

**MINUTES OF THE 62<sup>ND</sup> MEETING OF THE  
SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS  
HELD ON 1 DECEMBER 2010 IN PARMA, ITALY**

**(ADOPTED ON 26 JANUARY 2011)**

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## **PARTICIPANTS**

### *GMO Panel:*

Hans Christer Andersson, Detlef Bartsch, Josep Casacuberta, Gerhard Flachowsky, Lieve Herman, Patrick du Jardin, Huw Jones<sup>1</sup>, 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.

*GMO Unit:* Jaime Aguilera, Per Bergman, Zoltan Diveki, Antonio Fernández, Ana Gomes, Karine Lheureux, Yi Liu, Sylvie Mestdagh, Claudia Paoletti, Reinhilde Schoonjans and Elisabeth Waigmann.

### *European Commission:*

Sébastien Goux (DG SANCO).

## **APOLOGIES**

### *GMO Panel:*

Salvatore Arpaia and Howard Davies.

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## **1. WELCOME AND APOLOGIES FOR ABSENCE**

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

## **2. ADOPTION OF THE AGENDA**

The agenda was adopted as proposed.

## **3. DECLARATION OF INTERESTS**

EFSA secretariat screened the ADoI and SDoI filled in by the scientific experts invited at this meeting in accordance with EFSA's Policy on Declarations of Interests.

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.

## **4. ADOPTION OF THE MINUTES OF THE 61<sup>ST</sup> PLENARY MEETING HELD ON 20-21 OCTOBER 2010**

The minutes of the 61<sup>st</sup> Plenary meeting (20 – 21 October 2010) were adopted with minor editorial changes and will be published at: <http://www.efsa.europa.eu/en/events/event/gmo101020.htm>

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<sup>1</sup> Participated on 1 December am only, via teleconference.

## **5. DISCUSSION AND POSSIBLE ADOPTION OF OPINIONS ON:**

None

## **6. DISCUSSION OF OPINIONS**

The EFSA GMO Panel discussed with the European Commission the scope of two applications for market approval of GM maize comprising stacked events, for which the EFSA GMO Panel recently published its scientific opinions related to the data presented in the applications (EFSA-GMO-NL-2009-65 and EFSA-GMO-CZ-2008-62). The discussion concerned the coverage of progeny of the maize evaluated in these two applications in the GMO Panel opinions. According to the European Commission the scope of these applications should cover all sub-combinations of the events independently of their origin (from the segregating progeny of the higher stack or otherwise). The EFSA GMO Panel emphasized that the scientific opinions on EFSA-GMO-NL-2009-65 and EFSA-GMO-CZ-2008-62 cover the sub-combinations from the segregating progeny, while the risk assessment of sub-combinations not resulting from segregation is still under consideration.

## **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**

One new application was received:

- Application for authorisation of genetically modified maize DAS-40278-9 for food and feed uses, import and processing submitted under Regulation (EC) No 1829/2003 by Dow AgroSciences (EFSA-GMO-NL-2010-89) (EFSA-Q-2010-01326).

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

None

### **8.3. Other requests and Mandates**

- Scientific Report of EFSA “Evaluation of trial descriptions of strains of *Bacillus licheniformis* and *Aspergillus niger* genetically modified with alpha-amylase gene(s)”. The draft Scientific Report of EFSA was discussed and endorsed by the GMO Panel. The report will be published during the first semester of 2011.

- Mandate to update the 2006 Opinion of the GMO Panel on the Post Market Environmental Monitoring of genetically modified plants. (EFSA-Q-2010-01253). The mandate is under discussion.
- Request from the European Commission to EFSA to assess the MON810 monitoring report for the 2009 cultivation season provided by Monsanto (EFSA-Q-2010-01254). EFSA will report through the adoption of an opinion, including an analysis of the appropriateness of the methodology of implementation and a clear indication on the potential consequences of this assessment on the safety of the GMO in question. The mandate was accepted subject to an extension of the proposed deadline to allow for the consideration of reports from Member States.

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

**Food/Feed and MC Guidance Document:** EFSA plans to proceed with the finalisation and publication of its updated FF/MC Guidance Document for the risk assessment of GM plants, based on the draft submitted to the European Commission and the Member States in December 2009. Meetings will take place on 2 December 2010 and 16 December 2010 to work on the draft EFSA Guidance Document. The next meeting will take place on 28 January 2011. Adoption of the final document by the EFSA GMO Panel is expected early in 2011.

**Guidance on the risk assessment of GM microorganisms and their food and feed products:** The draft document was published for public consultation on 29 November 2010. The consultation will finish on 24 January 2011.

**Guidance on selection of comparators for the risk assessment of GM plants:** The draft document was published for public consultations until 15 January 2011. A consultative workshop will take place at the end of March 2011.

**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>. However, 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 will hold 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. A major concern is the difficulty to find new members with complementary expertise in the relevant fields.
- GM Insects: The final report from the external contractor on criteria to be considered when developing guidance for the environmental risk assessment of GM insects was published on EFSA website on 10 September 2010. An EFSA GMO Working Group on GM insects is being set-up.
- GM mammals and birds. A Workshop on GM Mammals and Birds took place in Parma on 29 October to discuss the report of the external contractors. The external contractors delivered the final report on 11 November.

**Human health safety assessment of GM animals:** The Working Group held a meeting on 15-16 November and continued the discussion on the draft Guidance Document. The strategy to be followed for the assessment of potential allergenicity of the food/feed products derived from GM animals has been discussed among the Panel experts of the Working Group and experts of the EFSA NDA Panel. The document was further elaborated and has been submitted for final commenting to the Working Group. The draft Guidance Document on Food/Feed Safety assessment of GM animals is planned to be presented for discussion at the January 2011 Plenary meeting.

**Statistics ERA Guidance:** The EFSA call for tender for “Software development in support of EFSA statistical requirements for GMO dossiers” closed on 28 June 2010. Two offers were received and evaluated. One offer was selected and a contract was signed on 22 October with DLO Plant Research International, The Netherlands.

The deadline for reception of offers for the negotiated procedure “**Statistics Training GMO plants risk assessment**” was 4 October 2010. Two offers were received. However, recent analysis has shown that some of the conditions specified in this negotiated procedure are no longer in the interest of the service. A contract has not been awarded. The issue is still under consideration by EFSA.

**Update on the negotiated procedure “Faunistic baseline data on NTOs to support the environmental risk assessment of GM plants”:** A negotiated procedure on “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 launched on 19 July 2010 with deadline for submission of offers of 20 September 2010. Three offers were received and one was selected<sup>2</sup>. The opening meeting took place on 27 September 2010 and the evaluation meeting took place on 6 October 2010. The contract is expected to be signed by the end of December 2010 and a kick-off meeting is scheduled for 14 January 2011.

**Update by the GMO Panel of the Environmental Risk Assessment of GM maize 1507 for cultivation”:** In the frame of the Environmental Risk Assessment (ERA) of similar insect-resistant GM maize (MON810), the EFSA GMO Panel developed and used a mathematical model to simulate and assess potential adverse effects resulting from the exposure of non-target Lepidoptera to pollen of that GM maize. Consequently, in the light of such a new methodology, the EFSA GMO Panel felt the need to update its 2005 safety assessment of GM maize 1507 for cultivation by applying the mathematical model. A request for a self-task mandate on an update of the ERA of the GM maize 1507 for cultivation (EFSA-Q-2010-01470) was submitted to EFSA and approved on 26 November 2010. A first discussion with WG Environment is scheduled for 15 December 2010. Another meeting is scheduled for 14 & 15 February 2011. Additional information on NTO data will be required from the applicant.

**90-day feeding study protocol.** The EFSA Scientific Committee is working on amendments required to the OECD protocol 408 when testing whole foods (e.g. novel foods and GM foods).

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<sup>2</sup> Jörg Romeis, Fernando Álvarez-Alfageme and Michael Meissle Agroscope Reckenholz-Tänikon Research Station ART, Zurich, Switzerland

ANSES (Agence Nationale de Sécurité Sanitaire, France) has also launched a Working Group for this purpose and was invited to present the progress of its work.

## 10. FEEDBACK FROM EFSA AND THE SCIENTIFIC COMMITTEE

**Emerging Risks Internal Collaboration WG:** The EFSA EMRISK unit asked the feedback of EFSA Panels on the recent advancement of synthetic cell biology and whether it should be dealt in the future by the GMO Panel, by SC or EMRISK. The EFSA GMO Panel was informed that the European Commission set up a Working Group on New Technologies, including synthetic cell biology. Pending the outcome of this official Working Group deciding whether synthetic cell biology falls under the legislative definition of GMOs, the Panel indicated that although the products of synthetic biology may be consistent with the scientific definition of GMOs, risk assessment might require a different approach. This was already mentioned in the GMM Guidance Document, in which the Panel indicated that an adaptation of the GMM Guidance (or a separate Guidance) would be needed. The European Commission pointed out that the JRC is working on a comprehensive information package related to the status of this technology and its expected applications. The outcome of this work will be helpful to assess the maturity of this technology.

At the Scientific Committee Plenary meeting of 9 November, the results of the latest **Eurobarometer report 2010 on food-related risks** were presented, including: the different risk perceptions in different EU countries; the ranking of top food concerns in each country; the position of GMO as a middle-ranked concern in most countries (except in Austria where it is the top concern along with pesticides); trust in information sources on food safety issues; and perception of the role of public authorities in protecting consumers from food-related risks. See <http://www.efsa.europa.eu/en/riskcommunication/riskperception.htm>.

Feedback from the **6<sup>th</sup> meeting of Chairs and Secretariats of the EU Commission and Agencies 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. A study of FERA (Food and Environment Research Agency, UK) was presented by Villie Flari and David Wilkinson, focusing on harmonization and consistency of such terminology. Based on the outcome of the SANCO network group meeting, Andy Hart gave an overview of the different expressions of uncertainties and proposed a more structured approach to describe and quantify them and to assess their impact (e.g. uncertainty regarding methodology or regarding biological impact). In this context, the GMO Panel Members were informed that an EFSA Working Group is preparing a document and will consider further the proposals from the presenters.

Key topic research proposals: In the frame of the **EFSA internal mandate on “Defining key research priorities”** the Scientific Committee discussed key research topics based on proposals from EFSA scientific Units and Panels, including topics from the GMO unit and GMO Panel. Pending further discussions with the Advisory Forum the outcome of this EFSA internal mandate will be published in the near future.

## **11. FEEDBACK FROM THE COMMISSION**

Not dealt with.

## **12. DATE AND PLACE OF FUTURE MEETINGS**

Plenary meetings dates **for 2011** as proposed in the 56<sup>th</sup> March Plenary meeting were confirmed:

- 26-27 January 2011
- 9-10 March 2011
- 13-14 April 2011
- 25-26 May 2011
- 6-7 July 2011
- 7-8 September 2011
- 19-20 October 2011
- 30 November - 1 December 2011

New Plenary meeting dates **for 2012** were proposed:

- 25-26 January 2012
- 7-8 March 2012
- 18-19 April 2012
- 30-31 May 2012
- 4-5 July 2012
- 5-6 September 2012
- 17-18 October 2012
- 5-6 December 2012

## **13. ANY OTHER BUSINESS**

**EFSA scientific network for risk assessment of GMOs:** EFSA received from 24 EU Member States through its Advisory Forum nominations of Member Organisations for the GMO Network in the area of food/feed safety and/or environmental risk assessment of GMOs. The network is composed of up to two member organisations per Member State (1 for MC/FF, 1 for ENV). In addition, other European countries and candidate accession countries were invited to nominate Member Organisations (see <http://www.efsa.europa.eu/en/gmo/gmonetworks.htm>). The GMO Network Member Organisations appointed 41 experts as representatives to attend the first meeting that took place on 22-23 November in Parma. The agenda was built according to the proposals of Network Members. The minutes will be circulated to the network for commenting, before publishing on the EFSA website. The European Commission was invited as observer and participation of GMO Panel/EFSA staff took place according to the content of the agenda.