

**MINUTES OF THE 42ND PLENARY MEETING OF THE
SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS
HELD ON 21-22 MAY 2008 IN PARMA, ITALY
(ADOPTED ON 2 JULY 2008)**

AGENDA

1. WELCOME AND APOLOGIES FOR ABSENCE	2
2. ADOPTION OF THE AGENDA	2
3. DECLARATION OF INTERESTS.....	2
4. ADOPTION OF THE MINUTES OF THE 41ST PLENARY MEETING HELD ON 16-17 APRIL 2008	3
5. DISCUSSION AND POSSIBLE ADOPTION OF OPINIONS ON:	3
5.1. UPDATED OPINION ON DANISCO XYLANASE G/L (ENDO-1,4-BETA-XYLANASE).....	3
5.2. THE NON-AUTHORISED GENETICALLY MODIFIED EVENT DAS 59132-8 FOUND IN US MAIZE.....	3
5.3. UPDATED DRAFT GUIDANCE DOCUMENT FOR THE RISK ASSESSMENT OF GENETICALLY MODIFIED PLANTS AND DERIVED FOOD AND FEED (FOR SUBMISSION TO THE EUROPEAN COMMISSION AND THE MEMBER STATES).....	4
6. UPDATE ON APPLICATIONS RECEIVED UNDER DIRECTIVE 2001/18/EC, REGULATION (EC) NO 1829/2003 AND REGULATION (EC) NO 1831/2003.....	5
7. NEW REQUESTS TO EFSA: DISCUSSION AND ADOPTION OF MANDATES.....	5
7.1. GREEK MINISTERIAL DECISION CONCERNING THE EXTENSION OF VALIDITY AND AMENDMENT OF THE PREVIOUS MINISTERIAL DECISION ON THE TRADING OF MON810 SEEDS (EFSA-Q-2008-313)	5
7.2. SAFEGUARD CLAUSE INVOKED BY AUSTRIA UNDER ARTICLE 23 OF DIRECTIVE 2001/18/EC IN RELATION TO MON810 AND T25 (EFSA-Q-2008-314 ⁷).....	6
7.3. SAFEGUARD CLAUSE INVOKED BY AUSTRIA UNDER ARTICLE 23 OF DIRECTIVE 2001/18/EC IN RELATION TO OILSEED RAPE GT73 (EFSA-Q-2008-315)	6
7.4. SAFEGUARD CLAUSE INVOKED BY HUNGARY UNDER ARTICLE 23 OF DIRECTIVE 2001/18/EC IN RELATION TO MON810 MAIZE (EFSA-Q-2008-316 ⁸).....	6
7.5. REQUEST FOR CONSOLIDATED OPINION ON USE OF ANTIBIOTIC RESISTANCE MARKER (ARM) GENES AS MARKER GENES IN GM PLANTS (EFSA-Q-2008-411).....	7
8. UPDATE ON SELF TASKING ACTIVITIES AND GUIDANCE ON GMO RISK ASSESSMENT	7
8.1. GUIDANCE FOR THE ASSESSMENT OF GM PLANTS USED FOR NON-FOOD/FEED PURPOSES	7
9. FEEDBACK FROM EFSA AND THE SCIENTIFIC COMMITTEE	7
10. FEEDBACK FROM THE COMMISSION	8
11. DATES OF FUTURE MEETINGS	8
12. ANY OTHER BUSINESS	8

PARTICIPANTS

GMO Panel:

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

EFSA:

GMO Unit: Per Bergman, Elisa Bianco, Anna Christodoulidou, Yann Devos, Zoltan Diveki, Antonio Fernandez Dumont, Ana Gomes, Karine Lheureux, Sylvie Mestdagh, Claudia Paoletti, and Reinhilde Schoonjans.

Risk Assessment Directorate: Riitta Maijala¹.

European Commission:

Sebastien Goux, Sabine Pelsser (DG SANCO), and Aurélie André ²(DG ENV).

Dutch Competent Authority and COGEM³

Frank van der Wilk (COGEM); Hanneke Bresser, Heddy de Wijs, and Boet Glandorf (Dutch Competent Authority).

APOLOGIES

GMO Panel:

Josep Casacuberta, Ilona Kryspin-Sorensen and 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

Panel members were invited to declare possible interests on topics included on the agenda. No specific declarations of interest were declared.

¹ Only present for Agenda item 9

² Only present on 21 May

³ Only present for Agenda item 6

4. ADOPTION OF THE MINUTES OF THE 41ST PLENARY MEETING HELD ON 16-17 APRIL 2008

The minutes of the 41st Plenary meeting (16-17 April 2008) were adopted after reviewing and will be published at:

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178700175832.htm

5. DISCUSSION AND POSSIBLE ADOPTION OF OPINIONS ON:

5.1. Updated opinion on Danisco Xylanase G/L (endo-1,4-beta-xylanase)

Introduction

The European Commission requested EFSA to update the Opinion on the Danisco Xylanase G/L (endo-1,4-beta-xylanase) feed additive, adopted in September 2007, based on new data provided by the applicant in the supplementary dossier.

Discussion

The GMO Panel, who has previously adopted and published a co-opinion with the FEEDAP Panel on October 2007 (see item 5.1 of the minutes of the 35th Plenary meeting⁴), has been asked to issue an updated scientific opinion on the enzyme preparation of trade name “Danisco Xylanase G/L (endo-1-4-beta-xylanase)” based on the supplementary information provided by the company on December 2007.

“Danisco Xylanase G/L (endo-1-4-beta-xylanase)” is an enzyme feed additive for laying hens and chickens and ducks for fattening. No recombinant DNA was detected in the enzyme preparation when it was diluted to the activity level corresponding to the final marketable product. Since no additional purification steps of the enzyme preparation which could have removed the traces of DNA have been reported, the presence of trace amounts of recombinant DNA below the quantification limit in the final product cannot be excluded. In its previous opinion, the GMO Panel already concluded that the presence of trace amounts of DNA raises no safety issues.

Adoption

The updated opinion was adopted unanimously by the Panel. The updated opinion can be found on the EFSA website at:

http://www.efsa.europa.eu/en/science/gmo/gmo_opinions.html.

5.2. The non-authorized genetically modified event DAS 59132-8 found in the US in US maize

Introduction

⁴ http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178654544327.htm

Following a request from the European Commission, the Panel on Genetically Modified Organisms was asked to deliver a scientific opinion on the non-authorized genetically modified maize event DAS 59132-8 found at low levels in certain maize hybrid lines of DAS 59122-7 in the US.

Discussion

Adventitious presence of DAS 59132-8 in DAS 59122-7 has until now not been found in Europe. The available data are not sufficient to allow a full risk assessment of DAS 59132-8 in accordance with the EFSA guidance document for the risk assessment of GM plants for authorization under the EU legislation. However, taking the data from the similar maize event DAS 59122-7 into account, and considering that the level of DAS 59132-8 in certain maize hybrid lines is low (less than 3 seeds/1000 seeds), the GMO Panel concludes that it is unlikely that there is a specific risk for human health or the environment from exposure to maize event DAS 59132-8, in case it would occur as an admixture in maize DAS 59122-7 imported in the EU for food and feed purposes.

Adoption

The opinion was adopted unanimously by the Panel and can be found on the EFSA website at: http://www.efsa.europa.eu/en/science/gmo/gmo_opinions.html.

5.3. Updated Draft Guidance Document for the risk assessment of genetically modified plants and derived food and feed (for submission to the European Commission and the Member States)

Introduction

EFSA's GMO Panel regularly reviews its guidance to take account of scientific developments and of experience gained through the risk assessment process. When doing so the Panel consults interested parties including the European Commission, the Member States and stakeholders as well as the public. This document has the objective to provide guidance for the risk assessment of genetically modified (GM) plants and/or derived food and feed submitted within the framework of Regulation (EC) No 1829/2003 on GM food and feed and of the Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms.

This update was also requested by the European Commission who will use it as a basis for the preparation of the legal framework for the safety assessment of food and feed to be adopted through comitology.

Discussion and adoption

In 2008 the Panel started to update its guidance in the light of several years of experience in the risk assessment of GMO applications and of the outcome of the Panel's self-tasking activities. The updated draft guidance was presented to the Panel. This document provides updated guidance on the role of animal feeding trials with whole plant material – based on the report of the related self-tasking activity⁵ – and on the experimental design of field trials and the statistical analysis of the collected data. The update also incorporates the additional guidance on GM plants containing stacked events, already published by EFSA as separate document⁶.

⁵ http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178660555237.htm

⁶ http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178623591786.htm

The Panel adopted unanimously the updated draft ‘guidance document for the risk assessment of genetically modified plants and derived food and feed’ for submission to the European Commission and the Member States who will use it as a basis for the preparation of the legal framework for the safety assessment of food and feed to be adopted through comitology. The draft document is published on the EFSA website on http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620775747.htm

6. UPDATE ON APPLICATIONS RECEIVED UNDER DIRECTIVE 2001/18/EC, REGULATION (EC) NO 1829/2003 AND REGULATION (EC) NO 1831/2003

Ongoing applications including scope cultivation

- 59122 maize (Application NL-2005-23 for cultivation) and 1507x59122 maize (Application NL-2005-28 for cultivation): the Dutch Competent Authority gave an opinion on the dossiers, particularly on the environmental risk assessment of 59122 maize and 1507x59122 maize in accordance with Article 6.3(c) and 19.3(c) of Regulation (EC) No 1829/2003. Four delegates of the Dutch Competent Authority and the secretariat of the COGEM presented their opinions on the environmental risk assessment in both applications to the EFSA GMO Panel. The Panel thanked the Dutch Competent Authority and its scientific committee and appreciated the high quality of their reports which will be included as an annex to the final EFSA overall opinions.

7. NEW REQUESTS TO EFSA: DISCUSSION AND ADOPTION OF MANDATES⁷

7.1. Greek Ministerial Decision concerning the extension of validity and amendment of the previous Ministerial Decision on the trading of MON810 seeds (EFSA-Q-2008-313)

On September 2007 Greece notified to the Commission its Ministerial Decision no. 303061/7505/28.06.2007 concerning the extension of validity and amendment of the Ministerial Decision 243983/1127/30.01.2006 on the trading of MON810 seeds. This notification is supported by documents.

With a letter dated 18 April 2008, EFSA received from the Commission a request, under Article 29(1) and in accordance with Articles 22(2) and 22(5)(c) of Regulation (EC) No 178/2002, for a scientific opinion:

- *“to assess whether there is any scientific reason to deem that the placing on the market of MON810 seeds is likely to cause any adverse effects on human health and the environment justifying the Greek safeguard measure;*
- *in particular, EFSA is requested to take account of the statement and scientific information submitted by the Greek authorities to justify their national safeguard measures concerning this product.”*

⁷ Mandates can be viewed on the Register of Questions according to their EFSA-Q number http://www.efsa.europa.eu/EFSA/ScientificOpinionPublicationReport/efsa_locale-1178620753812_RequestsAndMandates.htm

The Panel will invite the Greek experts to a technical meeting within EFSA's premises. Afterwards, on the basis of the information provided and discussion in the technical meeting, the GMO Panel will conclude its scientific assessment.

7.2. Safeguard clause invoked by Austria under Article 23 of Directive 2001/18/EC in relation to MON810 and T25 (EFSA-Q-2008-314)

The Austrian authorities submitted new information to the European Commission in the context of its safeguard measures on MON810 and T25 invoked under Article 23 of Directive 2001/18/EC.

In the light of the mandate concerning further development of the environmental risk assessment of GMOs EFSA is now requested by the European Commission, with a letter dated 18 April 2008, under Article 29(1) and in accordance with Articles 22(2) and 22(5)(c) of Regulation (EC) No 178/2002:

- *“to assess whether the information submitted by Austria comprises information affecting the environmental risk assessment of existing information on the basis of new scientific knowledge such that detailed grounds exist to consider that the above authorised GMOs, for the uses laid down in the corresponding consent, constitute a risk to the environment.”*

The Panel will invite the Austrian experts to a technical meeting within EFSA's premises. Afterwards, on the basis of the information provided and discussion in the technical meeting, the GMO Panel will conclude its scientific assessment.

7.3. Safeguard clause invoked by Austria under Article 23 of Directive 2001/18/EC in relation to oilseed rape GT73 (EFSA-Q-2008-315)

The Austrian authorities submitted new information to the European Commission in the context of a safeguard measure adopted under Article 23 of Directive 2001/18/EC on oilseed rape GT73.

With a letter dated 17 April 2008 EFSA was requested, under Article 29(1) and in accordance with Articles 22(2) and 22(5)(c) 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 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.”*

The Panel will invite the Austrian experts to a technical meeting within EFSA's premises. Afterwards, on the basis of the information provided and discussion in the technical meeting, the GMO Panel will conclude its scientific assessment.

7.4. Safeguard clause invoked by Hungary under Article 23 of Directive 2001/18/EC in relation to MON810 maize (EFSA-Q-2008-316)

The Hungarian authorities submitted new information in the context of its safeguard measure on MON810 invoked under Article 23 of Directive 2001/18/EC.

In the light of the mandate concerning further development of the environmental risk assessment of GMOs, EFSA is now requested by the European Commission, with a letter dated 18 April 2008,

under Article 29(1) and in accordance with Articles 22(2) and 22(5)(c) of Regulation (EC) No 178/2002:

- *“to assess whether the information submitted by Hungary comprises information affecting the environmental risk assessment of existing information on the basis of new scientific knowledge such that detailed grounds exist to consider that the above authorised GMOs, for the uses laid down in the corresponding consent, constitute a risk to the environment.”*

The Panel will invite the Hungarian experts to a technical meeting within EFSA’s premises. Afterwards, on the basis of the information provided and discussion in the technical meeting, the GMO Panel will conclude its scientific assessment.

7.5. Request for consolidated opinion on use of antibiotic resistance marker (ARM) genes as marker genes in GM plants (EFSA-Q-2008-411)

On 21 May 2008, EFSA received the request by the European Commission for a consolidated opinion on the use of antibiotic resistance marker (ARM) genes used as marker genes in genetically modified plants.

The mandate and the time schedule are currently under consideration by EFSA.

8. UPDATE ON SELF TASKING ACTIVITIES AND GUIDANCE ON GMO RISK ASSESSMENT

8.1. Guidance for the assessment of GM plants used for non-food/feed purposes

The Panel was informed about the launch of the public consultation of the “draft opinion on the risk assessment of GM plants used for non-food or non-feed purposes”. This draft opinion was adopted for public consultation by the Panel at its 41st Plenary meeting of 16 April 2008 (see item 8.4 of the minutes of the 41st Plenary meeting⁸). The case studies work document was presented to the Panel. Since the case studies were considered of a more theoretical character and only provided a preliminary risk assessment, the Panel decided not to include them in the draft opinion.

9. FEEDBACK FROM EFSA AND THE SCIENTIFIC COMMITTEE

The Panel was updated on EFSA’s quality assurance policy, which involves internal and external experts supported by EFSA staff to review a selected number of Opinions from EFSA’s Panels in order to promote and guarantee consistency and quality of the scientific opinions uniformity. Furthermore the Panel was told about the IT tool developed for the declarations of interests. In addition to the annual declaration of interests, EFSA’s scientific experts are asked to fill in specific declarations of interests for every working group meeting and mandate received by using the electronic system.

⁸ http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178700175832.htm

10. FEEDBACK FROM THE COMMISSION

No feedback from the Commission.

11. DATES OF FUTURE MEETINGS

Dates for Plenary meetings in 2009 were proposed to the Panel. Plenary meeting dates for 2009 have been scheduled:

- 28 – 29 January
- 11 – 12 March
- 21 – 22 April
- 27 – 28 May
- 1 – 2 July
- 9 – 10 September
- 21 – 22 October
- 2 – 3 December

12. ANY OTHER BUSINESS

The Panel was informed about a letter received from the European Commission regarding its opinion on LLRICE62. Considering the specificity of this application the European Commission requests EFSA to reconsider the need of a 90-day toxicity study on rats with the view to provide additional assurance of the LLRICE62 safety.

The Panel was informed about an opinion of the French Food Safety Agency (AFSSA), on toxicity studies made in the context of GMO safety assessment for GMO authorisation to be placed on the EU market.