MINUTES OF THE 45TH PLENARY MEETING OF THE SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS HELD ON 29-30 OCTOBER 2008 IN PARMA, ITALY (ADOPTED ON 3 DECEMBER 2008)

PARTICIPANTS

GMO Panel:
Hans Christer Andersson, Salvatore Arpaia, Detlef Bartsch, Josep Casacuberta, Howard Davies, Patrick du Jardin, Niels Bohse Hendriksen, Lieve Herman, Sirpa Kärenlampi, Jozsef Kiss, Gijs Kleter, Ilona Kryspin-Sorensen, Harry Kuiper (Chair), Nickolas Panopoulos, Joe Perry[1], Annette Pöting, Joachim Schiemann, Willem Seinen, Jeremy Sweet and Jean-Michel Wal.

EFSA GMO Unit:
Jaime Aguilera, Per Bergman, Anna Christodoulidou, Yann Devos, Zoltán Divéki, Christina Ehlert, Antonio Fernández Dumont, Andrea Germini, Ana Gomes, Karine Lheureux, Yi Liu, Sylvie Mestdagh, Claudia Paoletti, Reinhilde Schoonjans, Elisabeth Waigmann

European Commission:
Michael Walsh and Sébastien Goux[2] (DG SANCO); Bernadette Murray and Helen Clayton (DG ENV)

APOLOGIES
GMO Panel: Ingolf Nes
DG SANCO: Sabine Pelsser

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1. WELCOME AND APOLOGIES FOR ABSENCE

The Chair opened the meeting and welcomed all. Apologies for absence were received from one Panel member and one colleague from DG SANCO 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 have been registered through the standard document submitted by the Panel members.

4. ADOPTION OF THE MINUTES OF THE 44TH PLENARY MEETING HELD ON 10-11 SEPTEMBER 2008

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[1] Only present on 29 October 2008

[2] Only present in the afternoon of 29th and on 30th September 2008

The minutes of the 44th Plenary meeting (10-11 September 2008) were adopted as proposed and will be published at:
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178718032781.htm

5. DISCUSSION AND POSSIBLE ADOPTION OF OPINIONS ON:

5.1. Avizyme 1505 (EFSA-Q-2007-020 under Regulation (EC) No 1831/2003; FEEDAP-GMO co-opinion)

Introduction

Within the framework of Regulation (EC) No 1831/2003 on additives for use in animal nutrition, 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 Avizyme 1505 which is a preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (ATCC PTA 5588), alpha-amylase produced by *Bacillus amyloliquefaciens* (ATCC 3978) and subtilisin (protease) produced by *Bacillus subtilis* (ATCC 2107) 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 this feed enzyme. The FEEDAP Panel will assess all other parts of the feed enzyme application.

Avizyme 1505 is an enzyme preparation with three declared activities, i.e., endo-1,4-β xylanase, α-amylase and alkaline protease (subtilisin). These three enzymes are produced by three genetically modified micro-organisms: end-1,4-β xylanase by *Trichoderma reesei*, α-amylase by *Bacillus amyloliquefaciens* and alkaline protease by *Bacillus subtilis*. In the *T. reesei* strain, no DNA sequences causing concern have been introduced. In the *B. amyloliquefaciens* strain, resistance genes for neomycin and bleomycin are present in a plasmid which has been made non-mobile. In the *B. subtilis* strain, a chloramphenicol resistance gene has been inserted into the chromosome. The production micro-organisms are removed after fermentation and are not detected in the final enzyme preparations. The recombinant DNA is below the limit of detection in the final enzyme preparations. With respect to the genetic modification, there are no environmental safety concerns in relation to the final product.

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. Ronozyme NP (EFSA-Q-2007-133 under Regulation (EC) No 1831/2003; FEEDAP-GMO co-opinion)

Introduction

Within the framework of Regulation (EC) No 1831/2003 on additives for use in animal nutrition, EFSA has been requested to deliver an opinion on the efficacy and the safety for the target animal(s), the consumer, user and the environment of the product Ronozyme® NP which is a preparation of 6-phytase produced by the genetically modified micro-organism *Aspergillus oryzae* (DSM 17594), 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 this feed enzyme. The FEEDAP Panel will assess all other parts of the feed enzyme application.

Ronozyme® NP is produced by fermentation of *Aspergillus oryzae* PhME3-38. Multiple copies of the 6-phytase gene cassette sequence are inserted in the genome of the production strain. No exogenous antibiotic resistance marker sequences were added. The recipient organism is considered as safe and no harmful sequences have been introduced in the recipient strain. After fermentation, the enzyme is separated from the cells and concentrated. The final enzyme preparation contains no cultivable production organisms, no antimicrobial activity or mycotoxins, and the level of the newly introduced DNA is below the limit of detection of 0.4 ng of recombinant DNA g^{-1} enzyme product.

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.

5.3. Safeguard clause invoked by France according to Article 23 of Directive 2001/18/EC in relation to maize MON 810 (EFSA-Q-2008-077)

Introduction

On 27 February 2008, EFSA was requested by the European Commission, under Article 29(1) and in accordance with Articles 22(5) and 22(5)(c) of Regulation (EC) No 178/2002, "*To assess:*

1. *the opinion of the "comité de préfiguration" of the High Authority for GMOs, dated 9 January 2008, which is mentioned as reference in the first "considérant" of the Order*[3]*;*

2. *the French position that the justifications presented by Monsanto on 30 January 2008 are not sufficient to invalidate the data of the French Order, as presented in the second "considérant" of the Order;*

3. *the scientific evidence which is presented in the accompanying note of the Order and in the note forwarded to the European Commission under Regulation (EC) No 1829/2003;*

4. *the scientific justification of the duration of the measure, which is linked to the ongoing procedure on the notification for the renewal of MON810, as referred to in Article 1 in the Decree.*"

[3] French Order of 7 February 2008 suspending the cultivation of seed varieties maize MON810.

Following the receipt of the mandate and upon request of EFSA, the aforementioned data package was supplemented with missing documents as well as, at a later stage, with an additional report from Professor Yvon Le Maho submitted in June 2008.

The GMO Panel considered and assessed all the written evidences provided by the French authorities in support of their safeguard clause. On 9 June 2008, experts of the GMO Panel met French scientists in order to discuss the scientific concerns and to identify whether there is new scientific evidence which was not considered in earlier risk assessments of maize MON810.

Discussion

Having assessed the information package provided by France in support of its safeguard clause and having considered all relevant publications on the subject, the GMO Panel concludes that, in terms of risk to human and animal health and the environment, the provided information package does not present new scientific evidence that would invalidate the previous risk assessments of maize MON810. Therefore, no specific scientific evidence, in terms of risk to human and animal health and the environment, was provided that would justify the invocation of a safeguard clause under Article 23 of Directive 2001/18/EC and an emergency measure under Article 34 under Regulation (EC) No 1829/2003.

Adoption

The opinion was adopted unanimously by the Panel. The opinion can be found on the EFSA website at: http://www.efsa.europa.eu/EFSA/ScientificPanels/GMO/efsa_locale-1178620753812_GMOOpinions455.htm.

5.4. Request from the European Commission to review scientific studies related to the impact on the environment of the cultivation of maize Bt11 and 1507 (EFSA-Q-2008-679)

Introduction

On 24 July 2008, EFSA was requested by the European Commission "*to review eleven scientific studies published after the adoption of the EFSA opinions as well as any other relevant study and to confirm its risk assessment of Bt11 and 1507 maize or comment on whether they would lead EFSA to alter its conclusions or refine it*".

Discussion

On 19 January 2005 and 20 April 2005, the Panel on Genetically Modified Organisms (GMO Panel) of the European Food Safety Authority (EFSA) issued scientific opinions on genetically modified maize Bt11 and 1507, both including the scope of cultivation.

At a meeting of the European Commission with national Competent Authorities on 19 June 2006, some Member States raised objections to the original opinions of the GMO Panel. Most of these objections related to potential effects of maize Bt11 and 1507 on non-target organisms and in particular lepidopteran species and to post-market environmental monitoring. Following the meeting with Competent Authorities and upon request of the European Commission, the GMO Panel amended its previous scientific opinions on 7 November 2006 by adopting an Annex of clarifications. In the Annex, the GMO Panel concluded that the information available for maize

Bt11 and 1507 addresses objections and questions raised by Member States, and confirmed that maize Bt11 and 1507 are unlikely to have adverse effects on human and animal health or the environment in the context of their proposed uses.

On 24 July 2008, the GMO Panel received a new request from the European Commission to review the previous scientific opinions of maize Bt11 and 1507 in the light of 11 scientific publications, published after the adoption of the previous scientific opinions of the GMO Panel, as well as any other relevant study.

The GMO Panel concludes that neither the 11 scientific publications selected and provided by the European Commission, nor recent peer-reviewed papers identified as relevant by the GMO Panel, invalidate the former risk assessments of maize Bt11 and 1507 performed by the GMO Panel.

Adoption

The opinion was adopted unanimously by the Panel. The opinion can be found on the EFSA website at: http://www.efsa.europa.eu/EFSA/ScientificPanels/GMO/efsa_locale-1178620753812_GMOOpinions455.htm

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

Ongoing applications

- An overview of ongoing applications (including the applications for renewal of the authorization of products already on the market) was given to the Panel with clear indications on the timelines.

- Application 31 (NL-2006-31, maize LY038, Renessen): questions to the applicant for additional information on the food/feed safety of LY038 maize were identified by the Panel and discussed. In case additional information is requested from the applicant, the assessment procedure is kept on hold (the clock is stopped).

- Application 41 (UK-2007-41, Cotton MON88913, Monsanto): applicant's responses were received and discussed. The Panel will continue its evaluation.

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

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

Application for authorisation of genetically modified PL73 Escherichia coli (LM) for feed use (dried killed bacterial biomass) was received through France (EFSA-GMO-FR-2008-61) (EFSA-Q-2008-669).

Member States 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. On its own initiative EFSA has broadened this consultation also to Competent Authorities of the Member States under Regulation (EC) No 1829/2003 and

other national risk assessment bodies. The comments will be considered during the scientific evaluation by the GMO Panel of the risk assessment performed by the applicant.

The summary of the application EFSA-GMO-FR-2008-61, as well as the information on the current status can be found through the following webpage leading to EFSA's Register of Questions: http://registerofquestions.efsa.europa.eu/roqFrontend/questionsList.jsf..

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

None

7.3. Request from the EC to EFSA regarding the safeguard clause invoked by Austria according to Article 23 of Directive 2001/18/EC in relation to maize lines MON863 (Ref. C/DE/02/9, Commission Decisions 2007/608/EC and 2006/68/EC).

With a letter dated 3 September 2008, the European Commission requested EFSA under Article 29(l) and in accordance with Articles 22(2) and 22(5)(c) of Regulation (EC) No 178/2002, to provide a scientific opinion by 31 October 2008 as to:

- *"whether in accordance with Article 23 of the Directive 2001/18/EC, the statement and documents submitted by the Austrian authorities comprise new information affecting the environmental risk assessment, such that detailed grounds exist to consider that the above authorised GMO, for the uses laid down in the corresponding consent, constitute a risk to human health, animal health or the environment."*

In the spirit of reinforcement of scientific cooperation with national institutions and in order to ensure a more effective mode of collaboration on the scientific issues, DG ENV invited EFSA *"to contact the Austrian experts to clarify all the requested information and the potential sources of divergence before adopting the opinion".*

When the supporting documentation is formally received, a technical meeting with Austrian scientists will be convened. On the basis of the information provided and the discussion in the technical meeting, the GMO Panel will conclude its scientific assessment.

7.4. Request from the EC to EFSA regarding the safeguard clause invoked by Austria according to Article 23 of Directive 2001/18/EC in relation to oilseed rape lines Ms8, Rf3, Ms8xRf3 (Ref. C/BE/96/01, Commission Decision 2007/232/EC).

With a letter dated 31 July 2008, the European Commission requested EFSA under Article 29(l) and in accordance with Articles 22(2) and 22(5)(c) of Regulation (EC) No 178/2002, to provide a scientific opinion by 15 October 2008 as to:

- *"whether in accordance with Article 23 of the Directive 2001/18/EC, the statement and documents submitted by the Austrian authorities comprise new information affecting the environmental risk assessment, such that detailed grounds exist to consider that the above authorised GMO, for the uses laid down in the corresponding consent, constitute a risk to human health or the environment."*

In the spirit of reinforcement of scientific cooperation with national institutions and in order to ensure a more effective mode of collaboration on the scientific issues, DG ENV invited EFSA "*to contact the Austrian experts to clarify all the requested information and the potential sources of divergence before adopting the opinion".*

When the supporting documentation is formally received, a technical meeting with Austrian scientists will be convened. On the basis of the information provided and the discussion in the technical meeting, the GMO Panel will conclude its scientific assessment.

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

8.1. Updated Guidance Document for the assessment of GM plants and derived food or feed

The European Commission informed the Panel about the progress in the preparation of EC guidelines. To assist in the process the GMO Panel intends to evaluate comments from the public consultation on the Draft Updated Guidance Document for the risk assessment of genetically modified plants and derived food and feed and to discuss the comments, in a working group meeting of the Standing Committee with Member states (http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902079063.htm) organised by the Commission.

8.2. Self-tasking activity on Non-Target Organisms (EFSA-Q-2008-089)

The draft document is in an advanced stage of development and the aim is to finalize the draft for public consultation and present it to the GMO Panel in autumn 2009. The final outcome of this EFSA self-task is to support the Updated Guidance for Environmental Risk Assessment of GM plants and derived food or feed, see section 8.3 below.

8.3. Updated Guidance for Environmental Risk Assessment of GM plants and derived food or feed (EFSA-Q-2008-262)

The work plan for this mandate of the DG Environment was presented to the GMO Panel. It includes the 4 issues covered by the mandate and in addition an update of all sections of the current ERA Guidance Document in light of the experience gained with the previous assessment of applications, recent scientific development, outcome of the EFSA Colloquium on ERA challenges and approaches, guidance on GM herbicide tolerant crops and guidance for GM stacked events. Some of the sections of the Updated Guidance Document will be provided by the NTO self-task. The timeline for this mandate is March 2008 to March 2010, and will include a public consultation as is usual for EFSA risk assessment Guidance Documents.

8.4. Guidance for the risk assessment of GM animals (EFSA-Q-2008-069)

The work plan for this broad and complex mandate was presented to the Panel. For a guidance part dealing with food/feed safety, the standing WG on food/feed supplemented with *ad hoc* experts will elaborate on existing Guidance Documents available for example through *Codex Alimentarius*. For the environmental part on the deliberate release of GM animals, guidance must be developed focusing on GM fish, mammals, birds (poultry) and insects, according to the principles of the Annexes II and III A of Directive 2001/18/EC. As a first step in the work plan the call for procurement on GM fish is to be evaluated.

8.5. Self-tasking on Statistics

For the envisaged update of the environmental part of the Guidance Document, the EFSA working group on statistics will ask a prolongation of its mandate for the duration of 2009-2010.

9. FEEDBACK FROM EFSA AND THE SCIENTIFIC COMMITTEE

The Chairman gave an overview of the outcome of the 32nd Plenary meeting of the Scientific Committee held on 25-26 September 2008. The minutes of this meeting can be found on the EFSA website:
http://www.efsa.europa.eu/EFSA/ScientificPanels/ScientificCommittee/efsa_locale-1178620753812_PanelMeetings414.htm

10. FEEDBACK FROM THE EUROPEAN COMMISSION

The representatives of the European Commission provided the Panel with the status of applications that have been presented to the Standing Committee on the Food Chain and Animal Health for possible authorisation, and for which no qualified majority was reached. It was also confirmed that the presence of EFSA in the Council meeting on 20 October 2008 was beneficial to explain that EFSA cooperates much more with Member States than is foreseen in the legal framework and broadens its consultations to include Competent Authorities under Regulation (EC) No 1829/2003 and other national risk assessment bodies. Furthermore, EFSA consults for all applications. For cultivation dossiers, EFSA delegates the environmental risk assessment to a Member State as foreseen in the Art. 6 of Regulation (EC) No 1829/2003.

11. DATES OF FUTURE MEETINGS

Meeting dates for 2009 were agreed at earlier Plenary meetings.

12. ANY OTHER BUSINESS

An update on the progress of the mandate to be co-adopted by the GMO and BIOHAZ Panels on "A consolidated opinion on the use of antibiotic resistance genes as marker genes in GM plants" was presented to the Panel. Discussions between EFSA, EMEA and ECDC have resulted in good progress and the draft opinion of the GMO and BIOHAZ Panels has been presented to the Panel for discussion.

In addition to the two requests still pending on the safeguard clauses invoked by Austria on MON810 and T25 (EFSA-Q-2008-314) and on GT73 (EFSA-Q-2008-315), there are two new safeguard clauses invoked on Ms8, Rf3 and Ms8xRf3 (EFSA-Q-2008-743) and on MON863 (EFSA-Q-2008-742) as mentioned under sections 7.3 and 7.4. The Panel discussed practical considerations related to these 4 pending Austrian safeguard clauses. The negotiated deadline for the EFSA opinion on the safeguard clause on MON810 and T25 is December 31, 2008, whereas the deadline for the safeguard clause on GT73 has been negotiated for March 31, 2009.