Pesticide Steering Committee
Minutes of the 16th meeting
Held on 18 – 19 February 2014, Parma

(Agreed on 11 November 2014)[1]

Participants

- **Network Representatives of Member States:**

Country	Name[2]	Country	Name
Austria	Sonja Ecker	Ireland	Tom Medlycott
Belgium	Herman Fontier	Lithuania	Kristina Valioniene
Bulgaria	Iva Romanova	Netherlands	Hanneke Westland
Croatia	Gorana Peček	Netherlands	Linda Sibbes
Czech Republic	Martin Prokop	Poland	Robert Bańkowski
Denmark	Nina Sørup Hansen	Portugal	Bento De Carvalho
Estonia	Jan-Roland Raukas	Slovakia	Bronislava Škarbová
Finland	Kaija Kallio-Mannila	Spain	Carmen López Goti
Germany	Herbert Köpp	Sweden	Sylvia Karlsson
Greece	Danae Pitarokili	Sweden	Katarina Lundberg
Hungary	Tamás Griff	United Kingdom	John Dale

- **Panel Members**

  None

- **Hearing Experts**

  None

- **European Commission, European Institutions and/or Member States representatives:**
  - Wolfgang Reinert (DG SANCO)
  - Jani O. Honkanen (ECHA)

[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.
[2] Indicate first full name and then surname (John Smith) all throughout the document

European Food Safety Authority – Via Carlo Magno 1/a, 43126 Parma, ITALY
Tel: (+39) 0521 036 111 • Fax: (+39) 0521 036 110 • www.efsa.europa.eu

- **EFSA:**
  - Pesticides Unit (José V. Tarazona, Head of Unit)
  - Pesticides Unit (Luc Mohimont, Deputy Head of Unit)
  - Pesticides Unit (Tunde Molnar, Coordination Team)
  - Pesticides Unit (Jürgen Sturma, Coordination Team)
  - Pesticides Unit (Christopher Lythgo, Fate and Behaviour Team)
  - Applications Desk Unit (Tom Meyvis, scientific officer)
- **Others (if applicable such as WGs/other country representatives)**
  - Lucia Klauser (Switzerland)

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes regarding Declarations of Interests (DoIs)[3] and the Decision of the Executive Director implementing this Policy[4], members of networks, peer review meetings, networking meetings and their alternates shall be invited to complete and submit an Annual Declaration of interest (ADoI).

EFSA screened the ADoI filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of interest (ODoI) at the beginning of this meeting.

The Chair thanked the representative(s) that has/have submitted an ADoI and/or has/have declared some interest at the beginning of this meeting in the ODoI.

4. Agreement of the minutes of the 15th meeting of the Pesticide Steering Committee held on 11 – 12 June 2013, Parma.

4.1. Minutes of the 15th Pesticide Steering Committee held on 11-12 June 2013:

The minutes were agreed.

4.2. Minutes of the 1 Pesticide Steering Committee dedicated to bees held on 17-18 December 2013:

The minutes were agreed.

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

4.3. Follow up on the workshop on Risk assessment on bees and the Pesticides Steering Committee dedicated to bees

A presentation was given by EFSA summarising the results of the Workshop and the Pesticide Steering Committee dedicated to bees. A flow chart, showing the procedure for the peer review of the study protocols was distributed. In the context of the upcoming post-approval procedures for the neonicotinoids clarifications were sought as regards the uses that need to be covered in the assessment (all authorised uses or representative uses at the time of approval). It was clarified that the confirmatory data procedure should address the uses which are approved and will not allow to lift the restrictions imposed since the approval of these substances. These 2 procedures should be kept separately.

Action point:

- Commission will further reflect on this issue.

The European Commission is preparing a roadmap for the implementation and future update of the guidance document for bees. An expert meeting will be organised in April 2014. EFSA will conduct a restructuration. Member States are invited to submit proposals for the restructuration of the guidance document by the end of March and EFSA will draft a proposal for the restructuration of the guidance document. MS were asked to ensure that no delays should be introduced in the procedure.

Action point:

- EFSA to organise the expert meeting

Two Expert Groups have been created and the experts have been endorsed:

<u>Expert group for the short-term revision of Bee Guidance:</u>

- Rosie Oates, United Kingdom
- Emily McVey, Netherlands
- Veronique Poulsen, France
- Germany (tbc)
    - the participants agreed that Germany may nominate the relevant experts after the meeting
    - <u>Post meeting note:</u> the nominated experts for Germany are:
        - Dirk Süßenbach
        - Jens Pistorius

<u>Expert group for the EFSA calculator</u>

- Marit Randall, Norway
- Piotr Medrzycki, Italy
- José Luis Alonso Prados, Spain (Post-meeting note: following a request from Spain, this expert was replaced by Elena Alonso Prados and Elena Alonso García)
- Veronique Poulsen, France (limited)
- Germany tbc.

- the participants agreed that Germany may nominate the relevant experts after the meeting

Action point:

- EFSA to organise the expert meetings

5. Topics for discussion

5.1.Work programme for

5.1.1 NAS:

EFSA gave a short presentation on the status of the works. Three substances falling under Commission Regulation (EU) No 188/2011 are still under peer review. 13 substances falling under Regulation (EC) No 1107/2009 are under peer review. Concerning the pilot case sulfoxaflor MS were invited to comment on the draft conclusion during the written procedure as the structure of the conclusion was amended to cover also MRL applications.

MS were reminded to inform EFSA in case of delays expected during the preparation of DARs, to facilitate planning of the upcoming work programme.

5.1.2. AIR II:

29 substances are falling under the AIR II regulation (Regulation (EU) No 1141/2010). Most of them will be finalised this year.

5.1.3. confirmatory data:

The Commission guidance document on confirmatory data was adopted in December 2013 and will be implemented as from 1 March 2014. For commenting rounds launched after 1 March 2014, EFSA will complete column 4 of the reporting table.

EFSA informed that the legal deadline for the risk assessment of imidacloprid for operators and workers and the risk to birds and mammals is 30 June 2014.

5.1.4: Art 21

Based on Art 21 of Regulation (EC) No 1107/2009 the Commission mandated EFSA to evaluate particular issues on imidacloprid (risk to aquatic organisms), chlorpyrifos (human health assessment) and the risk to bees from the so called neonicotinoids (thiamethoxam, imidacloprid and chlothianidin) for uses other than those covered by the EFSA conclusions. The peer review is ongoing and the legal deadlines are falling in 2014.

The legal deadline for the evaluation of neonicotinoids (thiamethoxam, imidacloprid, clothianidin) as regards the risk to bees, all uses other than seed treatments is 31 October 2014

5.1.5 AIR III

In accordance with Art. 3(6) of Reg. 844/2012 COM will publish on its website in the coming weeks the names and addresses of the applicants of the first batch of substances, the status will be clarified at the next meeting of the Standing Committee

5.2. EFSA's Applications Desk

APDESK provided a presentation that addressed some practical issues in regard to the various work flows:

AIR II: overview of the justification forms for the confidentiality claims of the sanitised summary supplementary dossiers

NAS and AIR III: overview table to be published on EFSA web pages indicating what applicants should submit to EFSA at what time in the procedure and in which format

An overview was also presented of the various parts of the legislations of NAS, AIR II and AIR III workflows dealing with confidentiality claims in order to clarify who (RMS or EFSA) is responsible for evaluation of the claims. In this context MSs highlighted the need to have a harmonized and consistent approach for the acceptance of confidentiality claims.

The MSs suggested making the AIR III overview table available on extranet.

5.3 Classification and labelling

Presentation from ECHA. The importance of the alignment of the CLH and the active substance evaluation procedures was highlighted: the main aspect is the impact of classification on the approval of active substances, and in addition, the alignment would facilitate the efficient use of resources and avoiding conflicts in the opinions adopted by both agencies. ECHA's website provides detailed information for the planned activities in the Register of Intentions to facilitate the planning. An early exchange of information is preferable for aligning the procedures under the pesticides peer review and the CLH process. ECHA offered support for MSs during the preparation of the CLH dossiers, MS are encouraged to contact ECHA for clarifications and support already at an early stage. Various options are currently being considered for reducing the burden of MSs (e.g. joint preparation of dossiers, involvement of industry). The guidance for CLH dossier preparation is under revision (expected to be finalised in summer 2014). In addition, a submission manual is planned to be prepared.

Sulfoxaflor is a first pilot case for the alignment. The alignment of flumioxazin is currently ongoing in the context of the AIR II peer review procedure.

COM will consider whether Regulation (EC) No 1107/2009 can be amended to further align the procedures.

It was highlighted that the dossier for the same substance under evaluation at EFSA and ECHA must be the same. For a successful alignment it is important that the CLH dossier is submitted in advance of the DAR and that the RAC Opinion could be adopted before the Conclusion is finalised.

5.4. Problems faced by Member States prioritising substances for classification

The document prepared by the United Kingdom on the prioritization of substances for classification needs to be amended. So far only Sweden submitted comments on this proposal. It was briefly discussed how to deal with the backlog for those substances waiting for classification and labelling and what criteria should be applied for prioritization.

Action point:

- Member States are invited to comment again on the document and provide proposals on the way forward prior to the coming meeting of the Pesticide Steering Committee by 31 October 2014.

5.5. Requests for access to documents and recent court case on glyphosate

COM informed that a request for access to documents for glyphosate has been made and a court case is ongoing.

5.6. Guidance documents

5.6.1. Update on the development process of guidance documents

A guidance on the risk assessment for bees has been approved by EFSA and published in June 2013. A guidance on the tiered risk assessment for aquatic organisms in edge-of-field surface waters was adopted by the PPR Panel and published in July 2013.

EFSA gave an overview of recently completed activities supporting the development of guidance documents. This includes two opinions of the PPR Panel in the area of cumulative risk assessment (Opinion on the identification of pesticides to be included in cumulative assessment groups adopted in June 2013 and Opinion on the relevance of dissimilar mode of action adopted in November 2013), a technical report of the public consultation on the opinion on the establishment of cumulative assessment groups, and the second opinion of the PPR Panel on the 2009 report of the FOCUS groundwater working group (assessment of higher tiers) adopted in June 2013.

Two EFSA draft guidance documents were submitted to public consultation in 2013 (guidance on clustering and ranking of emissions of active substances and transformation products from protected crops to relevant environmental compartments and guidance on evaluating laboratory and field studies to obtain DegT50 values of active substances and their transformation products).

A new mandate was allocated to the PPR Panel in December 2013 in order to prepare a guidance on the residue definition for dietary risk assessment.

The establishment by COM of the e-WG on risk management questions related to the assessment of cumulative exposure was welcomed as an essential forum to ensure coherence between risk assessment and regulatory needs in the next actions related to the implementation of cumulative risk assessment.

Members of the Pesticide Steering Committee showed interest in knowing the EFSA views regarding the possibility and opportunity to review the FOCUS surface water scenarios and to update the EFSA guidance on the submission of scientific peer-reviewed open literature for the approval of pesticide active substances after publication of the external scientific report on case studies on its application (AGES, 2013).

5.6.2. Coverage of seed treatments in EFSA Guidance on terrestrial ecotoxicology and operator exposure

A brief discussion took place regarding the risk assessment related to seed treatment. It was acknowledged that redundancies between the EFSA guidance documents regarding terrestrial ecotoxicology and the guidance document on seed treatments developed by Member States and the commission should be avoided.

In the context of the development of the EFSA guidance document on operator exposure, EFSA indicated that the Seed Tropex Task Force could not provide the data supporting their model for reasons of confidentiality.

5.7. Update on grants and procurements

The following final external scientific report was published:

- Scientific support, literature review and data collection and analysis for risk assessment on microbial organisms used as active substances in plant protection products – lot environmental risk characterisation (Bio Intelligence Service, December 2013)

The following cooperation activities were officially started:

- Retrospective analysis of the immunotoxic effects of plant protection products as reported in draft assessment reports (Grant agreement with the Chemicals Regulation Directorate)
- Literature review on in vitro and alternative developmental neurotoxicity testing methods (Procurement contract with the Leibniz Institut für Umweltmedizinische Forschung)
- Data collection to support the establishment of CAGs (nervous system, liver, adrenals, eyes, reproduction and development and thyroid system) (Grant agreement with ANSES, RIVM and ICPS)
- Comparison of NOEC values to EC10/EC20 values, including confidence intervals, in aquatic and terrestrial ecotoxicological risk assessment (Grant agreement with the Azienda Ospedaliera Luigi Sacco)
- Literature search and data collection on risk assessment for human health for microorganisms used as plant protection products (Procurement contract with the Austrian Institute of Technology)
- Extensive literature search and review as preparatory work for the update of the EFSA guidance on the Risk assessment for birds and mammals (Procurement contract with the Food and Environment Research Agency)
- Scenario selection and scenario parameterisation for permanent crops and row crops on ridges in support of predicting environmental concentrations of plant protection products and their transformation products in soil (Procurement contract with the Food and Environment Research Agency)

5.8. Assessing MRL applications in connection with the peer review process

EFSA gave a presentation. The procedure for MRL setting under Regulation (EC) No. 1107/2009 was explained. All residue data will be summarised in Volume 3 B.7, for the peer review in the first part of the chapter and for the MRL setting in a separate sub-chapter. Import tolerances will not be assessed, if for the commodity concerned there is no authorisation for that substance in the exporting country.

MSs may comment on the presentation by 5 March 2014.

5.9. Procedure for the MRL review under Article 12 of Regulation (EC) No 396/2005: deadlines for Member States for providing input.

In response to the concerns raised by Germany regarding the short deadlines for Member States to provide input on the review of MRLs, EFSA presented its views for possible improvements of the MRL review process. Member States welcomed the proposals of EFSA but highlighted the need to discuss the proposals with the relevant colleagues at national level.

Action point:

- MSs were therefore invited to provide comments for discussion at the next meeting.

5.10: Strategic actions on risk communications of pesticides during 2014

EFSA's communication department informed about the activities planned on risk communication for pesticides, which is a key theme for EFSA in 2014, and introduced the various communication tools and communication milestones. The key message is to reinforce EFSA's leading role in:

- producing high quality scientific risk assessments of pesticides
- incorporating the scientific knowledge into risk assessments methodology
- key monitoring and support role of pesticides in the EU
- co-operation with MSs and the European Commission in the risk assessment of pesticides

In the context of EFSA's communication on the ongoing issues for pesticides, MSs are invited to communicate to EFSA any ongoing or envisaged activity in the area. In the communication plan it is envisaged to consider the involvement of MSs and offer the possibility for cooperation with the aim to align the process in EFSA with projects, initiatives ongoing at national level.

EFSA aims for an open communication, confidence in the work and that facts speak for themselves.

EFSA informed about the ongoing and planned open exchange activities with the applicants, including participation in meetings and workshops.

5.11: Changing the conclusion "critical area of concern" criterion in relation to the potential for long range atmospheric transport

EFSA gave a short introduction on that issue. The potential for long range transport will no longer be mentioned under the critical areas of concern and EFSA will follow the criteria under Regulation (EC) No 1107/2009, Annex II, 3.7.1. The potential for long range transport will be flagged in the Conclusion text, however a critical area of concern will only be raised if all the three POP criteria, as defined in the legislation, are fulfilled (of which the potential for long range transport is only one criterion).

This approach will be followed for all conclusions from now on.

6. AOB

6.1.: Feedback on the bilateral teleconference with EFSA and COM on the content of the EFSA conclusions regarding the assessment of effects related to endocrine disruption.

EFSA received a request from the Commission to include a more clear indication in the EFSA conclusions regarding the potential for endocrine disruption properties (relevant for mammalian toxicology and ecotoxicology), which is an approval criterion to be considered for all NAS substances under Regulation (EC) No 1107/2009 and all AIR II substances.

EFSA gave a brief feedback from the bilateral teleconference between EFSA and COM held on 18 February 2014. It was agreed that it is a complex topic and further discussion is needed.

Overall, EFSA acknowledged the need for more details on this concern in order to support the subsequent potential request of confirmatory data, however, expressed the difficulty in the scientific determination of endocrine disrupting properties in the absence of specific scientific criteria to address points 3.6.5 and 3.8.2 of Annex II of Regulation (EC) No. 1107/2009.

EFSA will carry out case studies which will be further discussed with MS experts as a separate topic in the framework of the Pesticides Peer Review expert meetings in May 2014 (in both mammalian toxicology and ecotoxicology). Commission will also participate.

6.2.: Face to face meetings needed for the section on physical-chemical properties and methods for analysis

It was proposed to organise a face-to-face expert meeting for the section on physical-chemical properties and methods for analysis. These meetings have not taken place for a longer period and the need for a scientific exchange is seen.

In relation to this discussion it was recommended to update the so called EFSA handbooks (record of decisions from expert meetings) and make them available to the MSs via CIRCABC.

Action point:

- EFSA to review and update these documents if needed and to inform MSs at the next PSC meeting

6.2.: AIR II and AIR III substances

It was briefly discussed which guidance should be used for the evaluation of active substances under the renewal procedures. The issue is in particular difficult in the area of ecotoxicology. Some MSs evaluate all old studies in the light of the current and relevant guidance. If a study is no longer acceptable a new study will only be required, if the organism is at risk. MSs highlighted the need to have a harmonized approach in view of the equal treatment of all active substances.

MSs expressed their wish to receive a communication from Commission whenever a new test guideline becomes available. COM will consider how the information on the guidance in place can be communicated better.

Action point:

- MSs are invited to inform about the current practice on that issue by 31 July 2014 for further consideration in the next PSC meeting.