Pesticide Steering Committee
Minutes of the meeting dedicated to the Risk Assessment of Bees
held on 17 – 18 December 2013, Parma

(Agreed on 18 02 2014)[1]

Participants

- **Network Representatives of Member States:**

Country	Name[2]	Country	Name[2]
Austria	Daniela Jölli	Hungary	Tamás Griff
Belgium	Ilse Pittomvils	Hungary	Zoltán Repkényi
Croatia	Maja Kravarščan	Ireland	Dermot Sheridan
Croatia	Tina Fazinic	Ireland	Keith Armstrong
Czech Republic	Martin Prokop	Poland	Robert Bańkowski
Czech Republic	Hanna Kubátova-Hiršova	Italy	Piotr Medrzycki
Denmark	Fred. F. Brødsgaard	Latvia	Dace Bumane
Estonia	Jan-Roland Raukas	Latvia	Laila Mizga
Estonia	Rain Reiman	Lithuania	Kristina Valioniene
Finland	Kaija Kallio-Mannila	Lithuania	Vaida Deveniene
France	Thierry Mercier	The Netherlands	Peter van Vliet
France	Véronique Poulsen	Portugal	Bento de Carvalho
Germany	Thomas Schneider	Spain	Carmen Lopez Goti
Germany	Rolf Forster	Spain	Elena Alonso-Prados
Greece	Danae Pitarokili	The United Kingdom	John Dale
Greece	Konstantinos Kasiotis	The United Kingdom	Rosie Kittoe

[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

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- **Panel Members**

  None

- **Hearing Experts**
  - ECPA: Euros Jones
  - JSCI (representing Sumitomo): Gavin Lewis
  - Bayer: Jürgen Keppler
  - BASF: Christof Schneider
  - Syngenta: Georg Diriwächter

- **European Commission and/or Member States representatives:**
  - Marianna Paolino (DG SANCO)
- **EFSA:**
  - Pesticides Unit (Jose Tarazona, Head of Unit)
  - Pesticides Unit (Luc Mohimont, Deputy Head of Unit)
  - Pesticides Unit (Jürgen Sturma, Coordination Team)
  - Pesticides Unit (Tünde Molnar, Coordination Team)
  - Pesticides Unit (Domenica Auteri, Ecotox Team)
  - Pesticides Unit (Rachel Sharp, Ecotox Team)
  - Pesticides Unit (Csaba Szentes, Ecotox Team)

- **Others (if applicable such as WGs/other country representatives)**
  - Jean-Daniel Charriere (Switzerland)

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted with the following additional point added under any other business:

- Cyantraniliprole: a new systemic molecule highly toxic for bees (letter from the Bee Life European Beekeeping Coordination to the European Commission).

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).

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

EFSA screened the ADoI filled in by the experts invited for the present meeting and those submitted by the hearing experts. For the experts nominated by the Member States, 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 informed the participants that conflicts of interest had been identified for the hearing experts.

The Chair thanked the representatives that have submitted an ADoI.

4. Introduction to the dedicated meeting on bees risk assessment

Following the recent developments regarding the neonicotinoids assessment and the EFSA guidance on risk assessment for bees[5], there was the need for organising a dedicated meeting of the Pesticide Steering Committee focused on the risk assessment for bees. The need for such a meeting has arisen in the Neonicotinoids Tripartite Meeting as a consequence of the industry need for getting a broad acceptance of the test protocols for the submission of new data for their substances. Therefore, with a view to give advice to industry on the possible acceptance of the study protocols, a hearing session was also included to offer the opportunity to industry representatives to present a summary of their intended study work plans. In addition, the dedicated meeting aimed to follow up the discussions at the workshop held in Brussels on 11 - 12 December 2013 regarding the EFSA guidance on bees.

5. Hearing of industry experts

Representatives from industry were invited and allowed to participate at the meeting exclusively for agenda point 5 (hearing of industry experts) and were asked to leave the meeting afterwards.

At the Neonicotinoids Tripartite Meeting between EFSA, COM (DG SANCO) and industry representatives (ECPA) held in Brussels on 27 November 2013, the industry representatives raised the need for the acceptance of the test protocols to be submitted by applicants for the generation of new data in support of their substances following the regulatory measures taken for the 3 neonicotinoids (clothianidin, imidacloprid, thiamethoxam) and for fipronil. For this purpose, a hearing session with industry experts has been organised, in order to allow companies to present their study plans and their needs for Member States'/EFSA comments on non-guideline study protocols.

COM gave an overview of the relevant regulatory frameworks applicable for these substances, in particular of the confirmatory data procedure and the review under Article 21 of Regulation (EC) No 1107/2009 (see point 7 for further details).

Following a general introduction by ECPA, the Applicants for each active substance individually presented an overview of their intended study work plans and general planning for the forthcoming submissions.

Concerning the scientific aspects to be considered in the process, it was highlighted that the scientific basis for the evaluation of the confirmatory data will be the Opinion[6] and those parts of the EFSA guidance document which will be identified by risk managers for immediate implementation (see point 7 for further details). Concerning field studies, applicants were recommended to provide argumentations / justifications in their study protocols in case certain recommendations of the Opinion / EFSA guidance cannot be achieved. In such cases further investigation of the statistical analysis may be useful.

[5] European Food Safety Authority, 2013. Guidance on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees). EFSA Journal 2013;11(7):3295, 266 pp. doi:10.2903/j.efsa.2013.3295.

[6] EFSA Panel on Plant Protection Products and their Residues (PPR); Scientific Opinion on the science behind the development of a risk assessment of Plant Protection Products on bees (Apis mellifera, *Bombus* spp. and solitary bees). EFSA Journal 2012; 10(5) 2668. [275 pp.] doi:10.2903/j.efsa.2012.2668.

Industry was also recommended to link the evaluation of the higher tier studies to the representative uses.

Furthermore, it was clarified that the responsible rapporteur Member State for the evaluations of the confirmatory data will be the rapporteur Member State of the first evaluation of the active substance, while for the review of other additional data in accordance with e.g. Article 21 of Regulation (EC) No 1107/2009 the responsible rapporteur Member State will be the one that has been nominated for the AIR 3 review for the active substance.[7]

Post-meeting note:

Industry was asked to propose a firm deadline achievable for all companies for the submission of the study protocols. It was highlighted that it will be impossible to accept protocols for the peer review submitted after this deadline for studies to be initiated in 2014. The deadline of 28 February 2014 was communicated to EFSA.

Action:

Industry to submit the study protocols to the rapporteur Member States, with the European Commission, EFSA and all Member States in copy by **28 February 2014** at the latest.

6. Scientific and procedural aspects for the peer review process of the study plans and protocols related to confirmatory data

EFSA, in consultation with COM, has considered the convenience for conducting a peer-review of the study protocols to be submitted in the context of the confirmatory data assessment. This procedure aims to support the rapporteur Member States and ensure common understanding and harmonisation of the assessments between the different Member States/EFSA, covering the concerns expressed by ECPA and the companies during the Tripartite Meeting in Brussels. It was highlighted that the review of study protocols will be restricted exclusively for new studies, protocols for studies already ongoing will not be considered.

For details of that procedure and the timing see Annex I at the end of this document

7. Preparatory work for the assessment of the study outcomes and timelines

The Committee considered the need for any preparatory work to facilitate the assessment of the study outcomes in the confirmatory data evaluation process.

Concerning the **scientific elements** to be taken into account in the process it was confirmed that the scientific basis for the evaluation will remain the Opinion, as this was also the basis for the risk assessment outlined in the EFSA Conclusions for the 4 active substances[8]. In addition, those parts of the EFSA guidance on bees should also be applied which will be identified by risk managers for immediate implementation based on the roadmap for the guidance (subject to adoption by the SCOFCAH). Therefore Member States are advised to carefully monitor the timelines for the implementation of the guidance document. In this context it was also concluded that there is no scope for re-opening discussions on the potential revision of the protection goals as identified in the guidance document at this stage.

[7] Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for the active substances as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market. OJ No. L 252, 19.9.2012, pp 26 ff

[8] European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment for bees for the active substance **clothianidin**. EFSA Journal 2013;11(1):3066. [58 pp.] doi:10.2903/j.efsa.2013.3066.
European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment for bees for the active substance **thiamethoxam**. EFSA Journal 2013;11(1):3067. [68 pp.] doi:10.2903/j.efsa.2013.3067.
European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment for bees for the active substance **imidacloprid**. EFSA Journal 2013;11(1):3068. [55 pp.] doi:10.2903/j.efsa.2013.3068.
European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment for bees for the active substance **fipronil**. EFSA Journal 2013;11(4):3158. [51 pp.] doi:10.2903/j.efsa.2013.3158.

In order to ensure a harmonisation in the interpretation of the results of higher tier field studies during the assessment of the study outcomes EFSA offered to set up a working group with Member States in the second half of 2014, based on the experience gained during the production of the EFSA Conclusions. In general, the Member States welcomed the initiative.

Concerning the **procedural aspects**, COM clarified the various procedures in line with the relevant regulatory frameworks and timelines applicable, i.e.:

- **Confirmatory data procedure** in support of the already approved uses based on the relevant SANCO guidance currently in place[9]. The legal deadlines are provided in the Commission Implementing Regulations (EU) No 485/2013[10] and 781/2013[11].
- **Review** of the new scientific information (recital 16 of the Commission Implementing Regulations (EU) No 485/2013 and 781/2013) in accordance with **Article 21 of Regulation (EC) No 1107/2009** to be initiated by COM. The review is related to the uses currently not anymore allowed after the entry into force of Commission Implementing Regulations (EU) No 485/2013 and 781/2013. COM is committed to initiate this review within 2 years from the entry into force of those Regulations. It was highlighted that in the context of this exercise any new scientific information may be taken into account.
- **AIR 3 procedure**: re-evaluation and peer review of complete data package in the context of the renewal of the approval of these substances under Commission Implementing Regulation (EU) No 844/2012.

Action point:

- EFSA to ensure the harmonisation in the interpretation of the results of higher tier field studies during the confirmatory data assessment of the study outcomes.

8. Prioritisation of the EFSA tasks regarding the GD on bees

As a follow up of the discussions at the workshop held in Brussels on 11 - 12 December 2013 regarding the EFSA guidance on bees, it was intended to agree with PSC members on the best way for implementing the tasks for EFSA. COM presented the main outcomes from the workshop. The following suggestions were made to increase the manageability / handling of the EFSA guidance for both national and EU registration processes:

- Roadmap for a step by step implementation of the guidance, with special regard to:
  - Issues for immediate implementation
  - Medium-term: 2 years
  - Long-term > 2 years: research needed
- Creation of a working group for finalization, implementation and monitoring of the Roadmap
- Restructure of the guidance to improve it further
- Training for Member State experts on use of the guidance
- Clarifications on the requirements for applicants to improve quality of dossiers

[9] Guidance document on the procedures for submission and assessment of confirmatory information following approval of an active substance in accordance with Regulation (EC) No 1107/2009, SANCO/5634/2009 rev. 6.1, dated December 2013.

[10] Commission Implementing Regulation EU) No 485/2013 of 24 May 2013 amending Implementing Regulation (EU) No 540/2011, as regards the conditions of approval of the active substances clothianidin, thiamethoxam and imidacloprid, and prohibiting the use and sale of seeds treated with plant protection products containing those active substances. OJ L 139, 25.05.2013. p.12.

[11] Commission Implementing Regulation EU) No 781/2013 of 14 August 2013 amending Implementing Regulation (EU) No 540/2011, as regards the conditions of approval of the active substance fipronil, and prohibiting the use and sale of seeds treated with plant protection products containing this active substance.OJ L 219, 15.08.2013, p.22.

- Agreed/validated calculator including testing by Member State experts
- Review of protection goals/safety factors and triggers
- Uniform principles: consideration of the need to adapt them to the data requirements.

EFSA has already reflected on the comments received during the workshop in order to facilitate the use of the guidance and harmonize the work undertaken by the rapporteurs. In particular EFSA identified the need for further development of the first-tier calculator tool by extending the number of crops contained in it. MS are invited to check the functionality and perform thereby a validation of the tool. Member States, being the main user of the guidance, are encouraged to participate in this exercise. Once validated, it is envisaged that the calculator tool will be made available on the EFSA website for use by industry and MS. In general, the Member States supported the initiative however they raised concerns over potential capacity and / or resource problems. The possibility for outsourcing of the checking of the tool may be considered by EFSA.

As another task for EFSA, the need for restructuring of the guidance to facilitate its use in the regulatory context was highlighted. The aim is to correct errors / mistakes occurred and to provide clarifications for the options for refinement in the risk assessment. It was clarified that the content and scientific part of the guidance will remain unchanged. A revision of the content including the protection goals is aimed at medium term level, i.e. in around 2 years time. In the meantime risk managers may decide to take on board changes concerning trigger values or endpoints to use. At this stage EFSA may clarify the different levels of conservativism linked to the protection goals in the guidance to aid risk managers in their decision-making.

The main work concerning the restructure will be lead by EFSA, however support is required from Member States. A general timeframe for the restructuring of the guidance will be discussed with COM. COM confirmed that the restructuring of the guidance will still be under the scope of the initial mandate

Some MS indicated their willingness to support EFSA in this task; feedback from other Member States are invited. EFSA will prepare a listing of the implementation needs to be considered during the restructure based on all the comments received at the workshop in Brussels. Discussions are envisaged to be started in January 2014, any Member State experts are welcome to participate. An expert consultation with Member States will also be organised.

Action points:

- COM to prepare an official document on the outcome of the workshop for distribution to Member States.
- Member States to express their interest in attending the working group for checking the functionality of the calculator tool by 31 January 2014
- Member States to express their interest in attending the working group for providing support in the restructuring of the guidance by 31 January 2014
- EFSA to prepare a listing of the implementation needs to be considered during the restructure of the guidance based on all the comments received at the workshop in Brussels.

8. AOB: "Cyantraniliprole - a new systemic molecule highly toxic for bees" (letter from the Bee Life European Beekeeping Coordination to COM)

A letter has been sent by the Bee Life European Beekeeping Coordination to COM, with EFSA in cc., raising concerns over the toxicity of the active substance cyantraniliprole to bees. The letter has been distributed to the Committee for consideration.

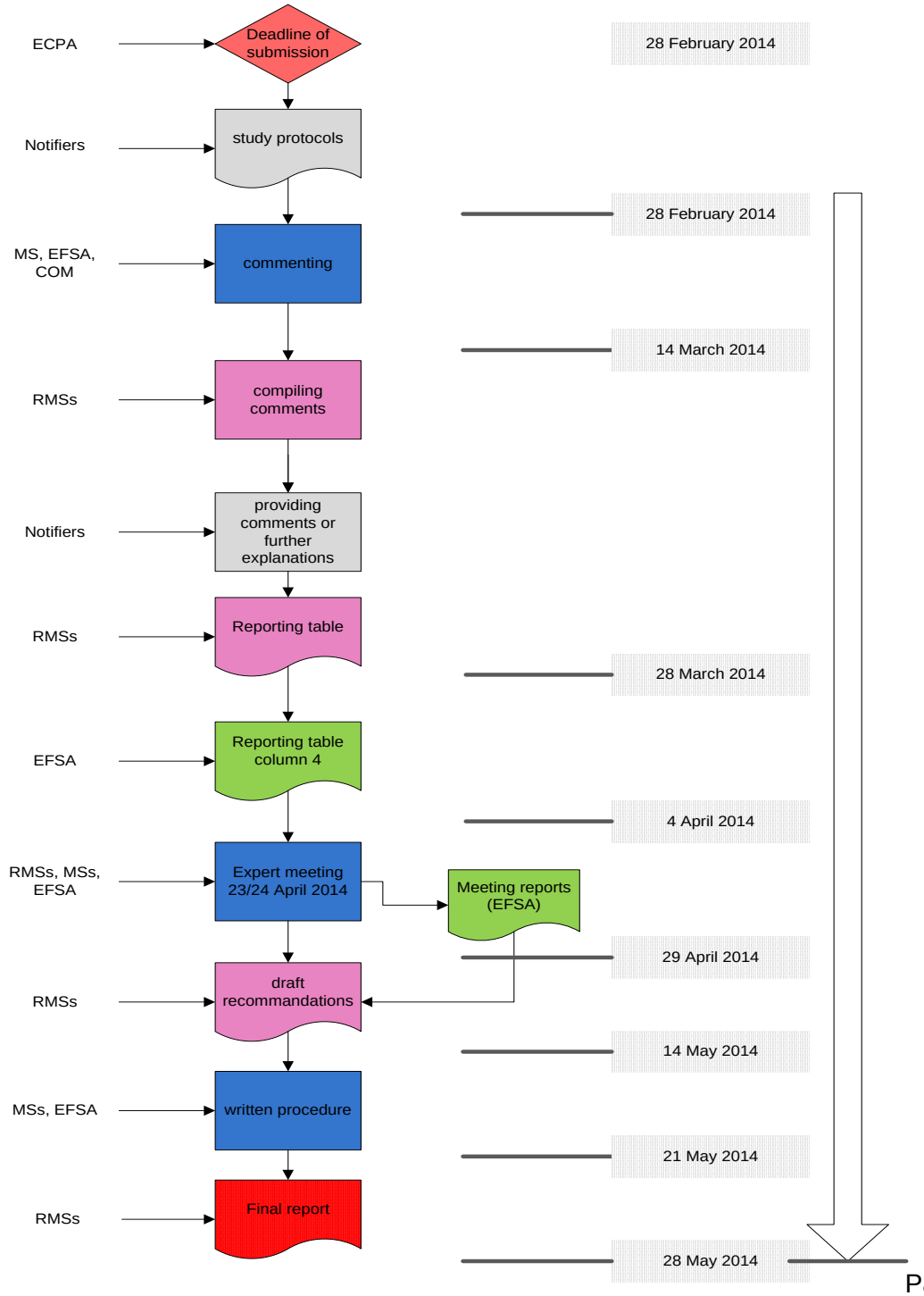
Cyantraniliprole is a new active substance, for which the EU peer review is currently ongoing (RMS: UK, Co-RMS: FR). The substance is in the stop the clock phase awaiting the rapporteur Member State's assessment of the additional information that was submitted by the applicant. An expert meeting in ecotoxicology is envisaged to take place around the first quarter of 2014. It was noted that the bee risk assessment carried out for cyantraniliprole was in line with the data requirements and guidance current at the time of submission (10 August 2011) and it was agreed that this was appropriate. Any new elements in the risk assessment arisen from the consideration of the new guidance may be raised and will be considered by risk managers.

Next meeting of the Pesticide Steering Committee: 18 and 19 February 2014

The minutes will be circulated at least 2 weeks before the next meeting.

Annex I

Peer review process of study plans and protocols submitted in the context of confirmatory data assessment



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