European Food Safety Authority

MINUTES OF THE 28TH PLENARY MEETING OF THE SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS HELD ON 13-14 SEPTEMBER 2006 (ADOPTED ON 7 NOVEMBER 2006)

AGENDA

PARTICIPANTS

GMO Panel:
Salvatore Arpaia, Detlef Bartsch, Josep Casacuberta, Howard Davies, Ralf Einspanier, Marc De Loose, Lieve Herman, Sirpa Kärenlampi (Vice-Chair), Jozsef Kiss, Ilona Kryspin-Sorensen, Harry Kuiper (Chair), Ingolf Nes, Joe Perry, Annette Pöting, Joachim Schiemann, Willem Seinen, Jeremy Sweet (Vice-Chair) and Jean-Michel Wal.

EFSA:
GMO Unit: David Carlander, Karine Lheureux, Luisa Mannu, Sylvie Mestdagh, Claudia Paoletti, Suzy Renckens, Reinhilde Schoonjans, Ellen Van Haver.

European Commission:
Aurélie André (DG ENV)[1], Sébastien Goux (DG SANCO) and Michael Walsh (DG SANCO).

APOLOGIES

GMO Panel:
Hans Christer Andersson and Niels Bohse Hendriksen.

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1. WELCOME AND APOLOGIES FOR ABSENCE

The Chairman 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. Declarations of interests with regard to applications already announced during previous Plenary meetings are noted in the corresponding minutes. There were no new applications on the agenda of this meeting.

4. ADOPTION OF THE MINUTES OF THE 27TH PLENARY MEETING HELD ON 4-5 JULY 2006

The minutes of the 27th plenary meeting (4-5 July 2006) were adopted as proposed. The minutes of this meeting are published at:

http://www.efsa.europa.eu/en/science/gmo/gmo_meetings/gmo_27th_plenmeet.html.

5. FEEDBACK FROM EFSA AND THE SCIENTIFIC COMMITTEE

The Panel was informed about two ongoing EFSA public consultations of a working document on the development of an approach for the environmental risk assessment of additives, products and substances in animal feed (http://www.efsa.europa.eu/en/science/feedap/feedap_consultations.html) and of a guidance document on risk assessment for birds and mammals under Council Directive 91/414/EEC (http://www.efsa.europa.eu/en/science/ppr/ppr_consultation.html).

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[1] Only present on 14 September 2006.

6. FEEDBACK FROM THE COMMISSION

The Commission representative informed the Panel that the report on the implementation of Regulation 1829/2003 will be adopted by the Commission and submitted to the Council and the European Parliament.

7. DISCUSSION AND POSSIBLE ADOPTION OF OPINIONS ON:

7.1. Comments from the Member States on 5 applications under Regulation (EC) 1829/2003

Introduction

The Panel was requested by the European Commission to provide more detailed justifications on how scientific comments, provided by the Member States during the three-month consultation period for five GMO applications (EFSA-GMO-UK-2004-01, EFSA-GMO-DE-2004-03, EFSA-GMO-UK-2004-05, EFSA-GMO-UK-2004-06 and EFSA-GMO-BE-2004-07) were considered by the Panel during the risk assessment and in the final opinions.

Following this request, EFSA has contacted all Member States that submitted scientific comments to EFSA during the consultation period for these five applications. Seven Member States[2] and Norway expressed interest to have further clarifications on their comments.

Discussion

The Panel prepared individual answers to the comments for which the Member States requested further clarifications. Where no clarifications were requested from the Member States, no written answers were provided.

Adoption

The individual answers to the comments from the Member States on the 5 applications were adopted unanimously by the Panel. These will be published together with the EFSA overall opinions on the EFSA website at:
http://www.efsa.europa.eu/en/science/gmo/gm_ff_applications/more_info/486.html
http://www.efsa.europa.eu/en/science/gmo/gm_ff_applications/more_info/505.html
http://www.efsa.europa.eu/en/science/gmo/gm_ff_applications/more_info/650.html
http://www.efsa.europa.eu/en/science/gmo/gm_ff_applications/more_info/703.html
http://www.efsa.europa.eu/en/science/gmo/gm_ff_applications/more_info/720.html

Following the EFSA GMO forum (15 May 2006)[3] and EFSA strategy paper on GMO risk assessment[4], EFSA and the GMO Panel will maintain a high level of visibility to the procedure in

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2 Austria, Belgium, Finland, Denmark, Germany, Italy and Spain

3 http://www.efsa.europa.eu/etc/medialib/efsa/science/gmo/109.Par.0009.File.dat/gmoforumdetailedreport1.pdf

4 http://www.efsa.europa.eu/etc/medialib/efsa/science/gmo/109.Par.0010.File.dat/gmo_actionplan1.pdf point 2.5

place to address the Member State's comments and will, from now on, systematically address each comment raised by the Member State if within the remit of the Panel.

7.2. Safeguard clause invoked by Greece according to Article 23 of Directive 2001/18/EC and to Article 18 of Directive 2002/53/EC

The draft opinion was presented to the Panel. Although there was overall agreement on the content of the opinion, some parts of the opinion need further elaboration. The adoption of the opinion was therefore referred to the next plenary meeting.

8. REQUEST FOR SCIENTIFIC SUPPORT FROM THE COMMISSION ON LLRICE601

Introduction

EFSA received a request from the European Commission, dated 25 August 2006, for scientific support on the issue of the inadvertent release in the United States and potential export into the EU of rice containing a genetically modified (GM) rice line LLRICE601 that has not been authorized for release into the US or EU markets.

The Commission has requested EFSA "to examine the data from the company and the US and to provide, by the end of September, scientific support on the safety of LLRICE601 and to assess, whether these data are sufficient to allow a safety assessment to be carried out according to EU legislation".

Discussion and adoption

The Panel has performed an evaluation of the available data and concluded that the data are not sufficient to allow the safety of LLRICE601 to be assessed in accordance with the EFSA guidance for risk assessment. However, on the basis of the available molecular and compositional data and on the toxicological profile of PAT proteins, the Panel considers that the consumption of imported long grain rice containing trace levels of LLRICE601 is not likely to pose an imminent safety concern to humans or animals.

The statement from the Panel is published on the EFSA website at: http://www.efsa.europa.eu/en/science/gmo/statements0.html.

As similar cases of inadvertent presence of non-authorised GMOs may happen in the future, the Panel proposed to establish a Task Force within the Panel consisting of members representing the different disciplines in order to handle future cases timely and efficaciously.

9. RENEWAL OF AUTHORISATIONS, INCLUDING EXISTING (NOTIFIED) PRODUCTS

According to Articles 11(6) and 23(6) of Regulation 1829/2003, EFSA shall publish detailed guidance to assist applicants in the preparation and presentation of applications for renewal of authorisation of genetically modified food and feed according to Articles 11 and 23 of Regulation (EC) 1829/2003. This guidance would also apply for authorisation-holders who have products referred to as notified (existing) products, according to Articles 8 and 20, which have been published in the community register established according to Article 28 of the same regulation.

The Community Register of genetically modified food and feed is maintained by the European Commission and provides information on the genetically modified food or feed authorised according to Articles 7 and 19 of the Regulation. The register also contains the notified (existing) products lawfully placed on the market, notified according to Articles 8 and 20. The register can be found at http://ec.europa.eu/food/dyna/gm_register/index_en.cfm.

A preliminary draft guidance for renewal of authorisations was presented to the Panel. The Panel needs further discussions on the amount of information required for those products that are already on the market, e.g. starting during the meetings in October of the working groups' molecular characterisation, food/feed safety and environmental risk assessment.

10. UPDATE ON APPLICATIONS RECEIVED UNDER DIRECTIVE 2001/18/EC, REGULATION (EC) 1829/2003 AND REGULATION (EC) 1831/2003

10.1. Past scientific opinions

- EFSA received a request from the Commission for clarifications on the opinions issued by EFSA on the notifications for the placing on the market, under Part C of Directive 2001/18/EC of 1507 maize (C/ES/01/01)[5] and Bt-11 maize (C/F/96/05.10)[6]. EFSA is requested to address potential adverse effects of Bt-toxins on non-target organisms, particularly Lepidoptera species, and to recommend whether more precise risk management measures notably monitoring plans, including specific scientific research studies and taking account of geographical regions, in the context of non-target organisms should be implemented.
  As regards the request for more specific information concerning the Lepidoptera species, the Panel will provide the requested increased level of detailed information in an attachment to the original opinion. Regarding the request for more precise risk management measures, the Panel has published an opinion with respect to studies which preferably should be included in monitoring[7].
  As requested by the European Commission, EFSA contacted the relevant French scientific body, namely the Commission du Génie Biomoléculaire (CGB) in charge of the GMO risk assessment related to public health and the environment for the French Competent Authority. Further to bilateral discussions, the secretariat of the CGB clarified the need for additional scientifically-based data on 1507 maize. The Panel will clarify this issue in the attachment to the original opinion as mentioned above.

- EFSA received from the European Commission (DG ENV) a letter from the Hungarian government with scientific arguments in relation to the Hungarian safeguard clause on MON810 maize for which the Panel has already adopted a scientific opinion on 8 June 2005[8]. In this letter, the "*Hungarian government invites EFSA to reassess its opinion of 8 June 2005 in light of the findings presented*".
  The Panel considered the arguments presented in the submitted letter, and agreed that Hungary has special environments and insect species of particular ecological interest. The Panel considered that the accompanying information submitted to support the view that *serious environmental consequences of MON810 maize are likely to emerge in relation to*

5 http://www.efsa.europa.eu/en/science/gmo/gmo_opinions/827.html
6 http://www.efsa.europa.eu/en/science/gmo/gmo_opinions/922.html
7 http://www.efsa.europa.eu/en/science/gmo/gmo_opinions/1381.html
8 http://www.efsa.europa.eu/etc/medialib/efsa/science/gmo/gmo_opinions/1046.Par.0001.File.dat/gmo_opinion_ej228_safeguards_en1.pdf

soil and certain protected butterflies, are not of a type and quality that allows the Panel to reach similar conclusions. The accompanying information from Hungarian scientists did not contain sufficient details of the materials & methods, the results and the statistical analysis of the results to allow a proper scientific assessment by the Panel. On this basis and having considered all information presented for its scientific merit, the Panel considers that no new evidence was presented that would invalidate the adopted scientific opinion on the Hungarian safeguard application on MON810 maize.

The Panel noted that there are studies of effects on non-target organisms of Bt maize currently being conducted in Hungary and would be pleased to see the new data from these studies when the research has been completed and results have been fully analyzed. In addition the Panel would like to invite Hungarian experts for a bilateral meeting at which this and other raw data could be presented and discussed. This message will be clarified in a letter EFSA will send to the Commission (DG ENV) for the purpose of the Regulatory Committee under Directive 2001/18/EC that will take place on 18 September 2006.

10.2. Ongoing applications

Now that EFSA has finalised its response to the request of the Commission on the 5 applications (see item 7.1), the work on the ongoing applications, for which no further information is awaited, can be resumed and will be discussed at the forthcoming meetings of the working groups' molecular characterization, food/feed safety and environmental risk assessment.

11. UPDATE ON SELF TASK ACTIVITIES AND GUIDANCE ON GMO RISK ASSESSMENT

The Panel was updated on the approach taken by the working group establishing guidance for the assessment of GM plants used as production platform for non-food/feed products. Such plants would be used for the production of, for example, industrials or pharmaceuticals. The proposed outline of the draft document was presented. The next working group meeting will take place in October.

12. DATE OF FUTURE MEETINGS

Plenary meeting dates for the second part of 2007 have been scheduled:

- 4 – 5 July
- 12 – 13 September
- in the week of 19 November (to be confirmed)
- 5 – 6 December.

13. ANY OTHER BUSINESS

The Panel was updated on the activities of the Codex Alimentarius Task Force on Foods derived from Biotechnology for drafting guidelines for the conduct of food safety assessment of foods derived from recombinant-DNA animals and of foods derived from recombinant-DNA plants modified for nutritional or health benefits. The Panel members were invited to comment on these guidelines and EFSA will coordinate the answer to the Commission.