MINUTES OF THE 52ND PLENARY MEETING OF THE SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS HELD ON 9-10 SEPTEMBER 2009 IN PARMA, ITALY (ADOPTED ON 21 OCTOBER 2009)

PARTICIPANTS

GMO Panel:
Hans Christer Andersson, Salvatore Arpaia, Detlef Bartsch, Howard Davies, Gerhard Flachowsky, Patrick du Jardin[1], Lieve Herman, Sirpa Kärenlampi (Chair), Jozsef Kiss, Gijs Kleter, Antoine Messéan, Joe Perry, Annette Pöting, Jeremy Sweet, and Jean-Michel Wal.

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

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

APOLOGIES

GMO Panel:
Josep Casacuberta, Huw Jones, Harry Kuiper, Kaare Nielsen, Christoph Tebbe, Atte Von Wright.

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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 51ST PLENARY MEETING HELD ON 1-2 JULY 2009

The minutes of the 51st Plenary meeting (1-2 July 2009) were adopted as proposed and will be published at: http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902245037.htm

[1] Only present on 10 September

5. DISCUSSION AND POSSIBLE ADOPTION OF OPINIONS ON:

5.1. Application for renewal of authorisation for continued marketing of existing food and food ingredients and feed materials produced from Ms8, Rf3 and Ms8 x Rf3 oilseed rape submitted by Bayer CropScience under Reg. (EC) No 1829/2003 (EFSA-GMO-RX-Ms8/Rf3)

Introduction

This document provides the scientific opinion of the Panel on Genetically Modified Organisms (GMO Panel) of the European Food Safety Authority (EFSA) on request from the European Commission on an application submitted by Bayer CropScience under Regulation (EC) No 1829/2003 (reference EFSA-GMO-RX-Ms8/Rf3) for renewal of the authorisation for continued marketing of existing products produced from genetically modified oilseed rape Ms8, Rf3 and Ms8 x Rf3.

The scope of this application covers the continued marketing of (1) existing foods produced from oilseed rape Ms8, Rf3 and Ms8 x Rf3 (processed oil) and (2) existing feeds produced from oilseed rape Ms8, Rf3 and Ms8 x Rf3, which were lawfully placed on the market in the Community before the date of entry into force of Regulation (EC) No 1829/2003. After the date of entry into force of Regulation (EC) No 1829/2003 these products were notified to the European Commission according to Articles 8(1) (a) and 20(1) (b) of that Regulation and included in the Community Register of genetically modified food and feed[2].

Discussion

The EFSA GMO Panel has previously issued a scientific opinion related to notification C/BE/96/01 for the placing on the market of glufosinate-tolerant hybrid oilseed rape Ms8 x Rf3 derived from genetically modified parental lines Ms8 and Rf3 for import and processing for feed and industrial uses under Part C of Directive 2001/18/EC. In this earlier opinion, the EFSA GMO Panel concluded that "*the placing on the market of Ms8, Rf3 and Ms8 x Rf3 oilseed rape for import and processing for feed and industrial purposes is unlikely to have an adverse effect on human or animal health or, in the context of its proposed uses, on the environment. This is in addition to the present uses of oil for food purposes and processed meal for feed purposes, both derived from Ms8 x Rf3 oilseed rape, which are already lawfully placed on the market.*"

In delivering the present opinion, the EFSA GMO Panel considered the information provided in the renewal application (reference EFSA-GMO-RX-Ms8/Rf3) as well as additional information submitted by the applicant upon request of the EFSA GMO Panel. In accordance with the Guidance Document for renewal of authorisations of existing GMO products, the EFSA GMO Panel has taken into account the new information, experience and data, which have become available during the authorisation period.

Regarding the molecular data which have already been evaluated in the context of the previous notification on oilseed rape Ms8, Rf3 and Ms8 x Rf3, the EFSA GMO Panel refers to its previous scientific opinion. The scientific assessment included the transformation process, the vectors used and the transgenic constructs in the GM oilseed rape. The further assessment presented here is based on the information provided by the applicant in application EFSA-GMO-RX-Ms8/Rf3, including an updated molecular characterization. These updated molecular and bioinformatic

[2] http://ec.europa.eu/food/dyna/gm_register/gm_register_auth.cfm?pr_id=15

analyses provided for oilseed rape Ms8 and Rf3 as well as additional data, provided upon request of the EFSA GMO Panel, do not indicate any concerns.

According to the information provided by the applicant, food and feed products produced from oilseed rape Ms8, Rf3 and Ms8 x Rf3 that have been approved in the EU, have been consumed without reports of adverse effects. Bioinformatic studies comparing the amino acid sequences of the newly expressed Barnase, Barstar and PAT proteins in oilseed rape Ms8, Rf3 and Ms8 x Rf3 with amino acid sequences in updated databases of toxic or allergenic proteins confirmed the results of the older studies which identified no relevant similarities to known toxic or allergenic proteins. In addition, a 42-day feeding study in broiler chickens showed that the tested material of oilseed rape Ms8 x Rf3 is nutritionally equivalent to its non-GM counterpart.

The scope of this application excludes import of viable plant material and cultivation. Therefore, there is no requirement for scientific information on environmental safety assessment of accidental release or cultivation of oilseed rape Ms8, Rf3 and Ms8 x Rf3. A post-market environmental monitoring plan for oilseed rape Ms8, Rf3 and Ms8 x Rf3 is not required.

Conclusion

The EFSA GMO Panel concludes that there is no new information provided by the applicant or in the scientific literature that would require changes of its previous scientific opinion on oilseed rape Ms8, Rf3 and Ms8 x Rf3. Therefore, the EFSA GMO Panel reiterates the previous conclusions that GM oilseed rape Ms8, Rf3 and Ms8 x Rf3 is unlikely to have an adverse effect on human and animal health or, in the context of its proposed uses, on the environment. This also applies to the products which are the subject of the present application.

Adoption

This opinion was adopted unanimously by the Panel. The adopted scientific opinion will be published on the following EFSA website: http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_ScientificDocuments.htm

5.2. Application for authorisation of genetically modified MON 89034 x NK603 maize and derived food and feed (EFSA-GMO-NL-2007-38).

Introduction

Following the submission of an application (EFSA-GMO-NL-2007-38) under Regulation (EC) No 1829/2003 from Monsanto, the Panel on Genetically Modified Organisms was asked to deliver a scientific opinion on herbicide tolerant and insect resistant maize MON 89034 x NK603 (Unique identifier MON-89Ø34-3 x MON-ØØ6Ø3-6) for food and feed uses, import and processing.

Discussion

In delivering its scientific opinion, the EFSA GMO Panel considered the application EFSA-GMO-NL-2007-38, additional information supplied by the applicant and scientific comments submitted by Member States. Further information from applications for placing the single maize events MON 89034 and NK603 on the market under EU regulatory procedures was taken into account where appropriate. The scope of application EFSA-GMO-NL-2007-38 is for food and feed uses, import and processing of maize MON 89034 x NK603 and all derived products, but excludes cultivation in the EU. The EFSA GMO Panel assessed maize MON 89034 x NK603 with reference to the

intended uses and appropriate principles described in the Guidance Document of the Scientific Panel on Genetically Modified Organisms for the risk assessment of genetically modified plants and derived food and feed and the Guidance Document of the Scientific Panel on Genetically Modified Organisms for the risk assessment of genetically modified plants containing stacked transformation events. 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, as individual proteins and in combination, 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.

Maize MON 89034 x NK603 was produced by crosses between maize inbred lines containing maize MON 89034 and NK603 events to combine the resistance trait to certain lepidopteran species in maize MON 89034 and the tolerance to glyphosate in maize NK603.

The stability of the genetic modification has been demonstrated over several generations in the single events and Southern analysis has confirmed that the structural integrity of the single events was maintained in the hybrid MON 89034 x NK603. Appropriate analyses of the integration sites in maize MON 89034 and NK603, including flanking regions, were carried out. The bioinformatic analysis demonstrated the absence of any potential new ORFs coding for known toxins or allergens. The expression of the new proteins has been sufficiently analysed in MON 89034 x NK603 and is comparable to expression in the single event. The Cry1A.105 and Cry2Ab2 proteins expressed in the parental maize MON 89034 and the CP4 EPSPS and CP4 EPSPS L214P protein expressed in maize NK603 have been assessed previously and no safety concerns have been identified. Furthermore, the results of the compositional analysis of grain and forage material of maize MON 89034 x NK603 collected at field trials in Argentina during the season 2004-2005, indicated that, with the exception of the newly introduced proteins, maize MON 89034 x NK603 is compositionally and agronomically equivalent to its non-GM counterpart. Based on the comprehensive data available, including responses of the applicant to questions posed by the GMO Panel, the Panel concluded that there was no indication that crossing maize MON 89034 with maize NK603 results in an interaction of the newly expressed proteins affecting composition or agronomic characteristics. Furthermore, the nutritional properties of maize MON 89034 x NK603 do not differ from its non-GM counterpart.

Given all the information provided, the GMO Panel concludes that interactions between the proteins expressed by the single events that might impact on food and feed safety are unlikely and that the nutritional properties of maize MON 89034 x NK603 are not different from those of its non-GM counterpart. Therefore, the Panel considers that maize MON 89034 x NK603 is as safe and as nutritious as its non-GM counterpart and that the overall allergenicity of the whole plant is not changed.

Considering the intended uses of maize MON 89034 x NK603, which exclude cultivation, there is no requirement for scientific assessment of possible environmental effects associated with the cultivation of this GM maize. In case of accidental release into the environment of maize MON 89034 x NK603 viable grains during transportation and processing, there are no indications of increased likelihood of establishment and spread of feral maize plants. Also, the low levels of environmental exposure through other routes indicate that the risk to non-target organisms is likely to be extremely low. The scope of the post-market environmental monitoring plan provided by the applicant is in line with the intended uses of maize MON 89034 x NK603.

The EFSA GMO Panel advises that appropriate management systems should be in place to prevent seeds of maize MON 89034 x NK603 entering cultivation as the latter requires specific approval under Directive 2001/18/EC or Regulation (EC) No 1829/2003.

Conclusion

In conclusion, the EFSA GMO Panel considers that information available for maize MON 89034 x NK603 addresses the outstanding questions raised by the Member States and considers it unlikely that maize MON 89034 x NK603 will have any adverse effect on human and animal health or on the environment in the context of its proposed uses.

Adoption

This opinion was adopted unanimously by the Panel. The adopted scientific opinion will be published on the following EFSA website: http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_ScientificDocuments.htm

5.3. Self-mandate on Assessment of allergenicity of genetically modified foods (EFSA-Q-2005-125)

Introduction

During the Plenary meeting of 27-28 May 2009, the previous draft of the report of the self mandate on the assessment of allergenicity of GM foods was presented to the EFSA GMO Panel. The EFSA GMO Panel was of the opinion that a dedicated chapter comprising not only suggestions for the risk assessment but also for future research should be the backbone for guidance for risk assessors, as well as advice for the scientific community. It was agreed that a revised version of the report would be presented to the Panel at its September Plenary meeting. The revised draft will then be forwarded to the EFSA NDA Panel and the Scientific Committee for their comments before its final adoption by the EFSA GMO Panel and public consultation.

Discussion and conclusion

The EFSA GMO Panel discussed and agreed on the new version with minor amendments. The draft document will be forwarded to the EFSA NDA Panel and Scientific Committee to take into account their comments before final adoption of the draft document at the GMO Panel's plenary meeting of October. Afterwards, the document will be launched for public consultation.

6. DISCUSSION OF OPINIONS:

6.1. Application for renewal of authorisation for continued marketing of food additives, feed materials and feed additives produced from MON 531 cotton (EFSA-GMO-RX-MON531).

The EFSA GMO Panel identified some questions to be sent to the applicant which are related to the presence of antibiotic resistance marker genes in MON 531 cotton.

6.2. Application for renewal of authorisation for continued marketing of food additives, feed materials and feed additives produced from MON 1445 Cotton (EFSA-GMO-RX-MON1445).

The EFSA GMO Panel identified some questions to be sent to the applicant which are related to the presence of antibiotic resistance marker genes in MON 1445 cotton.

6.3. Application for renewal of authorisation for continued marketing of food additives, feed materials and feed additives produced from MON 15985 Cotton (EFSA-GMO-RX-MON 15985).

The EFSA GMO Panel identified some questions to be sent to the applicant which are related to the presence of antibiotic resistance marker genes in MON 15985 cotton.

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

7.1. Written adoption for authorisation of genetically modified maize Bt11 x GA21 for food and feed uses, import and processing (EFSA-GMO-UK-2007-49) (EFSA-Q-2007-195).

The application for authorisation of genetically modified maize Bt11 x GA21 for food and feed uses, import and processing submitted under Regulation (EC) No. 1829/2003 (EFSA-GMO-UK-2007-49) will be adopted by written procedure (date of adoption is foreseen for 15 September 2009).

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

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

EFSA received a new request from the European Commission (EFSA-Q-2009-00781) to review a scientific publication on the gene flow from GM rice to its wild relatives that was brought to their attention by Greenpeace and to indicate whether it contains new information that would alter the environmental safety conclusions of the opinion on LLRICE62 (application EFSA-GMO-UK-2004-04; opinion published in November 2007). In addition, Greenpeace also released a report criticising the safety of maize MON 810, on which EFSA has recently published an opinion (application EFSA-GMO-RX-MON810). EFSA through its stakeholder forum has invited NGOs to a meeting to discuss these issues on 2 October 2009.

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

None

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

Self-task on the choice of comparators. The kick off meeting took place on 17 June 2009 and the working group will have their next meeting on 28 October.

Self-task for updating the Guidance for risk assessment of GM microorganisms. The working group had its first meeting on 25-26 June, during which it defined its workplan and timetable. Remaining meetings for 2009 are scheduled for 24-25 September and 17-18 of December.

Self-task on Non-Target Organisms (NTO). The draft opinion will be presented to the EFSA GMO Panel at the October Plenary meeting. Comments made at the stakeholders' consultation meeting of 16-18 June 2009 have been addressed in the document. Final adoption by the EFSA GMO Panel was initially scheduled for October Plenary but is likely to be postponed to December Plenary (jointly with adoption of the updated ERA guidance document).

Mandate for updating the Environmental Risk Assessment (ERA) section of the EFSA Guidance Document. A joint meeting between the ERA working group and the NTO working group is scheduled for 21-22 September 2009 to discuss common issues. A preliminary draft document will be presented to the EFSA GMO Panel at the October Plenary meeting.

Mandate for Guidance on GM animals. The working group on human health safety assessment of GM animals met on 4 September and will reconvene on 29 October 2009. The EFSA GMO Panel was also informed about the status of the tenders for GM fish, insects, mammals and birds. For GM fish, a contract was awarded in May 2009, and the first interim report of the contractor was delivered in August 2009. For GM insects, several offers were received and are under evaluation. For GM mammals and birds a call was launched on 1 July 2009. Deadline for reception of offers is 22 September 2009. A WG on GM animals ERA was set up in August 2009 to discuss incoming reports of the contractor(s) and initiate further activities for the elaboration of guidelines.

10. FEEDBACK FROM EFSA AND THE SCIENTIFIC COMMITTEE

The EFSA GMO Panel was informed about the nomination of Per Bergman as Head of the EFSA GMO Unit.

Riitta Maijala, Head of the Risk Assessment Directorate, gave a presentation, which was initially scheduled for the inaugural plenary meeting in July, to the EFSA GMO Panel with regard to declarations of interests and the EFSA expert survey.

Carola Sondermann, senior scientific officer in the Scientific Cooperation Unit, presented to the EFSA GMO Panel the key aspects of the new EFSA Journal, foreseen to be launched end of 2009, and the implications on the EFSA templates for scientific outputs.

Training required as a result of the Guidance of the Scientific Committee on transparency in the scientific aspects of risk assessment carried out by EFSA will be organised for all EFSA Scientific Panels and take place next year.

11. FEEDBACK FROM THE COMMISSION

The Commission representative provided the EFSA GMO Panel with the status of the EC guidelines on the risk assessment of genetically modified food and feed, as well as of applications that have been presented to the Standing Committee on the Food Chain and Animal Health for possible authorization, and for which no qualified majority was reached. It was also indicated that comments were received from EuropaBio on the draft EC guidelines.

The EFSA GMO Panel was informed about the nomination of Dorothée André as Head of the Unit Biotechnology and Plant Health in DG SANCO.

12. DATE AND PLACE OF FUTURE MEETINGS

Meeting dates were agreed at earlier plenary meetings.

13. ANY OTHER BUSINESS

The EFSA GMO Panel was informed about the following forthcoming meetings:

- EFSA GMO Conference on 14-15th of September 2009, Brussels
- EFSA meeting with NGOs on 2 October 2009, Parma
- European Conference on the Use of GMOs in Agriculture organised by the Ministry of Agriculture of the Netherlands on 25-26 November 2009, The Hague
- European Advisory Committees on Biosafety (MEACB) meeting on the 29-30 October 2009, Brussels
- JRC Workshop on "Allergy as mechanism-based case study to apply omics in food and chemicals safety assessment" on 30 September – 1 October 2009, Ispra, Italy.

Per Bergman, Head of the GMO Unit, informed the EFSA GMO Panel about a new EFSA initiative to create a network of GMO scientific experts from all EU Member States. The aim of this network will be to build mutual understanding of risk assessment principles of GMOs and to provide increased transparency in the current process among Member States.