Parma, 25 April 2012

PESTICIDE STEERING COMMITTEE

Minutes of the 13th meeting

Parma, 24 – 25 April 2012

EFSA / PESTICIDES / 13

Agreed by the PSC on 16 October 2012

Participants

Members:

EFSA Herman Fontier (Chair)
AT Robert Womastek
BE Philippe Castelain
BU Neli Mancheva
CZ Martin Prokop
DE Herbert Köpp
DK Nina Sörup Hansen
EE Jan-Roland Raukas
ES Carmen López Goti
FI Kaija Kallio-Mannila
FR Thierry Mercier
GR Kalliopi Kokkinaki
HU Tamas Griff
IE Gordon Rennick
LV Dace Bumane
LT Kristina Valioniene
MT Joanne Galea
NO Abdelkarim Abdellaue
NL Annette Smits-van Prooije
PL Jan Krzysztof Ludwicki
SK Marta Galusová
SE Lennart Romert
UK Steve Dobson

Observers:

COM Wolfgang Reinert
JRC Judit Janossy
TR Pelin Aksu
MK Fikret Ajdini
HR Iva Pavlinic Prokurica
ME Nedeljko Latinović

EFSA:

Jane Barling (Pesticides)
Jürgen Sturma (Pesticides)
Bruno Dujardin (Pesticides)
Jean Pierre Cugier (Pesticides)
Luc Mohimont (Pesticides)

Stakeholder representatives attending for agenda item 17:

ECPA representatives:	IBMA representatives:
Euros Jones	Bent Iversen
Jean-Pierre Busnardo	Ulf Heilig
Martyn Griffiths	Sergio Franceschini
Harald Seulberger	David Cary
	Antonella Arcuri

1. Declarations of interest

In accordance with EFSA's Policy on Declarations of Interests, EFSA screened the available Annual Declaration of Interest (ADoI) completed by the participants invited for the meeting. No conflicts of interests related to the issues discussed in the meeting were identified during the screening process or at the beginning of the meeting.

2. Approval of agenda

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

- Information on recent calls for grants and procurements
- MSs actions on 2 new studies on neonicotinoids
- Assessment of groundwater metabolites
- Status of the e-consultation group
- Further meetings

3. Approval of the minutes of the previous meeting

The minutes were approved without any changes.

Follow up on:

- point 6: A final discussion concerning the interpretation of Art. 14(3) of Regulation 1141/2010 (interpretation of 'additional information') has not yet been scheduled in the SCFCAH. It was noted that RMSs are now evaluating the dossiers and therefore clarification on this point is urgently required.
- point 7: EFSA has launched a procurement for scientific support, literature review, and data collection and analysis for risk assessment of microbial organisms used as active substances in plant protection products (EFSA-Q-2012-00298 refers). Further information on this point given at agenda item 6.
- point 8: EFSA is investigating the necessary formalities and logistics of establishing an e-consultation group in the area of phys-chem.
- point 10: MSs have nominated participants for the GHSTS user group, and several teleconferences have already taken place.
- point 11: The EFSA proposals were considered to be agreed.
- point 12: The point was further discussed at agenda item 13.

- point 13: COM advised that two documents will be presented at the next SCFCAH (a draft guidance document and a scheme for submission of information). It is hoped that the documents can be taken note of at the July meeting of the SCFCAH.
- point 19: The first meeting of the working group on environmental cut-off crtieria will take place on 25 April 2012.

4. Work programme for new a.s.

With regard to the Art 11(4) and 11(6) procedures (Commission Regulation (EU) No 188/2011), RMSs gave feedback on the expected date for the submission of the DAR/addenda to EFSA.

It was noted that Regulation (EC) No. 1107/2009 requires EFSA to make several types of documents available to the public, including the summary dossier for NAS. According to the provisions of Articles 7(3), 9(1) and 10 of the Regulation, in practice the RMS and EFSA have a shared responsibility for the sanitisation of the summary dossier. RMSs were requested to ensure that the procedure, as set out in the working document discussed and agreed by the PSC at its meeting in October 2011, is followed systematically and without delay for all NAS.

Action point:

- RMS to complete the procedure for those active substances that have been judged complete under Regulation 1107/2009.

5. DAR and Dossier format revision

Presentation from the COM expert group. A general update was given on the status of the work programme for the DAR and the dossier format revision. The current developments are principally focused towards the format of the DAR, and a proposal for the new format is available on CIRCA.

In terms of next steps, it is proposed to implement the new Level 3 of Volume 1 for all AIR II Renewal Assessment Reports, and this will be discussed at the May/June meeting of the SCFCAH. Thereafter, it is intended to present the proposal for discussion at the OECD Registration Steering Group in November 2012. The overall aim is to implement the changes for the AIR III Renewal Assessment Reports and the NAS Draft Assessment Reports where the new data requirements apply.

Action point:

- MS to submit comments on the proposals by 14 May 2012 to EFSA (Jürgen Sturma) and COM (Jeroen Meeussen).

6. Work programme for green track a.s. of stage 4

Presentation from EFSA. A general update was given on the status of the work programme for the green track active substances of stage 4.

As a follow-up to the discussions at the October meeting of the PSC, EFSA reported that a procurement has been launched in the area of microorganisms for scientific support, literature review, and data collection and analysis for risk assessment of microbial organisms used as active substances in plant protection products. The procurement is broadly split into 2 lots, focusing on environmental risk characterisation and toxicology, with the content of the lots primarily based on the experience so far gained from the peer review of microorganisms. It is estimated that the work will be undertaken from July 2012 – April 2013.

It was agreed that the outcome of the EFSA procurement exercise would provide useful information for further discussion on general issues for microorganisms. The possible organisation of a workshop in 2013 was discussed, and some MSs expressed their willingness to participate in the organisation of such a workshop, in cooperation with EFSA and COM.

7. Guidance document on seeds

COM reported that a guidance document is under development in cooperation with MSs. The period for commenting on the draft guidance document has been extended and an amended draft is intended to be presented at the next meeting of the SCFCAH. It was noted that the guidance document to be taken note of will in effect be a 'living' document, and will continue to be developed, in particular in the light of the forthcoming EFSA guidance on worker exposure, and in view of developments in the area of ecotoxicology with regard to protection goals.

8. National experts in professional training

Presentation by EFSA. EFSA reported that it has launched a call for expression of interest for National Experts in Professional Training (NEPTs), and further details are available on the EFSA website. The call is open until 16 February 2014.

9. Advice to applicants

Presentation from EFSA. It was noted that during the pre-submission phase applicants sometimes contact EFSA as well as the RMS for advice on issues such as data requirements/waivers, guidance documents etc. In order to avoid misunderstanding, and in the interests of efficiency, it was agreed that EFSA will refer requests from the applicant during the pre-submission phase to the RMS, and the RMS may consult EFSA as necessary. It was briefly discussed whether and how an inventory of the issues raised might be made available for reference by MSs and EFSA.

Action point:

- EFSA to consider possible options for maintaining/sharing an inventory of issues raised during pre-submission contacts.

10. Assessment of post-approval data

Presentation from EFSA. It was agreed that there is a need to clearly differentiate between post-approval data that are submitted and evaluated in response to confirmatory data requirements, and post-approval data that are submitted for the purpose of amending the conditions of approval of an active substance. COM advised that the procedures for consideration of confirmatory data and applications for amendment to approval conditions are under discussion with the COM Legal Service, and it is hoped that further clarification on these points can be given in the SCFCAH.

With regard to the assessment of confirmatory data, RMSs were reminded of the need to submit a copy of the sanitised DAR addendum to EFSA for publication on the EFSA website, in accordance with GD SANCO/5634/2009 rev. 4.5.

Action point:

- COM to clarify the procedures for consideration of confirmatory data and applications for amendment to approval conditions.

11. Global joint review (GJR)

Presentation from EFSA. Exchange of views on the issues raised by global joint reviews in light of recent experience gained in consideration of the EU peer review of the NAS chlorantraniliprole (which was also a GJR substance), and EFSA participation in the secondary review of the global joint review of cyantraniliprole. In particular, it was noted that issues may arise in relation to the EU risk assessment in the area of residues and MRL setting where non-EU GAPs are worst case in the GJR process, and where applications for import tolerances are added to the EU active substance approval application before the relevant uses are authorised in the third country.

12. Overlap between Art. 12 reviews and renewal of approval

EFSA reported that it has developed a progress table to communicate progress with the Article 12 reviews, which will be published in the MRL workspace on the EFSA extranet every month.

13. Classification and labelling: working document on processes

RMSs were encouraged to share the working document with applicants and to discuss the possibility of pilot project substances. The RMS for the NAS sulfoxaflor indicated that it could be considered as a candidate for the pilot project. On this basis, the RMS is working towards making parallel submissions of the DAR and the CLH report to EFSA and ECHA respectively.

14. Preparation of the discussion with ECPA and IBMA

The PSC considered the documents provided by IBMA and ECPA in preparation for the technical hearing with stakeholder representatives on 25 April.

15. Any other business

- **Information on recent calls for grants and procurements**

  EFSA reported that a number of calls for grants and procurements have been launched as follows:

  - Procurement for a literature review of epidemiological studies linking exposure to pesticides and health effects.
  - Procurement for scientific support, literature review, and data collection and analysis for risk assessment of microbial organisms used as active substances in plant protection product.
  - Procurement for the collection of pesticide application data in view of performing the environmental risk assessment for pesticides.
  - Procurement for the development of software models for predicting environmental concentrations of plant protection products in soil.
  - Article 36 Grant on collection and evaluation of relevant information on crop interception.
  - Article 36 grant to perform case studies for the application of the Guidance of EFSA on the Submission of scientific peer-reviewed-open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009.

- **MSs actions on 2 new studies on neonicotinoids**

  COM has mandated EFSA to prepare a Statement on the findings in two recently published studies investigating sub-lethal effects in bees of some neonicotinoids. The Statement will be available by the end of May. MSs are kindly requested to make EFSA aware of any ongoing or finalised evaluations of these studies. Any information should be sent to EFSA by 27 April 2012.

- **Assessment of groundwater metabolites**

  It was discussed whether a risk-based or a hazard-based assessment should be performed for groundwater metabolites. EFSA always applies the guidance document on relevant metabolites. It was noted that there might be a need to discuss the interpretation of the guidance document in the SCFCAH.

- **Status of the e-consultation group**

  EFSA is investigating the necessary formalities and logistics of establishing an e-consultation group in the area of phys-chem.

- **Further meetings**

  Members of the PSC are invited to propose agenda items for the October meeting by 31 July 2012.

16. Guidance documents

EFSA gave an overview of the situation regarding the development of guidance documents, and of the related outsourced activities. A scientific opinion on the science behind the risk assessment for bees and a guidance on dermal absorption have been adopted by the PPR Panel. The Terms of Reference regarding the update of the SANCO Med-Rice guidance were agreed. UK presented draft Terms of Reference regarding the use of aged sorption data in regulatory assessment and MS were invited to send comments by the end of May.

17. Discussion with ECPA and IBMA

A short introduction was given by EFSA to explain the role, remit and tasks of the PSC. Representatives from IBMA and ECPA gave presentations outlining issues of importance in their fields, followed by a discussion session with the PSC.