**PESTICIDE STEERING COMMITTEE**

**Minutes of the 8th meeting**

**Held on 08 – 09 June 2010, Parma**

**EFSA / PRAPeR / 08**

**(Agreed on 14 September 2010)**

## Participants

Members:

EFSA Herman Fontier (Chair)
AT Robert Womastek
BE Samira Jarrah
BG Rositsa Mladenova
CZ Martin Prokop
DE Herbert Köpp
DK Nina Sørup Hansen
EL Kalliopi Kokkinaki
FI Kaija Kallio-Mannila
FR Thierry Mercier
IE Dermot Sheridan
IT Elena Redolfi
LT Kristina Valioniene
MA Joanne Galea
NL Jeroen Meeussen
PT Bento de Carvalho
SE Lennart Romert
SK Bronislava Škarbová
ES Carmen López Goti
UK Steve Dobson
COM Wolfgang Reinert

Observers:

HR Iva Pavlinic Procurica (observer)
MK Vera Risteska (observer)
NO Abdelkarim Abdellaue (observer)
TR Pelin Aksu (observer)
CH Lucia Klauser (observer)

EFSA:

| | |
|---|---|
| Jane Barling (PRAPeR) | Jürgen Sturma (PRAPeR) |
| Mark Eggsmose (PPR) | Muriel Dunier Thomann (PPR) |
| Luc Mohimont (PPR) | Karin Nienstedt (PPR) |

## 1. Welcome and apologies

The Chair welcomed the participants. Apologies were received from Arpad Ambrus (HU), Katarina Groznik (SI), Tony Hardy (**PPR Chairman),** and Hermine Reich (EFSA).

## 2. Adoption of agenda

The agenda was adopted, with the following additional points for discussion under AOB:

- consideration of two ECPA letters concerning i) a request for a hearing at the final meeting of the PSC in November/December 2010, and ii) a new concept for dossier submission.
- format of dossiers.

## 3. Declaration of interests

No interests were declared by the participants of the PSC.

## 4. Approval of the minutes of the previous meeting

The minutes were approved with the following amendment: BE to be added to the list of Member States willing to support a workshop on MRL risk assessment methodology (point 9 refers).

An update was given on the following points:

Point 4: it is noted that COM has included a provision in the AIR II regulation that the representative formulation should contain only one active substance.

Point 5a: EFSA has recently given presentations to industry to encourage applicants to submit MRL proposals at the same time as the new active substance (NAS) dossier. EFSA will draft a guidance document for consideration by COM.

## 5. Decision concerning the establishment and operation of networks; remit of the PSC

Presentation from Herman Fontier. The members of the PSC confirmed having signed the confidentiality declaration. Where a document/discussion item is to be considered confidential this will be clearly indicated, otherwise information discussed at the PSC can be disclosed to third parties.

The remit of the PSC was confirmed with the addition of a specific point to consider the prioritisation of guidance documents. The remit regarding cooperation with ECHA was re-defined as co-ordination with ECHA.

**Action Points:**

1. EFSA to update the PRAPeR area of the EFSA website, and to include a section on the PSC. Following approval, the minutes to be published on the website.
2. EFSA to ensure that meeting documents are checked for confidentiality and classified appropriately.

## 6. Situation with regard to the resubmissions

Presentation from Herman Fontier. EFSA gave an overview of the status of the resubmission programme. It was agreed that the focused peer review and streamlined EFSA conclusion format had proved to be efficient and effective. The expert teleconferences were also considered to be effective and time saving, although face-to-face meetings were preferred for difficult substances. It was agreed that EFSA will continue with the focused approach and the streamlined conclusion, and will continue to make use of teleconferencing options as well as organising face-to-face meetings. The rapporteur Member States (RMS) provided feedback on the current status and expected dates for submission of the Additional Report for the remaining resubmitted active substances.

**Action points**:

1. RMSs to keep EFSA updated on any changes in submission dates of Additional Reports.
2. EFSA to check and maintain the information provided to Member States for planning (timelines, MS project etc).

## 7. Work programme 2011 for NAS

Presentation from Herman Fontier. The RMSs provided an update on the summary status information set out in the 4$^{th}$ draft of the inventory of NAS prepared by EFSA. RMSs were asked to advise COM of any NAS that are no longer supported in order that the process can be formally terminated by withdrawal of the completeness decision.

It is intended that the new regulation setting out procedures and timelines for NAS to be considered under Council Directive 91/414/EEC will be submitted for a vote in the July meeting of the Standing Committee on the Food Chain and Animal Health (SCFCAH), with a view to subsequent adoption and publication in the following weeks. The question of whether or not there will be a requirement to apply new guidance will be clarified in the final text of the regulation. Once the regulation has been voted it will be necessary to finally establish the procedures that should be applied in case there is a need to update dossiers in the light of new guidance.

Due to the various timelines and possibilities to stop the clock for the provision and evaluation of additional information set out in the new regulation it is difficult to plan the NAS work programme far in advance. A strategy was proposed to plan the work programme on a quarterly basis via the PSC meetings. In order to ensure a constant workflow, and to avoid as far as possible peaks in the workload, it was agreed to fully integrate the work programme on the 4th stage green track active substances (GTAS) in the planning for 2011/2012. It was agreed that the GTAS should be grouped and prioritised as appropriate to ensure that the peer review process is completed in the most efficient and effective way. The first quarterly planning for the NAS and GTAS programmes will be discussed in-depth at the next PSC meeting in September 2010.

**Action Points:**

1. RMSs to keep EFSA updated on the status of the NAS
2. RMSs to circulate the so-called "information sheet" also to EFSA
3. COM to make the draft regulation for the pending NAS available on CIRCA
4. MSs to provide comments on the draft regulation
5. Once the text of the regulation is finalised with regard to the application of new guidance, RMSs to make a detailed check of the situation for each NAS for which they are responsible, preferably together with the applicant, in order to discuss the planning at the next meeting of the PSC in September 2010.
6. MSs to submit comments/ideas on the planned programme for the GTAS to EFSA (with COM in cc) by the end of August 2010.

## 8. Regulation 1107/2009

MRL setting for new active substances

Presentation from Herman Fontier. EFSA has made some recommendations to the Commission concerning possible options to ease the process for plant protection product (PPP) authorisation and mutual recognition, and MRL setting, in order to avoid any difficulties with conflicting timelines for these activities. The recommendations were also presented to industry at the ECPA conference in May 2010. Recommendations include the following:

- where possible, MRLs should be applied for together with the active substance application under Regulation 1107/2009 (even for uses other than the representative uses);
- where there is a need to set new MRLs, the evaluation report to be drafted under 396/2005 should be finalised within 3 months, with the follow-up steps to be taken in the next 9 months, enabling a PPP authorisation to be granted within 1 year;

- to avoid a potential duplication of work, a single MS should evaluate all MRL applications. Ideally this should be the RMS under Directive 91/414/EEC, i.e. the RMS would have the overview of all GAPs and MRL applications and would be able to select the most critical GAP/MRL combination, identify exceedence of ADI etc;
- where an exceedence of the ADI is identified, the issue could be referred to the Inter-zonal Steering Committee for a selection of uses before the evaluation report is submitted to EFSA.

Cooperation EFSA/ECHA

In order to make further progress, EFSA proposes that a workshop would be useful to bring together all parties involved and facilitate discussions on:

- a.s. approval and classification;
- a.s. approval and health cut-off criteria;
- a.s. approval and environmental cut-off criteria;
- document formatting;
- GHS.

The workshop should consider the streamlining and integration of the procedures. DE offered to host such a workshop and will draft a proposal for consideration at the next PSC meeting in September 2010. FR, FI, COM and EFSA offered to take part in the organisation committee for the workshop.

**Action points**:

1. MSs to indicate to DE their willingness to participate in the organisation committee by 18 June 2010.
2. EFSA to liaise with ECHA regarding their possible participation in the organisation committee.
3. COM to liaise with DG Enterprise regarding their possible participation in the organisation committee.

Basic substances

Presentation from Herman Fontier. According to Article 23(4) of Regulation 1107/2009 COM shall ask EFSA for an opinion or for scientific or technical assistance. Therefore, in principle, this may be an issue for either PPR or PRAPeR. There is still some uncertainty concerning the definition of a basic substance. Before referring an application to EFSA, COM should first carefully consider whether it concerns a basic substance or a PPP.

**Action points:**

1. RMSs to provide EFSA with all available information concerning expected applications for basic substances.
2. MSs/COM to provide comments on their expectations with regard to the content of an opinion/results of scientific or technical assistance on a basic substance by the end of July 2010.

Evaluation of efficacy data for an application approval

Presentation from Herman Fontier. The scope of the efficacy assessment to be performed under Regulation 1107/2009 was discussed in order to provide feedback for the forthcoming meeting of efficacy experts organised by COM on 20 July 2010. Taking into consideration the reason for including the evaluation of effectiveness in the new regulation, it was generally agreed that the primary purpose is to establish whether the representative GAP is effective. On this basis a "light" approach was recommended, also in acknowledgement of the fact that a full evaluation of efficacy is conducted at MS level for PPP authorisation.

**Action point:**

1. COM to give feedback to the efficacy expert meeting regarding the views of the PSC.

Guidance on scientific peer reviewed open literature

EFSA thanked all parties who had provided comments. The guidance is in the last stages of finalisation and will be published by mid-June 2010.

Distribution of work between PRAPeR and PPR

Presentation from Herman Fontier. It was noted that the tasks foreseen for EFSA in certain articles of Regulation 1107/2009 make a distinction between the provision of an opinion, and the provision of other scientific technical assistance. With reference to Articles 28(1) and 31 of Regulation 178/2002, these tasks may therefore involve PPR and/or PRAPeR. It is a matter for COM to seek advice from their legal service when mandating EFSA for tasks in order to avoid any conflict in interpretation of the legislation in this area.

## 9. MRL risk assessment methodology

There was no further discussion of this topic.

## 10. Revision of guidance document on persistence in soil

Presentation from Mark Egsmose. An update was given of the revision of the guidance document on persistence in soil: exposure assessment in soil for terrestrial effect

assessment. If the PPR Panel agrees, then the draft guidance document will be sent out for public consultation by the end of August 2010. This will be announced to MSs. The methodology proposed for deriving the DeGT50 value in the draft guidance may have implications for exposure assessments in other compartments e.g. groundwater.

## 11. Consultation on guidance documents

An updated version of the document on the survey on needs and priorities regarding guidance documents has been presented to the PSC. The layout of the table has been modified. Action points are now clearly stated and proposed, planned or ongoing specific activities of relevance are also mentioned, when known, to avoid duplication of efforts and resources. Information regarding these specific activities is also now archived on CIRCA in specific folder to ease consultation by Member States. The content of the table has also been updated according to the information and exchange of views prior to and during the meeting. The updated table is attached to these minutes. This point will be regularly put on the agenda of the Pesticide Steering Committee.

## 12. Feedback on consultation of risk managers on protection goals

Presentation from Karin Nienstedt. The PSC was informed about the feedback obtained on the draft opinion on developing protection goals from the consultations with stakeholders (workshop in Parma, April 2010) and with risk managers (consultation of COM and MS risk managers, Brussels, May 2010). In general terms there were no fundamental concerns raised during these consultations; rather the need for further clarifications was identified. EFSA would like to thank COM and MS for the comments received, which will be considered by the WG and the Panel for their further work. The stakeholder report, written by rapporteurs and compiled by EFSA, was published in July 2010 and is available at www.efsa.europa.eu. The output of the risk manager consultations consist of 3 rapporteur reports corresponding to the 3 break-out groups, and 2 Member State positions. All documents are available on CIRCA.

## 13. Feedback from the OECD WG on Pesticides, May, Paris

Feedback was given on the following points:

- EFSA was asked to coordinate a test phase for the MRL calculator with the MSs. This issue was under discussion at the WG Residues meeting in June, and will be confirmed following the outcome of the discussion.
- The Globally Harmonised Transfer System (GHTS) will be established in the format of CADDY xml. The OECD harmonised templates have been agreed upon.

Discussions on these issues will take place in the EU IT-group, although a meeting date has yet to be confirmed.

- Regarding "Metapath", the plan has been approved and a user group will be established.

**14. Planning for list 3 green track active substances**

According to Article 12a of Regulation 1095/2007, EFSA should deliver its view on the final three list 3 green track active substances (i.e. dicamba, difenoconazole, and imazaquin) by 31 December 2010. EFSA proposed a draft schedule for the remaining steps to be undertaken in the peer review, which was agreed by the respective RMSs.

**15. Any other business**

- To support the preparation for the meetings of the PSC it would be desirable to identify the agenda point to which the available documents relate.

- The PSC agreed to have a meeting with representatives from industry since feedback from the companies on different issues is considered helpful. It was proposed to dedicate one afternoon to the session with industry. ECHA should also be invited to participate in the discussion. It was agreed that the industry session would take place as part of the PSC meeting in November/December 2010, and that the industry participants should provide all documentation at least 14 days before the meeting.

- The new dossier format (as set out in the letter from ECPA) should be discussed in the EU expert group. The meeting is planned to take place end of June/beginning of July.

- It was noted that dossiers submitted in the CADDY format using an msg format can lead to IT problems and MSs should not accept such dossier submissions.

- Global joint reviews - EFSA could participate during the commenting phase. If hazard issues can be resolved then this is also helpful for the peer review. Similarly, experts from outside the EU zone could also participate in the PRAPeR expert meetings. MSs should inform EFSA about these projects in order to give the opportunity for PRAPeR to participate in the initial phase. A guidance document on work sharing will be updated by COM to take this issue into account.

## 16. Date of next meeting

14 – 15 September 2010. MSs are invited to send ideas, position papers, thought-starters, suggestions and comments ahead of the next meeting.