Scientific Panel on Plant Protection Products and their Residues

Minutes of the 70th Plenary meeting

Held on 08-09 October 2014, Parma (Italy)

(Agreed on 16 December 2014)

Participants

- **Panel Members:**

  Theodorus Brock, Sabine Duquesne, Metka Filipič, Antonio F. Hernandez-Jerez, Karen Ildico Hirsch-Ernst, Susanne Hougaard Bennekou, Michael Klein, Thomas Kuhl, Ryszard Laskowski, Matthias Liess, Alberto Mantovani, Colin Ockleford, Bernadette Ossendorp, Robert Smith, Ingvar Sundh, Aaldrik Tiktak, Ton van der Linden.

- **EFSA:**
  - Pesticides Unit: Charlotte Bergkvist, Federica Crivellente, Arianna Chiusolo, Mark Egsmose, Magda Florio, Anja Friel, Luc Mohimont, Ragnor Pedersen, Marize Solano, Franz Streissl, Andrea Terron, Manuela Tiramani, Laura Villamar Bouza
  - Executive Office: Diane Lefebvre

- **Observers:**
  - René Bibars-Reiter (Nufarm GmbH & Co.KG), Peter Day (ECPA), Klaus Hammel (Bayer CropScience), Patrick Kabouw (BASF – The Chemical Company), Carole Langrand-Lerche (Bayer CropScience), Karin Lautenschlager (AGROSCOPE), Francesca Militello (EXPEDIA MRCC), Claudia Mochen (OXON ITALIA S.p.A.), Enrica Pierobon (EXPEDIA MRCC), Christian Strupp (ADAMA Germany GmbH).

1. Welcome and apologies for absence

The Chair of the Panel, Bernadette Ossendorp, welcomed the participants.

Apologies were received from Alf Aagaard, Ettore Capri and Paulo Sousa (Panel Members), Michael Walsh (DG SANCO), Vincenzo Ferrantelli (Istituto Zooprofilattico Sperimentale della Sicilia), Alberto Linguadoca (EXPEDIA MRCC Srl), Peter Sutton (Syngenta), Antonio Vella (Istituto Zooprofilattico Sperimentale della Sicilia) (Observers).

The Panel was informed that Daniel Pickford resigned from the Panel and its Working Groups.

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2. Brief introduction of Panel members and Observers

The Panel Members and the Observers introduced themselves, indicating their affiliation and their specific interest in attending the meeting.

3. Adoption of agenda

The agenda was adopted without changes.

4. Declarations of Interest of Scientific Panel members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes[1] and the Decision of the Executive Director on Declarations of Interest[2], EFSA screened the Annual Declarations of Interest and the Specific Declarations of Interest filled in by the Scientific Panel members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

5. Presentation of the Guidelines for Observers

The secretariat presented the EFSA guidelines for observers and provided information on the code of conduct during and after the Plenary meeting.

6. Agreement of the minutes of the 69th Plenary meeting held on 21-22 May 2014, Parma (Italy)

The minutes of the 69th Plenary meeting, held on 21-22 May 2014, were agreed by written procedure on 11 July 2014 and published on the EFSA website.

7. Report on the written procedures since 69th Plenary meeting

The Scientific Opinion addressing the state of science on the risk-assessment for non- target terrestrial plants was adopted by written procedure on 10 July 2014 (**EFSA-Q-2011-00982**).

8. Scientific outputs submitted for discussion

8.1 Scientific Opinion on a proposal for a Guidance on how aged sorption studies for pesticides should be conducted, analysed and used in regulatory assessment (FERA, 2012) (EFSA-Q-2014-00217)

The chair of the WG updated the Panel on the progress of the Scientific Opinion. The WG will meet again on the 9th and 10th of October 2014. Three selected hearing experts will present information and answer specific questions from the Working Group on the guidance proposal during a technical hearing in November 2014.

Question asked by Klaus Hammel after the Panel discussion:

a) Will field studies be considered in this Opinion?

[1] http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf
[2] http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf

Answer: This is currently not considered as an option in the proposal for guidance. Therefore it is not likely that the Panel will consider the usefulness of field studies for this Scientific Opinion.

8.2 Scientific opinion addressing the state of science on risk assessment for non-target arthropods (EFSA-Q-2011-00975) and Scientific Opinion addressing the state of the science on in-soil risk assessment (EFSA-Q-2011-00978)

The chair of the working group gave a short overview on the draft opinion which was sent to the Panel members in advance of the Plenary meeting. Main issues identified and comments submitted by the Panel Members were discussed. The recommendations of the Panel to improve the document were noted and will be forwarded to the Working Group in view of preparing a revised draft opinion. The adoption of the opinion is planned to take place at the forthcoming Plenary meeting.

Comments by Patrick Kabouw after the discussion:

a) The data which have led to the conclusion in ESCORT 2 that the two standard test species are the most sensitive ones are still available. It was offered to send them to EFSA. These data could also be used to explore further the use of SSDs as an intermediate step in a tiered risk assessment.

   Answer: the Panel welcomes this offer to receive the data. They will be considered when developing the Guidance.

b) It was suggested to use the database for GMOs to identify focal species for non-target arthropods.

   Answer: EFSA will consider this database when developing the Guidance.

c) It was proposed to develop intermediate tiers linking field scale and landscape scale assessments for non-target arthropods.

   Answer: EFSA will consider this approach when developing the Guidance.

Question asked by Patrick Kabouw after the discussion:

a) Was the program ALMASS which was used as an example to illustrate off-field effects from in-field impacts evaluated according to the good modelling opinion of EFSA? It was recommended to look also into other models.

   Answer: The working group did not look in detail whether the ALMASS model is in line with the good modelling practice. It is used as an example in the opinion and it is not recommended at this stage to use the ALMASS model for risk assessment.

b) What is the timeline of the development of the GD?

   Answer: The Guidance Document will be developed within two years after agreement on specific protection goals by risk managers (EU commission and Member States).

Comment by Christian Strupp after the discussion:

a) It would be appreciated if EFSA can make it very clear in scientific opinions that the principles discussed are not all ready for regulatory decision making. The line between scientific opinions and guidance got recently blurred, and the choice of titles was unfortunately supporting that (i.e. for example among others: EFSA Journal 2012;10(4):2665: "Scientific Opinion: Guidance on…", filed in the EFSA systems incorrectly under status "Guidance Document"). The consequence is that MS are starting to use Scientific Opinions like guidance, while the document clearly concludes that for many issues, the methodologies are not available at the time.

Answer: The mentioned example (EFSA Journal 2012;10(4):2665) is actually a guidance document. The confusion comes from the fact that both scientific opinions and guidance documents adopted by a Panel of EFSA under article 29 of Regulation (EC) No 178/2002 (General Food Law) are legally defined as 'Scientific Opinions'. The difference is only captured in the title of the document itself ("Scientific Opinion on…" or "Guidance on…"). It is important however to keep in mind that a guidance formally acquires a status of reference document only after the Standing Committee on Plants, Animal, Food and Feed (formerly the Standing Committee on the Food Chain and Animal Health) has taken note of it and decided on an implementation date. Only Guidance documents (and not Scientific Opinions) are subject to this procedure.

8.3 Scientific opinion on the effect assessment of pesticides for sediment organisms in edge-of-field surface water (EFSA-Q-2012-00959)

The Chair of the Working Group informed the Panel on the progress of the activities. Two Working Group members have resigned and the tasks of these members have been re-distributed to the remaining members. The Working Group met on the 7/8 October 2014. The Chair of the Panel has sent a request to EFSA for an extension of the deadline to adopt the Opinion.

Comments by Klaus Hammel after the discussion:

a) More dissipation and processes factors will need to be considered due to the complexity of the sediment compartment.

Answer: We agree to your consideration. A solution could be to run TOXWA over longer time window e.g. 20 years.

Question asked by Patrick Kabouw after the discussion:

a) Does the Panel consider introducing a tiered approach – and if this is the case what will it look like?

Answer: The intention is to introduce a tiered approach in the Scientific Opinion. As it is still under development an outline of the structure is not available.

8.4 Scientific Guidance of the PPR Panel on the establishment of the residue definition to be used for dietary risk assessment (EFSA-Q-2013-01001)

The Panel was informed that the Standing Working Group of the Scientific Committee on genotoxicity has been asked to provide comments on the strategy proposed by the Working Group for the assessment of the genotoxicity of pesticide metabolites.

A call for application for the compilation of a database, specific for the pesticide active substance and their metabolites, comprising the main genotoxicity endpoints has been

launched by EFSA in summer and closed on 30th of September 2014. The submitted applications are under the evaluation process.

Considering that the guidance will imply the application of new tools and approaches which have so far never been used systematically in pesticide regulatory assessments and will require new resources, the Panel agreed to convey this information to the Pesticide Steering Network for raising the awareness of Member States and anticipate the need for preparation and eventual training programmes.

Question asked by Carole Langrand-Lerche after the discussion:

a) How does the guidance under development articulate with the current OECD guidance document on the residue definition and the OECD test guideline 501, in particular regarding the identification of metabolites?

   Answer: The guidance does not alter the data requirements and respective recommended test methods to perform the studies, in particular regarding the identification of metabolites, and assumes that the information provided on the residue behaviour of active substance meets the requirements of the regulation. It will propose an approach allowing the toxicological characterization of each metabolite identified in conformity to the legal requirements. It intends to translate the general principles of the OECD guidance document into a consistent and stepwise process using factual information and specific methodologies, which leads to reproducible outcomes.

Question asked by Christian Strupp after the discussion:

a) What is the scientific evidence to consider genotoxicity as an endpoint independent of carcinogenicity?

   Answer: Rodent carcinogenicity data are considered as the "gold standard" in the context of correlations between in vitro genotoxicity and carcinogenicity in order to assess if a chemical substance can be considered to be an in vivo carcinogen. Historically the genetic toxicology testing battery has been designed to be used as a surrogate for carcinogenicity testing. The potential issue is whether a negative rodent carcinogenicity study can over-rule positive in vivo genotoxicity results. Clear evidence of genotoxicity in somatic cells in vivo should be considered as an adverse effect per se, since genotoxicity is also implicated in degenerative diseases other than cancer (EFSA journal 2011;9(9):2379). The accumulation of DNA changes in somatic cells has been proposed to play a role in degenerative conditions such as accelerated aging, immune dysfunction, cardiovascular and neurodegenerative diseases (Hoeijmakers 2009; Slatter and Gennery 2010, De Flora & Izzotti 2007, Frank 2010).

Note: Additional and very topical questions were raised about this agenda point, which cannot be addressed in these minutes because they would request making public elements of the draft guidance which are still confidential and not finalized.

8.5 Scientific Opinion of the PPR Panel investigating experimental toxicological properties of plant protection products having a potential link to Parkinson's disease and childhood leukaemia (EFSA-Q-2014-00480)

This mandate has been approved by EFSA on the 1st of July 2014. Considering the interest and the importance of the topic, EFSA finds appropriate to place this new activity of the PPR Panel in the context of a wider corporate project with participation of the national and international partners of EFSA. This will include at least the organisation of a stakeholder conference in 2015 and of a scientific conference in 2017.

Considering the scientific complexity of this work, and in the expectation that it might consider scientific approaches not commonly used in current risk assessment of pesticides, EFSA also finds appropriate to proceed with a public consultation on a draft of the scientific opinion before its adoption. The deadline for the adoption of this Opinion is the 30th of June 2016.

The establishment of a Working Group was agreed and the Chair of the Panel nominated Susanne Hougaard as Chair of this Working Group and Alberto Mantovani as vice-Chair. The areas of scientific expertise needed for this mandate include neurotoxicity, neurodegeneration, Parkinson's disease, blood disorders, childhood leukaemia, development and assessment of Adverse Outcome (AOP) Pathway for Parkinson's disease and childhood leukaemia and regulatory assessment of pesticides. The need for external expertise was identified.

The Secretariat informed the Panel that a call for tender for a systematic literature review on Parkinson's disease and childhood leukaemia had been launched by EFSA. The deadline for submission of offers was the 29th of October 2014.

8.6 Scientific Opinion of the PPR Panel on the follow-up of the findings of the External Scientific report 'Literature review on epidemiological studies linking exposure to pesticides and health effects' (University of Ioannina Medical School, 2013) (EFSA-Q-2014-00481)

This mandate has been approved by EFSA on the 1st of July 2014. Considering the interest and the importance of the topic, EFSA finds appropriate to place this new activity of the PPR Panel in the context of a wider corporate project with participation of the national and international partners of EFSA. This will include at least the organisation of a stakeholder conference in 2015 and of a scientific conference in 2017.

As the work about epidemiological studies on pesticides is a new type of scientific activity, EFSA also finds appropriate to proceed with a public consultation on a draft of the Scientific Opinion before its adoption. The deadline for the adoption of this Opinion is the 31st of March 2017.

The establishment of a Working Group was agreed and the Chair of the Panel nominated Antonio Hernandez as Chair of this WG. The areas of scientific expertise needed for this mandate include pesticide toxicology, pesticide exposure assessment, pesticide exposure method/analysis, epidemiology, biostatistics and regulatory assessment of pesticides. The need for external expertise was identified.

9. Feedback from the Scientific Committee, the Scientific Panel, EFSA, the European Commission

9.1 Scientific Committee and other Scientific Panel(s)

The Panel was informed on the outcome of the last meetings of the Scientific Committee which took place in July and September 2014 and about the progress of the Working Groups of the Scientific Committee with representatives of the Panel (Working Groups on guidance review, on environmental risk assessment (overarching issues), on uncertainties in risk assessment and on emerging risks). Bernadette Ossendorp has been appointed as member of the Working Group of the Scientific Committee on uncertainties and Thomas Kuhl agreed to substitute Metka Filipič in the Working Group of the Scientific Committee on guidance review.

9.2 EFSA

9.2.1 Update 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 Panel agreed changes to the Scientific Opinion on the identification of pesticides to be included in cumulative assessment groups on the basis of their toxicological profile, as a result of the comments submitted during the public consultation which was conducted from 17th of July to 30th September 2013, after the adoption of the Opinion. An updated version of the Scientific Opinion will be republished by EFSA, replacing the previous one.

9.2.2 Update on the Scientific Opinion on the developmental neurotoxicity potential of acetamiprid and imidacloprid (EFSA-Q-2012-00958).

EFSA met informally in June 2014 with the companies supporting the active substance acetamiprid and imidacloprid, or their representatives, about their respective responses to the Opinion.

The Panel was informed by the Secretariat on the content of the responses and decided to ask the Working Group which was in charge of the preparing the opinion to consider the submitted arguments in detail and make proposal to the Panel on follow-up actions, including a possible technical hearing.

10. Other scientific topics for information and discussion

10.1 Implementation of cumulative risk assessment of pesticides residue

The Secretariat informed the Panel on the approval by the EFSA management of a new project on the implementation of cumulative risk assessment of pesticides.

This project will include the following deliverables:

a) 2 External Scientific Reports on the cumulative exposure assessment to pesticides regarding their effects on the nervous system and thyroid, using the Monte Carlo Risk Assessment (MCRA) tool developed under the ACROPOLIS project and owned by the Rijksinstituut voor Volksgezondheid en Milieu (RIVM) in the context of a Framework Partnership Agreement between EFSA and RIVM;

b) 2 Scientific Reports of EFSA on the cumulative exposure assessment to pesticides regarding their effects on the nervous system and thyroid, using the SAS (Statistical analysis Software) programme;

c) 2 Scientific Reports of EFSA on the cumulative risk assessment to pesticides regarding their effects on the nervous system and thyroid;

d) 1 External Scientific Report on the toxicological data collection and analysis to support grouping of pesticide active substances for cumulative risk assessment of effects on the nervous system, the liver, adrenals, eyes, reproduction, development and thyroid;

e) 7 Scientific Reports of EFSA on the establishment of cumulative assessment groups of pesticides regarding their combined effects on the nervous system, the liver, adrenals, eyes, reproduction, development and thyroid.

The Scientific Reports of EFSA mentioned under c) and e) will be submitted to the Panel for peer-review and endorsement.

Questions from and answers to Observers

1. Mr Christian Strupp

1.1 In absence of guidelines to attempts to harmonize investigations: what kind of scientific quality criteria is EFSA planning to follow in evaluation of epidemiology data?

Answer: Point 5.9.4 of section 1, part A of the Annex to the Commission Regulation (EC) No 283/2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market indicates that applicants should submit relevant epidemiological studies, where available; and they have to be evaluated during the approval process.

In 2013, EFSA published an External Scientific Report 'Literature review on epidemiological studies linking exposure to pesticides and health effects' carried out by the University of Ioannina Medical School (Ntanzi et al., 2013).

The report is based on a systematic review of epidemiological studies published between 2006 and 2012 and summarises the association between pesticide exposure and 23 major categories of human health outcomes. Despite the large number of research articles and analyses (>6,000) available, the authors of the report could not draw any firm conclusions for the majority of the health outcomes. This observation is in line with previous studies on environmental epidemiology and in particular on pesticides which all acknowledge that such epidemiological studies suffer from many limitations and large heterogeneity of data. Nevertheless, the results of the report are in line with similar reports published in Europe, and thus raise a number of questions and concerns, with regard to pesticide exposure and the associations with human health outcomes. The results of the report also open the way for a discussion on how to integrate epidemiological studies into pesticide risk assessments.

As a follow up of this report, EFSA launched in 2013 a project which is including the preparation of a Scientific Opinion on the follow-up of the findings of the External Scientific report 'Literature review on epidemiological studies linking exposure to pesticides and health effects'. The purpose of the Scientific Opinion is to address the methodological limitations identified in epidemiological studies and make recommendations to improve the studies in order to facilitate their integration into the regulatory pesticide risk assessment. More details on the tasks of the PPR Panel can be found in the respective mandate.

1.2. What is the scientific basis for shifting the quantitative hazard characterization (i.e. NOAEL SETTING) of insecticides from the relevant endpoint (i.e. CNS or PNS cholinesterase inhibition) to an indicator/marker without biological function (blood cholinesterase inhibition) despite availability of the relevant data?

Answer: The question refers to the endorsement by the PPR Panel of the approach taken in the peer review to set the relevant chlorpyrifos reference values. The rationale adopted by the MSs, and endorsed by the PPR Panel, while discussing the ChE inhibition, was based on the following points:

- The importance of measuring acetylcholinesterase activity in both central and peripheral nervous tissues for a complete hazard assessment.
- Whole brain measurements of AChE inhibition may reveal little or no change in activity while masking significant changes in specific brain regions.
- Significant inhibition of red blood cell (RBC) ChE occurred at doses below those that cause brain ChE inhibition.

- RBC cholinesterase inhibition is a surrogate of the peripheral nervous system in animals and of the peripheral and central nervous systems in humans.
- AChE inhibition data from the peripheral nervous system potentially have unique value because many of the adverse signs and symptoms are based on effects on the peripheral nervous system.

In addition, there is increased evidence supporting a new role for AChE in bone marrow, where red blood cells (RBC) are produced, particularly in the regulation of hematopoiesis (proliferation and differentiation of blood cell lines from their progenitors). This data, along with the fact that both neural and RBC AChE are encoded by the same gene, supports RBC AChE to be used as the most sensitive and reliable endpoint for risk assessment of OPs.

AChE also plays a role for axonal outgrowth, synaptogenesis, cell adhesion and neural migration during nervous system development. This role is unrelated to acetylcholine hydrolysis in synaptic clefts. Thus, as AChE inhibition in neural tissue would dismiss this relevant function during neurogenesis, a more sensitive endpoint should be used instead for risk assessment of OPs (e.g., RBC AChE).

Considering the available studies, cholinesterase inhibition was considered the most sensitive endpoint on which reference values should be based. It was proposed to use the Red Blood Cell (RBC) cholinesterase (ChE) inhibition (>20 % decrease), decreasing earlier and more than brain cholinesterase, and considered as reliable and relevant 'surrogate' as brain cholinesterase inhibition, to derive reference values.

1.3. THE EFSA Scientific Opinion on Dietary Metabolites (EFSA Journal 2012;10(07) asks (if the exposure exceeds the TTC) for a comparative 28 d Toxicity study as a 'first step' using the 'same experimental conditions'. Is this meant to be a repeat of the 28 d study on the active substances, as in many cases 'the same experimental conditions' – are difficult to archive – or will there be clear guidance under which circumstances existing vertebrate data still will be acceptable?

Answer: The scientific opinion on the evaluation of the toxicological relevance of pesticide metabolites adopted in 2012 reviewed different approaches to identify relevant metabolites for dietary risk assessment, but has not the status of a guidance document. The PPR Panel is now elaborating this guidance which should be a practical instrument, aimed at helping risk assessors and stakeholders to adopt such definitions based on a combination of the scientific tools described in the opinion. This guidance should also be used for identifying cases where further toxicological data are needed to characterise pesticide metabolites, including guidance on experimental conditions.

2. Mr Patrick Kabouw

2.1 EFSA is currently developing a new opinion on addressing the state of the science on in-soil risk assessment. In parallel EFSA has opened a consultation of the new draft guidance for calculating predicable environmental concentrations in soil. As both documents are highly dependent on each other (e.g. definition of protection goals) could EFSA consider merging both documents?

Answer: For practical reasons the two documents should be kept separate. Of course the final GD on risk assessment for in-soil organisms will take into account the PEC in soil GD. The opinion on in-soil risk assessment will primarily address the state-of-the art of the effect assessment and the overall risk assessment scheme. This requires different scientific disciplines. During the development of this opinion, the exposure assessment methodology (including the exposure assessment goals) as developed for the EFSA Guidance on PEC in

soil currently under development will be taken as a boundary condition. The link between exposure and effect assessment will be ensured through participation of fate experts and ecotoxicology experts in the future work.

2.2 To what extent has EFSA considered the proceedings of the ESCORT workshops in their scientific opinion on addressing the state of science of risk-assessment for non-target arthropods?

Answer: Results from the ESCORT workshops have been a starting point for the upcoming opinion. Further details on how this has been taken into account cannot be given since the opinion is still under the deliberations of the PPR Panel.

2.3 How can stakeholder present their work and inputs during the creation of scientific outputs of EFSA?

Answer: Public consultations and technical hearings during Panel or Working Group meetings are formal mechanisms to allow stakeholders to provide their input to the preparation of outputs of the Scientific Panels and of EFSA.

The procedures applicable to these events are described in corporate documents available on the EFSA website:

http://www.efsa.europa.eu/en/aboutefsa/keydocs.htm.

In addition, when EFSA is aware of scientific information owned by stakeholders which would be useful to the development of an output, these stakeholders are generally contacted and invited by EFSA to share the information. Stakeholders may also possess information that EFSA is not aware of. In such case, this information can be made available to EFSA at the initiative of the stakeholder when it finds this information useful in scope of the respective mandate.

2.4 The underlying question is that ECPA would like to show and discuss a TER recalibration project with the members of the working group on addressing the state of the science on in-soil risk assessment. Is it possible to attend as a hearing expert a working group meeting?

Answer: As explained above, this information can be submitted spontaneously or in the context of a forthcoming public consultation. After considering the information, the Panel or the WG may suggest EFSA to organise a technical hearing if it considers this helpful for the development of the output. EFSA will in such case proceed with an internal procedure in order to organise the technical hearing.

2.5 How was the Environmental Relevant Concentration (ERC) derived for the draft EFSA Guidance Document Predicted Environmental Concentrations (PECs) in soil (in prep.)

Answer: The ERCs were proposed from a Scientific Opinion (EFSA, 2009) (doi:10.2903/j.efsa.2009.922) and have been used as the basis for the EFSA Guidance Document for Predicting Environmental Concentrations of substances in soil which was requested by the EU Commission in a separate mandate *M-2012-0252.*

2.6 The procedure for Tier 1 has been tested in the EFSA Guidance Document Predicted Environmental Concentrations in soil (in prep.) and compared to the current

procedure used in risk assessment of plant protection products: only 20% of the substances do not fail this tier.

Answer: The procedure of Tier 1 is the first tier and deliberately developed to be conservative. In contrast to the current procedure used in soil exposure assessment the draft EFSA Guidance Document provides a tiered exposure assessment scheme for refinement of the PECs. We see this as an important improvement compared to the existing methodology.

3. Mr Peter Sutton

3.1 Will ESFA consider the impact of the over-protective approach suggested in the opinion on non-target plants will have on agricultural production, and will EFSA discuss this approach in advance with growers and independent advisors?

Answer: This is a risk management question. EFSA is not tasked to look into that.

3.2 – Does EFSA agree that when it comes to choosing to protect weeds in crops there are trade-offs between optimising food production and other ecosystem services that need to be accepted, and given the introduction of EFSA surely there is no need for the suggested in-field and indirect effects risk assessment?

Answer: It would certainly be beneficial if such trade-offs are investigated in detail to facilitate risk management decisions. Biodiversity is one of the protection goals deriving from Regulation (EC) No 1107/2009. If non-target plants are removed completely from in-field areas then this has not only a direct effect on rare arable weeds but also indirect effects on the food web support. A certain abundance of non-crop plants is needed as a food source for pollinators and also maintenance of other non-target arthropods which are needed as food source (e.g. chick survival of farmland bird species depends very much on abundance of arthropods). The question involves elements of risk management and is not purely a risk assessment issue. It is agreed that it would be beneficial to look into this risk management question in a more holistic way e.g. if weeds are removed completely from treated fields then compensatory measures to mitigate the impact on biodiversity and the food web are needed. It would be highly beneficial if such mitigation measures are developed further.

3.3 Does the panel believe that all the data used are representative of short term (21-28 day) and long term (>60 day) testing? (I do not). And surely a median EF value (with a 95th percentile HC05 value) would be protective for both biomass and reproduction?

Answer: The approach presented in the opinion is based on the data which were available to the working group. Whether the suggested approach is over or under-protective can be evaluated further once the specific protection goals are agreed with risk managers and a full risk assessment scheme is developed.

4. Ms Carole Langrand-Lerche

4.1 Agenda point 8.2.2: Could you please provide update on the Sc Op on ACE (EFSA - Q 2012- 00958)?
Answer: See point 8.2.2.

4.2 We would like to know if additional info and rationale submitted by Bayer CropScience have been considered by the WG and whenever any additional clarification.

Answer: See point 9.2.2.

4.3 Can the WG provide feedback on its evaluation of the additional data submitted and the impact they have on the conclusion of the Op regarding Imidacloprid.

Answer: See point 9.2.2.

5. Mr Klaus Hammel

5.1. We frequently notice inconsistencies between draft guidances and corresponding opinions such as new science occurring in the guidance. For example, adjustment factors were changed in the draft PECs Soil guidance due to changes in the underlying data. How will these inconsistencies being resolved? Will there be an amendment to the opinion?

Answer: As stated in the draft EFSA GD for predicting PECs in soil the scenario adjustment factors have been included at lower tiers to ensure that these tiers are more conservative than higher tiers. In the underlying scientific opinion (EFSA, 2012) the adjustment factors were named crop extrapolation factors but the underlying concept has not changed. EFSA was informed by a stakeholder that there was a shift of pixels in the underlying data. EFSA contacted JRC and the shift was corrected. Both EFSA Spatial Data sets - the original (Version 1.0) and the corrected (Version 1.1) are available on the JRC soil portal. The underlying opinion (EFSA, 2012) will not be changed.

5.2. We notice that EFSA is basing their assessment schemes on a so-called reference tier. The definition of this reference tier is very sophisticated and usually involves big and complex databases, for example on geodata which may change due to source and time. How robust is EFSA considering the resulting guidances and what procedure is foreseen to deal with such changes?

Answer: Spatial and temporal data may change over time when additional data is collected and the quality of the data is improved. EFSA does not expect this will happen very frequently. The robustness of the procedure depends on the quality of the underlying data. EFSA has established a procedure with JRC to retain the previous versions of the EFSA Spatial data sets when replaced by updated data sets. EFSA recommends when using the data-sets always to make clear which version of the data set has been used.

5.3 Complex risk assessments include exposure and effect assessment. We notice that guidance for these parts is usually developed separately. Thereby the overall risk addressed is likely to remain undefined which is compensated by overly conservative assessment. What is the rationale of EFSA to develop separate guidance for a specific risk assessment?

Answer: Linking exposure and effects is a core issue of all guidance documents. Existing guidance in different areas is taken into account in the development of new risk assessment guidance documents. Exposure experts are members of the working groups developing risk assessment guidance to ensure that the exposure and effect assessments are correctly linked.

12. Any Other Business

The following was brought to the attention of the PPR panel:

a) The launch by EFSA of a call for proposals on a scientific support for the interpretation of mammalian toxicology and ecotoxicology data on potential endocrine disrupting effects in the ecotoxicological assessment of pesticides under regulation (EC) N° 178/2009;

b) The road map of the EU Commission regarding the establishment of criteria for the identification of endocrine disruptors;

c) The Horizon 2020 framework programme for research and innovation. Proposals of Panel members were sent to the EFSA Scientific Committee Unit by the Secretariat;

d) The Guidance of the Panel on the tiered risk assessment for aquatic organisms in edge-of-field surface water was noted by the Standing Committee on the Food Chain and Animal Health in July 2014;

e) A public consultation of EFSA on the draft EFSA Guidance for the prediction of environmental concentrations of pesticides in soil was conducted during summer and closed in September 2014;

f) The publication of an External Scientific Report on extensive literature search and reviews regarding dermal and inhalation exposure in the context of pesticide risk assessment for birds and mammals.