MINUTES OF THE 35TH PLENARY MEETING OF THE SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS HELD ON 12-13 SEPTEMBER 2007 IN PARMA, ITALY (ADOPTED ON 30 OCTOBER 2007)

AGENDA

PARTICIPANTS

GMO Panel:

Hans Christer Andersson, Salvatore Arpaia, Detlef Bartsch, Josep Casacuberta, Howard Davies, Niels Bohse Hendriksen, Lieve Herman, Sirpa Kärenlampi, Jozsef Kiss, Ilona Kryspin-Sorensen, Harry Kuiper (Chair), Nickolas Panopoulos, Joe Perry, Annette Pöting, Joachim Schiemann, Willem Seinen, Jeremy Sweet and Jean-Michel Wal.

Ad Hoc experts:
Hilko Van der Voet[1] (Wageningen University and Research Centre, Biometrics and RIKILT).

EFSA:
GMO Unit: Anna Christodoulidou, Zoltan Diveki, Ana Gomes, Karine Lheureux, Sylvie Mestdagh, Claudia Paoletti, Suzy Renckens, Reinhilde Schoonjans and Ellen Van Haver.
Director of Science and Deputy Executive Director: Herman Koëter[2].
Scientific Committee and Advisory Forum Unit: Djien Liem[2].

European Commission:
Sébastien Goux, Sabine Pelsser and Michael Walsh (DG SANCO).

APOLOGIES

GMO Panel:
Marc De Loose and Ingolf Nes.

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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

Panel members were asked to update their annual declarations of interest that are published on the EFSA website[3], based on the new template as prepared by EFSA.

In addition, Panel members were invited to declare possible interests on topics included on the agenda. No specific declarations of interest were declared.

4. ADOPTION OF THE MINUTES OF THE 34TH PLENARY MEETING HELD ON 4-5 JULY 2007

The minutes of the 34th plenary meeting (4-5 July 2007) were adopted as proposed and will be published at:

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178621341446.htm.

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[1] For agenda item 8 only.
[2] For agenda item 9 only
[3] http://www.efsa.europa.eu/en/science/gmo/gmo_members.html

5. DISCUSSION AND POSSIBLE ADOPTION OF OPINIONS ON:

5.1. Danisco Xylanase (FAD-2006-0024 under Regulation (EC) 1831/2003; GMO/FEEDAP co-opinion)

Introduction

Within the framework of Regulation (EC) N° 1831/2003, EFSA has been requested to deliver an opinion on the efficacy and the safety for the target animals, the consumer, user and the environment of the product Danisco Xylanase G/L which is a preparation of endo-1,4 beta-xylanase produced by the genetically modified microorganism *Trichoderma reesei* (ATCC PTA 5588) when used under the proposed conditions.

Discussion

The GMO Panel has been asked to perform the assessment of the GM aspects of the microorganism used for the production of the feed enzyme. The FEEDAP Panel will assess all other parts of the application.

The *Trichoderma reesei* sequence that encodes xylanase was modified to render the enzyme thermotolerant (Xylanase Y5). The final enzyme preparation contains no cultivable producer organism. Fragments of recombinant DNA are present in the final concentrate in trace amounts. Since no sequences which cause concern are introduced, the genetic modification and the presence of the low concentration of recombinant DNA in the final product do not raise any particular safety concern.

Adoption

The opinion with regard to the risk assessment of the genetic modification of the application was adopted unanimously by the Panel. Once the other part has been adopted by the FEEDAP Panel, the co-opinion will be published on the EFSA website at:

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

5.2. GA21 Maize (application EFSA-GMO-UK-2005-19 and renewal EFSA-GMO-RX-GA21 under Regulation (EC) 1829/2003)

Introduction

The Panel was requested in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003, to carry out a scientific assessment of the genetically modified maize GA21 for food and feed uses, import and processing of maize GA21 and all derived products (EFSA-GMO-UK-2005-19).

Within the framework of the same Regulation, EFSA received from the European Commission an application for renewal of the authorisation of maize GA21 (EFSA-GMO-RX-GA21). This application covers the continued marketing of existing food additives, feed materials and feed additives produced from maize GA21.

All data required for the risk assessment of the application EFSA-GMO-RX-GA21 have also been provided in application EFSA-GMO-UK-2005-19.

The Panel performed one single comprehensive risk assessment for all intended uses of genetically modified maize GA21 and issued a single comprehensive scientific opinion for both applications.

The opinion of the Panel corresponds to the safety assessment report as referred to in Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003 and will be part of the overall EFSA opinion as required by Articles 6(5) and 18(5) of Regulation (EC) No 1829/2003.

Discussion

The assessment is based on the information provided in the application, including additional information from the applicant in reply to questions from Members States (MS) and from EFSA.

The comments from MS that were submitted during the three-month consultation period were addressed individually by the Panel in a separate annex.

The draft opinion and the table with comments from MS were presented to the Panel members during the plenary meeting followed by a discussion on outstanding issues.

The Panel is of the opinion that the molecular characterisation of the DNA insert and flanking regions of maize GA21 does not raise safety concerns, and that sufficient evidence for the stability of the insert structure was provided. Comparative analysis has shown that maize GA21 is compositionally and agronomically equivalent to conventional maize, except for the introduced transgenic trait. The assessment included an evaluation of data from analytical studies, bioinformatics, and *in vitro* and *in vivo* studies. The Panel concluded that the maize GA21 is as safe as its non-GM counterparts and that the overall allergenicity of the whole plant is not changed.

The application EFSA-GMO-UK-2005-19 concerns food and feed uses, import and processing of maize GA21 and all derived products. The application EFSA-GMO-RX-GA21 covers the continued marketing of existing food additives, feed materials and feed additives produced from maize GA21. There is therefore no requirement for scientific assessment of possible environmental effects associated with the cultivation of the GM maize. There are no indications of increased likelihood of establishment or survival of feral maize plants in case of accidental release into the environment of GA21 seeds during transportation and processing. The scope of the monitoring plan provided by the applicant is in line with the intended uses of maize GA21.

In conclusion, the Panel considers that information available for maize GA21 addresses the comments raised by the Member States and considers it unlikely that maize GA21 will have any adverse effect on human and animal health or on the environment in the context of its intended uses.

Adoption

The opinion was adopted unanimously by the Panel. The opinion and the table containing the responses of the Panel to MS comments (Annex G of the overall opinion) can be found on the following EFSA website at:

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620785956.htm

5.3. Safety and nutritional assessment of GM plants and derived food and feed – The role of animal feeding trials (Self tasking activity)

Introduction

The self tasking activity of the Panel on the use of animal feeding trials for the safety evaluation of *whole* GM food and feed started in January 2005. A draft document was published on the EFSA website from 15 December 2006 until 15 February 2007 for an 8-week period of public consultation. The Working Group considered all comments of scientific nature, before finalizing its report, but did not consider political or socio-economic issues, or issues related to the risk management of GMOs.

Discussion

The draft report was presented to the Panel. The report discusses the various elements of the safety and nutritional assessment procedure for genetically modified (GM) plant derived food and feed, in particular the potential and limitations of animal feeding trials for the safety and nutritional testing of *whole* GM food and feed.

In Chapter 1 the mandate, scope and general principles for risk assessment of GM plant derived food and feed are discussed.

Chapter 2 provides an overview of studies performed for the safety and nutritional assessment of whole food and feed. Extensive experience has been built up in recent decades from the safety and nutritional testing in animals of irradiated foods, novel foods and fruit and vegetables. These approaches are also relevant for the safety and nutritional testing of whole GM food and feed.

In Chapter 3 toxicological *in vivo*, *in silico*, and *in vitro* test methods are discussed which may be applied for the safety and nutritional assessment of specific compounds present in food and feed or of whole food and feed derived from GM plants. Moreover the purpose, potential and limitations of the 90-day rodent feeding trial for the safety and nutritional testing of whole food and feed have been discussed.

In Chapter 4 standards for test sample preparation, test materials, diet formulation and analysis are evaluated. Specific attention is paid to the choice of control diets and comparators, dietary stability, and nutritional balancing of diets.

Chapter 5 provides information on the collection, analysis and interpretation of data and findings obtained from animal feeding studies.

In Chapter 6 strategies are outlined for the safety and nutritional assessment of GM plant derived food and feed. The generation of studies for pre-market assessment of the safety and nutritional properties of food and feed from GM plants should follow a structured stepwise approach and consideration of the data obtained at each step in order to formulate the questions to be asked and answered at the next step.

The final chapter of the report provides conclusions and recommendations on:

- The comparative approach to safety and nutritional testing of food and feed derived from GM plants;

- *In silico* and *in vitro* tools available for safety and nutritional testing of GM plant derived food and feed;
- Testing of defined single substances from GM plant derived food and feed in *in vivo* studies;
- Testing of whole GM plant derived food and feed in animal feeding studies;
- Importance of a structured approach for development of data for the pre-market safety and nutritional testing of GM plant derived food and feed;
- Role of post-market monitoring.

Adoption

The report was adopted unanimously by the Panel. The report will be available on the EFSA website after preparation of the document for publication.

6. UPDATE ON APPLICATIONS RECEIVED UNDER DIRECTIVE 2001/18/EC, REGULATION (EC) NO 1829/2003 AND REGULATION (EC) NO 1831/2003

Ongoing applications

- LLRICE62 Rice (application UK-2004-04): the answer from the applicant to the request from the Panel for clarification of the molecular characterization of LLRICE62 rice was not considered satisfactory and another request for further clarification was therefore identified.

- MIR604 Maize (application UK-2005-11): the Panel identified a request for further clarification regarding the food/feed safety of MIR604 maize to be sent to the applicant.

- T45 Oilseed rape (application UK-2005-25): the Panel identified a request for further information regarding the molecular and food/feed safety aspects of T45 oilseed rape.

- LY038 Maize (application NL-2006-31): further questions to the applicant for additional information on the molecular characterization and food/feed safety of LY038 maize were identified by the Panel.

In case additional information is requested to the applicant, the assessment procedure is kept on hold (the clock is stopped).

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

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

EFSA received, via the Netherlands, one new application (NL-2007-46: T25 Maize) within the framework of Regulation (EC) No 1829/2003 for an overall opinion including the scientific opinion on the GMO for import and processing, food and feed use.

Nominated risk assessment bodies of the Member States and national 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 application is valid. These comments will be considered during the scientific risk assessment of the application by the EFSA GMO Panel.

The summary of this application, as well as the information on its current status can be found on the following website:
http://www.efsa.eu.int/science/gmo/gm_ff_applications/catindex_en.html.

7.2. Applications for renewal under Regulation (EC) No 1829/2003

EFSA received from the European Commission 24 applications for renewal of authorisation of existing products according to Articles 11 and 23 of Regulation (EC) No 1829/2003. EFSA is requested to perform the scientific risk assessment of the following applications covering 20 events:

- GM maize: NK603 x MON 810 (RX[4]-603x810), 1507 (RX-1507), MON 863 x NK603 (RX-863x603), MON 863 (RX-863), MON 863 x MON810 (RX-863x810), Bt11 (RX-Bt11), T25 (RX-T25), GA21 (RX-GA21), MON 810 (RX-810);
- GM oilseed rape: MS8/RF3 (RX-MS8/RF3), GT73 (RX-GT73), T45 (RX-T45);
- GM cotton: MON 531 x MON1445 (RX-531x1445), MON 15985 (RX-15985), MON 15985 x MON1445 (RX-15985x1445), MON 531 (RX-MON531), MON 1445 (RX-MON1445);
- GM soybean: 40-3-2 (RX-40-3-2);
- GM yeast: pMT742 or pAK729 (RX-pM/pA);
- GM bacteria: PL73 (RX-PL73).

The summary of these applications can be found on the following website:
http://www.efsa.europa.eu/EFSA/1178620831951/efsa_locale-1178620753812_GMOApplicationsforRenewal.htm

8. UPDATE ON SELF TASKING ACTIVITIES AND GUIDANCE ON GMO RISK ASSESSMENT

8.1. Statistical considerations in the safety evaluation of GMOs

A presentation on the current status of the draft document on "Statistical considerations for the safety evaluation of GMOs" was given by the Chair of the working group (WG) on Statistics, Hilko Van der Voet. The different principles and steps that have been and will be taken by the WG to come to the identification of a strategy to ensure a better harmonization of approaches for data evaluation in GMO risk assessment and a more precise definition of experimental design requirements were presented.

8.2. Allergenicity assessment of GM foods

A plenary WG meeting took place on 16 July 2007 following several sub-WG meetings that were held previously. The aim of the plenary working group meeting was to go through the different contributions of the sub-WGs and to identify gaps and redundancies. The WG was also informed about a letter EFSA received with comments from Norway on the possible adjuvant effect of Cry proteins within the framework of Regulation 1829/2003-applications and the corresponding opinions of the GMO Panel. The issue of adjuvanticity has been considered during the risk assessment of GMO applications as a reply to Member States' comments and will be further investigated by this WG.

[4] RX = Renewal of eXisting products

8.3. Guidance for the assessment of GM plants used for non-food/feed purposes

A seventh working group meeting was held on 18 July 2007 during which specific case studies of GM plants used for non-food/feed purposes were further elaborated. The aim is to present a first draft of the whole document to the GMO Panel at their next plenary meeting in October.

9. FEEDBACK FROM EFSA AND THE SCIENTIFIC COMMITTEE

The Panel was informed about the outcome of the 25th Plenary meeting of the Scientific Committee held on 9-10 July 2007. The minutes of this meeting can be found at: http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178621343383.htm.

The Director of Science and Executive Deputy Director, Herman Koëter and the Head of Unit of the Scientific Committee and Advisory Forum, Djien Liem, informed the Panel about the special Advisory Forum on GMOs EFSA will organise on 13 November in Brussels. The aim of this meeting will be to discuss the GMO risk assessment approach applied by EFSA and the GMO Panel and in the different Member States. The Member States will be requested beforehand to fill in a questionnaire in order to fine-tune the agenda of that meeting.

10. DATES OF FUTURE MEETINGS

Meeting dates were agreed at earlier plenary meetings.

11. ANY OTHER BUSINESS

The Panel was informed about a letter to Commissioner Kyprianou from Eurogroup for Animals as a reaction to recent demands from some Members States for long term animal feeding studies to be made mandatory for the safety assessment of foodstuffs containing GM plants. This NGO, which represents a united voice for animal welfare organisations in Europe, supports the case-by-case approach as described in the EFSA guidance document of the GMO Panel for the risk assessment of GM plants and derived food and feed. In addition, it also acknowledges the difficulties and drawbacks of feeding studies for the safety evaluation of GM food and feed as addressed in the EFSA draft report on animal feeding trials that was published on the EFSA website for public consultation, and described previously by OECD and EU funded research projects such as FOSIE and ENTRANSFOOD. Eurogroup is of the opinion that any requirements for mandatory testing which do not allow the flexibility of the EFSA approach would inevitably result in the use of experimental animals in unnecessary and useless studies.