
**MINUTES OF THE 44TH PLENARY MEETING OF THE
SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS
HELD ON 10-11 SEPTEMBER 2008 IN BERLIN, GERMANY
(ADOPTED ON 29 OCTOBER 2008)**

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PARTICIPANTS

GMO Panel:

Hans Christer Andersson, Detlef Bartsch, Josep Casacuberta, Patrick du Jardin, Niels Bohse Hendriksen, Sirpa Kärenlampi, Jozsef Kiss, Gijs Kleter, Iona Kryspin-Sorensen, Harry Kuiper (Chair), Joe Perry, Annette Pötting, Joachim Schiemann, Willem Seinen, Jeremy Sweet and Jean-Michel Wal.

EFSA:

GMO Unit: Per Bergman, Elisa Bianco, Karine Lheureux, Sylvie Mestdagh and Claudine Ziegelmeier.

European Commission:

Sabine Pelsser (DG SANCO), Paula Rey Garcia (DG ENV).

German Competent Authority¹

Hans-Jörg Buhk, Achim Gathmann, Anja Vaasen, and Christiane Koziolk from the German competent Authority (Directive 2001/18/EC) - Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL).

APOLOGIES

GMO Panel:

Salvatore Arpaia, Howard Davies, Lieve Herman, Ingolf Nes and Nickolas Panopoulos.

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.

Patrick du Jardin was welcomed as new Panel member. Dr. du Jardin, who was already actively involved in the work of the GMO Panel as *ad hoc* expert to EFSA working groups, introduced himself. His biography and his annual declaration of interest will be published on the EFSA website at:

http://www.efsa.europa.eu/EFSA/ScientificPanels/GMO/efsa_locale-1178620753812_MembersAndWorkingGroup453.htm

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. Declarations have been registered through the standard form submitted by the Panel members.

4. ADOPTION OF THE MINUTES OF THE 43RD PLENARY MEETING HELD ON 2-3 JULY 2008

The minutes of the 43rd Plenary meeting (2-3 July 2008) were adopted as proposed and will be published at:

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178718032781.htm

¹ Only present for Agenda item 5

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

Ongoing applications including scope cultivation

- An overview of ongoing applications for renewal of the authorization of products already on the market was given to the Panel with clear indications on the timeline. Furthermore Panel members were also informed about the status of the other applications received so far.
- 40-3-2 soybean (Application NL-2005-24 for cultivation): the German Competent Authority under Directive 2001/18/EC gave an opinion on the dossier, particularly on the environmental risk assessment of 40-3-2 soybean in accordance with Article 6.3(c) and 18.3(c) of Regulation (EC) No 1829/2003. Four delegates of the German Competent Authority and the secretariat of the BVL presented their opinion on the environmental risk assessment in 40-3-2 soybean application to the EFSA GMO Panel. The Panel thanked the German Competent Authority and its scientific committee and appreciated the high quality of their report which will be included as an annex to the final EFSA overall opinion under Regulation (EC) No 1829/2003.

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

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

EFSA received within the framework of Regulation (EC) No 1829/2003, via the UK and France, two new applications (UK-2008-60 for GA21 Maize for import and processing, food and feed use and cultivation (EFSA-Q-2008-481); FR-2008-59 for PT73 Escherichia coli (TM) dried killed bacterial biomass for feed use (EFSA-Q-2008-412)).

For GA21 a Member State is nominated to conduct the initial evaluation of the environmental Risk Assessment as foreseen in Regulation (EC) No 1829/2003. For both applications, Member States Competent Authorities 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 applications are 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 EFSA-Q-2008-481 and EFSA-Q-2008-412, as well as the information on their current status can be found through the following webpage leading to EFSA's register of Questions: http://www.efsa.eu.int/science/gmo/gm_ff_applications/catindex_en.html.

6.2. Request to review recent scientific studies relating to the impact on the environment of the cultivation of two genetically modified maize plants: 1507 and Bt11

EFSA received a letter from the European Commission, dated 24 July 2008, requesting to review recent scientific studies relating to the impact on the environment of the cultivation of 1507 and Bt11 genetically modified maize.

The Commission has provided a non exhaustive list of recent scientific publications dealing with potential effects of Bt maize on non target organisms and requested EFSA *“to review these studies*

as well as any other relevant study and to confirm its risk assessment of Bt11 and 1507 maize or comment on whether they would lead EFSA to alter its conclusions or refine it”.

The time schedule for finalisation of this request is currently under consideration by EFSA.

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

7.1. Allergenicity assessment of GM foods

A Working Group meeting took place on 27 August 2008. The draft document is in an advanced stage of development and the aim is to finalise the draft for public consultation and present it to the Panel by the end of the year.

7.2. Assessment of the impacts of GM plants on non-target organisms

A Working Group meeting took place on 30 June 2008. During this meeting the Working Group identified the main topics to be further developed in the final opinion; further discussion of these topics is required.

7.3. Update Guidance for the assessment of GM plants and derived food or feed

The Panel was informed about the future timeline for the EFSA Draft Update Guidance Document for the risk assessment of genetically modified plants and derived food and feed. The public consultation on this document is open until 21 September; the comments received will be then sent to the European Commission. After revision of the Guidance Document to include the comments received, the aim is to present the document to the Panel at forthcoming plenary meetings; this adopted version will be also sent to the European Commission.

8. FEEDBACK FROM EFSA AND THE SCIENTIFIC COMMITTEE

The Chairman gave an overview of the outcome of the 31st Plenary meeting of the Scientific Committee held on 15-16 July 2008. The minutes of this meeting can be found on the EFSA website:

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178718510757.htm

9. FEEDBACK FROM THE EUROPEAN COMMISSION

The representatives of the European Commission provided the Panel with the status of applications that have been presented to the Standing Committee on the Food Chain and Animal Health for possible authorisation, and for which no qualified majority was reached.

10. DATES OF FUTURE MEETINGS

Meeting dates for 2009 were agreed at earlier Plenary meetings.

11. ANY OTHER BUSINESS

The Panel was informed about the activity of the ad-hoc Working Party on GMOs organised under French Presidency. This Working Party will open a debate on the basis of a working document about GMOs, which has been prepared through consultation of national member states' risk assessors and managers. EFSA has been invited to take part in the debate and will give a presentation on topics falling under EFSA's remit.

The Panel has been informed about the preparatory work on the mandate for a consolidated opinion on the use of antibiotic resistance marker genes as marker genes in GM plants. A first draft of the opinion has been presented to the Panel for discussion.

For the establishment of EFSA's 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.