. A draft scientific report will be presented for discussion to the Scientific Committee in March and to the GMO Panel afterwards. Upon the presentations of ANSES (Agence Nationale de Sécurité Sanitaire, France) regarding its work to develop a 90-day test protocol and approach towards statistical analysis, further harmonisation is envisaged for the statistical approaches.

Guidance on selection of comparators for the risk assessment of GM plants. The GMO Panel was notified that the GMO Unit is currently screening the public comments received. A new meeting of the Comparators WG is scheduled for the 16th February and there the WG will discuss the public comments and start to work on the new text for the draft guidance. The guidance will be presented at the March plenary and will go for possible adoption at the April plenary.

10. FEEDBACK FROM EFSA AND THE SCIENTIFIC COMMITTEE

Updated ERA Guidance. The document was presented at the Standing Committee meeting with Competent Authorities 2001/18/EC on 13 December 2010 in Brussels. An EFSA scientific officer reported that upon her presentation at the Standing Committee, the member states indicated that progress has been made but that they preferred to have an opportunity for more discussions. Various comments were received, including the need for updating the document with the latest revisions to the Comparator Guidance Document. It was also clarified that single events are evaluated first, before the stacked events containing the single event.

GMO comparators consultative workshop 31 March 2011, Brussels. The public consultation closed on 15 January 2011. Eighteen organisations submitted comments that will be discussed at the Working Group meeting of 16 February, followed by the workshop in Brussels on 31 March 2011. During the workshop, the comparative approach for risk assessment of GMOs will be further explained including “substantial equivalence. Presentations will be given by speakers from the OECD and EU, followed by a session on the content of the draft EFSA Guidance Document on the selection of comparators, and a session in which the various specific topics will be discussed. The

Guidance Document is to be discussed at the March Plenary, while adoption is scheduled to take place at the April Plenary.

EFSA invited by ALDE for GMO discussion on 12 January 2011 in Brussels: The updated EFSA FF and ERA Guidance Documents were debated at the European Parliament. The EFSA GMO scientific officers, who presented the work done by EFSA, and the two other speakers who presented their views, committed to provide the audience with answers. The two MEP's of ALDE organising the debate wanted to elicit the scientific basis of the comparative approach (in particular the aspect of substantial equivalence being a part of such approach), and the openness of EFSA towards stakeholders views, respectively. For more information see <http://www.efsa.europa.eu/en/press/news/gmo110119.htm>.

SCoFCAH meeting 14 December, Brussels. EFSA GMO scientific officers presented summaries of GMO opinions at the SCFoCAH meeting on 14 December 2010. Requests for clarifications had been received in advance through the European Commission. The GMO Panel remarked that repetitiveness of questions transmitted from the same Member States and the corresponding answers, is prone for evaluation.

Emerging Risks Internal Collaboration WG. No meeting took place.

11. FEEDBACK FROM THE COMMISSION

At this first Plenary meeting of 2011, the delegate from the European Commission was invited to inform the GMO Panel about ongoing activities in the European Commission related to the EFSA's work on GMOs. A comprehensive overview as well as the planning of future initiatives was presented by the Delegate.

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.

13. ANY OTHER BUSINESS

EFSA scientific network for risk assessment of GMOs. The next network meeting, gathering appointed experts from the Member States for FF and ERA areas is planned for 9-10 June 2011. The GMO Panel was invited to give its view on the selection of the proposed agenda items. The GMO Panel encouraged to secure high quality scientific debates, to focus on recurrent issues from Member States comments on applications and to seek through this forum direct feedback from Member States on new upcoming aspects of GMO risk assessment.

Expression of uncertainties. At the "6th Meeting of Chairs and Secretariats of the Commission and Agency Scientific Committees and Panels involved in Risk Assessment", a discussion took place on the use of terminology on risk, benefit and uncertainty by all EU parties involved in risk assessment (see minutes of the 62nd GMO Plenary meeting). The GMO Panel monitors the follow-up of that meeting. The GMO Panel suggested that Andy Hart be invited to present his proposed methodology for characterizing uncertainty using, among others the two papers by Perry et al (2010; 2011) and the paper by Lang et al (2011) on non-target Lepidoptera

Panel Members reporting on meetings/conference they attended for EFSA. None

Letter to EuropaBio on single and stacked events.

A letter was sent to EuropaBio to inform about the EFSA's approach on single and stacked events. This approach is in line with the draft EC Guidelines and with the draft EFSA Guidance on selection of comparators.

Commission question on publication on variability in susceptibility towards Cry proteins

The EFSA GMO Panel has considered the study by Gaspers et al. (2010) on variability in baseline susceptibility towards Cry proteins like Cry1Ab and Cry1F and its possible implications to the safety assessment of maize Bt11 and MON810.

The Gaspers et al. study (2010) provides scientific background information on the susceptibility of target pest, the European Corn Borer (ECB, *Ostrinia nubilalis*), to Bt-maize expressing Cry1F protein in Europe. Baseline data on susceptibility to the Cry1F protein have been determined for 24 USA populations as well as for European populations of ECB originating from 11 sampling sites from France, Germany, Italy and Spain. A comparison between European and American ECB populations showed that susceptibility estimates for ECB populations from Europe and the USA were similar when comparing the lethal concentrations (LC₅₀ and LC₉₀ values) and exhibited similar levels of variation among the populations tested. When comparing the ability of Cry1F to inhibit larval growth, European EC₅₀s were approximately 3.5-fold higher compared to the value from the USA. The authors noted that the different criteria used to identify survivors could influence the comparability of the susceptibility estimates.

The EFSA GMO Panel expects that the use of standard procedures will allow baseline susceptibility testing on small numbers of European populations for an efficient monitoring of the resistance development to Bt-toxins, similar to the monitoring methods developed for maize MON810 or maize Bt 11 expressing Cry1Ab protein. The EFSA GMO Panel recalled that the issue of variability in susceptibility of ECB populations was already considered and addressed in the EFSA GMO Panel scientific opinion on the French safeguard clause on MON810 (EFSA 2008a). In addition, the results of modelling mortality of non-target Lepidoptera in the MON810 Opinion are robust to the degree of variability of susceptibility reported by Gaspers et al. (2010).

In conclusion, the publication of Gaspers et al. 2010 does not provide new scientific information which will change the previous EFSA GMO Panel opinions on MON810 or Bt11 (EFSA, 2005, 2008b, 2009).

References:

- Gaspers C, Siegfried BD, Spencer T, Alves AP, Storer NP, Schuphan I and Eber S, 2010. Susceptibility of European and North American populations of the European corn borer to the Cry1F insecticidal protein. *Journal of Applied Entomology*. doi: 10.1111/j.1439-0418.2010.01541.x
- EFSA, 2005. Opinion of the Scientific Panel on genetically modified organisms [GMO] related to the notification (C/F/96/05.10) for the placing on the market of insect resistant genetically modified maize Bt11, for cultivation, feed and industrial processing *The EFSA Journal* 213, 1-33.
- EFSA, 2008a. Scientific Opinion of the Panel on Genetically Modified Organisms on a request from the European Commission related to the safeguard clause invoked by France on maize MON810 according to Article 23 of Directive 2001/18/EC and the emergency measure according to Article 34 of Regulation (EC) No 1829/2003. *The EFSA Journal* 850, 1-45.
- EFSA, 2008b. Request from the European Commission to review scientific studies related to the impact on the environment of the cultivation of maize Bt11 and 1507 - Scientific opinion of the Panel on Genetically Modified Organisms *The EFSA Journal* 851, 1-2.7
- EFSA, 2009. Scientific Opinion of the Panel on Genetically Modified Organisms on applications (EFSA-GMO-RX-MON810) for the renewal of authorisation for the continued marketing of (1) existing food

and food ingredients produced from genetically modified insect resistant maize MON810; (2) feed consisting of and/or containing maize MON810, including the use of seed for cultivation; and of (3) food and feed additives, and feed materials produced from maize MON810, all under Regulation (EC) No 1829/2003 from Monsanto. *The EFSA Journal* 1149, 1-85.

ANNEX 1

Interests and actions resulting from declared interests

In line with his ADoI, Detlef Bartsch declared an interest for update on applications received under Regulation (EC) No 1829/2003, item 7.1: Application DE-2008-63 H7-1 and for newly received applications announced under item 8.1: EFSA-GMO-BE-2010-90. The interests arise from the current employment where expert is in charge of the national assessment of these applications 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 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.b⁵, the said expert will be excluded from participating in EFSA activities concerned by the interests in question.

⁵ 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>