MINUTES OF THE 57TH PLENARY MEETING OF THE SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS HELD ON 28-29 APRIL 2010 IN PARMA, ITALY

(ADOPTED ON 26 MAY 2010)

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PARTICIPANTS

GMO Panel:
Hans Christer Andersson, Salvatore Arpaia, Detlef Bartsch[1], Howard Davies, Gerhard Flachowsky, Patrick du Jardin, Huw Jones, Jozsef Kiss, Harry Kuiper (Chair), Antoine Messéan, Joe Perry, Annette Pöting, Jeremy Sweet, Christoph Tebbe, Atte Von Wright and Jean-Michel Wal.

GMO Unit: Jaime Aguilera, Per Bergman, Anna Christodoulidou, Yann Devos, Zoltán Diveki, Christina Ehlert, Antonio Fernández, Andrea Germini, Karine Lheureux, Nancy Podevin, Reinhilde Schoonjans, Ellen Van Haver, Elisabeth Waigmann, Malene Ydesen.

European Commission:
Sabine Pelsser (DG SANCO).

APOLOGIES

GMO Panel:
Josep Casacuberta, Lieve Herman, Sirpa Kärenlampi, Gijs Kleter, Kaare Nielsen.

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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 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 56TH PLENARY MEETING HELD ON 10-11 MARCH 2010

The minutes of the 56th Plenary meeting (10-11March 2010) were adopted as proposed and will be published at: http://www.efsa.europa.eu/en/events/event/gmo100305.htm

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[1] Only present on 28 April.

5. DISCUSSION AND POSSIBLE ADOPTION OF OPINIONS ON:

5.1. Scientific Opinion on application (EFSA-GMO-UK-2007-48) for the placing on the market of insect resistant and herbicide tolerant genetically modified maize MIR604xGA21 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Syngenta Seeds.

Introduction

Following the submission of an application (Reference EFSA-GMO-UK-2007-48) under Regulation (EC) No 1829/2003 from Syngenta Seeds, the Panel on Genetically Modified Organisms of the European Food Safety Authority (EFSA GMO Panel) was asked to deliver a scientific opinion on the safety of insect resistant and herbicide tolerant genetically modified (GM) maize MIR604 x GA21 (Unique Identifier SYN-IR6Ø4-5xMON-ØØØ21-9) for food and feed uses, import and processing.

Discussion

In delivering its scientific opinion, the EFSA GMO Panel considered the application EFSA-GMO-UK-2007-48, additional information provided by the applicant and scientific comments submitted by Member States. Further information from applications for placing the single maize events Bt11, MIR604 and GA21, as well as the stacked maize events Bt11 x MIR604 x GA21 on the market under EU regulatory procedures was taken into account. The scope of application EFSA-GMO-UK-2007-48 is for food and feed uses, import and processing of maize MIR604 x GA21 and all derived products, but excludes cultivation in the EU.

Maize MIR604 x GA21 has been produced by conventional crossing methods between maize lines containing the single maize events MIR604 and GA21 to combine both the resistance trait against certain coleopteran target pests and the ability to use mannose as sole carbon source in maize MIR604 with tolerance to glyphosate-based herbicides in maize GA21. These single maize events have been the subject of separate risk assessment evaluations by the EFSA GMO Panel. No new genetic modifications were introduced in maize MIR604 x GA21.

Conclusion

The EFSA GMO Panel considers that the information available for maize MIR604 x GA21 addresses the scientific comments raised by Member States and concludes that the maize MIR604 x GA21 assessed in this application is as safe as its conventional counterpart and other appropriate comparators. In addition, the EFSA GMO Panel is of the opinion that crossing of maize MIR604 and GA21 results in no interaction between the single maize events, which would affect the safety of maize MIR604 x GA21 with respect to potential effects on human and animal health, and on the environment in the context of its intended uses. The EFSA GMO Panel concludes that maize MIR604 x GA21 is unlikely to have an adverse effect on human and animal health and on the environment, in the context of its intended uses.

Adoption

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

5.2. Scientific Opinion on application (EFSA-GMO-UK-2007-50) for the placing on the market of insect resistant and herbicide tolerant genetically modified maize Bt11x MIR604, for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Syngenta Seeds.

Introduction

Following the submission of an application (Reference EFSA-GMO-UK-2007-50) under Regulation (EC) No 1829/2003 from Syngenta Seeds, the Panel on Genetically Modified Organisms of the European Food Safety Authority (EFSA GMO Panel) was asked to deliver a scientific opinion on the safety of insect resistant and herbicide tolerant genetically modified maize Bt11xMIR604 (Unique Identifier SYNBTØ11-1xSYN-IR6Ø4-5) for food and feed uses, import and processing.

Discussion

In delivering its scientific opinion, the EFSA GMO Panel considered the application EFSA-GMO-UK-2007-50, additional information provided by the applicant and scientific comments submitted by Member States. Further information from applications for placing the single maize events Bt11, MIR604 and GA21, as well as the stacked maize events Bt11xMIR604 x GA21 on the market under EU regulatory procedures was taken into account. The scope of application EFSA-GMO-UK-2007-50 is for food and feed uses, import and processing of maize Bt11xMIR604 and all derived products, but excludes cultivation in the EU.

Maize Bt11xMIR604 has been produced by conventional crossing methods between lines containing the single maize events Bt11 and MIR604 to combine both the lepidopteran resistance trait and tolerance to glufosinate-ammonium herbicides in maize Bt11 with the coleopteran resistance trait and the ability to use mannose as sole carbon source in maize MIR604. These single maize events have been the subject of separate evaluations by the EFSA GMO Panel. No new genetic modifications were introduced in maize Bt11xMIR604.

Conclusion

The EFSA GMO Panel considers that the information available for maize Bt11xMIR604 addresses the scientific comments raised by the Member States, and concludes that the maize Bt11xMIR604, assessed in this application, is as safe as its conventional counterpart and other appropriate comparators. In addition, the EFSA GMO Panel is of the opinion that crossing of maize Bt11 and MIR604 results in no interactions between the single maize events which would affect the safety of maize Bt11xMIR604 with respect to potential effects on human and animal health, and on the environment in the context of its intended uses. The EFSA GMO Panel concludes that maize event Bt11xMIR604 is unlikely to have an adverse effect on human and animal health and the environment, in the context of its intended uses.

Adoption

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

5.3. Scientific Opinion on application (EFSA-GMO-UK-2008-56) for the placing on the market of the insect resistant and herbicide tolerant genetically modified maize Bt11 x MIR604 x GA21 , for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Syngenta Seeds.

Introduction

Following the submission of an application (Reference EFSA-GMO-UK-2008-56) under Regulation (EC) No 1829/2003 from Syngenta Seeds, the Panel on Genetically Modified Organisms of the European Food Safety Authority (EFSA GMO Panel) was asked to deliver a scientific opinion on the safety of insect resistant and herbicide tolerant genetically modified (GM) maize Bt11 x MIR604 x GA21 (Unique Identifier SYNBTØ11-1xSYN-IR6Ø4-5xMON-ØØØ21-9) for food and feed uses, import and processing.

Discussion

In delivering its scientific opinion, the EFSA GMO Panel considered the application EFSA-GMO-UK-2008-56, additional information provided by the applicant and scientific comments submitted by Member States. Further information from applications for placing the single maize events Bt11, MIR604 and GA21, as well as the stacked maize events MIR604 x GA21, Bt11 x GA21 and Bt11 x MIR604 on the market under EU regulatory procedures was taken into account. The scope of application EFSA-GMO-UK-2008-56 is for food and feed uses, import and processing of maize Bt11 x MIR604 x GA21 and all derived products, but excludes cultivation in the EU.

Maize Bt11 x MIR604 x GA21 has been produced by conventional crossing methods between lines containing the single maize events Bt11, MIR604 and GA21 to combine the lepidopteran resistance trait and tolerance to glufosinate-ammonium herbicides in maize Bt11, with the coleopteran resistance trait and the ability to use mannose as sole carbon source in maize MIR604 and the tolerance to glyphosate-based herbicides in maize GA21. These single maize events and the double stacked maize events MIR604 x GA21, Bt11 x GA21 and Bt11 x MIR604 have been the subject of separate assessments by the EFSA GMO Panel. No new genetic modifications were introduced in maize Bt11 x MIR604 x GA21.

Conclusion

The EFSA GMO Panel considers that the information available for maize Bt11 x MIR604 x GA21 addresses the scientific comments raised by Member States and concludes that the maize Bt11 x MIR604 x GA21 assessed in this application is as safe as its conventional counterpart and other appropriate comparators. In addition, the EFSA GMO Panel is of the opinion that crossing of maize Bt11, MIR604 and GA21 results in no interactions between the single maize events which would affect the safety of maize Bt11 x MIR604 x GA21 with respect to potential effects on human and animal health, and on the environment in the context of its intended uses. The EFSA GMO Panel concludes that maize Bt11 x MIR604 x GA21 is unlikely to have an adverse effect on human and animal health and on the environment, in the context of its intended uses.

Adoption

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

6. DISCUSSION OF OPINIONS

a) Written adoption of the scientific opinion on the revised molecular characterisation of Rf3 oilseed rape received under Directive 2001/18/EC (EFSA-Q-2009-00956).

The DG Environment of the European Commission has requested the EFSA Panel on Genetically Modified Organisms to deliver a scientific opinion on the revised molecular characterisation for Rf3 oilseed rape received from the Competent Authority of Belgium under Article 20(3) of Directive 2001/18/EC. The GMO Panel was asked to consider whether the new information received in respect of oilseed rape Rf3 could have consequences for the risks of this GMO to human health or the environment within the scope of Directive 2001/18/EC. In particular, EFSA was requested to take account of the objections raised by the Competent Authority of Austria in this context. Based on the revised molecular characterisation and on the additional information submitted in the frame of assessment of application EFSA-GMO-RX-Ms8-Rf3, the GMO Panel concludes that (1) the new information received on oilseed rape Rf3 does not have consequences for the risks of this GMO to human health or the environment within the scope of Directive 2001/18/EC and (2) the points raised by the Competent Authority of Austria are addressed in the opinion of the EFSA GMO Panel on application EFSA-GMO-RX-Ms8-Rf3.

The GMO Panel adopted the opinion on 13 April 2010 by written procedure. The opinion was adopted unanimously and will be published on the following EFSA website: http://www.efsa.europa.eu/en/scdocs.htm

b) Discussion on the risk assessment approach for GM plants containing higher stacked transformation events and its possible segregants

The three standing Working Groups of the EFSA GMO Panel continued the discussion on applications for GM plants containing higher stacked transformation events (see item 6 of the Minutes of the 56th Plenary meeting[2]). The EFSA GMO Panel agreed on some modifications to the text of the EC draft Regulation on the implementing rules for genetically modified food and feed[3]. These modifications will be sent to DG SANCO for its consideration. Moreover, it was reminded that detailed requirements for the risk assessment of stacked events and their possible segregants will be further elaborated by the self-mandate Working Group on choice of comparators.

c) Discussion on the risk assessment approach for GM plants with respect to genetic background of varieties

The three standing Working Groups of the EFSA GMO Panel presented their analysis on the possible effects of the genetic background on the risk assessment of GM plants. The GMO Panel agreed on concluding sentences for the scientific opinions on applications submitted under Regulation (EC) No 1829/2003.

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[2] http://www.efsa.europa.eu/en/events/event/gmo100305.htm

[3] Draft Commission Regulation on implementing rules concerning applications for authorisation of genetically modified food and feed in accordance with Regulation (EC) No 1829/2003 of the European Parliament and of the Council and amending Regulations No (EC) 641/2004 and (EC) No 1981/2006

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

7.1. Regulation (EC) No 1829/2003.

EFSA-GMO-NL-2009-70 (MON87460 maize): The EFSA GMO Panel identified a number of questions to be sent to the applicant which are related to the molecular characterization, food/feed safety and possible environmental impacts of maize MON 87460.

7.2. Regulation (EC) No 1831/2003

None

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

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

None

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

One new application has been received:

- Application for authorisation of FAD-2010-0019 RONOZYME® HiPhos L and M (6-phytase), a zootechnical additive for poultry and swine (EFSA-Q-2010-00782).

The summary of the applications as well as the information on their current status can be found through the following webpage leading to the EFSA's Register of Questions: http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2010-00782

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

Self-mandate on the choice of comparators. The Working Group held a meeting on 15 April 2010. Discussions were focussed on the type of comparators for stacked events. A draft opinion is in preparation and the aim is to present it to the EFSA GMO Panel in autumn 2010.

Self-mandate for updating the Guidance for risk assessment of GM microorganisms. The Working Group will hold its next meeting on 14-16 July. The Working Group has been reinforced with an extra Panel member expert for environmental risk assessment.

Environmental risk assessment of GM animals. Two of the three interim reports from external contractors have been received. The interim report on GM fish has been analysed and the Working Group has provided its feedback to the contractor. The GM insect interim report is under assessment by the steering group and will need to be elaborated to follow an environmental risk assessment approach. The interim report on GM mammals and birds is expected in November and all reports will be made publically available through EFSA's website.

Human health safety assessment of GM animals. The Working Group will reconvene on 20 May 2010 to discuss a revised draft guidance document. Animal welfare issues will be included as far as they relate to safety aspects.

Self mandate Allergenicity assessment of GM foods. Comments that were received during the public consultation are being processed by the Working Group through web-conferences and will be further discussed during a meeting scheduled for 19 May 2010.

10. FEEDBACK FROM EFSA AND THE SCIENTIFIC COMMITTEE

The activities and workplan of ERIC (Emerging Risks Internal Collaboration group) were presented by Tobin Robinson, head of Unit of the EFSA EMRISK Unit. An Update on EFSA's strategy for the identification of emerging risks in the food/feed chain was given. Regarding GMOs, the signals identified so far relate to reporting of imports in the EU of unauthorised GM plant crops. The EFSA GMO unit is in contact with the EMRISK unit to monitor evolutions in this area.

Citation of applicants studies in GMO Panel scientific opinions are further investigated upon receipt of feedback from LPA (Legal and Policy unit of EFSA) and editors of the EFSA Journal.

11. FEEDBACK FROM THE COMMISSION

The European Commission informed the GMO Panel about recent and planned SCFCAH meetings with the Member States where decisions on authorisations of GMOs are taken. The May meeting is cancelled and the June meeting will be held with the MS Competent Authorities of the Member States (MS) under Regulation (EC) No 1829/2003 and the MS competent authorities under Directive 2001/18/EC. On this occasion, the responsibility of the Member States in GMO applications for cultivation under Art. 6 and 18 of Regulation (EC) No 1829/2003 will be discussed. In this context, procedures for the ERA on GA21 maize application for cultivation (EFSA-GMO-UK-2008-60), was discussed with the EFSA GMO Panel.

12. DATE AND PLACE OF FUTURE MEETINGS

None

13. ANY OTHER BUSINESS

None