
SCIENTIFIC COMMITTEE AND ADVISORY FORUM UNIT

Parma, 22 December 2008
EFSA/AF/PLH/M/2008/205/PUB/FINAL

Minutes

First Meeting of the EFSA Advisory Forum

Representatives on Plant Health

Parma, Italy, 8-9 October 2008

MEMBERS OF THE ADVISORY FORUM ON PLANT HEALTH

Chair: *Riitta Maijala*, Risk Assessment Director, EFSA

Austria	<i>Leopold Girsch</i>	Italy	<i>Maurizio Desantis</i>
Belgium	<i>Olivier Wilmart</i>	Latvia	<i>Ringolds Arnitis</i>
Bulgaria	<i>Ana Traykova</i>	Lithuania	<i>Silvija Saunoriute</i>
Czech Republic	<i>Vaclav Stejskal</i>	Malta	<i>Marica Gatt</i>
Denmark	<i>Christiane Scheel</i>	Netherlands	<i>Dirk-Jan van der Graag</i>
Finland	<i>Hannu Kukkonen</i>	Poland	<i>Witold Karnkowski</i>
France	<i>David Caffier</i>	Portugal	<i>Miriam Cavaco</i>
Germany	<i>Jens-Georg Unger</i>	Slovenia	<i>Vlasta Knapic</i>
Ireland	<i>Matthew Clarke</i>	United Kingdom	<i>Stephen Hunter</i>

Observers and Invitees

Norway	<i>Elin Thingnæs Lid</i>	European Commission	<i>Guillermo Cardon</i> <i>Michael Walsh</i>
Switzerland	<i>Alfred Klay</i>	PLH Panel	<i>Jan Schans</i>

Staff of the European Food Safety Authority

<i>Bernhard Berger</i>	<i>Olaf Mosbach-Schulz</i>
<i>Gian Luca Bonduri</i>	<i>Torben Nilsson</i>
<i>Elzbieta Ceglarska</i>	<i>Jane Richardson</i>
<i>Sharon Cheek</i>	<i>Guiseppe Stancanelli</i>
<i>Hubert Deluyker</i>	<i>Sara Tramontini</i>
<i>Georgi Grigorov</i>	<i>Didier Verloo</i>
<i>Elena Marani</i>	<i>Sybryn Vos</i>
<i>Jeffrey Moon</i>	

1 WELCOME AND OPENING OF THE MEETING

Riitta Maijala, Risk Assessment Director of EFSA, opened the meeting by welcoming the Advisory Forum Representatives to the first meeting on Plant Health. Riitta Maijala conveyed the apologies of Catherine Geslain-Lanéelle, Executive Director of EFSA. Apologies were received from Greece, Iceland, Slovakia and Sweden.

A brief introduction to the background of the meeting was provided, indicating EFSA's role with regard to Plant Health and the importance of working in collaboration with Member States in this area. Riitta Maijala introduced Jan Schans, Chair of the EFSA Scientific Panel on Plant Health to the participants.

2 ADOPTION OF THE AGENDA

The Agenda was agreed without amendment or addition. Representatives were reminded by the Chair of the importance of completing the Declaration of Interest (DoI) and advised that support was available from the AF secretariat to help with any problems.

3 ROLE OF THE ADVISORY FORUM

Torben Nilsson provided a brief summary of the functioning of EFSA and explained in detail the operation of the Advisory Forum and the working groups associated with it.

4 EFSA SCIENTIFIC PANEL ON PLANT HEALTH

Jan Schans provided an overview of the EFSA Scientific Panel on Plant Health's involvement in the area of Plant Health since 2006, citing the legal basis for the

work (Regulation 575/2006) and summarising the Mandate. The composition and operation of the Panel was explained providing detail on the tasks of the panel including the 'self tasking' activities. Examples were provided of some of the work.

Latvia thanked the Chair for the invitation to attend the meeting and welcomed the involvement of the Member States (MS). The role of EFSA and the Plant Health Panel (PLH Panel) in risk assessment of new pests where there would be a lack of information was questioned and how this role compared to that of the European and Mediterranean Plant Protection Organization (EPPO). Latvia also requested clarification on the handling of requests from the Commission and peer review of existing PRA where trade with third countries was restricted.

In reply, Jan Schans indicated that EPPO was a valuable organisation for providing Pest Risk Analysis (PRA) and EFSA's main role was in the review of existing PRAs produced by EPPO or MSs. EFSA's work contributes to the evidence and science on which the Commission base their decisions and it would be for the Commission to decide the basis and needs of restrictions. For EFSA to undertake new PRA would depend on the requests from the Commission. Regarding the Phyto-Sanitary controls (SPS) of third countries, this may be something for the Commission to consider.

Germany thanked EFSA for involving MS in the PHL work and raised a number of points. The questions of what is considered to be the point where the PHL panel work should stop and whether risk management options or SPS controls should be considered or if the work should be confined to the point of assessment were raised, along with a request for clarification of the roles of EFSA and EPPO and the associated guidelines that are being produced, indicating the high degree of MS involvement with EPPO.

Jan Schans replied that the Terms of Reference of the Panel and the specific question from the Commission form the basis of how far the work of the Panel will go. The identification of the risk management options and an evaluation of these – rather than a justification – is within the remit of EFSA. The aspects of social, economic and environmental impact can be considered in the formulation of a conclusion. Regarding EPPO guidelines, reference was made in the presentation to the International Standards for Phytosanitary Measures (ISPM) guidelines as these were globally recognised, whereas those of EPPO are not.

The UK welcomed the involvement of MS in EFSA's work and reiterated the need for clarity between the roles of EPPO and EFSA and the interactions between the Commission, EFSA, MS and EPPO and saw the continuation of dialogue between the parties as helpful. The questions of how the Panel makes use of the 'precautionary principle' and how an assessment can be made of the socio-economic aspects of the impacts of pests, citing the difficulty in identifying expertise, were posed

Jan Schans responded indicating that the ‘precautionary principle’ was not an element of PHL work as it related to risk management and not risk assessment. There is particular attention paid to ‘uncertainty’ which will affect the conclusions and therefore influence the likely control measures which will be taken. Jan Schans agreed that as there were no universally accepted models for assessing socio-economic impact, this was a difficult task. Consideration is given to the relative importance of an affected crop and consideration made of the value and prevalence of the crop in formulating the conclusions. Having the range of expertise from MS assists in the considerations and the conclusions, which are not ‘yes/no’, but an indication of the level of the impacts.

5 COMMUNITY PLANT HEALTH POLICY

Guillermo Cardon provided a presentation on the EU Plant Health Regime, giving information on the Commission’s involvement with Plant Health, explaining the legislative framework, activities and emergency measure provisions. The question of whether “the current Community plant health regime responds to the current and expected future needs” was posed with an indication of the history of the development of the regime and Standing Committee on Plant health and Council Working Party of Chief Plant Health Officers (COPH) agreed in-depth evaluation of the existing Community regime and the proposal for a renewed Community plant health strategy and new plant health legislation.

6 DISCUSSION 1: FUTURE ROLE OF EFSA IN PROTECTING PLANT HEALTH IN THE EUROPEAN COMMUNITY

Giuseppe Stancannelli provided a detailed overview of the role of EFSA in the Plant Health context presenting the draft discussion paper on work for the next five years which is aligned to the EFSA Strategic Plan for 2009-2013. Each of the Objectives and Key Initiatives were explained in detail. The strategy had been developed in consultation with the PLH Panel, the Commission and the COPHS.

The UK expressed some disappointment that the proposed EFSA strategy was moving ahead at a time when the EU regime was about to be evaluated and updated and urged that there was a linkage maintained between the two. Similarity was noted between the Objectives and Key Initiatives of EFSA and the EPPO strategy.

Elzbieta Ceglarska replied that the Objectives and Key Initiatives of the PHL Unit were aligned with the EFSA strategic plan which covered all aspects of EFSA’s work. The review by the Commission will be focussed on meeting the needs of European risk managers and during the five years of EFSA’s strategic plan, there will be continued appraisal of the Commission’s activities. This will contribute to the evolution of the Strategy. With regard to EPPO, while there are parallels, EFSA’s primary focus is on the provision of scientific advice in Europe for the use by European risk managers. The importance of cooperation and collaboration is highlighted in the Strategic Plan and, in relation to Plant Health, this will also include a cooperative approach with EPPO.

Poland raised the issue that it is important not only to have PRA but also training courses and workshops where information can be distributed and experience shared. This is something that EPPO do and something that EFSA could be involved in.

Jan Schans acknowledged the work that EPPO has done in this area and agreed the need for cooperation between EFSA and EPPO on a range of initiatives.

Germany stated that EPPO had been serving the Commission with scientific and technical support, playing a role in providing independent advice, since the 1990s and Europe had developed well in the area of PRA through the work of EPPO. Germany highlighted the need for close cooperation and building on what already exists and was very supportive of the EFSA objectives. The importance of developing work in this area for Europe as a region in order to have global acceptance is seen as an important aspect of the work. One area of weakness seen was response to 'outbreaks' and intercepting invasive species and the diversity of reactions between Member States. Often there is a political decision for action before a risk assessment is carried out.

Jan Schans posed the question that if EPPO had provided all the necessary independent scientific advice to the Commission, why was the Commission not always able to use this information for decisions making? Often decisions are made at Member State level as this is where problems are first identified and there is a need for reaction. The EFSA strategy describes how it will input and maximise the effectiveness of its resources in this area.

The Commission indicated that any decision is always based on the available information at a given time. In cases where action needs to be taken urgently, it is not always possible to wait for a full scientific evaluation. The existing legal framework and agreements provide for the ability to take action in such emergencies. Riitta Maijala advised that EFSA requires a request from the Commission to initiate a risk assessment, but there have been situations which require a quicker response and EFSA is continuing to develop the ability to provide robust risk assessment in very short time frames.

France shared the view that the tasks of EPPO were different to those of EFSA and did not see competition between the organisations as both are necessary and complementary.

7 **DISCUSSION 2: DATA COLLECTION AND INFORMATION EXCHANGE**

Hubert Deluyker provided an overview of the Scientific Cooperation and Assistance Directorate, highlighting the importance and need of cooperation and collaboration on data collection and data analysis.

Jane Richardson presented details on the data collection and review of data sources for PRA in Europe and explained how the data will be processed and accessed. Olaf Mosbach-Schulz provided further details on the use of Pest Risk models using climatic data outlining the potential problems and advantages of the system.

Bernhard Berger provided an overview of the scientific cooperation activities, detailing the roles of the Focal Points, the Information Exchange Platform (IEP), Article 36 projects and the Expert Database.

The Netherlands welcomed the call for PRA and the development of a harmonised approach but saw there was potential overlap with the PRATIQUE project. The need for making best use of resources was highlighted.

Elzbieta Ceglarska indicated that EFSA will be collaborating with PRATIQUE over the three years of the project and indicated that there will not be duplication of effort with EFSA taking a broader approach to the risk assessment process.

Poland proposed that the Expert Database include experts with identifiable expertise which can be used by Member States as needed. Bernhard Berger confirmed that this is the case with the applicant being required to specify details of expertise which is then searchable. The database will be accessible to Member States.

Bernhard Berger provided extra information about the development of the expert database and of the criteria that experts must reach in order to be eligible to be included on the database. He explained that the information included is quality checked, but the selection criteria is determined as needed at time of selecting experts for specific functions.

Norway welcomed the development of the expert database and stated it would be useful if the Advisory Forum Plant Health Representatives could have access to the database. This was agreed.

Germany welcomed the information provided on the various initiatives and saw the range of activities as exciting, noting that EFSA was not starting at a zero base and was concerned about possible overlaps with the PRATIQUE project. The questions of whether organisations such as EPPO could participate in the Article 36 research calls and if there was validation of the self declared competence in the applicants on the expert database were posed.

Riitta Maijala acknowledged that EFSA was not starting from zero, but saw no overlapping of work, but rather that EFSA would be collaborating and contributing to other projects. Bernhard Berger provided further details on Article 36 which excluded organisations such as EPPO, because funding is only available to Member State institutions. The Commission agreed that it was not possible for

organisations like EPPO to participate in Article 36 funding, but advocated continuing dialogue between EFSA, EPPO and the Commission. The work of EPPO is seen by the Commission as complimentary to that of EFSA.

Denmark thanked EFSA for the opportunity to participate in the meeting and supported the comments made by Germany regarding avoidance of duplication of activities, with specific reference to the EPPO expert database. The exchange of information and availability of information for the public at national level were seen as important areas to address. Hubert Deluyker responded indicating that EFSA have no desire to duplicate any existing databases and are collaborating with others such as SAFEFOODERA. This could also be pursued with EPPO. On communications to the public, he provided details on the AF communications working group and the development of publications on specific topic areas such as plant health. These are useful ways of sharing communications between EFSA and Member States and can support the requirement to provide information at national level. Torben Nilsson provided information on the activities of the AF working group on communication.

Latvia thanked EFSA for the information that was being provided and also supported the comments from Germany. Regarding the expert database, Latvia asked how the situation is dealt with where the competent authority rejects an expert who requests inclusion. Bernhard Berger replied indicating that the operation of the expert database is done in a clear, transparent way, with an explanation provided on the EFSA website. There are strict eligibility criteria, but the competent authorities have no role in the nomination of experts as they enrol as independent experts.

Action 1: EFSA to provide link to explanation of selection of experts on website along with a link to the expert database site.

The UK reiterated the concerns on duplication of databases and stated other concerns on the use of Member State resources and the difficulties of providing support to all of the organisations such as EPPO and EFSA. The work of EFSA in the area of Bee Health is an example of where EFSA are filling a gap and this is important work, but the UK was cautious about how it could commit funds or resources at a time of decreasing national budgets for supporting laboratory and other services.

Riitta Maijala reemphasised that that EFSA does not wish to duplicate any activities being carried out by other organisations and with limited resources will be developing a cooperative and collaborative approach to progressing work within the remit of the PLH Unit.

8 DISCUSSION 3: HARMONISING APPROACHES TO PEST RISK ASSESSMENT

Jan Schans opened this session with a presentation on Harmonising approaches, using the objectives and conclusions of the 10th Colloquium on Pest Risk Assessment as a basis for the discussion. Some detail was also provided on EFSA's

‘self tasking’ mandate towards harmonisation and of the development of guidance, the evaluation of requests and the evaluation process.

The Netherlands saw the use of Appropriate Level of protection (ALOP) as part of a political decision making process based on assessments of the levels of protection by possible management options in relation to the pests’ potential impacts. The development of guidelines were of a concern as the potential for overlap exists where there are multiple guidelines, although value was seen in having preformatted PRA methodology which EPPO has made progress towards.

Jan Schans responded indicating that most PRAs are not being made following the EPPO guidelines and suggested that there could be a tiered approach with an initial simplified approach being used at national level in many instances.

Poland saw a need for involving experts from various disciplines in the risk assessment process because of the diversity of impacts and a need for a harmonised approach between disciplines. Jan Schans agreed with this view.

Germany expressed the view that any guidance developed by EFSA must maintain a balance and not be in conflict with other developments and welcomed further discussion on the possible use of an ALOP approach, which is not well developed in the Plant Health sector due to difficulties in assessing the diversity of consequences from pest species. With regard to the PRA, Germany saw EFSA as having a major involvement in this area and posed the rhetorical question of what EPPOs continuing role would be, welcoming further discussion on how the mechanisms, expertise and resources can be used to best effect.

Jan Schans response indicated that a role for EFSA in considering ALOP was not suggested, but that there was a need for such a discussion and acknowledged that ALOP is more complicated for this sector.

Switzerland raised concern on the PRATIQUE project on PRA which would deal with general PRA methodology and preformed data sets and advocated a greater understanding of what PRATIQUE’s involvement in PRA is, and what the potential overlap with EFSA is likely to be. Jan Schans outlined EFSA’s interaction with PRATIQUE to date highlighting the different role of developing PRA compared to EFSA’s role of evaluating PRA. Elzbieta Ceglarska added that EFSA will have representation on PRATIQUE and will not only be able to contribute to the process, but also ensure that the work of EFSA does not overlap.

Latvia expressed a desire to have greater clarity in understanding which organisations were doing what and why in order to avoid concerns over duplication of work. Benefit was seen in integrating schemes and procedures, where possible, into an EU framework which will ensure that the work is complimentary and not duplicative. The use of harmonised data across Member States or by the Commission will make comparison of PRA possible and avoid different conclusions. With the increasing requirements for standards in data production (such as accreditation, use of ISO standards) concern was expressed that this could lead to a reduction in PRA at national level because of resource limitations in producing

data that meets the requirements. Latvia also saw the difficulty in using the ALOP approach, but saw value in the approach. With regard to PRA, Latvia saw more importance on them being done rather than who did them and saw the need for exploring all possibilities while avoiding duplication of effort.

Slovenia raised the point of the EU Council discussions and the continuing role of EPPO. The role of the Standing Committee in coordinating the PRA development role and the Commission's interaction with EFSA were seen as important in balancing the work between organisations. The Commission having an observer role in EPPO was seen as a further opportunity to assist in coordination of PRA.

Riitta Maijala stated it was important for EPPO to continue its work and that EFSA desired a collaborative approach with the organisation. The development of EFSA guidance on how to peer review PRA is expected to be complete by the end of the year and with the limited resources available, EFSA does not see a major role in developing PRA.

Austria did not see how the term 'generic' could be applied to PRA, which needed systematic methodology and agreed criteria in each case. Difficulties were seen in how a harmonised approach compared to a case by case approach could be developed with differing levels of data available between different Member States. Austria posed the question of who will be responsible for 'mapping' the data at Member State level to use at EU level, citing potential problems in explaining what exactly the data held related to and the use it had been put to at national level. Regarding the use of the ALOP approach, Austria questioned how the priorities (human health, animal health, environmental and social) would be determined and there would be the need for agreement at EU level on the prioritisation.

The UK followed with comments on the use of a generic approach at national level as a quick process to help pre-screen pests in order to focus on those which are most likely to have adverse impacts. The UK supported the view of Latvia with regard to detailed, structured methodology possibly leading to a decrease in PRA which would have overall negative consequences. Too much focus on methodology could use resources which would be better used in carrying out PRA, with rapidness being required to focus resources where needed.

Jan Schans agreed on the importance of pre-screening to quantify the risks posed. He stated that the Commission found difficulty in basing decisions on current methodologies and PRAs being produced and developments in harmonisation and methodology need to be seen in the context of the purpose of better decision making.

France supported the UK views and welcomed guidance on how to do better PRA, but expressed the need for them not to be too restrictive. Excess use of process and 'ticking all boxes' should not be seen as the objective. France identified difficulties in finding adequate data at national level which weakened PRAs produced. Where minor crops were concerned economic impacts are likely to be small, but other socio-economic aspects are likely to be significant and further

guidance would be welcome in this area. Guidance should also take into consideration pests which are environmental problems.

9 CONCLUDING REMARKS

Riitta Maijala provided a short summary, concluding that the discussions had clearly identified harmonisation, integration and collaboration between all organisations involved in PRA as an important consideration in order to maximise the use of resources and that the EFSA strategic plan for Plant Health will consider these views in detail as it is further developed.

The development of guidance on peer review of PRA was supported and it is necessary to maintain transparency in conducting PRA. The need for data to improve the PRA process is evident and that collecting and identifying available data needs to be done with knowledge of the uncertainty associated with it to assist in the decision making process. Riitta Maijala identified the needs of balancing a harmonised, structured, methodological approach against the ability to conduct quick screening of new threats without always having the time to undertake a full, and longer, scientific assessment and that the role of EFSA is not primarily in the area of conducting PRA but on the evaluation of PRA and promoting PRA methodology development.

The difficulties with the ALOP approach being adapted to PRA were seen as needing further discussion and it would be most likely for the Commission services to progress these discussions as there were not within the EFSA remit.

In closing the meeting, Riitta Maijala restated that it was EFSA's role to progress work in the Plant Health area in a continuous, collaborative means and that the discussions during the meeting were helpful and constructive to EFSA and hopefully were constructive and helpful to the participants.

The participants were thanked for their contributions and attendance.