MINUTES OF THE 6th PLENARY MEETING OF THE EFSA SCIENTIFIC PANEL ON PLANT HEALTH HELD IN PARMA ON 11-12 JULY 2007

(ADOPTED ON 19 SEPTEMBER 2007)

PARTICIPANTS

Members of the PLH Panel

Richard BAKER, David CAFFIER, James William CHOISEUL, Patrick DE CLERCQ, Erzsébet DORMANNSNÉ SIMON, Olia Evtimova KARADJOVA, David MAKOWSKI, Charles MANCEAU, David MAKOWSKI, Luisa MANICI, Angelo PORTA PUGLIA, Jan SCHANS, Gritta SCHRADER, Anita STRÖMBERG, Kari TIILIKKALA, Johan Coert VAN LENTEREN, Irene VLOUTOGLOU

Apologies

Bärbel GEROWITT, Gábor LÖVEI, Alfons OUDE LANSINK, Dionyssios PERDIKIS, Angelo PORTA PUGLIA, Thierry CANDRESSE (ad hoc, chair WG Viruses), Robert STEFFEK, Johan Coert VAN LENTEREN

European Commission (DG SANCO)

Harry ARIJS, Michael WALSH

EFSA

Elzbieta CEGLARSKA, Sharon CHEEK, Giuseppe STANCANELLI, Anna CAMPANINI, Ann DE BLOCK

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1. WELCOME, APOLOGIES FOR ABSENCE

The Panel's Chair welcomed the panel members and the Commission observers.

Apologies were received from Bärbel GEROWITT, Gábor LÖVEI, Alfons OUDE LANSINK, Robert STEFFEK and Thierry CANDRESSE, *ad hoc*, chair WG Viruses (entire meeting), Dionyssios PERDIKIS, Johan Coert VAN LENTEREN (1st day), Angelo PORTA PUGLIA (2nd day).

2. ADOPTION OF THE DRAFT AGENDA

The agenda was adopted without changes.

3. DECLARATIONS OF INTERESTS

No conflict of interests was reported.

4. ADOPTION OF THE MINUTES OF 5TH PLENARY MEETING

The minutes were adopted with minor amendments.

5. RENEWAL OF ANNUAL DECLARATIONS OF INTERESTS

The Panel chair presented the new forms for the annual and specific declarations of interests introduced by EFSA with the aim to enhance transparency of its work.

The PLH Panel Secretariat circulated the new forms of the annual DoIs to the Panel with the request to submit them before the end of July. The Secretariat will then review the DoIs. Questions for clarifications should be addressed to the Panel Sc. Coordinator or directly to the legal department.

The Panel members expressed their concerns with regard to publication of their signature and suggested that the originally signed copy should be retained at EFSA and the unsigned copy should be made public.

6. PRESENTATION AND POSSIBLE ADOPTION OF DRAFT OPINIONS ON PRAS MADE BY FRANCE ON ORGANISMS WHICH ARE CONSIDERED BY FRANCE AS HARMFUL IN 4 FRENCH OVERSEAS DEPARTMENTS, I.E. GUADELOUPE, FRENCH GUIANA, MARTINIQUE AND REUNION

EFSA was requested to provide a scientific opinion on 30 PRAs made by France on organisms which are considered by France as harmful in 4 French overseas departments, i.e. Guadeloupe, French Guiana, Martinique and Réunion, and in particular whether these organisms can be considered as harmful organisms for the endangered area of the above departments in the meaning of the definition mentioned in Art. 2.1. (e) of the Directive 2000/29/EC and thus potentially eligible for addition to the list of harmful organisms in Directive 2000/29/EC.

The question was accepted for opinion at the Panel's plenary meeting in October 2006. The Panel was given 18 months period for elaboration on the question.

Two types of PRAs were prepared by the French risk assessors:

- Full based on the EPPO scheme [PM 5/3(1)] only for harmful organisms for which the probability of introduction into the DOMs is high with economically important crops and,
- Simplified for organisms for which the probability of introduction is extremely low.

The Rapporteurs presented the following draft opinions for the Panel's discussion:

- **PRA on *Metcalfa pruinosa* (full)**

The rapporteur expressed his concerns due to poor quality of the DOM PRAs in general and strongly supported the procedure for evaluation in order to save time and increase efficiency. The PRA on the organism in question required a lot of additional search for information especially with regard to the economic impact of the pest. The panel strongly recommended making explicit in the opinion what has been added to the PRA by the Panel. The comment was felt valid for all the 30 opinions.

The conclusion of the opinion is that the organism is not eligible for inclusion in the list of harmful organisms. The Panel commented that the conclusion should be reformulated in terms of risk

assessment terminology/ISPM 111. The gradation of harmfulness from being injurious to plant until economic impact and thus the level of risk should be addressed. The new version will be circulated before the next plenary meeting, following agreement on formulation of wording for conclusions. The Commission commented that the Panel should not be afraid of making strong statements in the conclusions. Comments and amendments to the text by email prior to the WG meetings were strongly recommended, so that main points can be discussed and conclusions finalised at the WG meeting. Adoption is envisaged at the next plenary subject to the necessary amendments.

- **PRA on *Prays citri* (full)**

Misidentification of P. citri with other Prays species was noted as a complicating issue and required extensive review and interpretation of the available literature. The importance of citrus to the DOMs was critical for concluding on the risk of P. citri and other pests such as Aceria sheldoni in particular. The Panel has found no evidence to indicate citrus was an important crop for the DOMs. EFSA was requested to seek information on the economic importance of citrus before conclusions could be formulated. The Secretariat would check for further information (e.g. AGRESTE database for France).

After agreement on standardised wording on the concluding statements, the draft would be amended and circulated for the Panel's consideration before the next plenary meeting.

- **PRA on *Mycosphaerella eumusae* (simplified)**

A thorough analysis of a very vague PRA on the new Sigatoka or Eumusae leaf spot disease has been done by the working group. There is a very high level of uncertainty about the pathogen, particularly concerning its distribution, biology, epidemiology, control strategies and impacts. Closely related pathogens, e.g. M. musicola are present in the PRA area. M. eumusae and M. musicola are similar and can be easily confused. The conclusion is that M. eumusae is harmful but due to discussed uncertainties it is not considered eligible for listing. The Panel recommended making comparisons with closely related species. The uncertainties must be stressed so that the risk manager can make use of it. Lack of information should not be a reason for qualification of an organism as harmful.

The panel recommended rephrasing the conclusions, stating clearly that it always refers to the scientific info available at this moment and addressing the uncertainties.

Once amended the opinion will be adopted at the next plenary meeting.

General issues arising from the discussion on the draft opinions presented:

- It was confirmed that ISPM 11 should be used as guide for the evaluation procedure, with conclusions formulated to comment on the risk of entry, establishment, spread and impact.
- The PRAs in general are lacking the management options thus making difficult to conclude on the status of the pest. Based on the PRAs it can only be concluded whether the organisms can be potentially eligible for consideration of management options.

[1] FAO (Food and Agriculture Organisation of the United Nations) 2007. International standards for phytosanitary measures 1 to 29 (2007 edition). ISPM 11 (2004) Pest risk analysis for quarantine pests, including analysis of environmental risks of genetically modified organisms, p. 141-166.

- Wording based on standardised risk assessment terminology should be used in the opinions and the concluding statements, to ensure a consistent approach.
- The panel agreed that the conclusions need common agreement and should not be an individual Rapporteurs task. The elements of risk should be formulated explicitly.
- The understanding of the term harmful by the Commission services and by the Panel seems different. For the Commission it is important to differentiate between "harmful" and "harmful and eligible for listing". Requests from the Commission to the Panel should be interpreted as to provide an opinion about the harmfulness of an organism as well as about its eligibility for listing. For the Panel the organism appears harmful to a plant but due to numerous uncertainties is not recommended for phytosanitary/quarantine measures. The Commission services would welcome a more specific answer in terms of the probability for entry, establishment and spread and the high level of uncertainty should be explicitly expressed.
- With regard to personal communications The EFSA Scientific Committee confirmed personal communications should be avoided but where used should clearly distinguish between information with supporting (e.g. unpublished) data, and expert opinion, and written text would now be requested to provide documentary evidence to be retained by EFSA.

7. PRESENTATION OF A PROPOSAL ON THE PROCEDURE FOR REVIEW OF PRAS

The Panel Chair presented a draft proposal for the procedure for scientific review of PRAs on quarantine pests. The procedure is suited for one-pest PRA and structured on a scheme which follows ISPM 11. The proposal includes two-stage evaluation: (1) a quick scan followed by (2) a comprehensive evaluation of the PRA. The procedure also includes the writing of the opinion and self- and internal review of the final drafts. The procedure is supported by an Excel spread-sheet, a practical tool for conduction of the evaluation. It is intended to help the evaluator to proceed in a systematic way and to document the work. It assures continuity of the work should personal changes occur in the working group. The procedure does not address the criteria for quality of the information. The criteria will be worked-out at a later stage.

Discussing the draft proposal the Panel commented that although the procedure is based on ISPM 11, different countries follow the standard in different ways and therefore it might prove impractical to strictly follow the standard item by item. It was suggested that the procedure should primarily follow the risk assessment process and the evaluator should look at the PRA through the risk profile. It was recommended to use “detailed evaluation” instead of “comprehensive”. Also, the level of details requested/expected should serve the fitness for purpose principle with wording helpful for the risk manager. With regard to the “shortcomings” it was commented that information is always scarce and therefore the uncertainties should be addressed. The Panel proposed that information identified as important but missing from the PRA and potentially available elsewhere should be included. EFSA could contact the risk assessor asking for additional information. The author of the PRA should make clear if information was not available and deal with uncertainties. In relation to the self- and internal review aimed at assuring the scientific quality of the opinions the Panel commented that it should be fast and the comments inevitably dealt with. Common

approach is needed concerning the risk management options: should they be included and if yes, to what extent?

On the Quick scan the Panel commented that it should be done by the rapporteur or by the working group. Answers "yes/no" are dangerous, the answers might be "grey" and the rapporteur should not decide on it alone. Wording in Initiation should be reconsidered. The question on conclusions should be based on details and some indication of the extent of details needed should be given. The pest categorisation should be based on references. Initial screening of references available for a particular organism should be made by the evaluators to judge whether the risk assessor used relevant references for the PRA. The Quick scan should be done quickly after receipt of the question. It should include discussion in the working group.

The Commission services expressed their concerns with regard to the value of the quick scan for the formulation of the opinion. The clock-stop envisaged by the evaluator at the quick-scan stage to allow for completion of the information needed was perceived negatively. In their view asking for additional references does not require extra time and the decisions on scientific inputs should be made in short time. In addition, making contact with the originator of the PRA endangers the Panel's independence. The Panel should be able to express and justify a negative opinion, too. If a PRA is found to be of poor quality, this should be communicated to the originator of the question. The emphasis should be on delivering first then rectifying the situation. The Panel should formulate its expectations regarding PRAs as the Member States follow their own ways in this process.

The Panel argued that poor PRAs do not allow to answer the Commission question and that the Quick scan is intended to screen for PRAs not suitable for a proper evaluation. The Commission services agreed that more communication with the Panel is needed.

The panel agreed that the procedure needs further refinement and a new draft be presented at the next plenary meeting.

8. MISCELLANEOUS

- Feedback from the Scientific Committee

- EFSA Steering Group on Cooperation (SGC) meeting , 15th May 2007

The Panel Chair reported on the discussion of proposals for scientific cooperation between Member States and EFSA. The outcome of these EFSA scientific cooperation projects (ESCO projects) would be a report or technical advice for the Executive Director. ESCO project groups, consisting of members of Member State Institutions and EFSA Scientific Panels and Scientific Committee, will be set up in 2007 on topics related to harmonisation of risk assessment approaches and emerging risks.

- EFSA Management Board meeting, 19th June 2007

The Panel Chair provided feedback from the MB meeting with particular regard to new rules governing the reimbursement of costs incurred by panel experts and locations of meetings.

- Definition of Emerging Risk

A draft EFSA working definition on emerging risk was adopted, subject to minor amendments and will be published on the EFSA web site. This definition has legal implications, since the term is mentioned in Regulation (EC) No 178/2002.

- Annual Declaration of Interests

A new annual DoI form has been developed, which needs to be filled in now by all Scientific Panel/committee members and its working groups.

- EFSA Review System

The proposal for a review system developed by the Scientific Committee is comprised of four components, i.e. a self review, an internal scientific review, an external scientific review and an appreciation of EFSA's scientific work by the intended user. Such a review system is meant to be understood as an evaluation of the conformity of EFSA's scientific work with best risk assessment practices and should not result in a new evaluation of the data. A revised version will be sent to the Scientific Committee for adoption by written procedure by end of July 2007.

- Standing Committee on Plant Health 29 June 2007

The Scientific Coordinator and the Panel Chair attended the Standing Committee on Plant Health (SCPH) meeting on 29 June 2007 with the aim to present the first year of activity of the Panel and to discuss the opinions on the APHIS document and *Bactrocera zonata*.

Regarding the discussion in the SCPH the Panel Chair reported that the Member States (MS) were satisfied with the quality of the two opinions. The detailed and well referenced work was very much appreciated and considered useful for the risk manager. However, the MS pointed out that the imbalance between the time invested in the risk assessment and its evaluation should be addressed. The MS noticed that a PRA made for one country or region is difficult to adopt for the entire EU. The Panel was advised to address the concept of PRA area versus endangered area. MS criticised the use of personal communications in scientific opinions as in their view the information is usually difficult or impossible to check. France expressed it willingness to reconsider the next set of PRAs envisaged for the EFSA's evaluation.

Commenting on the discrepancy between inputs and outputs the Commission services pointed out that the Panel should strive to achieve balance in its work in order to meet the deadlines and to be transparent and consistent. The Commission services welcomed the Panel's initiative to develop internal protocol for evaluation of PRAs emphasising that the process of review of PRAs needs to be accelerated. Listing of organisms in the EU plant health directive includes specific requirements for import and a good scientific justification for that is needed. EFSA as competent in review of PRAs should express its criticism to inspire the risk assessors to deliver better documents. Dialog is desirable with the Member States and the Commission to achieve common understanding of the level of details required for a PRA.

Responding to the comments from the SCPH the Panel agreed that endangered area is a complex issue and therefore needs to be addressed after deeper consideration probably in consultation with the stakeholders. With regard to personal communications the Chair informed the Panel about recommendations made by the EFSA Working Group on internal and external review of EFSA scientific work (WG INEX). The approach is that the personal communication should be stated by the expert concerned in writing and should indicate the nature of the information involved: whether

it is a personal opinion of the expert or is based on scientifically generated but unpublished data. The value of data is considered higher than expert judgement. For example unpublished data may origin from MS reports, surveys and other sources considered reliable. The emphasis is on reliability of data to realise evidence-based reviewing and decision making. In order to satisfy the risk manager needs in this matter the Panel needs feedback from the Commission services on the detail required.

The Panel also expressed its concerns arising from the review of the DOM PRAs. Applying positive approach to the PRAs with the aim to help the risk manager the Panel conducts time-consuming searches for data and information to complete the PRAs. This in turn leads to conflict between the Commission demand of delivering on time and the scientific quality of the opinions. The Panel stressed that it should be the task of the risk assessor to provide the relevant information. The Panel insisted that preliminary review of a PRA intended for EFSA review should be done so that the missing elements are noticed in time and addressed. The Panel should also be given opportunity to formulate questions to the risk assessors/applicants. It seemed likely to the Panel that guidance for those who prepare PRAs is needed.

- PLH meeting calendar

    - Next WGs for DOM PRAs will convene in July (Viruses – 19-20/07), September (Bacteria – 12-13/09; Fungi – 13-14/09; Arthropods – 20-21/09, Viruses – 25-26/09) and October (Bacteria – 10/07; Arthropods – 12-13/07).

    - Scheduling of plenary meetings:

- 7th plenary meeting – Parma, **19-20 September 2007**;
- Additional 8th plenary meeting, **17-18 October**; the venue to be confirmed;
- The dates of the 9th plenary have been modified and are now **28-29 November**. The WGs need to be rescheduled.
- Meetings in 2008: **16-17 January**, **12-13 March**, **21-22 May**.