European Food Safety Authority

PESTICIDES UNIT

SCIENTIFIC PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES

Minutes of the 61st plenary meeting

Held on 28/29 November 2012 at Parma
Session open to observers (with the exception of point 6.1)

(Agreed on 14 January 2013[1])

Participants

- **Panel Members**:

  Mr A. AAGAARD, Mr T. BROCK, Mr E. CAPRI, Ms S. DUQUESNE, Ms M. FILIPIC, Mr A.F. HERNANDEZ-JEREZ, Ms K. HIRSCH-ERNST, Ms S. HOUGAARD BENNEKOU, Mr M. KLEIN, Mr T. KUHL, Mr R. LASKOWSKI, MR M. LIESS, Mr A. MANTOVANI, MR. C. OCKLEFORD, Ms B. OSSENDORP, Mr D. PICKFORD, Mr R. SMITH, Mr P. SOUSA, Mr I. SUNDH, Mr A. TIKTAK, Mr T. VAN DER LINDEN

- **EFSA:**
  - **Pesticides Unit:** Mr H. FONTIER, Mr L. MOHIMONT, Ms M. ARENA, Ms. C. BERGKVIST, Ms S. BOPP, Mr M. EGSMOSE, Mr J. STEINKELLNER, Mr F. STREISSL, Ms. G. BOSCHETTO, Ms A. PASQUIN, Ms M. SODANI, Ms J. RICKETTS
  - **Other EFSA Units/Directorates:** Mr A. SZORADI, Mr D. DETKEN, Mr R. KIRBY, Ms D. MAURICI, Mr R. HARRINGTON

- **Observers:**

  Ms A. ALDRICH (Agroscope ACW - Switzerland), Mr G. GOTTESBUEREN (BASF-Germany)

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Ms J. HOUINS-ROULET (DG SANCO), Mr C. FINARDI (Confederazione Nazionale Coldiretti, Observer) and Mr G. MAZZA (Confederazione Nazionale Coldiretti, Observer).

Observers were invited to introduce themselves before being informed about the code of conduct to be followed during and after attendance.

2. Adoption of the agenda

The agenda was adopted.

[1] The publication of the minutes shall be made without delay in compliance with the Founding Regulation and no later than 15 working days following the day of their agreement.

3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes regarding Declarations of Interests (DoIs)[2] and the Decision of the Executive Director implementing this Policy[3], EFSA screened the Annual Declaration of Interest (ADoI) and the Specific Declaration of Interest (SDoI) filled in by the experts invited for the present meeting. For further details on the outcome of the screening of the ADoI and SDoI, as well as the Oral Declaration of Interest (ODoI) at the beginning of the meeting, please refer to Annex I.

4. Agreement of the minutes of the 60th Plenary meeting held on 3/4 October 2012, Parma

The minutes of the 60th Plenary meeting held on 3/4 October 2012 were agreed by written procedure on 6 November 2012.

5. Report on written procedures since the 60th Plenary meeting

No written procedure has taken place since the 60th Plenary meeting.

6. Scientific outputs submitted for discussion and possible adoption

6.1. Discussion on the Scientific Opinion on the identification of pesticides to be included in cumulative assessment groups on the basis of their toxicological profile (EFSA-Q-2009-00860)

The Chair of the Working Group informed the Panel about the progress made at the WG meetings in October and November. A first consolidated draft opinion is available which follows a new structure, the outline of which was presented.

EFSA informed the Panel about the progress of the outsourced project on data collection for liver, neurotoxicity and developmental/reproductive toxicity carried out in support of the establishment of cumulative assessment groups.

The Panel was informed about the successful application of the methodology of the WG (hazard identification and characterisation of toxicological effects relevant for cumulative risk assessment) on several organs. This will be followed by a focused data collection for these organs in view of elaborating the respective cumulative assessment groups.

The Chair of the WG pointed out that collection of data for grouping is very laborious and requires intensive support from the Pesticides Unit. EFSA appreciated these concerns and is taking actions in this regard.

6.2. Discussion on the Scientific Opinions on the 2009 report of the FOCUS Groundwater working group (EFSA-Q-2011-00754 and EFSA-Q-2011-00753)

The Panel was informed about the progress of the WG regarding the two separate opinions on the FOCUS groundwater report for assessing potential movement of active substances and their metabolites to groundwater in EU (2009).

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[2] http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf
[3] http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf

An initial draft of the first opinion has been circulated to members of the Panel in advance of the meeting for comments. The Panel proposed the expert Jeanne Kjaer to be occasionally invited to the WG as a hearing expert for scientific clarifications regarding the functional tool FOOTPRINT.

6.3. Discussion on the Guidance on aquatic ecotoxicology (EFSA-Q-2009-00001)

The Panel was informed that the revised mandate on the revision of the Guidance Document on Aquatic Ecotoxicology was accepted by EFSA's Executive Director. The Panel was further informed that three rapporteurs have been appointed in consultation between the Chair of the WG and the Pesticides Unit for the first deliverable under this mandate. The Panel was further updated on the results of the Risk Manager consultation performed by the WG via the SCFCAH during the period September-November 2012. Risk Managers were consulted regarding the Specific Protection Goals and Exposure Assessment Goals proposed in the draft guidance on aquatic Risk Assessment. Risk Managers gave their preliminary agreement on the Specific Protection Goals but have asked us to wait until they have seen the full draft Guidance for their final decision.

The draft guidance on the tiered risk assessment scheme for pesticides for aquatic organisms in edge-of-field surface waters was presented to the Panel with the aim of endorsement for public consultation. An overview of the document was presented by two of the rapporteurs and the WG Chair. The full draft with comments provided by the Panel members was discussed. One Panel member raised concerns on the way several issues are dealt with in the draft guidance (e.g. recovery, assessment factors, relation to real field situations) and could not agree to endorsing the draft for public consultation. It was agreed that the Panel member would propose amendments to the draft guidance addressing these concerns for consideration by the WG. Endorsement by written procedure will be sought by mid-December 2012 on a revised draft guidance.

6.4. Discussion on the Scientific Opinion addressing the state of the science on risk-assessment for non-target terrestrial plants (EFSA-Q-2011-00982)

The Panel was informed that the WG is making progress as planned. The WG held an audio-webconference on 10 October 2012 to exchange information on the status of tasks distributed among the WG members regarding drafting and data analysis. The WG will restart with higher meeting frequency in 2013 with the aim of finalising a first full draft scientific opinion to be presented to the PPR Panel at the end of 2013/beginning of 2014.

6.5. Discussion on the Scientific Opinion addressing the state of science on risk assessment for non-target arthropods, the Scientific Opinion addressing the state of science on in-soil risk assessment, the Scientific Opinion on good modelling practice in the context of mechanistic effect models for risk assessment of plant protection products (EFSA-Q-2011-00975, EFSA-Q-2011-00978, EFSA-Q-2011-00989)

The Panel decided to establish a WG in charge of preparing the scientific opinion on good modelling practice and another WG addressing the state of science on risk assessment for non-target arthropods and the scientific opinion addressing the state of science on in-soil risk assessment.

The expertise needed for the development of the opinion on good modelling practice covers the use of effect and exposure models in regulatory risk assessment, statistical analysis and uncertainty analysis. A chair needs to be appointed for this WG. There is a need for external experts with regard to exposure and effects models and their use in regulatory risk assessment.

The area of expertise needed for these opinions includes risk assessment of pesticides for in-soil organisms and for non-target arthropods, statistical and uncertainty analysis, exposure of in-soil organisms and non-target arthropods to pesticides, laboratory and field studies for in-soil organisms and non-target arthropods, effect modelling for in-soil organisms and non-target arthropods, biology of specific groups of in-soil organisms and non-target arthropods, in-soil microbiology, risk assessment methodology and definition of protection goals. External expertise is needed at least in the areas of laboratory and field studies for in-soil organisms and non-target arthropods, effect modelling for in-soil organisms and non-target arthropods, risk assessment methodology and definition of protection goals. Chairs and co-chairs need to be appointed for these WG. Once appointed, and in consultation with the Head of Unit, they will proceed with the selection of external experts on the basis of the required scientific profiles.

7. New mandates

7.1. Discussion on the Scientific Opinion on the potential developmental neurotoxicity of acetamiprid and imidacloprid

EFSA informed the Panel that a new mandate has been received from the Commission requesting a scientific opinion on the potential developmental neurotoxicity of acetamiprid and imidacloprid. EFSA's Executive Director has approved the request, thus committing the Panel to adopt the opinion by 31 December 2013.
EFSA introduced the background and the terms of reference for this mandate requiring evaluation of the current regulatory assessment, existing toxicological reference values and the need for further data. In preparation of the activities, a literature review will need to be carried out.
The Panel decided to establish a WG for this particular mandate. EFSA presented a proposal for the areas of expertise to be covered to deal with the mandate and asked the Panel members for their feed-back and also to indicate their interest in joining the WG in writing after the meeting.
The Chair of the Panel nominated Mr HERNANDEZ-JEREZ as Chair of the WG following consultation with the secretariat.

8. Feed-back from the Scientific Committee/Scientific Panels, working groups, EFSA, the European Commission

8.1. Working Groups of the Scientific Committee

The Chair gave feed-back about the items of relevance for the Panel at the agenda of the 58th plenary meeting of the Scientific Committee which took place on 26 and 27 November. This included the EC mandate on endocrine disruptors, the work programme of the EFSA scientific committee working groups, the draft mandate on environmental risk assessment and the public consultation on the draft opinion 'Addressing the new challenges for risk assessment' of the EC Scientific Committees.

8.2. Feed-back from the Pesticide Steering Committee

The secretariat gave feed-back about the last meeting of the Pesticide Steering Committee which took place in October and informed the Panel about the state of the situation regarding the survey carried out on the needs and priorities identified by Members States regarding the revision and development of guidance documents.

9. Other scientific topics for information and/or discussion

9.1. Quality of EFSA scientific outputs

The EFSA Quality Manager presented the quality management system in place at EFSA and its 3 main components (strategic objectives, implementation and verification). Emphasis was placed on the intention of the EFSA management team to develop a quality management system based on ISO 9001:2008 covering the scientific activities implemented by the end of 2013 and on the external review processes of the scientific outputs.

9.2. Specialised courses on advanced aspects of risk assessment for EFSA Panel members and staff

EFSA has outsourced the organisation of specialised courses on advanced aspects of risk assessment for EFSA panel members and staff. The courses will be organised by the Institute of Environmental Medicine at the Karolinska Institute (SE), the Food and Environment Research Agency (UK) and the National Institute for Public Health and the Environment (NL) and will cover 3 different scientific areas. They will be delivered in 2013, 2014 and 2015.

9.3 WG deliverables

Further to the discussion initiated by the Chair of the Panel at the previous plenary meeting, the secretariat presented the different modes of consultation of risk management bodies on the specific needs of the decision-making processes to be considered in the preparation of the scientific outputs of the Panel.

10. Questions from observers

The Chair granted the observers the opportunity to ask questions in a dedicated session after they had observed the meeting. These questions, which had been circulated more than one week in advance of the meeting, were answered by the PPR Panel. An answer was also given to the question from Mr Corrado Finardi, who did not attend the meeting but made an explicit written request to have his question addressed.

Question from Ms Annette Aldrich (Agroscope ACW – Switzerland): How does EFSA see collaboration with non-EU states developing in the future?

Answer:

At individual level, the EFSA policy allows non-EU experts to become members of Panels and WGs, when appropriate candidates from Members States cannot be identified.

At institutional level, to ensure effective coherence between risk assessment, risk management and risk communication functions, EFSA has legal obligations of cooperation

with competent bodies in EU Member States, through the Advisory Forum, and the promotion of a European network of organisations operating in the fields within EFSA's mission (Article 36 of the General Food Law).

At international level, Article 31 ("Scientific and technical assistance") of the General Food Law stipulates that for the purpose of providing scientific and technical assistance to the Commission, EFSA shall work in close cooperation with all organisations operating in the field of data collection, including third-world countries or international bodies. In this regard, EFSA has already concluded cooperation agreements with the US-FDA, Health Canada, Food Safety Commission of Japan, FSANZ (Australian food safety authorities), NZFSA (New Zealand food safety authorities) and with WHO. These agreements are all more or less related to exchange of information and views on relevant scientific technical data in the fields of EFSA´s mission, including risk communication.

Finally, based on the objectives of EFSA´s Science Strategy 2012–2016 and EFSA´s document "International activities – a strategic approach" (2009) EFSA is preparing an implementation plan for a more integrated approach to future international activities.

Question from Mr Bernhard Gottesbueren (BASF – Germany): Could the PPR Panel provide greater clarity on the proposed timetables for transformation into guidance of the various opinions that are presently out there?

Answer:

EFSA received a mandate from the European Commission (DG SANCO) on 31 July 2012 requesting EFSA to prepare three separate EFSA Guidance Documents. The proposed timelines for the Guidance Documents are:

- EFSA Guidance Document on clustering and ranking of emissions of active substances of plant protection products and transformation products of these active substances from protected crops (greenhouses and crops grown under cover) to relevant environmental compartments: to be delivered 18 months after acceptance of the Terms of References by EFSA.
- EFSA Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT50 values of active substances of plant protection products and transformation products of these active substances in soil: to be delivered 18 months after acceptance of the Terms of References by EFSA.
- EFSA Guidance Document for predicting environmental concentrations of active substances of plant protection products and transformation products of these active substances in soil. After acceptance of the Terms of References by EFSA, the Guidance Document will be delivered nine months after the software tools have been received via the procurement CFT/EFSA/PRAS/2012/03. The software tools are expected to be available in the second half of 2013.

EFSA accepted the mandate from the European Commission on 9 October 2012. More information concerning the Mandate (M-2012-0252) can be found in the EFSA link to requests and mandates.

Could the PPR Panel explain how it is intended to sustain a high level of scientific guidance for risk assessment if at the same time, highly experienced scientists in academia and regulatory authorities, who have already been involved in regulatory RA schemes, are excluded or downgraded due to a strict interpretation of the rules on potential conflicts of interest?

Answer:

The Policy on Independence and Scientific Decision-Making Processes of the European Food Safety Authority has been established by the Management Board (MB) of EFSA and implementing rules regarding declarations of interest have been adopted by a decision of the Executive Director (ED) of EFSA. The Policy of the MB and the Decision of the ED are available on the EFSA website.

A key criterion of the new policy is now whether the organisation for which an interest is declared can be considered as a Food Safety Organisation (FSO) or not. To be considered as a Food Safety Organisation, the organisation must either be on the list drawn up by the MB of organisations which may assist EFSA with its mission (the so-called article 36 list) or meet 3 criteria:

- Carrying tasks in the EFSA's mission
- Pursuing public interest objectives
- Having a governance ensuring independence and integrity.

Universities and regulatory authorities normally meet these criteria and experts are never excluded based on employment by these organisations.

When an experienced scientist, from academia or regulatory authorities which have participated in a regulatory assessment scheme, is involved in an EFSA mandate overlapping with this scheme, the possible impact is that he would not be eligible to chair the EFSA WG. He can nevertheless draft parts of the opinion, participate to the decision-making phase of the working group and also be nominated as rapporteur.

Therefore the situation depicted in the question is not a threat for the scientific quality of the work of the Panel.

There are, however, situations where an experienced scientist from academia or regulatory authorities is excluded from a WG:

- when an expert would have to review his own work
- when the areas of research of the expert in the scope of the mandate of the WG are funded for more than 25% by the private sector
- when the expert has interests under activity I, II, III and V with non FSOs in the scope of the mandate of the WG.

Question from Mr Corrado Finardi (Confederazione Nazionale Coldiretti, Observer: I'd like to learn more about the more recent evidence on interaction effects or cumulative of different PPR which is quite an issue at least in Italy.

Answer:

Multiple pesticides occurring in food might exert combined actions, and indeed, over the last years an abundance of public literature on possible combination effects of chemicals in food has become available. In theory, such combination effects could be dose addition (when the toxicological effects of the individual compounds are based on the same mode of action), response-addition (individual compounds have different mode of actions, but they might sum their effects) and interaction of the compounds. Interactions could be that the effects of two or more substances are greater (synergistic, potentiating or even supra-additive) or less (antagonistic, inhibitive, sub-additive or infra-additive) than the individual effects of the substances.

In 2008 EFSA's PPR Panel already published a scientific opinion presenting a methodology for cumulative risk assessment applicable to dose addition. In 2009 a scientific opinion in which this methodology was tested with a group of pesticides (triazoles) was published. Currently a scientific opinion is being prepared in which cumulative assessment groups of

pesticides are established and this opinion is planned for adoption in April 2013. This will be the first step in the gradual implementation of cumulative risk assessment for pesticides in the EU.

In 2013, EFSA's PPR Panel will also commence its work on evaluating the relevance of response-addition for cumulative risk assessment of pesticides.

As far as the third mechanism of combined toxicity is concerned (interactions), and on the basis of a review of the available scientific information, EFSA's PPR Panel concluded in its opinion of 2008 that for pesticides residues, which occur in the diet only at very low concentrations (i.e. well below the No Adverse Observed Effect Level), such interaction effects are not anticipated.

I'd like to know if it still holds true the statement previously made by EFSA that the major health concerns may regard cumulative and not simply interaction effects (ie multi-site effects should be less detrimental than single site-effects).

The statement that cumulative effects caused by interaction of individual substances (see above) are not expected for pesticides present as dietary residues, still holds true as we are not aware of substantial scientific evidence proposing a potentially significant role of interaction effects for pesticide residues. Based on a review of the available data that showed that interaction of substances in mixtures is unlikely to occur at low doses (concentrations), EFSA's PPR Panel concluded that for pesticides residues, which occur in the diet only at very low concentrations (i.e. well below the No Adverse Observed Effect Level) such interaction effects are not anticipated. See PPR Panel Opinion from 2008, available at the EFSA webpage from http://www.efsa.europa.eu/en/efsajournal/pub/705.htm).

Furthermore, in the Scientific Opinion on "Toxicity and Assessment of Chemical Mixtures" (published on the DG SANCO website in 2011 and available from http://ec.europa.eu/health/scientific_committees/environmental_risks/docs/scher_o_150.pdf) there are no suggestions that the statement should be reconsidered.

11. Any Other Business

The final EFSA statement on the Séralini paper was circulated for information to the members of the Panel.

Annex I

INTERESTS AND ACTIONS RESULTING FROM THE SCREENING OF ADOI OR SDOI

In the ADoI or in the SDoI filled for the present meeting, Dr M. Klein and Dr A. Tiktak declared the following interest: membership of the FOCUS Groundwater Working Group. In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes regarding Declarations of Interests (DoIs) and the Decision of the Executive Director implementing this Policy, and taking into account the specific matters discussed at the present meeting, the above interest was deemed to represent a Conflict of Interest regarding the item 6.3 (Scientific Opinions on the 2009 report of the FOCUS Groundwater working group). This resulted in the impossibility for the experts to be present when that item was discussed by the Panel.