

**MINUTES OF THE 14TH PLENARY MEETING
OF THE EFSA SCIENTIFIC PANEL ON PLANT HEALTH
HELD IN PARMA ON 02-03 JULY 2008
(ADOPTED ON 10 SEPTEMBER 2008)**

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PANEL ON PLANT HEALTH

PARTICIPANTS

Members of the PLH Panel

Richard BAKER, David CAFFIER, James William CHOISEUL, Patrick DE CLERCQ, Erzsébet DORMANN SNÉ SIMON, Oľia Evtimova KARADJOVA, Gábor LÖVEI, David MAKOWSKI, Charles MANCEAU, Luisa MANICI, Dionyssios PERDIKIS, Angelo PORTA PUGLIA, Anita STRÖMBERG, Kari TIILIKKALA, Johan Coert VAN LENTEREN, Irene VLOUTOGLOU

Apologies

Bärbel GEROWITT, Alfons OUDE LANSINK, Jan SCHANS, Gritta SCHRADER, Robert STEFFEK, Representatives of the European Commission (DG SANCO) – entire meeting

James William CHOISEUL – second day

EFSA

Riitta MAIJALA, Director of Risk Assessment – agenda #8

Elzbieta CEGŁARSKA, Sharon CHEEK, Giuseppe STANCANELLI, Anna CAMPANINI, Ann DE BLOCK, Sybren VOS – PLH Secretariat

1. WELCOME, APOLOGIES FOR ABSENCE

The meeting was chaired by Mr. Gabor Lövei who welcomed the participants.

Apologies were received from Bärbel Gerowitt, Alfons Oude Lansink, Jan Schans, Gritta Schrader and Robert Steffek for the entire meeting and from James William Choiseul for the second day. Representative of DG SANCO sent their apologies as well.

New staff appointed to the PLH Unit were presented.

Director of the EFSA Risk Assessment Mrs. Riitta Maijala joined the plenary for the agenda #8.

2. ADOPTION OF THE DRAFT AGENDA

The agenda was adopted.

3. DECLARATIONS OF INTERESTS

No conflicts of interest were reported.

The new IT Tool for Declarations of Interest was commented on by Panel members as time consuming.

4. ADOPTION OF THE MINUTES OF 13TH PLENARY MEETING

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The minutes of the 13th Plenary were adopted with minor amendments. The Panel agreed that the draft minutes should be circulated for information purposes within the two weeks following the plenary meeting.

5. REPORT FROM SCPH ON 27 MAY 2008

The Panel Scientific Secretariat gave a report to the plenary from the meeting with the Standing Committee on Plant Health (SCPH) with respect to the DOMs (French overseas Departments) citrus opinions (mandate No EFSA-Q-2006-081 to 095). The SCPH acknowledged the effort evident in the preparation of the opinions, their overall quality and the panel's additional contribution to the formulation of the opinions achieved through searches to identify information and data not originally available in the documents submitted by the original risk assessor.

A discussion arose about the 100 remaining documents awaiting decision for submission to EFSA for evaluation. To optimise and rationalise the work the Panel suggested that the Guidance Document should be put in focus on the panel's activity. The aim is to finalise the Guidance Document in September in order to launch the consultation – involving various parties concerned including stakeholders and public – in October and to finalise it in December.

6. PRESENTATION OF THE STATISTICAL ANALYSIS OF THE SCORE-BASED DECISION RULES

To analyse the decision rule of the formulation of the conclusions by the Panel in the process of evaluation of the French documents, David Makowski studied the relationship between scores and conclusions in the opinions of the PLH Panel. In the DOM opinions where a binary conclusion (harmful – not harmful, as formulated in the Commission requests) had to be made the Panel applied a decision rule. A statistical analysis was made on the following criteria by using the Wilcoxon sum rank test: entry, establishment, spread, impact and uncertainty to identify the rule. The results showed that the Panel's conclusions were significantly based on the impact and that the decision threshold was related to medium-high rating given for this criterion. In conclusion the author stressed that non-binary decision would allow to provide more information on the risk.

The Panel discussed the results, pointing out that the rating values used by the risk assessors and by the Panel were not supported by quantitative data and therefore very subjective. The panel agreed that quantitative approach to pest risk would allow for better incorporation of entry and establishment. With regard to uncertainty it was noted that it should be clearly distinguished from variability. These two concepts need further defining. The panel recommended a closer look at the impact criterion in order to better define it. The panel suggested that other PRAs be included in this analysis.

This work was highly appreciated by the Panel and was considered as a good tool for self-reflection. The document will be shared with the other EFSA Panels. The work on the set of criteria, the combinations between criteria and their scorings will be continued in the Guidance WG.

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7. FIRST REPORTS ON THE PROGRESS OF THE NEW MANDATES

- **Guidance document on the evaluation of pest risk assessments prepared by third parties to justify phytosanitary measures under the Council Directive 2000/29/EC (EFSA-Q-2008-259)**

In order to ensure a transparent and consistent process for evaluation of pest risk assessments by the Panel, a self-task activity was initiated to produce a guidance document on evaluation of pest risk assessments. The reference number of the mandate as registered in the Register of Questions is EFSA-Q-2008-259.

The Rapporteur reported on the progress to date. The process is based on the International Plant Protection Organisation (IPPC) international standard ISPM 11 and the WG is seeking to harmonise the terminology of the IPPC and Council Directive 2000/29. The Panel discussed the proposal for the interpretation of the definition of a 'harmful organism' in Article 2.1.(e) of the Council Directive 2000/29. Further dialogue with the Commission is needed to harmonise the terminology. With regard to scoring issues it was proposed that ratings and descriptions would be developed to ensure a harmonised approach.

Economic, social and environmental impact will be described in the Guidance Document, and presented to the Panel in September following the 3rd meeting of the working group.

The need for fast track evaluation in cases of urgent requests was stressed.

The WG will continue with meetings during the summer period. New members have been accepted to join.

- **Citrus black spot (EFSA-Q-2008-299)**

EFSA was requested to provide a scientific opinion on the pest risk assessment and additional supporting evidence provided by South Africa on citrus black spot *Guignardia citricarpa* Kiely, with regard to the following issues:

- the suitability of the EU citrus fruit producing areas for establishment of CBS in terms of their climatic conditions,
- the likelihood of an introduction, leading to an establishment, of CBS to these areas on CBS infected citrus fruits,
- the appropriateness of the level of protection under the existing management options listed in Annex IV, Part A, Section I, point 16.4 of Council Directive 2000/29/EC.

EFSA was also requested to identify whether effective options, alternative to those already present in Directive 2000/29/EC, could be suggested to prevent introduction of citrus black spot into the Community.

The reference number of the mandate as registered in the Register of Questions is EFSA-Q-2008-299.

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To address the complexity of the question the following sub-working groups have been organized and their Rapporteurs provided the first brief reports:

- *sub WG 1 Climate*

This subgroup will analyse the suitability of the EU citrus fruit producing areas for establishment of CBS in terms of their climatic conditions. The CLIMEX simulation performed in the South African risk assessment was shown based on both the 1930-1950 weather station series and on the interpolated grid for the time series 1960-1990. The importance of repeating the CLIMEX simulations using more recent EU climatic data and thus representative of the EU citrus growing areas was discussed. For this reason collaboration on climatic data was established with the Joint Research Centre of the EU Commission in Ispra (IT). Uncertainties related to the scarce knowledge on the epidemiology of this disease were also discussed.

- *Sub WG2 Fruit pathway*

This subgroup will focus on the analysis of the citrus fruit pathway.

- *Sub WG3 Management options*

This subgroup will analyse the existing and alternative management options. The results of literature searches done on this topic were shown.

The Panel expressed concerns with regard to the reasonability of the deadline for delivery of the opinion. The calendar for submission of the opinion needs however to be respected and the panel will benefit from the full support of EFSA staff.

8. EFSA PLH ROLE IN THE EU FRAMEWORK ON PEST RISK ANALYSIS

Dr. Riitta Maijala, EFSA's Director of Risk Assessment shared with the Panel the presentation given at the meeting of the Chief Officers of Plant Health Services organised by the Slovenian Presidency on 12 June in Brussels. The presentation concerned the EFSA role in protecting plant health in the European Community.

The main objectives for the Panel's future activity were proposed to be two-fold:

- to provide high-quality, independent and transparent scientific advice for decision making in the EU and
- to develop a science-based approach for pest risk assessment in the EU in close collaboration with Member States

Also, information was provided about the mechanism of outsourcing under Article 36 and the call for nominating the institutions competent in the fields of activity of EFSA. In the current list there are 44 organisations from 17 Members States competent in the Plant health area. Currently EFSA has signed 26 Focal Point agreements. The discussion revolved around the role of the Panel, the

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forms of activities proposed and the tools made available by EFSA for collaboration with the member States.

The Panel welcomed the proposals for activities aimed at provision of scientifically sound and timely advice to the EU decision makers. The Panel raised their concerns with regard to the potential issue of independence when involving experts designated by Member States in EFSA activities. Attention must be paid to clear defining of the role of the national experts.

With regard to the ‘peer-review’ of documents submitted in support to claims for phytosanitary measures the Panel was strongly in favour of using the term ‘evaluation’, stressing that the evaluation should be limited to the evidence provided in the original documents, without upgrading.

Comments on the new version of the role paper need to be submitted by the end of August. The economic impact needs to be embedded in the concept of risk assessment of plant pests.

A comment was that some potential PLH organisations the Panel could collaborate with are not on the list of the competent organisations designated in Article 36 by the MS.

The Secretariat agreed to send to the panel details of the call for tender of Article 36 focal points

The Secretariat should inform the Panel in October on the inclusion or not of economic impact studies in the opinions. For the next plenary meeting of September the input of the EFSA Animal health Unit and its Panel on their approach and methodology will be valuable.

9. QUALITY ASSURANCE OF THE EFSA SCIENTIFIC DELIVERABLES

The presentation was postponed to the plenary meeting in September.

10. MISCELLANEOUS

- A draft questionnaire to MS was presented by the Secretariat. Another questionnaire was noted as having been sent recently by EFSA. An additional questionnaire specific to PLH would not be developed further.
- Giuseppe Stancanelli presented briefly the Mexico Guadalajara Colloquium of 9/12 June he attended focussing on the new format of Risk Assessment Aphis is implementing.