Parma, 26 October 2011

PESTICIDE STEERING COMMITTEE

Minutes of the 12th meeting

Parma, 25 – 26 October 2011

EFSA / PESTICIDES / 12

Agreed by the PSC on 24 April 2012

Participants

Members:

EFSA Herman Fontier (Chair)
AT Robert Womastek
BE Philippe Castelain
BU Rositsa Mladenova
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 Arpad Ambrus
IE Dermot Sheridan
IT Pasquale Cavallaro
LV Dace Bumane
MT Joanne Galea
NL Annette Smits-van Prooije
PL Jan Krzysztof Ludwicki
SK Marta Galusova
SL Katerina Groznik
SE Lennart Romert
UK Steve Dobson

Observers:

COM Wolfgang Reinert
COM: Francesca Arena
JRC Sazan Pakalin
CH Lucia Klauser

EFSA:

Jane Barling (Pesticides)
Jürgen Sturma (Pesticides)
Chris Lythgo (Pesticides)
Luc Mohimont (Pesticides)
Franz Streissl (Pesticides)

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 this 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 from COM on the GD on efficacy
- Information from COM on the GD on guidance documents

3. Approval of the minutes of the previous meeting

The minutes were approved without any changes.

Follow up on

- point 8: the issue has been discussed in the Post Annex I Group, but there is still need for further consideration.
- point 17: EFSA provided COM with a final update of the draft guidance document on MRL setting for NAS, which was subsequently discussed in the Pesticide Residue Risk Managers meeting.

4. Dates for meetings in 2012

It was agreed that 2 meetings will be sufficient.

The meeting scheduled for 2012 were confirmed to be on:

24/25 April 2012 and 16/17 September 2012

5. Work programme for new a.s.

With regard to the Art 11(6) procedure (Regulation (EU) No 188/2011) RMS gave feedback on the expected date for the submission of the updated DAR/addenda to EFSA.

6. Interpretation of additional information

Presentation from EFSA summarising the relevant Articles in the current legislation (i.e. Regulation 1141/2010, Regulation 188/2011, Regulation 1107/2009, Regulation 33/2008). It was agreed that there is a need to have a clear understanding of the interpretation of "additional information", and in particular whether new studies are included.

It was concluded that "additional information" includes new studies, unless explicitly excluded by the legislation.

It was noted that in relation to Regulation1141/2010 there is a distinction made between Art. 14(3) and 16(3) concerning the scope of information that may be requested by the RMS and EFSA respectively (i.e. EFSA may ask for additional information or data, whereas the RMS may ask for additional information only). COM will provide further advice on this point.

Action point:

- COM to schedule a final discussion concerning the interpretation of Art. 14(3) of Regulation 1141/2010 in the SCFCAH.

7. 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. It was noted that the peer review has now been started for all active substances, and the programme is on track to meet the overall legal deadline of 31 December 2012.

It was agreed that there is a need for further discussion on general issues for micro-organisms, although it was acknowledged that such discussions must not delay the ongoing peer review. To make progress it is necessary to identify the issues of concern and allocate priorities, in order to decide the best way forward (e.g. workshop, development of guidance, etc.). In addition EFSA will consider a possible project concerning an open literature search on the state of the art in this area.

Concerning plant extracts is was noted that COM has organised an expert meeting later this year to discuss general issues.

Action points:

- MS to submit to EFSA proposals for general issues to be discussed in relation to micro-organisms, together with suggestions for the best way forward by 18 November 2011.
- MS to submit to COM proposals for general issues to be discussed in relation to plant extracts, together with suggestions for the best way forward by 18 November 2011.
- EFSA to consider a possible project for literature search in relation to micro-organisms.

8. E consultation groups for EU experts

In view of the limited number of expert meeting in the areas of physical-chemical properties and methods of analysis it was agreed that an e-consultation group might be helpful in supporting the MS experts working in these fields. EFSA offered to set up a pilot project on the EFSA extranet to investigate the possibilities for and limitations of such a forum.

Action point:

- MS to nominate experts for the e-consultation group on physical-chem by 18 November 2011.

9. Removal of CBI from documents to be made publicly available

Presentation from EFSA. A brief document has been developed setting out the procedure to be followed by MS and the applicant in relation to the sanitisation of the summary dossier prior to submission to EFSA for publication. RMS are encouraged to share the document with applicants during the pre-submission phase.

COM is drafting a guidance document on the new completeness check procedure under Regulation 1107/2009. That GD should make reference to the sanitisation procedure for the summary dossier and may include the relevant documents (see above) as appendices.

Action point:

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

10. Progress with dossier/DAR format revision

Revision of DAR format:

Presentation from the small COM ad-hoc expert group. A next meeting of the expert group is scheduled to take place 29/30 November 2011.

Action points:

- MS to submit comments on the proposals and example documents by 11 November 2011.
- MS to nominate experts for the coming expert group on 29/30 November 2011.

Possible changes of the dossier in relation to GHSTS:

Dossiers might be affected by the development of the GHSTS, which is under discussion within an expert group of the OECD. The discussions are still ongoing, however, so far the impact on the dossier format appears to be relatively minor. Tier I and II study summaries will be replaced by the OECD harmonised templates. The next steps involve the establishment of a GHSTS user group.

Action point:

- MS to nominate participants for the GHSTS user group to COM by 18 November 2011.

11. MRL applications submitted with a.s. approval applications

Presentation from EFSA. In this context two documents were developed by EFSA and presented to the meeting, concerning how to proceed when MRL applications are evaluated in the Draft Assessment Report for approval of an active substance.

It was agreed that it would be optimal if the EFSA Conclusion would also cover the MRL evaluations in order to avoid duplication of effort, however, it was acknowledged that different timelines may apply to the approval evaluation and the MRL evaluation depending on the need for additional data.

Action point:

- MS and COM to submit comments on the two documents to EFSA by 18 November 2011

12. BfR Workshop on classification and labelling, working document on progress

Presentation from EFSA. The report on the outcome of the workshop will be made available soon on the COM website.

A draft working document on the process for a harmonised classification of active substances used in PPPs has been developed by EFSA. It was noted that the document could be shared with industry, although the status of the document (being a draft working document) should be made clear. It was considered useful to gain some practical experience with a small number of pilot projects, and RMS were invited to identify possible candidate substances.

Action point:

- RMS to inform EFSA and COM of possible candidate substances for the pilot project.

13. Basic substances

It was noted that MS and COM are receiving several requests in relation to applications for basic substances, and that there is a need for co-ordination of the requests in order to avoid duplication of effort. COM confirmed that there is a standing point on the meeting agenda of the SCFCAH to facilitate co-ordination of activities for basic substances. It was agreed that further clarifications are required concerning the scope of Art. 23 of Regulation (EC) No 1107/2009, and the procedures to be applied.

14. Letter of ACP on biological pesticides

It was noted that EFSA had received a letter from the UK Advisory Committee on Pesticides providing general comments on the EU data requirements for microbial pesticides. The comments were discussed in the context of the issues considered at agenda item 7.

15. Guidance documents; discussion on priorities

Presentation from EFSA, giving an update on the latest developments in the topics of interest as set out in the list of priorities for guidance development.

16. Expert Satisfaction Survey; discussions of the results

Presentation from EFSA concerning the results of the Expert Satisfaction Survey.

17. Progress with the resubmissions

An update was presented by EFSA. It was noted that the programme will be finalised by the end of 2011.

18. Changes to the format of the conclusions

Presentation from EFSA. The changes to the conclusion format were considered to be helpful in providing an overview of the outcome of the risk assessment for the representative uses evaluated.

19. Environmental cut-off criteria

Presentation from EFSA. It was agreed that there is a need for guidance in this area, and COM intends to establish a small working group to consider this further in 2012 as a matter of priority. It was considered important for the working group to include both risk managers and risk assessors, and consideration will also be given to the possible involvement of ECHA.

Action point:

- MS to nominate experts to participate in the working group to COM.

20. Any other business

20a. Information from COM on the GD on efficacy. MS are invited to submit comments and nominate experts to participate in this project.

20b. Information from COM on the GD on guidance documents. The GD is under development and a new amended draft is available.

20c. Management of EFSA extranet users. EFSA intends to undertake an annual exercise to renew the user confidentiality statements in order to update accounts in view of staff movements etc. MS are also requested to inform COM when staff leave the authority in order that CIRCA accounts can be managed as necessary.