

**MINUTES OF THE 18TH PLENARY MEETING
OF THE EFSA SCIENTIFIC PANEL ON PLANT HEALTH
HELD IN PARMA ON 21-22 JANUARY 2009
(ADOPTED ON 18 MARCH 2009)**

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PARTICIPANTS

PLH Panel

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Invited expert:

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EFSA

RA Directorate: Riitta Lisa MAIJALA

PLH Unit: Anna CAMPANINI, Elzbieta CEGLARSKA, Sharon CHEEK, Alexandra LIMPOK, Doreen RUSSELL, Giuseppe STANCANELLI, Sara TRAMONTINI, Sybren VOS, Malene YDESEN

European Commission (DG SANCO)

Guillermo CARDON, Michael WALSH

Apologies

James William CHOISEUL, Bärbel GEROWITT, Gábor LÖVEI, Robert STEFFEK and Anita STRÖMBERG from the PLH Panel and Harry ARIJS from the European Commission

1. WELCOME, APOLOGIES FOR ABSENCE

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

Apologies were received from James William CHOISEUL, Bärbel GEROWITT, Gábor LÖVEI, Robert STEFFEK and Anita STRÖMBERG (PLH Panel); Harry ARIJS (Commission).

2. ADOPTION OF THE DRAFT AGENDA

The agenda was adopted.

3. DECLARATIONS OF INTERESTS

EFSA secretariat screened the annual declaration of interest (ADoI) and specific declaration of interest (SDoI) filled in by the scientific experts invited at this meeting in accordance with EFSA's Policy on Declarations of Interests. With regard to this meeting no other interests than those already declared in the ADoI or in a previous SDoI and screened by EFSA in accordance with its Policy on Declarations of Interests and implementing documents thereof were declared by the experts (see Annex I).

4. ADOPTION OF THE MINUTES OF 17TH PLENARY MEETING

The minutes of the 17th Plenary were adopted.

5. SUMMARY OF THE PANEL ACTIVITY IN 2008 AND PLAN FOR 2009

A presentation on the activities and achievements of the Panel during 2008 was given. Prospects for 2009 were outlined. The Panel contributed to the discussion on this topic and offered their proposals for scientific events in 2009.

6. REPORT FROM THE MEETING WITH THE COMMISSION: EXCHANGE OF VIEWS ON ECONOMIC IMPACT ASSESSMENT IN PLANT HEALTH

In view of the renewal of EFSA Scientific Committee and scientific panels EFSA has requested the Commission to clarify its position regarding the assessment of economic impacts in plant health. The meeting was attended by the Panel Chair and Vice-chairs.

An overview of the discussion was given by the Panel Chair.

The Commission made it clear that the Panel will not be requested to consider economic impacts in their opinions. This does not diminish the importance of this impact, but it is the Commission's responsibility to assess this consideration; it is outside the scope of the Panel. The Commission stated that the Panel would not be required to evaluate social and economic impacts and the concomitant effects this could have on export markets. The risk assessment and risk management functions need to be kept separate but the Commission stressed that the Panel would still be asked to evaluate environmental impacts as it was the science and primarily the biology of plant pests that the Panel addresses in its work.

The Panel discussed the Commission conclusion. The Panel agreed that clarity is needed to formulate appropriate terms of reference for mandates. In response to the Panel's concern about the opinions already delivered, the EFSA RA Director confirmed that no published opinions would need to be re-drafted in the light of this decision as this is part of the evolution of the Panel's work.

In addition to the issue mentioned above the perceived overlap between the activities of EFSA and EPPO was tackled. The development of the new guidance serves the aim of implementing the EFSA principles of risk assessment, namely independence, transparency, high scientific excellence and separation of risk assessment from risk management in the plant health area. The document will use the EPPO scheme as a reference. An expert from EPPO will be invited by the WG to attend the meeting.

With regard to the time frame for the opinion on OPM the Commission was informed that the WG is actively involved in collecting and analysing the data. However while performing this activity it has emerged that data is not readily available nor is it largely applicable to the mandate. Appreciating the data constraints the Commission agreed on extending the deadline for delivery till May 2009 without amendment to the terms of reference, as originally suggested by EFSA.

A number of issues were raised by the Panel. The available data are neither suitable nor adequate to make this assessment, which could have consequences for the expectations of the risk managers. The Panel was informed that the issue of identifying and accessing data

for the scientific panels in EFSA is a recurrent issue throughout the organisation which is why efforts are underway to identify it through activities such as Article 36. The EC considers it important that EFSA starts producing pest risk analyses directly to make them available for an EU level analysis; as members states usually produce PRAs at a national level. A query raised was whether the Panel will be expected to evaluate its own PRAs, effectively performing the role of producer and assessor of the same output. To resolve this potentially problematic scenario, the likely outcome would be that EFSA will use a consultation process to seek comments on the opinion: in fact there is a precedent for this with the EFSA animal cloning consultation process.

The quantity of work and time constraints for making a new PRA constitutes important considerations for future discussion by the Panel.

7. UPDATE ON THE STATUS OF THE DRAFT OPINION ON THE PRA MADE BY UK ON PROCESSIONARY MOTH *THAUMETOPOEA PROCESSIONEA* EFSA-Q-2008-711.

EFSA is requested to provide a scientific opinion on a Pest Risk Analysis (PRA) provided by the United Kingdom on *Thaumetopoea processionea* L., the oak processionary moth (OPM) and in particular whether this organism can be considered as harmful within the meaning of definition mentioned in Art. 2.1(e) of the Council Directive 2000/29/EC.

A presentation on the progress made to date was given.

In recognition of the lack of data experts from EU countries where the pest is present will be invited to the next WG meeting. In an attempt to retrieve information on local situations, forestry entomologists have also been contacted in an effort to address this shortfall.

8. PRESENTATION OF EC PROJECT FUNDED UNDER FP7 PRATIQUE: ENHANCEMENTS OF PEST RISK ANALYSIS TECHNIQUES

A presentation on PRATIQUE project funded by the Commission DG Research under 7th Framework Programme was given to the Panel by the project Coordinator. The main factors behind the establishment of PRATIQUE was a recognition that Pest Risk Analysis is a young science, that there are problems associated with a lack of data, an identified need to enhance the techniques used in Pest Risk Analysis and to ensure that any Pest Risk Analysis produced were fit for purpose and user friendly.

PRA procedures are complex and a brief overview of PRA science was outlined.

The European standards, schemes and guidelines were described in relation to the PRATIQUE mandate. In total 15 different partners are involved in the project: 5 EU Universities, 6 EU Research Institutes, 2 international organisations (CABI & EPPO) and 2 partners from outside EU (CRCNPB & Bio-Protection). Observers are present from EU DGs and Standing Committee on Plant Health, EFSA, and Norway as well as other EU funded projects. The CAPRA template was shown to the Panel during the presentation. The project

is exploring new scientific developments and from this risk mapping has been identified as a useful tool for communicating risk. Selection of criteria to be considered and emergency cases were some of the main subjects addressed during the discussion. A query was raised concerning cost/benefit analysis that usually forms part of the assessment of risk management options. Another question concerned the difference between pest risk analysis and pest risk assessment. The speaker suggested that risk management in EFSA terms could be replaced by decision-making and pest risk assessment should be replaced by pest risk analysis.

A second presentation was given by the invited expert on the activity of Work Package 1 (WP1), which is constructing an inventory of national, European and global datasets to address the problem of lack of data. There are 6 main tasks contained in WP 1:

- 1) Collection of information on the pest and its current distribution
- 2) Collection of information on pathways including trade, production and economic datasets
- 3) Information on the area under consideration as the PRA area
- 4) Information on pest management/pest control measures
- 5) The collection of PRA schemes to enable the identification of good practice
- 6) A novel method to obtain lists of potential plant pests before introduction. This involves the use of sentinel plants and also tree surveys.

The Panel were given the opportunity to ask questions and request further clarification. The speaker emphasised the usefulness of other risk analysis procedures utilised in other disciplines such as animal health and GMOs and can consult other schemes used in impact assessment. Other comments and questions concerned the validation and testing of data, how the uncertainties present in the schemes are analysed, whether decision making is used in the process and who will maintain the database when the project finishes. It was suggested that the datasets from PRATIQUE and the EFSA Article 36 Project PRASSIS are harmonised.

9. DISCUSSION OF THE DRAFT OPINION ON GUIDANCE DOCUMENT ON HARMONISED FRAMEWORK FOR RISK ASSESSMENT IN PLANT HEALTH

To assist the panel with its work, a self task activity has been accepted to produce a guidance document on a harmonised framework for the assessment of risks of organisms harmful to plants and plant products. The mandate is registered as EFSA-Q-2008-704.

The final proposal for the Working Group (WG) structure, organisation and programme of meetings was outlined. In essence the proposal is that the main WG will be divided into sub WGs to address the terms of reference. The items discussed during the first meeting were presented and discussed with the whole Panel.

10. MISCELLANEOUS

In anticipation for increased Commission demand for opinions dealing with upgrading a PRA produced at national level to the EU situation a brain-storming exercise took place among the members of the Panel to identify the scientific requirements and data needed to address this issue.

Contributions from the Panel on this issue included the following. Data on the distribution of host plants and climatic conditions available for the establishment of pests are data which could be readily managed by EFSA with the assistance of the JRC. A distinction needs to be made between the separate elements of building data and using available data. It is envisaged that in the time EFSA has to resolve issues such as terms of reference with the Commission, the WG could commence collecting the available data so that valuable time is not lost. Mindful of the precedent set and experience of the discussions around the terms of reference of mandate for the OPM, the need to define the data required is essential. A further consideration relates to the diversity of crops as this will indicate the types of pest likely to cause problems. For example large geographic areas of the EU are used to cultivate a limited number of crops; areas such as the Po Valley in Italy and the citrus growing areas of the EU.

One of the main barriers for securing good data is the problem of updating the information a task which is often difficult and expensive for some EU countries. Accessing data on trade can also present difficulties. Free access to data is often a unrealistic proposition at present as there are issues around permissions and confidentiality. A further consideration to note in the making of PRAs is that it wholly depends on the capacity of the nation to do it and not all countries have the resources for PRA production.

The EU Directive 2007/2/EC INSPIRE (Infrastructure for Spatial Information in the European Community) was cited as a new reference to take into consideration. The directive can be accessed via the link below:

(http://eurlex.europa.eu/LexUriServ/site/en/oj/2007/l_108/l_10820070425en00010014.pdf)

as this is a European legislative instrument which the EU member nations are bound to. Further the availability of resources and organisation of data coming from EU countries should be the responsibility of the risk assessor (EFSA). It was added that the Commission should support the fact that EFSA fulfils this task.

The PRASSIS project will indicate where and if data are available in each MS. It was agreed that the coordinator of this project should provide the Panel with presentation on the project details.

EUROPHYT, which collects data on non-compliances and interceptions, was indicated as an important source.

In less resourced and smaller countries there are often problems collecting data because it is spread between several institutions. In this respect the intervention of EFSA could be useful for identifying both availability and location.

Also diversity in the methodologies and approaches used by different EU states was cited as an important consideration when collecting and assessing data.

The project SEAMLESS (System for Environmental and Agricultural Modelling: Linking European Science and Society) was indicated to be an important resource to take into consideration (further information is available at: <http://www.seamless-ip.org/> and in particular

http://www.seamless-ip.org/prototype/Documents/SLE_D3.7.5_final%20version.pdf)

Date of next plenary meeting: 18-19 March 2009, Angers, France

Annex I

I. INTERESTS AND ACTIONS RESULTING FROM THE SCREENING OF ADOIs OR SDOIs

a) CONFLICT LEVEL B:

EFSA secretariat screened the ADoI and SDoI filled in by the scientific experts invited to this meeting in accordance with EFSA's Policy on Declaration of Interests. In his ADoI Mr. David Caffier declared the following additional interest: French representative to EFSA special Advisory Forum on Plant Health. In accordance with EFSA's Policy on Declarations of Interests and Implementing documents thereof, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a conflict of Interest (level C). Pursuant to EFSA's procedure on Identifying and Handling Declarations of Interest, a waiver was granted to the expert. Therefore pursuant to EFSA's Procedure on Identifying and Handling Declarations of Interest, the said expert incurs in the limitations identified under point C.III.b¹. of the mentioned document that is indicative level of potential conflict of interest adjusted to level B.

b) INTERESTS BUT NO CONFLICT:

In the ADoI or in the SDoI filled for the present meeting Mr Richard Baker, Mrs. Olia Evtimova Karadjova, Mr. David Makowski, Mr. Alfons Oude Lansink, Mr. Jan Schans, Mrs. Gritta Schrader and Mr. Marc Kennis declared that they are involved in the EU funded research project PRATIQUE. In accordance with EFSA's Policy on Declarations of Interests and Implementing documents thereof, and taking into account the specific matters discussed at the meeting in question, the interest above was not deemed to represent a conflict of interest for the experts concerned.

II. INTERESTS AND ACTIONS RESULTING FROM DECLARATIONS DONE AT THE MEETING

c) NO FURTHER INTERESTS:

With regard to this meeting no other interests than those already declared in the ADoI or in a previous SDoI and screened by EFSA in accordance with its Policy on Declarations of Interests and implementing documents thereof were declared by the experts.

¹ Implementing act to the policy on declaration of interests procedure for identifying and handling potential conflicts of interest
http://www.efsa.europa.eu/cs/BlobServer/General/mb_annex_procedure_doi_en%20221008,0.pdf?ssbinary=true