MINUTES OF THE 65TH MEETING OF THE SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS HELD ON 13-14 APRIL 2011 IN PARMA, ITALY

(ADOPTED ON 25 MAY 2011)

PARTICIPANTS

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

GMO Unit: Per Bergman, Zoltán Divéki, Antonio Fernández, Andrea Germini, Ana Gomes, Karine Lheureux, Yi Liu, Sylvie Mestdagh, Claudia Paoletti, Nancy Podevin, Reinhilde Schoonjans and Elisabeth Waigmann.

European Commission:
Sabine Pelsser (DG SANCO).

APOLOGIES

GMO Panel:
Josep Casacuberta.

---

1. WELCOME AND APOLOGIES FOR ABSENCE

The Chair opened the meeting and welcomed all. Apology for absence was received from the Panel member indicated above.

2. ADOPTION OF THE AGENDA

The agenda was adopted as proposed.

3. DECLARATION OF INTERESTS

In accordance with EFSA's Policy on Declarations of Interests, EFSA screened the Annual Declaration of interest (ADoI) and Specific Declaration of interest (SDoI) filled in by the experts invited to the present meeting.

With regard to this meeting no other interests 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. The following was declared:

At the beginning of the meeting, the expert Detlef Bartsch declared an interest regarding item 5.2 (now 5.2): Discussion of Selection of Comparators for the Risk Assessment of GM Plants, for which the expert's institution has submitted comments during the public consultation.
For further details regarding the assessment of declared interests please refer to Annex 1 of these minutes.

4. ADOPTION OF THE MINUTES OF THE 64TH PLENARY MEETING HELD ON 9-10 MARCH 2011.

The minutes of the 64th Plenary meeting (9-10 March 2011) were adopted with minor editorial changes and will be published at: http://www.efsa.europa.eu/en/events/event/gmo110309.htm.

5. DISCUSSION AND POSSIBLE ADOPTION OF OPINIONS ON:

5.1. Application for authorisation of genetically modified Soybean A5547-127 and derived food and feed submitted under Regulation (EC) No 1829/2003 by Bayer CropScience (EFSA-GMO-NL-2008-52) (EFSA-Q-2008-290)

Introduction

Following the submission of an application (EFSA-GMO-NL-2008-52) under Regulation (EC) No 1829/2003 from Bayer CropScience, 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 herbicide tolerant genetically modified (GM) soybean A5547-127 (Unique Identifier ACS-GM∅∅6-4) for food and feed uses, import and processing.

In delivering its scientific opinion, the EFSA GMO Panel considered the application EFSA-GMO-NL-2008-52, additional information supplied by the applicant, scientific comments submitted by the Member States, and relevant scientific publications. The scope of application EFSA-GMO-NL-2008-52 is for food and feed uses, import and processing of soybean A5547-127 within the European Union as any non-GM soybean but excludes cultivation in the EU. The EFSA GMO Panel evaluated soybean A5547-127 with reference to the intended uses and appropriate principles described in its Guidance Document of the Scientific Panel on Genetically Modified Organisms for the Risk Assessment of Genetically Modified Plants and Derived Food and Feed (EFSA, 2006a). The scientific evaluation of the risk assessment included molecular characterisation of the inserted DNA and expression of the corresponding proteins. An evaluation of the comparative analysis of composition, phenotypic and agronomic characteristics was undertaken, and the safety of the new proteins and the whole food/feed was evaluated with respect to potential toxicity, allergenicity and nutritional wholesomeness. An evaluation of the environmental impacts and the post-market environmental monitoring plan was undertaken.

Soybean A5547-127 was transformed using particle bombardment. Soybean A5547-127 expresses the *pat* gene leading to the production of the enzyme phosphinothricin acetyl-transferase (PAT) that acetylates L-glufosinate. The PAT enzyme confers tolerance to glufosinate-ammonium containing herbicides.

Discussion

The molecular characterisation data establish that the genetically modified soybean A5547-127 contains one copy of an intact *pat* expression cassette in a single insertion locus. Other parts of the plasmid used for transformation and present in soybean A5547-127, include two truncated, non-functional parts of the beta-lactamase (*bla*) gene on each side of the *pat* expression cassette. Bioinformatic analysis of the open reading frames spanning the junctions created as results of the transformation did not raise safety concerns. The stability of the inserted DNA was confirmed over several generations. Analysis of the levels of the PAT protein in seed from a field trial performed in the USA did not raise safety concerns.

Based on the results of a comparative analysis of data, the EFSA GMO Panel concludes that from the compositional point of view, the differences observed between the soybean A5547-127 and the conventional counterpart were not consistent across sites and years and fell within the range of natural variation of soybean. From the phenotypic and agronomic points of view, the EFSA GMO Panel concludes that soybean A5547-127 is phenotypically and agronomically not different from its conventional counterpart A5547, with the exception of the newly introduced trait. The PAT protein is quickly degraded in simulated gastric and intestinal fluids without leaving stable peptide fragments.

Bioinformatics-supported studies demonstrated that the PAT protein shows no homology to known toxic and allergenic proteins. It also induced no toxicity when administered orally to mice in a repeated dose toxicity study. Testing the reaction of sera from soybean-allergic patients to extracts from soybeans A5547-127 and A5547 and commercial soybean varieties demonstrated that the overall allergenicity of soybean A5547-127 is not different from that of the conventional counterpart and commercial soybean varieties. A feeding study on broiler chickens confirmed that soybean A5547-127 is as nutritional as soybean A5547. The EFSA GMO Panel is of the opinion that soybean A5547-127 is as safe as its conventional counterpart and commercial varieties based on data from literature.

The application EFSA-GMO-NL-2008-52 is for food and feed uses, import and processing. Therefore, there is no requirement for scientific information of possible environmental effects associated with the cultivation of soybean A5547-127. There are no indications of an increased likelihood of establishment and spread of feral soybean plants in case of accidental release into the environment of viable seeds of soybean A5547-127 (e.g.; during transportation and processing), except in the presence of glufosinate-ammonium containing herbicides. Taking into account the scope of the application, the rare occurrence of feral soybean plants and the low levels of exposure through other routes, the risk to non-target organisms is extremely low. The risk caused by a possible transfer of the recombinant gene from soybean A5547-127 to environmental micro-organisms is regarded to be negligible due to the lack of any advantage that would be conferred in the context of its intended uses. The EFSA GMO Panel agrees with the reporting intervals proposed by the applicant in the general surveillance plan. The EFSA GMO Panel recommends that appropriate management systems should be in place to restrict seeds of soybean A5547-127 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 the information available for soybean A5547-127 addresses the scientific comments raised by the Member States and that the soybean A5547-127, as described in this application, is as safe as its conventional counterpart with respect to potential effects 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.

5.2. Report from the stakeholder consultative workshop held on 31 March 2011 followed by discussion and possible adoption of the Guidance Document on Selection of Comparators for the Risk Assessment of GM Plants (EFSA-Q-2009-00550)

Feedback was given on the GMO comparators consultative workshop held on 31 March, Brussels. The Unit is currently preparing an event report summarizing the discussions and the outcomes, to be published on the EFSA website http://www.efsa.europa.eu/en/events.htm.

The EFSA GMO Unit has also compiled a draft technical report on the public consultation which closed 15 January 2011, including the comments received and the responses of the working group. The draft report was presented to the EFSA GMO Panel for endorsement. The final version of the report will be circulated for final endorsement after the plenary meeting.

The comments received through the online public consultation and the outcomes of the workshop were addressed in the Guidance Document as appropriate..

Introduction

The European Food Safety Authority (EFSA) asked the Panel on Genetically Modified Organisms (GMO Panel) to develop further guidance in the area of comparators taking into account the requirements for the molecular characterisation, the food and feed and the environmental risk assessments. A key step in the risk assessment of GM plants and derived food and feed is the identification of intended and unintended differences and equivalences between the GM plant and its comparator(s), taking into account the range of natural variation. This information allows the assessment of the potential impact of the genetic modification with respect to human and animal health and the environment. Regulation (EC) No 1829/2003 on genetically modified food and feed defines the comparator (conventional counterpart) as "*similar food or feed produced without the help of genetic modification and for which there is a well-established history of safe use*". The EFSA GMO Panel has, to date, required as comparators either non-GM lines with a genetic background as close as possible to the GM plant under assessment in case of sexually propagated crops, or isogenic varieties in case of vegetatively propagated crops. The identification and production of such comparators is becoming increasingly challenging due to the increasing complexity of GM plants, e.g. those developed by combining (stacking) events through conventional breeding, or those in which significant compositional changes are targeted. The EFSA GMO Panel also considers situations where additional comparators may be required on a case-by-case basis and scenarios where appropriate comparators are not available (e.g. where extensive compositional changes are targeted). Whilst considering the requirements of Directive 2001/18/EC and Regulation (EC) No 1829/2003, the EFSA GMO Panel provides options which introduce flexibility in the selection of comparators based on sound scientific principles.

Discussion and conclusion

In summary the key conclusions and recommendations of this document are:

1. The EFSA GMO Panel supports the current concept that for GM plants containing a single event the choice of comparator must be the conventional counterpart which will be a non-GM genotype with a genetic background as close as possible to the GM plant. Applicants can also consider the use of additional comparator(s).

2. The same principle as outlined above applies to GM plants containing events stacked by conventional breeding or by other approaches, such as co-transformation, re-transformation and the use of multiple gene cassettes. In the case of GM plants containing stacked events, the risk assessment focuses on the potential interaction between the events present and their stability. However, where applicants can demonstrate that a conventional counterpart for the GM plant containing stacked events cannot be made available, applicants can use as comparators for the molecular characterisation (MC) and the food and feed (FF) risk assessment either:

a. A negative segregant(s) - but only where segregants are derived from crosses between GM plants containing events which have been risk assessed previously and which are all stacked in the GM plant under assessment. This approach is only possible if either no unintended effects have been identified for the single events, or where the presence of such unintended effects in the GM plant containing the stacked events does not raise safety concerns.
b. Any set of GM plants that have all been risk assessed on the basis of experimental data collected according to the principles of EFSA MC and FF risk assessment. This set of GM plants must include, between them, all of the events stacked in the GM plant under assessment and no others.

For the environmental risk assessment (ERA), in case the conventional counterpart cannot be made available, different comparator(s) are appropriate depending upon the issue(s) under consideration.

3. In cases where appropriate comparators are not available (e.g. where significant compositional changes have been targeted) the EFSA GMO Panel considers to carry out a comprehensive safety/nutritional assessment on the GM plant per se.

4. The risk assessment of GM plants, containing either single or stacked events, expressing specific traits such as herbicide tolerance, may require additional treatment comparisons.

The EFSA GMO Panel recognises that there may be different requirements for comparators for the molecular characterisation, the food and feed and the environmental components of the risk assessment and takes this into account in providing this guidance.

Adoption

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

5.3. Guidance for risk assessment of food and feed from genetically modified plants. (EFSA-Q-2003-005A)

Introduction

The European Food Safety Authority (EFSA) asked the Panel on Genetically Modified Organisms (EFSA GMO Panel) to update its document providing guidance for the risk assessment of food and feed containing, consisting or produced from genetically modified (GM) plants, submitted within the framework of Regulation (EC) No 1829/2003 on GM food and feed. The present version of this guidance document was prepared expanding and completing the previous version (EFSA, 2006a) taking into account the experience gained during the evaluation of past applications, and the outcomes of EFSA GMO Panel Working Groups relevant for the risk assessment of GM plants and derived food and feed. The document does not cover the environmental risk assessment of GM plants which is addressed in a stand-alone environmental risk assessment (ERA) guidance document developed by the EFSA GMO Panel and published in 2010.

Discussion and conclusion

The risk assessment of GM plants and derived food and feed involves generating, collecting and assessing information on a GM plant and its derived products in order to determine their impact on human and animal health. The strategy proposed in this document seeks to deploy appropriate approaches to compare GM plants and derived food and feed with their respective comparators. The underlying assumption of this comparative approach is that traditionally cultivated crops have gained a history of safe use for consumers and/or domesticated animals.

The document outlines the principles of the risk assessment of GM plants and derived food and feed, providing an overview of the comparative approach and definitions of the different steps and objectives of the risk assessment process. The document provides a detailed overview of the different components of the risk assessment: the molecular characterisation, which provides information on the structure and expression of the insert(s) and on the stability of the intended trait(s); the toxicological assessment, which addresses the impact on human and animal health of biologically relevant change(s) in the GM plant and/or derived food and feed resulting from the genetic modification; the assessment of the allergenic potential of the novel protein(s) as well as of the whole food derived from the GM plant; and the nutritional assessment, which aims to demonstrate that the food and feed derived from a GM plant is not nutritionally disadvantageous to humans and/or animals.

As compared to the previous versions, this document also provides up-to-date guidance on the following issues:

- the requirements for the risk assessment of GM plants containing stacked events described and addressed in each section, replacing previous EFSA guidance on this topic, published in 2007;
- the design of the field trials for protein expression analysis;
- the design of the field trials for compositional, agronomic and phenotypic characteristics ensuring sufficient statistical power in line with previously published opinion on this issue (EFSA 2010);
- the statistical analysis of field trials data, allowing for an objective quantification of observed differences between the GM plant and its comparator and equivalences between the GM plant and the commercial reference varieties, in line with previously published opinion on this issue (EFSA 2010);
- the selection of appropriate comparator(s) under different possible scenarios, see agenda item 5.2.;
- reference to internationally agreed protocols for toxicological assessment which may be selectively applied for GMO risk assessment;
- specific guidance updating and complementing the allergenicity assessment of newly expressed protein(s) and whole GM food and feed, in line with previously published opinion on this issue (EFSA 2010);
- animal feeding studies with whole food and/or feed from the GM plant when considered necessary, in line with previously published opinion on this issue (EFSA 2010).

The present document provides guidance for assessing potential effects of GM plants and derived food and feed on human and animal health, and the rational for data requirements in order to complete a comprehensive risk assessment and to draw conclusions.

Adoption

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

5.4. Mandate to update the 2006 Opinion of the GMO Panel on the Post-Market environmental monitoring

The draft Opinion by the EFSA GMO Panel providing guidance on Post-Market Environmental Monitoring (PMEM) of genetically modified plants was endorsed by the GMO Panel and is

published at http://www.efsa.europa.eu/en/consultations/call/gmo110418.htm for public consultation from 18 April 2011 to 22 May 2011.

6. DISCUSSION OF OPINIONS

6.1. Guidance on the risk assessment of genetically modified microorganisms and their products intended for food and feed use.

The draft Guidance on the risk assessment of genetically modified microorganisms and their food and feed products was published from 29 November 2010 until 31 January 2011 for public consultation. The comments received have been assessed by the working group and incorporated into the document as appropriate. The EFSA GMO Panel is invited to comment on the updated draft before the Working Group meets on 11-12 May to finalize the draft Guidance. It was clarified that the safety assessment of fermentation products like enzymes or vitamins as such are already covered by other guidance from different EFSA Panels.

6.2. Development of a protocol for 90-day feeding trials with whole food (EFSA-Q-2009-00941).

The draft document "EFSA guidance for testing of whole food/feed. Repeated-dose 90-day oral toxicity study in rodents" by the EFSA Scientific Committee was presented to the EFSA GMO Panel. This document informs about the risk assessment strategies for the different types of food/feed and the role of animal feeding trials with whole food/feed and the experience with testing of novel foods and GM plant derived foods/feed in rodents. The document makes recommendations with regard to protocols, including preparation of the diet for the testing; endpoints to be measured, animals for use in 90-day toxicity studies, experimental design and statistical method, etc. Experts of the EFSA GMO Panel are invited to provide their comments to this draft document. It was noted that ANSES published its report on "Recommendations for carrying out statistical analyses of data from 90-day rat feeding studies in the context of marketing authorisation applications for GM organisms".

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

7.1. Regulation (EC) No 1829/2003

None.

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.

None.

8.3. Other requests and Mandates.

None.

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

Item postponed to next meeting due to lack of time.

10. FEEDBACK FROM EFSA AND THE SCIENTIFIC COMMITTEE

None.

11. FEEDBACK FROM THE COMMISSION

The Commission provided the EFSA's Scientific Committee with written feedback on status and actions taken based on EFSA scientific opinions adopted during the period June 2009 to December 2010. In the GMO area, the European Commission's adopted and pending decisions (e.g. for authorisations) were added to the list with EFSA questions numbers. This overview will be presented at the next plenary meeting.

12. DATE AND PLACE OF FUTURE MEETINGS

Proposals for Plenary meeting dates for 2012 were presented to the EFSA GMO Panel at the Plenary meeting of December 2010.

13. ANY OTHER BUSINESS

Terminology in GMO Scientific Opinions.

The terminology used in the opinion Application for authorisation of genetically modified Soybean A5547-127 and derived food and feed submitted under Regulation (EC) No 1829/2003 by Bayer CropScience (EFSA-GMO-NL-2008-52) (EFSA-Q-2008-290) has been brought in line with the newly adopted Guidance for risk assessment of food and feed from genetically modified plants. However, when citing text of previous opinions, the previous terminology used in those opinions will be maintained. To indicate this situation, text from previous opinions will be quoted in inverted comma ("").

Meeting of EFSA Scientific Network for Risk Assessment of GMOs, June 2011.

Item postponed to next meeting due to lack of time.

Panel Members reporting on meetings and/or conference they attended for EFSA

None.

Research priorities 2011

Item postponed to next meeting due to lack of time.

Call for new Scientific Committee and Panel members 2011

The EFSA GMO Panel was informed that EFSA has launched a call for experts for the Scientific Committee and Scientific Panels of EFSA with expertise in the following fields: plant health and plant protection; GMOs; food additives and nutrient sources; food contact materials, enzymes and flavourings; feedstuffs; animal health and welfare; toxicology; contaminants in the food chain; biological hazards; dietetic products, allergies, novel foods and nutrition.
The deadline for applying is 31 May 2011. The GMO Panel members are encouraged to apply and to spread the information in the scientific community.

Reorganization of EFSA

EFSA has begun a re-organisation programme. The re-organisation aims to address growing demands, particularly with regards to applications for the assessment of regulated substances and products. The re-structuring will take place gradually throughout 2011 and will be completed by early 2012.

Five directorates now make up EFSA: three scientific directorates, which support the work of the Scientific Committee and EFSA's 10 scientific Panels; a reshaped Communications Directorate and the Resources and Support Directorate. More information is available on the EFSA website.

ANNEX 1

Interests and actions resulting from declared interests

Regarding interests declared by Detlef Bartsch
In this specific declaration of interest (SDOI) no conflict of interest is identified in relation to previously declared annual declaration of interest (ADOI) except under items 5.2. This item is declared by the expert as an interest based on his ADOI: "As an EFSA GMO panel member and WG member assessing applications and MS comments on applications I will declare through the specific declaration of interest prior of each meeting any involvement in commenting on applications I might have had as RA head of department of BVL." For item 5.2, EFSA has noted that the expert's institution has submitted comments during the public consultation on the comparator document. A conflict level C is assigned to this agenda item.

In accordance with EFSA's Policy on Declarations of Interests and Implementing documents thereof, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a conflict of Interest (level C). Pursuant to EFSA's Procedure on Identifying and Handling Declarations of Interest point C.III.b[1], the said expert will be excluded from participating in EFSA activities concerned by the interest in question.

[1] Implementing act to the policy on declaration of interests procedure for identifying and handling potential conflicts of interest. http://www.efsa.europa.eu/en/keydocs/docs/doiconflicts.pdf