MINUTES OF THE 37TH PLENARY MEETING OF THE SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS HELD ON 22-23 NOVEMBER 2007 IN BRUSSELS, BELGIUM (ADOPTED ON 18 DECEMBER 2007)

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PARTICIPANTS

GMO Panel:
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EFSA:
GMO Unit: Anna Christodoulidou, Zoltan Diveki, Sylvie Mestdagh, Claudia Paoletti, Suzy Renckens, Reinhilde Schoonjans and Ellen Van Haver.

European Commission:
Michael Fluëh, Sébastien Goux and Sabine Pelsser (DG SANCO)
Aurélie André and Bernadette Murray (DG ENV).

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1. WELCOME AND APOLOGIES FOR ABSENCE

The Chair opened the meeting and welcomed all. There were no apologies for absence.

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. No specific declarations of interest were declared.

4. ADOPTION OF THE MINUTES OF THE 36TH PLENARY MEETING HELD ON 30-31 OCTOBER 2007

The minutes of the 36th plenary meeting (30-31 October 2007) were adopted as proposed and will be published at:

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178656961668.htm.

5. DISCUSSION AND POSSIBLE ADOPTION OF OPINIONS ON:

[1] Present only 22 November.

5.1. The risk assessment of genetically modified plants used for non-food or non-feed purposes (for possible public consultation)

Introduction

The self-tasking activity of the Panel on the risk assessment of GM plants used for non-food or non-feed purposes started its activities in November 2005. The working group had several meetings between November 2005 and July 2007 to come to a finalized version of the document in November 2007.

Discussion and adoption

The draft opinion was presented to the Panel. The opinion provides guidance for the case-by-case risk assessment of the deliberate release into the environment of GM plants destined to be placed on the market as or in non-food or non-feed products under Part C of the Directive 2001/18/EC. Examples of such applications are GM plants with novel traits for the production of industrial or medicinal products, ornamental plants, plants for landscape recreation, and plants for phytoremediation. The scope thus covers GM plants destined for any purpose other than food or feed, but with the exception of GM plants as or in medicinal products, which are specifically excluded from Directive 2001/18/EC.

The Panel adopted the draft opinion on 'the risk assessment of GM plants used for non-food or non-feed purposes' for public consultation. Prior to publication, the European Commission and the European Medicines Agency (EMEA) will be consulted on the legal background as elaborated in the document. The draft report will be published in the first quarter of 2008 on the EFSA website for a 6-week period of public consultation. The working group and the Panel are seeking scientific views from interested parties, Member States and stakeholders.

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

Ongoing applications

- T45 oilseed rape (UK-2005-25): the Panel identified a question for clarification to be requested from the applicant on the compositional data of field trial data.

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

Since last plenary meeting, no working group meetings were held within the framework of the self tasking activities on Statistical considerations in the safety evaluation of GMOs and on the Allergenicity assessment of GM foods. The working group on risk assessment of genetically modified plants used for non-food or non-feed purposes finalized a draft for public consultation (see 5.1).

8. FEEDBACK FROM EFSA AND THE SCIENTIFIC COMMITTEE

The Panel was informed about the outcome of the 27th Plenary meeting of the Scientific Committee held on 19-20 November 2007. The minutes of this meeting can be found at: http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178637648399.htm.

9. SPECIAL MEETING OF THE EFSA ADVISORY FORUM ON GMO RISK ASSESSMENT IN EUROPE, HELD ON 13 NOVEMBER 2007

EFSA has organised a special Advisory Forum meeting on GMO risk assessment in Europe on 13 November 2007. Over 60 EU GMO risk assessment experts, nominated by the Advisory Forum members and representing the EU Member States, Norway, Switzerland and the European Commission met to share details of their national GMO risk assessment approaches, identify commonalities or possibly diverging procedures or methodologies among Member States or between Member States and EFSA.

It was concluded from the meeting that the vast majority of the risk assessors from the Member States is in agreement with the EFSA case-by-case approach for GMO risk assessment. In particular, there was agreement that 90-day feeding trials in rodents should not be prescribed as part of a standard test-package for the risk assessment of GM whole food and feed but are to be considered on a case-by-case basis. It was noted that guidance on environmental risk assessment should be continuously updated, especially in assessing the effects on non-target organisms. EFSA already planned starting a new self tasking activity on this issue. Furthermore, it was noted that more guidance is needed on how to interpret statistical significant findings on biological relevance. The Panel is currently considering this issue. In addition, clarification is needed in the guidance on the experimental design of field trials in order to achieve more harmonisation in trial design. Member States agreed that EFSA should continue to update its guidance in line with scientific progress.

A detailed report is in progress and will be circulated to the representatives of the Member States for commenting. The report and its Annexes provide a comprehensive overview of regulatory GMO risk assessment performed in Member states. This report will be submitted to the Advisory Forum for endorsement at its meeting in January 2008 and will be shared with the European Commission, the Member States and the Scientific Committee and Panels of EFSA. This report and its Annexes will be published at:
http://www.efsa.europa.eu/EFSA/PartnersNetworks/efsa_locale-1178620753812_AdvisoryForum.htm

10. FEEDBACK FROM THE COMMISSION

Michael Flueh (Head of the Biotechnology and Plant Health Unit, DG SANCO) gave the Panel an overview of activities of the Biotechnology and Plant Health Unit at DG SANCO and provided the Panel with background information on the guidelines for risk assessment that the EC shall implement in accordance with Art (5)7 of Regulation (EC) No 1829/2003. During the following consultation round, the Panel expressed its view on the concept of such guidelines, taken into account the existence of a detailed risk assessment Guidance Document produced and published by EFSA in May 2004 (updated in December 2005 and final edited and published version in May 2006), as required under Art 5(8) of Regulation (EC) No 1829/2003. The Panel referred to the overall support by the risk assessors in Member States to the EFSA risk assessment approaches (see item 9). The Panel stressed the importance of updating the guidance when necessary to take into account scientific progress. Some Panel members referred to the brief and concise concept of the

Annexes of Directive 2001/18/EC, wherein endpoints of the risk assessment are listed. When more details would be required in the EC Guidelines under Regulation 1829/2003, it is recommended to strive towards only one detailed guidance for applicants. In the latter case, the already existing EFSA Guidance Document as a whole is proposed as a starting point.

11. DATES OF FUTURE MEETINGS

Meeting dates were agreed at earlier plenary meetings.

12. ANY OTHER BUSINESS

12.1. Analysis of additional articles related to the EFSA statement on the fate of recombinant DNA fragments or protein in meat, milk and eggs from animals fed with GM feed

Further to the EFSA statement on the fate of recombinant DNA fragments or protein in meat, milk and eggs from animals fed with GM feed, published on 20 July 2007[2], the European Commission as well as the UK FSA have inquired about further relevant literature references (Sharma et al. 2006[3], Dugan et al, 2003[4], Mazza et al 2005[5] and Guertler et al, 2007[6] and more specifically whether or not they have an impact on the conclusion that "a large number of experimental studies with livestock have shown that recombinant DNA fragments or proteins derived from GM plants have not been detected in tissues, fluids or edible products of farm animals like broilers, cattle, pigs or quails". The literature survey given in support of this conclusion with the findings of many animal feeding studies, also includes an example of an experiment where indeed recombinant DNA fragments was found in an animal product (Agodi et al., 2006[7]). When more studies are carried out with more sensitive detection methods, such recombinant DNA fragments may be more frequently found in the future. As mentioned in the above EFSA statement "it is clear that the uptake of DNA fragments or proteins from the intestinal tract into the body is a normal physiological process for animals" and that "the recombinant sequence is present in the GM plant only as a single or low copy level, which makes the potential absorption a rare event and therefore difficult to detect". In conclusion, these additional references do not change the following conclusions as drawn in the EFSA statement[2]:

(1) Biologically active genes and proteins are common constituents of foods and feed in varying amounts. After ingestion, a rapid degradation into short DNA or peptide fragments is observed in the gastrointestinal tract of animals and humans.

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[2] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178623095798.htm

[3] Sharma R., Damgaard, D., Alexander T.W., Dugan M.E.R., Aalhus J.L., Stanford K. and McAllister T.A. (2006) Detection of transgenic and endogenous plant DNA in digesta and tissues of sheep and pigs fed Roundup Ready canola meal. *J Agric Food Chem* 54: 1699-1709.

[4] Dugan P.S., Chambers P.A., Heritage J. and Forbes J.M. (2003) Fate of genetically modified maize DNA in the oral cavity and in rumen of sheep. *British J Nutr* 89:159-166.

[5] Mazza R., Soave M., Morlacchini M., Piva G. and Marocco A. (2005) Assessing the transfer of genetically modified DNA from feed to animal tissues *Transgenic res* 14: 775-784.

[6] Guertler P., Lutz B., Kuehn R., Meyer H.H.D., Einspanier R., Killermann B. and Albrecht C. (2007) Fate of recombinant DANN and Cry1Ab protein after ingestion and dispersal of genetically modified maize in comparison to rapeseed by fallow deed (*Dama dama*). *Eur J Wildl Res* 8 February 2007.

[7] Agodi A., Barchitta M., Grillo M. and Sciacca S. (2006) Detection of genetically modified DNA sequences in milk from the Italian market. *Int J Hyg Environ Health* 209: 81-88.

(2) To date, a large number of experimental studies with livestock have shown that recombinant DNA fragments or proteins derived from GM plants have not been detected in tissues, fluids or edible products of farm animals like broilers, cattle, pigs or quails.

12.2. Analysis of an article published in PNAS (by Rosi-Marshall et al, 2007[8])

The Panel discussed a recently published article in PNAS by Rosi-Marshall et al., 2007 on "Toxins in transgenic crop byproducts may affect headwater stream ecosystems" (see the Annex to these minutes). In summary, the conclusions of the paper Rosi-Marshall et al. (2007) are not supported by the data presented in this paper. The GMO Panel is of the opinion that based on the available information such a low level of exposure to *Trichoptera* in aquatic ecosystems is unlikely to cause a toxic effect.

[8] Rosi-Marshall E.J., Tank J. L., Royer T. V., Whiles M. R., Evans-White M., Chambers C., Griffiths N. A., Pokelsek J., and Stephen M. L. (2007) Toxins in transgenic crop byproducts may affect headwater stream ecosystems. *PNAS*, 104, 41: 16204-08.

ANNEX: ANALYSIS BY THE GMO PANEL OF THE PNAS PUBLICATION OF ROSI-MARSHALL ET AL. 2007 "TOXINS IN TRANSGENIC CROP BYPRODUCTS MAY AFFECT HEADWATER STREAM ECOSYSTEMS"

The GMO Panel acknowledges that research is performed on this important issue as it can theoretically not be excluded that Lepidoptera-specific Cry1Ab protein may cause sub-lethal effects on *Trichoptera* as this insect order is closely related to the Lepidoptera order, at least more than to the order of *Diptera*.

There are some unclear points and weaknesses in the Rosi-Marshall et al. 2007 paper that might lead to very speculative conclusions:

The authors measured degradation rates in aquatic systems and found no difference between Bt and non-Bt maize plant material. The amount of Cry1Ab protein in leaves and pollen was not measured, so no dose-response relationship with Bt protein can be made.

It is thus unclear whether degradation of Bt protein is equal to degradation of plant material. It would also be interesting to know whether degradation in headwater stream ecosystems is similar to – and as fast as - degradation in soil and hydroponic pond solution reported by Icoz and Stotzky 2007[9] [with Cry3bb], but no information is provided on the degradation of Bt proteins/plant material, neither on degradation in headwater streams ecosystem / in soil and hydroponic pond solution.

The identity of the Bt maize used in the feeding test is not clear (could be for example Bt11 or MON810 or others). This would have been very important background information. If the pollen had come from MON810, the yearly deposition would be approximately 9 – 90 ng Cry1Ab protein per m² (Nguyen and Jehle, 2006[10]). It is considered that such a low dose is unlikely to cause a toxic effect.

No isogenic controls to compare with the GM material were used. The authors explain that they used controls with similar lignin and C/N ratio. No further details were given on nutritional equivalence of the maize material used.

There is no detailed information given on the amount of maize material fed to the test organisms: "Leaves were added to aquaria as needed".

The effects reported are relatively minor in comparison with known toxic chemicals. *H. borealis* had no significantly increased mortality when maize plant material was given. The only mortality effect was measured at a 2 - 3 fold above 'natural level' concentration of maize pollen.

There is no information on reproducibility of the feeding test.

The EFSA GMO Panel is of the opinion that important background information on levels of exposure and plant material used is missing. The GMO Panel will ask the authors of the paper for further clarification.

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[9] Icoz, I. and Stotzky G. (2007) Cry3Bb1 protein from Bacillus thuringiensis in root exudates and biomass of transgenic corn does not persist in soil. Transgenic Res. Sep 13; [Epub ahead of print].

[10] Nguyen, H.T. and Jehle, J.A. (2006) Quantitative analysis of the seasonal and tissue-specific expression of Cry1Ab in transgenic maize Mon810. Journal of Plant Diseases and Protection, 114 (2), 82–87.

In summary, the conclusions of the paper Rosi-Marshall et al. (2007) are not supported by the data presented in this paper. The GMO Panel is of the opinion that based on the available information such a low level of exposure to *Trichoptera* in aquatic ecosystems is unlikely to cause a toxic effect.