

**MINUTES OF THE 49<sup>TH</sup> PLENARY MEETING OF THE  
SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS  
HELD ON 21-22 APRIL 2009 IN PARMA, ITALY  
(ADOPTED ON 27 MAY 2009)**

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## **PARTICIPANTS**

### *GMO Panel:*

Hans Christer Andersson, Salvatore Arpaia, Detlef Bartsch<sup>1</sup>, Josep Casacuberta, Howard Davies, Patrick du Jardin, Niels Bohse Hendriksen, Lieve Herman, Sirpa Kärenlampi, Jozsef Kiss, Gijs Kleter, Harry Kuiper (Chair), Nickolas Panopoulos, Joe Perry, Joachim Schiemann, Willem Seinen and Jean-Michel Wal.

### *EFSA:*

GMO Unit: Per Bergman, Jaime Aguilera, Ana Christodoulidou, Yann Devos, Zoltán Diveki, Christina Ehlert, Antonio Fernández, Andrea Germini, Ana Gomes, Yi Liu, Sylvie Mestdagh, Claudia Paoletti, Claudia Parisi, Nancy Podevin, Reinhilde Schoonjans, Ellen Van Haver, Elisabeth Waigmann.

### *European Commission:*

Michael Walsh and Sébastien Goux (DG SANCO); Helen Clayton (DG ENV).

## **APOLOGIES**

### *GMO Panel:*

Ilona Kryspin-Sorensen, Ingolf Nes, Annette Pötting and Jeremy Sweet.

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

The Chair opened the meeting and welcomed all. Apologies for absence were received from some Panel members as mentioned above.

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

The agenda was adopted with modifications under “Update on applications”.

## **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.

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<sup>1</sup> Only present on 22 April 2009 PM

With regard to this meeting no other interest 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 48<sup>TH</sup> PLENARY MEETING HELD ON 11-12 MARCH 2009**

The minutes of the 48<sup>th</sup> Plenary meeting (11-12 March 2009) were adopted as proposed and will be published at: [http://www.efsa.europa.eu/EFSA/efsa\\_locale-1178620753812\\_1211902375365.htm](http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902375365.htm)

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

##### **5.1. Request for an updated opinion on Econase XT (EFSA-Q-2008-775)**

###### *Introduction*

The European Commission requested (EFSA) to update the Opinion on the Econase XT L and Econase XT P (Econase XT P/L) feed additive, adopted in May 2008, based on new data provided by the applicant in the supplementary dossier. The designations L and P refer to the liquid and powdered formulations, respectively, of the same product Econase XT (endo-1,4-beta-xylanase).

###### *Discussion*

The GMO Panel, who has previously adopted and published a co-opinion with the FEEDAP Panel in May<sup>2</sup>, has been asked to issue an updated scientific opinion on the enzyme preparation of trade name “Econase XT P/L (endo-1,4-beta xylanase)” based on the supplementary information provided by the company in September 2008.

“Econase XT P/L (endo-1,4-beta xylanase)” is an enzyme feed additive for chickens and turkeys for fattening, chickens reared for laying, turkeys reared for breeding and piglets (weaned). The presence of recombinant DNA from the production microorganism in the Econase XT P/L feed additive was assessed by two PCR tests. For the semifinal liquid product, the detection limits were 20 pg mL<sup>-1</sup> and 20 ng mL<sup>-1</sup> for the 663 bp and the larger fragment of 1974 bp, respectively. For the final liquid product, the detection limits were 20 pg mL<sup>-1</sup> and 2 ng mL<sup>-1</sup> for the 663 bp and the larger fragment of 1974 bp, respectively. No recombinant DNA was detected in any of the products tested.

###### *Adoption*

The updated opinion was adopted unanimously by the Panel. The updated opinion is published on the EFSA website at: [http://www.efsa.europa.eu/EFSA/ScientificPanels/GMO/efsa\\_locale-1178620753812\\_GMOOpinions455.htm](http://www.efsa.europa.eu/EFSA/ScientificPanels/GMO/efsa_locale-1178620753812_GMOOpinions455.htm)

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<sup>2</sup> [http://www.efsa.europa.eu/EFSA/efsa\\_locale-1178620753812\\_1211902004731.htm](http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902004731.htm)

## **5.2. Application for authorisation of genetically modified Maize 1507 x 59122 and derived food and feed (EFSA-GMO-NL-2005-15) (EFSA-Q-2005-123)**

### *Introduction*

EFSA received from the Competent Authority of The Netherlands an application (Reference EFSA-GMO-NL-2005-15), for authorisation of placing on the market of maize 1507 x 59122 (Unique Identifier DAS-Ø15Ø7-1xDAS-59122-7), carrying resistance to certain lepidopteran and coleopteran insect pests along with tolerance to glufosinate-containing herbicides. The requested application was a joint application submitted by Mycogen Seeds, c/o Dow AgroSciences LLC, and Pioneer Hi-Bred International, Inc., as represented by Pioneer Overseas Corporation, within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (EC, 2003) for food and feed uses, import and processing.

### *Discussion*

The GMO Panel discussed the draft opinion addressing issues related to molecular characterization, food and feed safety and environmental risk assessment. As conventional breeding methods were used in the production of maize 1507 x 59122, no additional genetic modification was involved. Based on the results of comparative analysis it was concluded that maize 1507 x 59122 is compositionally and agronomically equivalent to conventional maize, except for the presence of Cry34Ab1, Cry35Ab1, Cry1F, and PAT proteins. In addition, the GMO Panel has found no indication that crossing of maize 1507 and maize 59122 results in an interaction of the newly expressed proteins which causes compositional or agronomic changes. The Cry34Ab1, Cry35Ab1 proteins and PAT proteins expressed in the parental maize line 59122 and the Cry1F and PAT proteins expressed in the parental maize 1507 have been assessed previously and no safety concerns were identified.

The application concerns food and feed uses, import and processing, but excludes cultivation. There are no indications of an increased likelihood of establishment or survival of feral maize plants in case of accidental release into the environment of 1507 x 59122 seeds during transportation and processing for food and feed uses. Taking into account the scope of the application, both the rare occurrence of sporadic feral plants and the low levels of exposure through other routes indicate that the risk to non-target organisms is negligible. The scope of the monitoring plan provided by the applicant is in line with the intended uses of maize 1507 x 59122.

The GMO Panel concludes that maize 1507 x 59122 is as safe as its non-genetically modified counterpart with respect to potential effects on human and animal health or the environment.

### *Adoption*

The opinion was adopted unanimously by the Panel. The scientific opinion will be published on the following EFSA website: [http://www.efsa.europa.eu/EFSA/ScientificPanels/GMO/efsa\\_locale-1178620753812\\_GMOOpinions455.htm](http://www.efsa.europa.eu/EFSA/ScientificPanels/GMO/efsa_locale-1178620753812_GMOOpinions455.htm)

The overall opinion, including the table containing the responses of the Panel to Member States is published in the Register of Questions EFSA-Q-2005-123:

<http://registerofquestions.efsa.europa.eu/roqFrontend/questionsList.jsf>

## **5.3. Application for authorisation of genetically modified Maize NK603 and derived food and feed including cultivation (EFSA-GMO-NL-2005-22) (EFSA-Q-2005-249) and Application for renewal of**

## **authorisation for Maize NK603 continued marketing of food additives, feed materials and feed additives (EFSA-GMO-RX-NK603) (EFSA-Q-2008-075)**

### *Introduction*

EFSA received from the Competent Authority of the Netherlands an application for authorisation of GM maize NK603 (MON-ØØ6Ø3-6) submitted by Monsanto within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (reference EFSA-GMO-NL-2005-22).

From that date, EFSA has endeavoured to respect a time limit of 6 months in giving its overall opinion (Articles 6(1) and 18(1)). EFSA made the valid application available to Member States and the European Commission. Following the procedure laid down in Articles 6(4) and 18(4) of Regulation (EC) No. 1829/2003, EFSA consulted the Member States. In this context, the Member States risk assessment bodies, as well as the national competent authorities under Directive 2001/18/EC, were given three months after the date of receipt of the valid application (i.e. until 12 August 2006) within which to make their opinion known.

Making use of the provisions under Articles 6(2) and 18(2), EFSA requested additional information from the applicant and the clock was stopped from 22 September 2006 to 6 March 2009. Upon reception of additional information, a draft of the scientific opinion of genetically modified herbicide tolerant (GM HT) maize NK603 for food and feed uses, import and processing and cultivation was prepared.

### *Discussion*

On this occasion, the European Commission informed EFSA and the GMO Panel that, in line with their letter of 8 September 2008 (ref ENV/B3/AA/JH/YK/gm D (2008)), the section of the scientific opinion related to potential impacts on the specific cultivation, management and harvesting techniques would benefit from further development, in particular addressing as stated in the above cited letter “*the changes in agricultural practices due to the herbicide use on GM HT plants*”. The GMO Panel acknowledged the importance of addressing “*the changes in management including, when applicable, in agricultural practices*” as required under Directive 2001/18/EC (Annex II of Directive 2001/18/EC).

After an exchange of views it was agreed that, within the remit of Directive 2001/18/EC, the GMO Panel would clarify/expand its scientific opinion on maize NK603.

Thus, the GMO Panel agreed to revise the draft scientific opinion on GM maize NK603 accordingly and discuss and possibly adopt a new draft in the GMO Panel Plenary Meeting in May 2009. The European Commission observers acknowledged that the additional clarifications will cause a delay in finalisation of the overall opinion of GM maize NK603 beyond the legal deadline of 6 months specified under Regulation (EC) No 1829/2003.

## **5.4. Application for authorisation of genetically modified Maize MON88017 and derived food and feed (EFSA-GMO-CZ-2005-27) (EFSA-Q-2005-280)**

### *Introduction*

On 10 November 2005, EFSA received from the Competent Authority of Czech Republic an application (Reference EFSA-GMO-CZ-2005-27), for authorisation of the insect-resistant glyphosate-tolerant genetically modified maize MON88017 (Unique Identifier MON-88Ø17-3),

submitted by Monsanto within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (EC, 2003) for food and feed uses, import and processing.

### *Discussion*

In conclusion, the Panel considered that the information available for Maize MON88017 addresses the scientific comments raised by the Member States and that it is as safe as its non-genetically modified counterpart with respect to potential effects on human and animal health or the environment. Therefore the GMO Panel concludes that MON88017 is unlikely to have any adverse effect on human or animal health or on the environment in the context of its intended uses.

### *Adoption*

The opinion was adopted unanimously by the Panel. The scientific opinion will be published on the following EFSA website: [http://www.efsa.europa.eu/EFSA/ScientificPanels/GMO/efsa\\_locale-1178620753812\\_GMOOpinions455.htm](http://www.efsa.europa.eu/EFSA/ScientificPanels/GMO/efsa_locale-1178620753812_GMOOpinions455.htm)

The overall opinion, including the table containing the responses of the Panel to Member States is published in the Register of Questions EFSA-Q-2005-280:

<http://registerofquestions.efsa.europa.eu/roqFrontend/questionsList.jsf>

## **5.5. Opinion of the Scientific Panel on Genetically Modified Organisms on Guidance for the risk assessment of genetically modified plants used for non-food or non-feed purposes (EFSA-Q-2007-176)**

### *Introduction*

An increasing number of GM plants are being developed for a wide range of non-food or non-feed purposes such as to manufacture medicinal or industrial products, or others for purposes of energy production, phytoremediation, landscape improvement and ornamentals.

EFSA has provided for applicants a detailed Guidance Document for the risk assessment of GM plants and derived food and feed. This Guidance Document describes the data requirements and risk assessment criteria to assist the applicant in the preparation and presentation of a GM plant application. Based on risk assessment experience and new advancements in science, EFSA regularly updates its Guidance Document. The GMO Panel decided that additional guidance needed to be developed for the environmental risk assessment of GM plants used for non-food or non-feed purposes to supplement the Guidance Document.

On 26 September 2005 EFSA agreed to initiate a self-tasking activity on this issue and mandated the EFSA GMO Panel to give its Opinion on comprehensive guidance for the assessment of genetically modified plants used for non-food or non-feed purposes to supplement the Guidance Document.

### *Discussion*

Issues for the assessment of GM plants for non-food or non-feed purposes that would need special attention or may have more/less stringent requirements compared with the risk assessment requirements for GM plants for food and feed purposes have been identified. The wide range of possible GM plants for non-food or non-feed purposes is covered in this Opinion without pre-empting the case-by-case risk assessment of particular applications.

The Guidance Document with the practical templates for submission of dossiers, together with this Opinion that considers additional elements for the risk assessment of plants for non-food or non-feed purposes, is to be taken into account by future applicants. EFSA herewith advises applicants/regulators to read this Opinion in parallel with the Guidance Document. A regulatory flowchart is provided showing the interplay between the intended uses of a GM plant and the respective EU legislation applicable. The flowchart gives an overview not only of the regulatory bodies that are involved in scientific risk assessment but also the ones that are responsible for risk management and decisions on authorisations.

#### *Adoption*

The opinion was adopted unanimously by the Panel. The scientific opinion will be published on the following EFSA website: [http://www.efsa.europa.eu/en/science/gmo/gmo\\_opinions.html](http://www.efsa.europa.eu/en/science/gmo/gmo_opinions.html)

### **5.6. Statistical Considerations for the Safety Evaluation of GMOs (EFSA-Q-2006-080)**

#### *Introduction*

A draft document was published on EFSA website from 21 July 2008 until 21 September 2008 for a 2-month period of public consultation. Following the public consultation, the original document has been revised taking into account all the scientific comments that improved the scientific quality and clarity. The final outcome of this exercise is this opinion presented for adoption.

#### *Discussion*

The GMO Panel discussed the changes introduced after the public consultation, which were all accepted. The Panel also agreed to provide a summarized response to the most relevant comments received during the public consultation, which will be published on EFSA website as a separate document.

#### *Adoption*

The opinion was adopted unanimously by the Panel. The scientific opinion will be published on the following EFSA website: [http://www.efsa.europa.eu/en/science/gmo/gmo\\_opinions.html](http://www.efsa.europa.eu/en/science/gmo/gmo_opinions.html)

## **6. DISCUSSION OF OPINION ON:**

### **6.1. New information submitted by Austria in context of Safeguard measure adopted under Article 23 of Directive 2001/18/EC on oilseed rape GT73 (EFSA-Q-2008-315)**

The GMO Panel was requested under Article 29(1) and in accordance with Article 22(5) of Regulation (EC) No 178/2002, to provide a scientific opinion as to “whether, in accordance with Article 23 of Directive 2001/18/EC, the statement and documents submitted by the Austrian authorities comprise new or additional information affecting the environmental risk assessment, such that detailed grounds exist to consider that the above authorised GMO, for the uses laid down in the corresponding consent, constitute a risk to human health or the environment”.

In this context, and upon request of the European Commission/DG Environment, EFSA invited the Austrian scientists and representatives from the Competent Authority to present their arguments in support to their safeguard clause during a meeting with some members of the GMO Panel and

EFSA staff that is scheduled on 23 of April 2009. A report of the meeting will be prepared and shared with the Austrian delegation before publication.

## **6.2. New information submitted by Austria in the context of a safeguard measure adopted under Article 23 of Directive 2001/18/EC on oilseed rape lines Ms8, Rf3 and Ms8xRf3 (EFSA-Q-2008-743)**

The GMO Panel was requested under Article 29(1) and in accordance with Article 22(5) of Regulation (EC) No 178/2002, to provide a scientific opinion as to “whether, in accordance with Article 23 of Directive 2001/18/EC, the statement and documents submitted by the Austrian authorities comprise new or additional information affecting the environmental risk assessment, such that detailed grounds exist to consider that the above authorised GMO, for the uses laid down in the corresponding consent, constitute a risk to human health or the environment”.

In this context, and upon request of the European Commission/DG Environment, EFSA invited the Austrian scientists and representatives from the Competent Authority to present their arguments in support to their safeguard clause during a meeting with some members of the GMO Panel and EFSA staff that is scheduled on 23 of April 2009. A report of the meeting will be prepared and shared with the Austrian delegation before publication.

## **6.3. Information submitted by Austria in support of a safeguard measure adopted under Article 23 of Directive 2001/18/EC on maize MON863 (EFSA-Q-2008-742)**

The GMO Panel was requested under Article 29(1) and in accordance with Article 22(5) of Regulation (EC) No 178/2002, to provide a scientific opinion as to “whether, in accordance with Article 23 of Directive 2001/18/EC, the statement and documents submitted by the Austrian authorities comprise new or additional information affecting the environmental risk assessment, such that detailed grounds exist to consider that the above authorised GMO, for the uses laid down in the corresponding consent, constitute a risk to human health or the environment”.

In this context, and upon request of the European Commission/DG Environment, EFSA invited the Austrian scientists and representatives from the Competent Authority to present their arguments in support to their safeguard clause during a meeting with some members of the GMO Panel and EFSA staff that is scheduled on 23 of April 2009. A report of the meeting will be prepared and shared with the Austrian delegation before publication.

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

## **7.1. Written adoption on 3 April for Application for authorisation of genetically modified Maize 59122 x 1507 x NK603 and derived food and feed (EFSA-GMO-UK-2005-21) (EFSA-Q-2005-248)**

The GMO Panel adopted on 3 April 2009 by written procedure the opinion on the Application (EFSA-GMO-UK-2005-21) for authorisation of genetically modified Maize 59122 x 1507 x NK603 and derived food and feed (EFSA-Q-2005-248).

The opinion was adopted unanimously by the GMO Panel. The scientific opinion is published on the following EFSA website: [http://www.efsa.europa.eu/EFSA/ScientificPanels/GMO/efsa\\_locale-1178620753812\\_GMOOpinions455.htm](http://www.efsa.europa.eu/EFSA/ScientificPanels/GMO/efsa_locale-1178620753812_GMOOpinions455.htm)

The overall opinion, including the table containing the responses of the Panel to Member States is published in the Register of Questions under question number EFSA-Q-2005-248 - question documents: <http://registerofquestions.efsa.europa.eu/roqFrontend/questionsList.jsf>

## **7.2. Written adoption of the Scientific Opinion on consequences of the Opinion on the Use of Antibiotic Resistance Genes as Marker Genes in Genetically Modified Plants on Previous EFSA Assessments of Individual GM Plants (EFSA-Q-2008-04977)**

The GMO Panel adopted on 25 March 2009 by written procedure the opinion on Consequences of the Opinion on the Use of Antibiotic Resistance Genes as Marker Genes in Genetically Modified Plants on Previous EFSA Assessments of Individual GM Plants (EFSA-Q-2008-04977).

The opinion was adopted unanimously by the GMO Panel and is published as part of the EFSA statement “Consolidated presentation of the joint Scientific Opinion of the GMO and BIOHAZ Panels on the “Use of Antibiotic Resistance Genes as Marker Genes in Genetically Modified Plants” and the Scientific Opinion of the GMO Panel on “Consequences of the Opinion on the Use of Antibiotic Resistance Genes as Marker Genes in Genetically Modified Plants on Previous EFSA Assessments of Individual GM Plants” [http://www.efsa.europa.eu/EFSA/efsa\\_locale-1178620753812\\_1211902569473.htm](http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902569473.htm).

## **7.3. Application for renewal of authorisation for continued marketing of existing food and food ingredients produced from MON810 Maize (EFSA-GMO-RX-MON810) (EFSA-Q-2007-164).**

Representatives from the ENV WG presented the model developed to explore possible scenarios for the exposure of European non-target lepidopteran species to maize MON810 pollen. The GMO Panel acknowledged the modelling approach to help quantifying the risk assessment and to finalise the scientific opinion on this point.

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

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

- Application for authorisation of genetically modified soybean BPS-CV127 for food and feed uses, import and processing (EFSA-GMO-NL-2009-64) (EFSA-Q-2009-00360)
- Application for authorisation of genetically modified maize MON89034 x 1507 x NK603 for food and feed uses, import and processing (EFSA-GMO-NL-2009-65) (EFSA-Q-2009-00413)
- Application for authorisation of genetically modified maize Bt11 x MIR162 x MIR604 x GA21 for food and feed uses, import and processing (EFSA-GMO-DE-2009-66) (EFSA-Q-2009-00444)
- Application for authorisation of genetically modified maize Bt11 x MIR162 x GA21 for food and feed uses, import and processing (EFSA-GMO-DE-2009-67) (EFSA-Q-2009-00414)

- Application for authorisation of genetically modified cotton 281-24-236 x 3006-210-23 x MON88913 for food and feed uses, import and processing (EFSA-GMO-NL-2009-68) (EFSA-Q-2009-00491)

Competent Authorities of the Member States within the meaning of Directive 2001/18/EC as foreseen by Articles 6 (4) and 18 (4) of Regulation (EC) No 1829/2003 will be consulted by EFSA once the above mentioned application is valid. On its own initiative EFSA has broadened this consultation also to Member States' National Competent Authorities under Regulation (EC) No 1829/2003 and other national risk assessment bodies. The comments will be considered during the scientific evaluation by the EFSA GMO Panel of the risk assessment performed by the applicant.

The summary of these applications, as well as the information on their current status can be found on Register of Questions under the respective question numbers: <http://registerofquestions.efsa.europa.eu/roqFrontend/questionsList.jsf>.

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

- Request for a scientific opinion about the enzyme preparation of trade name "Danisco Xylanase G/L" (endo-1-4-beta-xylanase) as a feed additive for chickens for fattening, laying hens, ducks for fattening and turkeys for fattening (EFSA-Q-2009-00498).

## 9. UPDATE ON SELF TASK ACTIVITIES AND GUIDANCE FOR GMO RISK ASSESSMENT

- Assessment of allergenicity of genetically modified foods (Self tasking Working Group) (EFSA-Q-2005-125): a meeting with the whole working group took place on 1 April 2009 to finalise the conclusions and recommendations of the report. The draft report will be on the agenda of the next plenary of the Panel for possible adoption, after which the document will be published for public consultation.
- Formal consultation on the European Commission Guidelines on Risk Assessment of GM plants and derived food/feed: A draft working document was prepared by the European Commission, based on the updated guidance of the EFSA GMO Panel, on comments of stakeholders and Member States which were provided during the public consultation of EFSA as well as further discussions. EFSA was formally consulted on this document by the European Commission on 23 February 2009 and the GMO Panel adopted the document with proposed modifications at its plenary meeting in March 2009. The modified document has been sent to the European Commission in response to corresponding mandate (EFSA-Q- 2009-00500).
- Self task activity on Comparators: the text of the mandate has been finalized with the inclusion of updates in order to cover all the relevant issues. Planned activities are expected to cover a 12 months' time frame.
- Draft mandate for a self-tasking activity by the GMO Panel to update the Guidance Document for the risk assessment of genetically modified microorganisms and their derived products intended for food and feed use. The draft mandate was updated to include the main issues to be addressed and justifications for the need of updating. The draft is ready to be presented to the EFSA's hierarchy.
- Self-tasking on Non-target organism: Salvatore Arpaia (Chair of the NTO self-tasking WG) reported that the draft opinion was consolidated prior being forwarded to three external experts acting as peer-reviewers (likely to be first week of May). These referees will be given one-month time to review the consolidated draft opinion. He also mentioned the stakeholders' consultation on 16-17-18 June in Berlin.

- Self-tasking activity on GM Animals (EFSA-Q-2007-069). The call for procurement on GM animals has been successfully completed and the contract is granted to a team of international scientists forming a consortium. A kick-off meeting will be held in May 2009.

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

Feedback from the Standing Committee meeting 20 April 2009 on the FF and MC parts of the European Commission guidelines: EFSA was consulted to clarify certain issues regarding to the authorisation dossiers on the agenda. The Member States' risk managers welcomed the technical support and dialogue with EFSA risk assessors.

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

The European Commission submitted to the OECD a proposal for inclusion of whole food testing in the OECD Test guideline No. 408 "Repeated Dose 90-day toxicity study in rodents", in line with the recommendation outlined in the EFSA report on animal feeding trials<sup>3</sup> to develop supplementary guidelines for whole food testing by OECD. At the 15<sup>th</sup> meeting of the Task Force on Novel Foods and Feeds, no consensus was reached on this proposal and advice will be sought from the OECD Joint meeting of the Chemical Committee and the Working Party on Chemicals, Pesticides and Biotechnology at their next meeting in June 2009, on how to proceed further with this project.

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

## **13. ANY OTHER BUSINESS**

An EFSA GMO event "Assessing potential risk of GMOs for health and environment" will be organised by EFSA and is scheduled for 14-15 September 2009 in Brussels. Member States representatives as well as stakeholders will be invited through the EFSA Advisory Forum and Stakeholders platform respectively.

The European Commission has established scientific advisory committees on human health and environment that will provide the European Commission with scientific advice on sensitive issues. The remit of these committees does not overlap with the remit of EFSA to perform risk assessment on GMO applications.

In the context of the preparation of EFSA Strategic Plan 2009-2013 EFSA is preparing a draft document to be submitted to the Management Board. This document will be discussed by the Scientific Committee during future meetings. The draft has been presented to the GMO Panel to receive their comments.

The Panel discussed of the bioinformatic analysis performed by the applicants. A discussion took place regarding the involvement of the Panel Working Groups on Molecular Characterization

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<sup>3</sup> [http://www.efsa.europa.eu/EFSA/efsa\\_locale-1178620753812\\_1178660555237.htm](http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178660555237.htm)

(MC) and food/feed (FF) in the bioinformatic analyses. As for the collaboration with the JRC on the bioinformatic analysis, further ways of collaboration will be explored regarding the routine analyses to be performed by the JRC. All members agreed that this collaboration can be useful and that further efforts should be made on strengthening the present links.