

**MINUTES OF THE 64<sup>TH</sup> MEETING OF THE  
SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS  
HELD ON 9-10 MARCH 2011 IN PARMA, ITALY**

**(ADOPTED ON 13 APRIL 2011)**

---

<b>1. WELCOME AND APOLOGIES FOR ABSENCE.....</b>	<b>2</b>
<b>2. ADOPTION OF THE AGENDA .....</b>	<b>2</b>
<b>3. DECLARATION OF INTERESTS .....</b>	<b>2</b>
<b>4. ADOPTION OF THE MINUTES OF THE 63<sup>RD</sup> PLENARY MEETING HELD ON 26-27 JANUARY 2011 .....</b>	<b>3</b>
<b>5. DISCUSSION AND POSSIBLE ADOPTION OF OPINIONS ON:.....</b>	<b>3</b>
<b>6. DISCUSSION OF OPINIONS .....</b>	<b>3</b>
SELECTION OF COMPARATORS FOR THE RISK ASSESSMENT OF GM PLANTS.....	3
GUIDANCE DOCUMENT FOR THE RISK ASSESSMENT OF GM PLANTS AND DERIVED FOOD AND FEED.....	3
<b>7. UPDATE ON APPLICATIONS RECEIVED UNDER REGULATION (EC) NO 1829/2003 AND REGULATION (EC) NO 1831/2003.....</b>	<b>3</b>
7.1. REGULATION (EC) No 1829/2003.....	3
7.2. REGULATION (EC) No 1831/2003.....	4
<b>8. NEW REQUESTS TO EFSA: DISCUSSION AND ADOPTION OF MANDATES .....</b>	<b>4</b>
8.1. APPLICATIONS UNDER REGULATION (EC) No 1829/2003 .....	4
8.2. APPLICATIONS UNDER REGULATION (EC) No 1831/2003 .....	4
8.3. OTHER REQUESTS AND MANDATES .....	4
<b>9. UPDATE ON INTERNAL MANDATE ACTIVITIES AND GUIDANCE FOR GMO RISK ASSESSMENT .....</b>	<b>4</b>
<b>10. FEEDBACK FROM EFSA AND THE SCIENTIFIC COMMITTEE.....</b>	<b>6</b>
<b>11. FEEDBACK FROM THE COMMISSION .....</b>	<b>6</b>
<b>12. DATE AND PLACE OF FUTURE MEETINGS .....</b>	<b>6</b>
<b>13. ANY OTHER BUSINESS .....</b>	<b>6</b>
<b>ANNEX I .....</b>	<b>8</b>

---

## **PARTICIPANTS**

### *GMO Panel:*

Hans Christer Andersson, Salvatore Arpaia, Detlef Bartsch, Josep Casacuberta, Howard Davies<sup>1</sup>, Gerhard Flachowsky, Lieve Herman, Huw Jones, Sirpa Kärenlampi (Chair), Jozsef Kiss, Gijs Kleter, Antoine Messéan, Kaare Nielsen, Joe Perry, Jeremy Sweet, Christoph Tebbe, Atte Von Wright and Jean-Michel Wal.

*GMO Unit:* Per Bergman, Yann Devos, Zoltán Divéki, Antonio Fernández, Andrea Germini, Ana Gomes, Karine Lheureux, Yi Liu, Claudia Paoletti, Nancy Podevin and Reinhilde Schoonjans.

### *Invited expert<sup>2</sup>:*

Andy Hart, Food and Environment Research Agency (FERA), United Kingdom.

### *Belgium Competent Authority under Directive 2001/18/EC<sup>3</sup>:*

Martine Delanoy (Federal Public Service), Adinda De Schrijver and Katia Pauwels (Scientific Institute of Public Health, Biosafety and Biotechnology Service, and Patrick De Clercq (Ghent University, Department of Crop Protection).

### *European Commission:*

Alice Stengel (DG SANCO).

## **APOLOGIES**

### *GMO Panel:*

Patrick du Jardin, Harry Kuiper and Annette Pötting.

---

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

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

---

<sup>1</sup> Participated via tele conference on 9 March pm only.

<sup>2</sup> For agenda item 13.b) only.

<sup>3</sup> Participated via tele/web conference for agenda item 7.1 only.

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 newly received applications announced under item 8.1.: EFSA-GMO-NL-2011-91, EFSA-GMO-NL-2011-92, EFSA-GMO-NL-2011-93 and EFSA-GMO-NL-2011-94. At the beginning of the meeting, the expert also declared an interest regarding item 6.1: Discussion of Selection of Comparators for the Risk Assessment of GM Plants, for which the expert's institution has submitted comments during the public consultation. For further details regarding the assessment of declared interests please refer to Annex 1 of these minutes.

#### **4. ADOPTION OF THE MINUTES OF THE 63<sup>RD</sup> PLENARY MEETING HELD ON 26-27 JANUARY 2011**

The minutes of the 63<sup>rd</sup> Plenary meeting (26-27 January 2011) were adopted with minor editorial changes and will be published at: <http://www.efsa.europa.eu/en/events/event/gmo110126.htm>

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

None

#### **6. DISCUSSION OF OPINIONS**

##### **Selection of Comparators for the Risk Assessment of GM plants.**

The draft Guidance document on Selection of Comparators for the Risk Assessment of GM Plants was discussed and further reviewing in light of the updated and adopted ERA Guidance Document is envisaged. The draft document will be proposed for adoption at the April Plenary meeting.

##### **Guidance Document for the risk assessment of GM plants and derived food and feed.**

The draft Updated Guidance Document for the Risk Assessment of food and feed from GM plants was discussed. Further reviewing is envisaged through consultation with the two standing Working Groups for MC and FF. The Guidance will be proposed for adoption at the April 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**

**Application EFSA-GMO-CZ-2008-54 maize MON88017 for cultivation:** The Competent Authority of Belgium under Directive 2001/18/EC has carried out the evaluation of the environmental risk assessment (ERA) of application EFSA-GMO-CZ-2008-54 in accordance with articles 6.3(c) and 19.3(c) of Regulation (EC) No 1829/2003. Representatives of the Competent Authority of Belgium presented the ERA report on maize MON88017 to the GMO Panel by

tele/web conference. The GMO Panel discussed the report and will consider this report when assessing the environmental safety of maize MON88017. The members of the EFSA GMO Panel thanked the Belgian experts for their work and presentation. 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**

Four new applications were received:

- Application for authorisation of genetically modified soybean DAS-68416-4 for food and feed uses, import and processing submitted under Regulation (EC) No 1829/2003 by Dow AgroSciences (EFSA-GMO-NL-2011-91) (EFSA-Q-2011-00052).
- Application for authorisation of genetically modified maize 1507 x 59122 x MON810 x NK603 for food and feed uses, import and processing submitted under Regulation (EC) No 1829/2003 by Pioneer (EFSA-GMO-NL-2011-92) (EFSA-Q-2011-00116).
- Application for authorisation of genetically modified soybean MON87708 for food and feed uses, import and processing submitted under Regulation (EC) No 1829/2003 by Monsanto (EFSA-GMO-NL-2011-93) (EFSA-Q-2011-00122).
- Application for authorisation of genetically modified cotton GHB614 x LLCotton25 x MON15985 and the subcombination LLCotton25 x MON15985 for food and feed uses, import and processing submitted under Regulation (EC) No 1829/2003 by Bayer (EFSA-GMO-NL-2011-94) (EFSA-Q-2011-00134).

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

None

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

- Internal mandate on EFSA approaches to risk assessment in the area of antimicrobial resistance, with an emphasis in commensal microorganisms (EFSA-Q-2011-00080).
- Request for complementing the EFSA scientific opinion related to MON89034 x 1507 x NK603 maize with the complementary scope (EFSA-GMO-NL-2009-65) (EFSA-Q-2011-00169).
- Request for complementing the EFSA scientific opinion related to MON89034 x 1507 x MON88017 x 59122 maize with the complementary scope (EFSA-GMO-CZ-2008-62) (EFSA-Q-2011-00170).
- Request for an opinion on the adequacy of EFSA guidelines to perform a risk assessment of plants developed through a number of new techniques (EFSA-Q-2011-00152).

## **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 Document provides administrative support to applicants on the preparation and presentation of an application under Regulation (EC) No 1829/2003. It complements the FF/MC Guidance and ERA Guidance which focus on the scientific content of applications. Consequently, the Administrative Guidance Document will be a living document that will evolve as the FF/MC and ERA Guidances are updated. The Administrative Guidance Document and its annexes will be ready for expert review at the time of the April Plenary meeting. Three Panel Member Experts will be nominated by EFSA, each representing one of the standing Working Groups (food/feed, molecular characterisation and environment).

#### **Human health risk assessment of GM animals.**

The draft Guidance Document was amended taking into account the comments from the GMO Panel Members raised at the January Plenary meeting. The document will be submitted to the EFSA AHAW Panel for commenting. The comments from the AHAW Panel will be addressed by the GMO Panel and the modified final draft document will be presented for adoption for public consultation.

#### **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. An update was given on the status of the 3 Working Groups on Guidance Document for the environmental risk assessment of GM Fish, GM insects and GM mammals and birds.

#### **Post-Market Environmental Monitoring of GMOs (PMEM).**

- Mandate to update the 2006 Opinion of the GMO Panel on the Post-Market Environmental Monitoring (PMEM) of GM plants:  
Following the mandate from the European Commission, EFSA established a dedicated Working Group (PMEM WG) on the update of the 2006 scientific opinion providing guidance on PMEM. The kick-off meeting of the Working Group took place on 14 December 2010. The PMEM WG activities firstly focus on the chapter dedicated to case-specific monitoring (CSM) to detail the recommendations for monitoring strategy, methodology and analysis. Secondly the PMEM WG will update and supplement, where needed, the sections related to the concept and principles of General Surveillance (GS). The PMEM WG will make use of all available relevant information, including its own ongoing evaluation of the Annual PMEM report of maize MON810 cultivation in 2009 and the Member States comments to GM plant application. In addition, the Working Group organised on 8 March, a hearing with a Member State representative, experienced in GS, to discuss the existing networks of interest for GS. Reasonable progress was made in outlining the draft, which is expected to be discussed and adopted for public consultation at the April Plenary meeting. Since the document defines the interplay between risk assessment and post-market monitoring as risk management, it is expected that the comments will reflect the respective responsibilities of the Member States.
- Request to assess MON810 monitoring report (PMEM) for the 2009 cultivation season: The GMO Panel was informed about the status and progress of this work. During the kick-off meeting of the dedicated Working Group, the applicant presented the PMEM report followed by a technical discussion. Further clarifications from the applicant regarding the methodology are pending.

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

The GMO Panel was informed about the status and progress of this work. The Environment Working Group is currently moving forward with its evaluation of possible adverse effects of maize 1507 on non-target Lepidoptera. Based on different ERA scenarios, the Working Group is planning to provide risk managers with a set of management and monitoring measures in order to limit and survey the exposure of non-target Lepidoptera to maize 1507. Questions were identified by the Working Group and additional data on NTOs are awaited from the applicant.

### **Software development in support of EFSA statistical requirements for GMO dossiers.**

The GMO Panel was informed about the status and progress of this work and the aim to have a prototype of the software available by the end of 2011.

### **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”.**

Through its existing networks with Member States (EFSA scientific network for risk assessment of GMOs) and through the national Competent Authorities under Directive 2001/18/EC, EFSA invited EU Member States to submit relevant arthropod data to the Contractor. This type of data may support the literature searches and screening performed by the Contractor and will facilitate the identification of published data from regional studies in national languages. Feedback is expected before October 2011.

### **Development of a protocol for 90-day feeding trials with whole food/feed.**

A further meeting with ANSES (Agence Nationale de Sécurité Sanitaire, France) and the EFSA Scientific Committee Working Group took place regarding the respective work progress to develop a 90-day test protocol and approach towards statistical analysis. Further harmonisation is envisaged for the statistical approaches, and protocol details such as total number of test animals for each group (dose/treatment/sex) and number of animals per cage were further discussed.

## **10. FEEDBACK FROM EFSA AND THE SCIENTIFIC COMMITTEE**

### **Emerging Risks Internal Collaboration WG.**

There were no relevant comments to be brought to the attention of the Panel.

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

The Delegate from the European Commission informed 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**

It was reminded that proposals for Plenary meeting dates for 2012 were presented to the GMO Panel at the Plenary meeting of December 2010.

## **13. ANY OTHER BUSINESS**

### **EFSA scientific network for risk assessment of GMOs.**

The next GMO Network meeting, gathering appointed experts from the Member States for FF and ERA areas, is planned for 9-10 June 2011. The EFSA GMO Panel was informed about the drafting of the agenda, including a system for high quality scientific debates on recurrent MS comments

received during the evaluation of the applications. As for the previous GMO Network meeting, sessions dedicated to food/feed and environment issues will run in parallel.

### **Characterising uncertainties.**

Following a presentation at the “6<sup>th</sup> Meeting of Chairs and Secretariats of the Commission and Agency Scientific Committees and Panels involved in Risk Assessment” (see [minutes of the 62<sup>nd</sup> GMO Plenary meeting](#)), Andy Hart was invited to present his proposed methodology for characterizing uncertainty. In his presentation, Andy Hart underlined the importance of assessing and communicating uncertainty as part of the scientific risk assessment process to provide clear guidance to policy makers. He proposes methods to communicate quantitatively or categorically, depending on the definition and possible impact of the uncertainty identified. This presentation and the consideration of the methodology in GMO risk assessment was discussed with the GMO Panel.

### **Stakeholder workshop on selection of comparators for GM plants, 31 March 2011, Brussels.**

The EFSA GMO Panel was updated on the organisation of this workshop where, in the first session, the concept of substantial equivalence and the comparative approach for risk assessment of GMOs will be discussed and where, in a second session, the comments received during the public consultation of the Draft Guidance on the Selection of Comparators for the risk assessment of GM plants will be discussed.

### **Panel Members reporting on meetings/conference they attended for EFSA.**

Sirpa Kärenlampi attended the 2<sup>nd</sup> *International Conference on Risk Assessment* in Brussels on 26-28 January 2011. The Conference builds upon the Transatlantic Risk assessment Dialogue launched in 2008 between the US, Canada and the EU. These Conferences aim at promoting robust, effective and recognised risk assessment approaches. The workshops were devoted to in-depth discussion on three topics: risk assessment terminology; uncertainty in risk assessment; and exposure assessment.

## *ANNEX 1*

### **Interests and actions resulting from declared interests**

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 items 6.1 and 8.1. These items are declared by the expert as an interest based on his ADOI where he declares: “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 6a: the expert’s institution submitted comments during the public consultation on the draft guidance document on comparators for GM plants giving rise to a conflict of interest in assessing these comments as well as comments submitted by other interested parties during the public consultation . For item 8.1, expert declares an interest for the new applications EFSA-GMO-NL-2011-91 (soybean DAS-68416-4 DOW AgroSciences), EFSA-GMO-NL-2011-92 (maize 1507x59122xMON810xNK603 Pioneer), EFSA-GMO-NL-2011-93 (soybean MON87708 Monsanto) and EFSA-GMO-NL-2011-94 (GHB614xLLCottonxMON15985 cotton), related to his responsibilities as Head of the Risk Assessment department of BVL.

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.b4, the said expert will be excluded from participating in EFSA activities concerned by the interests in question.

---

<sup>4</sup> 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>