MINUTES OF THE 50TH PLENARY MEETING OF THE SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS HELD ON 27-28 MAY 2009 IN PARMA, ITALY (ADOPTED ON 1 JULY 2009)

CORRIGENDUM[1]

[1] Reflects changes in Title 5.1 and minor editorial mistakes.

PARTICIPANTS

GMO Panel:
Hans Christer Andersson, Salvatore Arpaia, Detlef Bartsch, Josep Casacuberta, Howard Davies, Patrick du Jardin, Niels Bohse Hendriksen, Lieve Herman, Sirpa Kärenlampi, Jozsef Kiss, Gijs Kleter, Harry Kuiper (Chair), Nick Panopoulos, Joe Perry, Annette Pöting, Joachim Schiemann, Willem Seinen, Jeremy Sweet and Jean-Michel Wal.

EFSA:
GMO Unit: Per Bergman, Anna Christodoulidou, Yann Devos, Zoltán Divéki, Antonio Fernández, Andrea Germini, Ana Gomes, Karine Lheureux, Yi Liu, Sylvie Mestdagh, Claudia Parisi, Nancy Podevin, Reinhilde Schoonjans, Ellen Van Haver, Elisabeth Waigmann.

European Commission:
Sabine Pelsser and Michael Walsh (DG SANCO); Helen Clayton and Bernadette Murray (DG ENV)

APOLOGIES

GMO Panel:
Ilona Kryspin-Sorensen, Ingolf Nes.

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 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 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 49TH PLENARY MEETING HELD ON 21-22 APRIL 2009

The minutes of the 49th Plenary meeting (21-22 April 2009) were adopted as proposed and will be published at: http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902375365.htm

5. DISCUSSION AND POSSIBLE ADOPTION OF OPINIONS ON:

5.1. Applications (references EFSA-GMO-NL-2005-22, EFSA-GMO-RX-NK603) for the placing on the market of the genetically modified glyphosate tolerant maize NK603 for cultivation, food and feed uses, import and processing and for renewal of the authorisation of maize NK603 as existing products, both under Regulation (EC) No 1829/2003 from Monsanto.

Introduction

This document provides a scientific opinion of the Panel on Genetically Modified Organisms (GMO Panel) of the European Food Safety Authority (EFSA) on two applications (References EFSA-GMO-NL-2005-22 and EFSA-GMO-RX-NK603) submitted by Monsanto under Regulation (EC) No 1829/2003 for (1) the placing on the market of the genetically modified (GM) glyphosate tolerant maize NK603 for cultivation, food and feed uses and import and processing, as well as for (2) the renewal of the authorisation of existing products produced from GM maize NK603 (Unique Identifier MON-ØØ6Ø3-6).

Maize NK603 (also referred to as GMHT crop) has been developed for tolerance to glyphosate-containing herbicides by the introduction, via particle gun acceleration, of a gene coding for 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) from *Agrobacterium* sp. strain CP4 (CP4 EPSPS).

In delivering its scientific opinion, the EFSA GMO Panel considered the applications EFSA-GMO-NL-2005-22 and EFSA-GMO-RX-NK603, additional information supplied by the applicant, the scientific comments submitted by the Member States and the report of the Spanish Competent Authority and its Biosafety Commission.

The EFSA GMO Panel assessed maize NK603 with reference to the intended uses and appropriate principles described in the guidance document of the EFSA GMO Panel for the risk assessment of GM plants and derived food and feed. The scientific assessment included molecular characterisation of the inserted DNA and expression of target proteins. A comparative analysis of agronomic traits and composition was undertaken, and the safety of the new proteins and the whole food/feed were evaluated with respect to potential toxicity, allergenicity and nutritional quality. An assessment of environmental impacts and the post-market environmental monitoring plan were undertaken.

The EFSA GMO Panel is of the opinion that the molecular data provided are sufficient and do not raise a safety concern. Based on the results of compositional analysis, the EFSA GMO Panel concludes that maize NK603 is compositionally equivalent to conventional maize, except for the presence of the CP4 EPSPS proteins. In addition, field trials did not show changes in phenotypic characteristics and agronomic performance except for the introduced trait.

There were no adverse effects in a 90 day feeding study on rats with NK603 maize grain. Feeding studies on broiler chickens, Angus-continental cross steers, Holstein dairy cows, growing-finishing pigs, and rats provided evidence of nutritional equivalence of maize NK603 to conventional maize. In addition it is unlikely that the overall allergenicity of the whole plant is changed. The EFSA GMO Panel is of the opinion that maize NK603 is as safe as conventional maize and that maize NK603 and derived products are unlikely to have any adverse effect on human and animal health in the context of the intended uses.

The Spanish Competent Authority and its Biosafety Commission provided to EFSA its opinion on the environmental risk assessment in line with Articles 6.3 (e) and 18.3 (e) of Regulation (EC) No 1829/2003. The Spanish Competent Authority and its Biosafety Commission conclude that "*according to the current state of scientific knowledge and after examining the existing information and data provided by the Monsanto Company, the Spanish Commission on Biosafety could give a favourable opinion to the commercialisation in the E.U. of maize NK603 if proposals and conditions established in the ERA report are implemented*".

The EFSA GMO Panel considers that maize NK603 has no altered survival, multiplication or dissemination characteristics, and it interacts with other organisms as does conventional maize. The likelihood of unintended environmental effects due to the establishment and spread of maize NK603 will be no different from that of traditionally bred maize. The EFSA GMO Panel considers that the potential environmental impacts of the specific cultivation, management and harvesting techniques of maize NK603 are indirect effects entirely associated with the use of the complimentary herbicide regimes. Thus the EFSA GMO Panel concludes that maize NK603 plants are unlikely to cause any direct adverse effects, but that potential adverse environmental effects of the cultivation of maize NK603 associated with the use of the complimentary glyphosate herbicide have been identified. This conclusion is in line with the conclusions of the Spanish Competent Authority and its Biosafety Commission.

The EFSA GMO Panel recommends that the potential adverse effects of the glyphosate should be evaluated for the specific use on maize NK603 during the national registration by the Member States under the pesticide Directive 91/414/EEC.

In conclusion, the EFSA GMO Panel considers that the information available for maize NK603 addresses the scientific comments raised by the Member States and that maize NK603 is as safe as its conventional counterpart with respect to potential direct effects on human and animal health and the environment. However, the EFSA GMO Panel concludes that the cultivation management of maize NK603 could have adverse effects on the environment in the context of its intended uses. The EFSA GMO Panel therefore recommends managing the use of glyphosate on maize NK603 in regimes that have similar or reduced environmental impacts compared with conventional maize cultivation.

Adoption

This 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

5.2. Applications for renewal of authorisation for continued marketing of existing products from MON810 maize (EFSA-GMO-RX-MON810) (EFSA-Q-2007-164, EFSA-Q-2007-153, and EFSA-Q-2007-150).

A report on the discussion with Member States was presented. EFSA had held a technical meeting with the Member State experts to exchange views on the environmental risk assessment of maize MON810 on May 26 2009. EFSA decided to invite Member State experts to this meeting to address the scientific issues raised in a letter signed by certain Member States. Scientific experts from all Member States and environmental experts of EFSA's GMO Panel were invited to the meeting. A final report of this meeting will be made available to the GMO Panel before it finalises the scientific opinion. The draft opinion was subsequently discussed. Thus after the Plenary meeting the draft opinion is to be circulated for written adoption by the Panel before 15 June 2009.

Adoption

The adopted scientific opinion will be published on the following EFSA website: http://www.efsa.europa.eu/en/science/gmo/gmo_opinions.html

The opinion was unanimously adopted by written procedure on 15 June.

This document provides a scientific opinion of the EFSA GMO Panel on the three applications submitted under Regulation (EC) No 1829/2003 for renewal of the authorisation of

- existing food and food ingredients produced from maize MON810 (Reference EFSA-GMO-RX-MON810[8-1a]) that have been placed on the market in accordance with Article 5 of Regulation (EC) No 258/97;

- feed consisting of and/or containing maize MON810 that were authorised under Directive 90/220/EEC (Commission Decision 98/294/EC), including the use of seed for cultivation (Reference EFSA-GMO-RX-MON810$_{[20\text{-}1a]}$);

- food additives produced from maize MON810 that were authorised under Directive 89/107/EEC, and feed produced from maize MON810, i.e., feed additives lawfully placed on the market under Directive 70/524/EEC and feed materials (Reference EFSA-GMO-RX-MON810$_{[8\text{-}1b/20\text{-}1b]}$).

Maize MON810 expresses a Cry1Ab insecticidal protein, derived from *Bacillus thuringiensis* subsp. *kurstaki*, which confers protection against lepidopteran target pests such as the European corn borer (*Ostrinia nubilalis*) and species belonging to the genus *Sesamia*.

In delivering its scientific opinion, the EFSA GMO Panel considered the three renewal applications (EFSA-GMO-RX-MON810$_{[8.1.a]}$, EFSA-GMO-RX-MON810$_{[20.1.a]}$ and EFSA-GMO-RX-MON810$_{[8.1.b/20.1.b]}$); additional information supplied by the applicant; the scientific comments submitted by the Member States; the report of the Spanish Competent Authority and its Biosafety Commission; and relevant information published in the scientific literature.

The EFSA GMO Panel assessed maize MON810 with reference to the intended uses and appropriate principles described in the guidance document of the EFSA GMO Panel for the risk assessment of GM plants and derived food and feed. The scientific assessment included molecular characterisation of the inserted DNA and expression of target protein. A comparative analysis of agronomic traits and composition was undertaken, and the safety of the new protein and the whole food/feed were evaluated with respect to potential toxicity, allergenicity and nutritional quality. An assessment of environmental impacts and the post-market environmental monitoring plan were undertaken.

The EFSA GMO Panel is of the opinion that the molecular characteristics of the DNA insert and flanking regions of maize MON810 do not raise any safety concern, and that sufficient evidence for the stability of the genetic modification was provided. Analyses carried out on materials from maize MON810 indicate that maize MON810 is compositionally, phenotypically and agronomically equivalent to the non-GM counterparts and conventional maize, except for the introduced trait. No concerns for humans and animals were identified regarding the safety of the Cry1Ab protein. In a 90-day feeding study in rats, no indications of adverse effects were observed. In addition, a 42-day broiler feeding study provided evidence of nutritional equivalence of maize MON810 kernels to the kernels of conventional maize. The toxicological and nutritional data on maize MON810 and

appropriate non-GM maize control published during the last ten years confirm that these maize varieties have comparable influence on the test systems. Therefore, the EFSA GMO Panel is of the opinion that maize MON810 is as safe as its non-GM counterparts and that the overall allergenicity of the whole plant is not changed through the genetic modification.

The Spanish Competent Authority and its Biosafety Commission provided EFSA its report on the environmental risk assessment in line with Articles 6.3(e) and 18.3(e) of Regulation (EC) No 1829/2003. The Spanish Competent Authority and its Biosafety Commission conclude that "*according to the current state of scientific knowledge and after examining the existing information and the data provided by the Monsanto Company, the Spanish Commission on Biosafety could give a favourable opinion to the renewal of commercialisation in the EU of maize MON810 if the proposals and conditions defined in this environmental risk assessment report are implemented*".

Since maize MON810 has no altered survival, multiplication or dissemination characteristics, the EFSA GMO Panel agrees with the assessment that the likelihood of unintended environmental effects due to the establishment and spread of maize MON810 will be no different from that of conventional maize varieties. The EFSA GMO Panel concludes that the likelihood of adverse effects on non-target organisms or on ecological functions is very low, especially if appropriate mitigation measures are adopted. In agreement with the environmental risk assessment by the applicant and the assessment conducted by the Spanish Competent Authority and its Biosafety Commission, the EFSA GMO Panel identifies the possible evolution of resistance in target species as a potential risk linked to the cultivation of maize MON810.

In conclusion, the EFSA GMO Panel considers that the information available for maize MON810 addresses the scientific comments raised by the Member States and that maize MON810 is as safe as its conventional counterpart with respect to potential effects on human and animal health. The EFSA GMO Panel also concludes that maize MON810 is unlikely to have any adverse effect on the environment in the context of its intended uses, especially if appropriate management measures are put in place in order to mitigate possible exposure of non-target Lepidoptera. Moreover, the EFSA GMO Panel advises that pest resistance management strategies continue to be employed.

5.3. Application for renewal of authorisation for continued marketing of feed materials and feed additives produced from 1507 maize (EFSA-GMO-RX-1507) (EFSA-Q-2007-144)

Introduction

This document provides the scientific opinion of the EFSA GMO Panel on an application submitted under Regulation (EC) No 1829/2003 (reference EFSA-GMO-RX-1507) for renewal of the authorisation of existing products derived from genetically modified maize 1507.

Maize 1507 was developed to provide protection against specific lepidopteran pests and tolerance to glufosinate-containing herbicides by the introduction of genes expressing Cry1F and PAT proteins.

Discussion

The EFSA GMO Panel has previously issued scientific opinions related to notifications C/NL/00/10 for the placing on the market of maize 1507 for import and processing, and C/ES/01/01 for the placing on the market of maize 1507 for import, feed and industrial processing and cultivation, under Part C of Directive 2001/18/EC. Furthermore, a scientific opinion for food use of maize 1507 under Regulation (EC) No 1829/2003 was issued and published. In these scientific opinions the

EFSA GMO Panel concluded that maize 1507 will not have an adverse effect on human and animal health or the environment in the context of its proposed uses.

According to the information provided by the applicant, feed products produced from maize 1507 and from maize containing 1507 event stacked with other GM events that have been approved in the EU, have been consumed without reports of adverse effects. Scientific publications, which have become available since the previous evaluation of maize 1507 by the EFSA GMO Panel, did not raise safety issues. Additional bioinformatic studies using updated databases have confirmed the results of the previous studies showing that no relevant similarities exist between the newly expressed proteins Cry1F and PAT and known allergens or proteins toxic for human and other mammals. Bioinformatic analysis of the flanking regions showed homology to retrotransposable elements, which raised no safety concern.

The scope of this application is for feed materials and feed additives produced from maize 1507. Thus the scope only includes products from maize 1507 which contain no viable plant parts. Therefore, there are no requirements for scientific information on the environmental safety of accidental releases or cultivation of maize 1507. A post-market environmental monitoring plan for maize 1507 is not required.

The EFSA GMO Panel concludes that the new information provided by the applicant and a review of the scientific literature that has been published since the previous opinions of the EFSA GMO Panel does not require changes of the previous scientific opinions on maize 1507, and that it addresses the scientific comments raised by the Member States. Therefore, the EFSA GMO Panel reiterates the previous conclusions that genetically modified maize 1507 is unlikely to have an adverse effect on human and animal health or the environment in the context of its proposed uses. This includes the use of feed materials and feed additives produced from maize 1507.

Adoption

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

5.4. New information submitted by Austria in the context of a safeguard measure adopted under Article 23 of Directive 2001/18/EC on oilseed rape GT73 (EFSA-Q-2008-315)

A report on the discussion with Austrian scientists was presented. EFSA held a technical meeting with Austrian scientists on 23 April 2009 in order to hear the arguments of Austria and to obtain clarifications on scientific issues addressed in the Austrian reports supporting their national safeguard clause. A final report of this meeting will be made available to the GMO Panel before it finalises its scientific opinion. A draft opinion was discussed. Thus, the draft opinion will be circulated for written adoption by the Panel before 15 June 2009.

Adoption

The adopted scientific opinion will be published on the following EFSA website: http://www.efsa.europa.eu/EFSA/ScientificPanels/GMO/efsa_locale-1178620753812_GMOOpinions455.htm

The opinion was unanimously adopted by written procedure on 15 June.

On 27 July 2007, Austria invoked Article 23 of Directive 2001/18/EC (safeguard clause) to provisionally prohibit the marketing of genetically modified oilseed rape GT73 on its territory. Austria provided detailed reasons listed in supporting documents, which were identical to the ones previously submitted to the Netherlands on 13 July 2006.

On 17 April 2008, EFSA was requested by the European Commission to provide a scientific opinion on the statement and the documents submitted by Austria in the context of a safeguard clause invoked under Article 23 of Directive 2001/18/EC.

In the light of the information package provided by Austria in support of its safeguard clause, and having considered all relevant scientific publications, the EFSA GMO Panel concluded that, in terms of risk to human and animal health and the environment, no new scientific evidence was presented that would invalidate the previous risk assessment of oilseed rape GT73. The EFSA GMO Panel also concluded that no new scientific data or information was provided in support of adverse effects of oilseed rape GT73 on the environment and on human and animal health in Austria. Therefore, no specific scientific evidence, in terms of risk to human and animal health and the environment were provided that would justify the invocation of a safeguard clause under Article 23 of Directive 2001/18/EC.

5.5. 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)

A report on the discussion with Austrian scientists was presented. EFSA held a technical meeting with Austrian scientists on 23 April 2009 to hear arguments from Austria and to obtain clarifications on scientific issues addressed in the Austrian reports supporting their national safeguard clause. A final report of this meeting will be made available to the GMO Panel before it finalises its scientific opinion. A draft opinion was discussed. The draft opinion will be circulated for formal written adoption by the Panel before 15 June 2009.

Adoption

The adopted scientific opinion will be published on the following EFSA website: http://www.efsa.europa.eu/en/science/gmo/gmo_opinions.html

The opinion was unanimously adopted by written procedure on 15 June.

On 15 July 2008, Austria invoked Article 23 of Directive 2001/18/EC (safeguard clause) to provisionally prohibit the marketing of genetically modified oilseed rape MS8, RF3 and MS8xRF3 on its territory. Austria provided detailed reasons listed in supporting documents.

On 31 July 2008, EFSA was requested by the European Commission to provide a scientific opinion on the statement and documents submitted by Austria in the context of a safeguard clause invoked under Article 23 of Directive 2001/18/EC.

In the light of the information package provided by Austria in support of its safeguard clause and, having considered all relevant scientific publications, the EFSA GMO Panel concluded that, in terms of risk to human and animal health and the environment, no new scientific evidence was presented that would invalidate the previous risk assessment of oilseed rape MS8, RF3 and MS8xRF3. The EFSA GMO Panel also concluded that no new scientific data or information was provided in support of adverse effects of oilseed rape MS8, RF3 and MS8xRF3 on the environment

and on human and animal health in Austria. Therefore, no specific scientific evidence, in terms of risk to human and animal health and the environment were provided that would justify the invocation of a safeguard clause under Article 23 of Directive 2001/18/EC.

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

A report on the discussion with Austrian scientists was presented. EFSA held a technical meeting with Austrian scientists on 23 April 2009 to hear the arguments of Austria and to obtain clarifications on scientific issues addressed in the Austrian reports supporting their national safeguard clause. A final report of this meeting will be made available to the GMO Panel before it finalises its scientific opinion. A draft opinion was discussed. The draft opinion will be circulated for written adoption by the Panel before 15 June 2009.

Adoption

The adopted scientific opinion will be published on the following EFSA website: http://www.efsa.europa.eu/en/science/gmo/gmo_opinions.html

The opinion was unanimously adopted by written procedure on 15 June.

On 16 July 2008, Austria invoked Article 23 of Directive 2001/18/EC (safeguard clause) to provisionally prohibit the import of the MON863 maize lines into its territory. Austria provided detailed reasons listed in the supporting documents.

On 3 September 2008, EFSA was requested by the European Commission to provide a scientific opinion on the statement and documents submitted by Austria in the context of the safeguard clause invoked under Article 23 of Directive 2001/18/EC.

In the light of the information package provided by Austria in support of its safeguard clause and, having considered all relevant scientific publications, the EFSA GMO Panel concluded that, in terms of risk to human and animal health and the environment, no new scientific evidence was presented that would invalidate the previous risk assessment of maize MON863. The EFSA GMO Panel also concluded that no new scientific data or information was provided in support of adverse effects of maize MON863 on the environment and on human and animal health in Austria. Therefore, no specific scientific evidence, in terms of risk to human and animal health and the environment were provided that would justify the invocation of a safeguard clause under Article 23 of Directive 2001/18/EC.

5.7. Self-tasking on the assessment of allergenicity of genetically modified foods (EFSA-Q-2005-125)

The chair of the Working Group, Jean-Michel Wal, presented to the Panel the draft report of the self-tasking activity on the assessment of allergenicity of GM food and feed. Daniel Soeria Atmadja (ad-hoc expert on bioinformatics for the working group) was invited to present the findings and conclusions of the bioinformatics chapter in the draft report.
Upon agreement by the Panel, the summary chapter comprising not only suggestions for risk assessment but also for future research should be the basis for a dedicated chapter providing further

guidance for risk assessors. A revised version of the report will therefore be presented to the Panel at its September Plenary meeting before the public consultation.

6. DISCUSSION OF OPINIONS:

None were discussed.

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

Regarding the coordination of the applications received under Regulation (EC) No 1829/2003, the GMO Unit informed the Panel about (1) the status of the recently received applications, (2) about the ongoing process of completion checks and (3) about the ongoing risk assessments, including the timelines in relation to the pending applications.

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

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

- Application for the authorisation of genetically modified potato AV43-6-G7 for food and feed uses and cultivation, submitted in accordance with Regulation (EC) No. 1829/2003 by AVEBE (EFSA-GMO-NL-2009-69; (EFSA-Q-2009-00552).

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 application is valid. On its own initiative EFSA has broadened this consultation also to the 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 in 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

None

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

EFSA published the report on the public consultation of **the Updated Guidance Document** on the risk assessment of GM plants and derived food and feed in its website. DG SANCO submitted the EC Guidelines with annexes to other DGs of the European Commission for inter-service consultation. Upon receipt of the comments from all DGs, DG SANCO will be able to progress and submit the EC Guidelines with annexes to the Regulatory Committee (Standing Committee on the Food Chain and Animal Health) of June.

Self-task on the choice of comparators. The mandate was approved by EFSA on 6 May and a working group was set up including 5 members of the GMO Panel. First meeting is scheduled for 17 June 2009.

Self-task for updating the Guidance for risk assessment of GM microorganisms. The mandate was approved by EFSA on 6 May and the working group has its first meeting scheduled for 25-26 June 2009.

Self-task on Non-Target Organisms (NTO). The draft opinion was submitted to three external reviewers whose feedback is expected by 5 June and will be presented to the working group on 9 June.

Mandate for updating the Environmental sections related to EFSA Guidance Document. All four elements of the mandate are being addressed in addition to other items related to the Environmental section of the EFSA Guidance Document. Consultation meetings with applicants, Member States and environmental institutions are organised on 16, 17 and 18 June 2009 respectively in Berlin. Discussions will take place on the approach followed so far by the EFSA Working Groups in areas of the mandate. A detailed presentation will be provided in advance of the meeting to all stakeholders.

Mandate for Guidance on GM animals. A procurement contract for a study of GM fish has been awarded to a scientific consortium composed of UK universities and research institutes. The Panel was informed that this contract focuses on fin fish (Teleost) and does not cover shell fish. It was explained that the call for tender for ERA for GM insects was launched on 20 May with a deadline of 27 July 2009. The call for the ERA on GM mammals and birds is being finalized and will be launched soon. Regarding the food/feed safety of GM animals, several working group meetings have taken place and the work is in progress. A first draft version of the Guidance, addressing topics related to food/feed safety and molecular characterization is currently being prepared. EFSA is now in contact with an FDA delegate responsible for the regulation and safety assessment of GM animals in the US. Organisation of a bilateral meeting between EFSA staff and the FDA delegate was encouraged and will take place on 17 June 2009.

10. FEEDBACK FROM EFSA AND THE SCIENTIFIC COMMITTEE

The results from the **Experts survey** were presented to the Panel.

Mandate on the use of Antibiotic Resistance genes as Markers in GM plants. The Chair of the GMO Panel informed that in the light of the minority opinions expressed by two BIOHAZ panel members, the EFSA Executive Director has asked the chairs of the GMO Panel and the BIOHAZ Panel and the joint working group if further work was required in order to complete the work process. The GMO Panel was further informed that the three chairs had answered the EFSA Executive Director that this was not the case. The Panel was further informed by the Head of the GMO Unit that the EFSA statement and relevant communication activities are being finalized and prepared for publication early June.

11. FEEDBACK FROM THE COMMISSION

DG SANCO and DG ENV gave an overview and follow-up on the various scientific outcomes produced by the Panel during its full term, such as Opinions given for applications under Regulation (EC) No 1829/2003, notifications under Directive 2001/18/EC, various safeguard clauses, guidance and general scientific issues. This feedback at the end of the Panel's mandate was welcomed by the experts.

12. DATE AND PLACE OF FUTURE MEETINGS

13. ANY OTHER BUSINESS

An EFSA GMO Conference will take place on 14-15 September 2009. The program is now finalized and speakers and participants have been invited.