European Food Safety Authority

**PRAPeR Unit**

Parma, 1 December 2010

**PESTICIDE STEERING COMMITTEE**

**Minutes of the 10th meeting**

**Parma, 30 November – 1 December 2010**

**EFSA / PRAPeR / 10**

**Agreed by the PSC on 22 March 2011**

## Participants

Members:

| | | |
|---|---|---|
| EFSA Herman Fontier (Chair) | FI Kaija Kallio-Mannila | PL Jan Krzysztof Ludwicki |
| AT Sonja Ecker | FR Thierry Mercier | SK Bronislava Škarbová |
| BE Philippe Castelain | HU Arpad Ambrus | SL Katerina Groznik |
| BG Rositsa Mladenova | IE Dermot Sheridan | ES Carmen López Goti |
| CZ Martin Prokop | IT Elena Redolfi | UK Steve Dobson |
| DE Herbert Köpp | MA Joanne Galea | EL Kalliopi Kokkinaki |
| DK Annika Boyle Petersen | NO Abdelkarim Abdellaue | |

Observers:

Anthony Hardy (PPR Chairman)

COM Wolfgang Reinert

CH Lucia Klauser

MK Vera Risteska

TK Pelin Aksu

EFSA:

Jane Barling (PRAPeR)

Jürgen Sturma (PRAPeR)

Muriel Dunier-Thomann (PPR)

Luc Mohimont (PPR)

Mark Egsmose (PPR)

Stakeholder representatives attending for agenda items 16 and 17:

| ECPA representatives: | IBMA representatives: |
|---|---|
| Euros Jones | Willem Ravensberg |
| Peter Day | Bent Iversen |
| Jean-Pierre Busnardo | Ulf Heilig |
| Martin Schäfer | Sergio Franceschini |
| Martyn Griffiths | David Cary |

## 1. Welcome and apologies

The Chair welcomed the participants. Apologies were received from Bento de Carvalho (PT), Robert Womastek (AT), Nina Sørup Hansen (DK), Lennart Romert (SE) and Sanja Milos (HR).

## 2. Adoption of agenda

The agenda was adopted with an additional point under any other business:

- change of specifications during the resubmission procedure

## 3. Declarations of interest

In accordance with EFSA's Policy on Declarations of Interests, EFSA screened the Annual Declaration of Interest (ADoI) filled in by the participants 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 beginning of this meeting.

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

The minutes were approved with minor changes:
The participant from ES was José Luis Alonso Prados instead of Carmen López Goti.

Update on action points:
Point 16: EFSA informed that no comments were received and therefore it is considered that the proposed procedure for import tolerance applications is agreed.
Point 19: EFSA informed that the call for Seconded National Experts (SNEs) has been prolonged for another year and Member States are encouraged to make nominations.

## 5. Planning PSC meetings 2011

The following dates were proposed:

22 – 23 March

21 – 22 June

6 – 7 September

6 – 7 December

Member States gave feedback on the suitability of the dates. EFSA will reconsider the meeting dates proposed for March and December.

Action point:

1. EFSA to reconsider the proposed meeting dates for March and December.

## 6. Preparation of the technical hearing with stakeholder representatives

The meeting considered the documents provided by IBMA and ECPA in preparation for the technical hearing with stakeholder representatives on 1 December.

## 7. Work programme for new active substances

Presentation from EFSA. It was noted that the new regulation setting out procedures and timelines for NAS to be considered under Council Directive 91/414/EEC was voted at the October meeting of the Standing Committee on the Food Chain and Animal Health (SCFCAH) and is expected to be published in early 2011. Taking into account the provisions of the regulation, and in particular the transitional measures, the NAS to be considered fall into 3 main workflows in terms of the initial action required and the related timelines:

1. DARs submitted to EFSA after the entry into force of the regulation. In accordance with Article 7(1) of the regulation EFSA will organise a commenting period within 30 days of receipt of the DAR.
2. DARs submitted to EFSA after 31/12/2009, for which a commenting period has not yet been launched. According to the regulation, COM will set the date for launching the commenting.
3. DARs submitted to EFSA before 31/12/2009. The transitional measures of Article 11(6) of the regulation will apply, i.e. within 1 month of entry into force of the new regulation the RMS will ask the applicant to inform the RMS and EFSA (within 1 month) whether additional information is available that might influence the outcome of the assessment, following which EFSA will decide within 2 months whether to ask the RMS to formally request the submission of the available information. Where additional information is requested the RMS has a period of 6 months to evaluate the information and submit their assessment to EFSA. COM will then decide on the schedule for commenting on the new assessment.

With regard to workflow 2 above, it was agreed that it would be helpful to launch the commenting period as soon as possible after the entry into force of the regulation. In relation to workflow 3 above, Member States are encouraged to begin consulting with the applicants concerning the availability of new information in order that progress can be made as soon as possible after the entry into force of the regulation. The form developed by EFSA should be used to provide feedback on this point to EFSA for further consideration at the PSC in March 2011.

The new regulation does not include any specific provisions concerning the application of new guidance documents that have been adopted since the dossiers were submitted. It was agreed that a common approach is required. Overall, and in view of the approach taken in the meantime at Member State level with regard to PPP authorisations, it was agreed that the latest guidance should apply, with the exception of the guidance document for birds and mammals, which has yet to be formally taken note of by the SCFCAH. It was agreed that new guidance adopted during the course of the peer review should not be applied.

Action Point:

1. RMSs to update the information sheet in consultation with applicants, and to submit it to EFSA as soon as possible.

## 8. Status of the resubmissions

EFSA gave an overview of the status of the resubmission programme.

## 9. Regulation (EC) No 1107/2009

9.a MRL setting for NAS

Following the last PSC meeting in September several Member States submitted comments on the draft guidance document prepared by EFSA. There were no further comments.

Action points:

1. COM to provide comments on draft guidance document within 10 days.
2. EFSA to amend the text considering the comments received.

9.b Co-formulants (Art 27)

Presentation from EFSA. Art. 27 of Regulation (EC) No. 1107/2009 sets out legal provisions in relation to co-formulants that are not accepted for inclusion in PPPs. According to Art. 27(5) detailed rules for the implementation of these provisions may be established, and it is currently foreseen that these may be available by mid 2015. In the meantime, and in accordance with the derogation set out in Art. 81(2), Member States may apply national provisions for co-formulants until 14 June 2016 (without prejudice to Community law).
DE is developing a discussion paper on this issue and interested Member States may contact DE to participate in these developments. DE hopes to provide the paper for consideration by the PSC in the 2$^{nd}$ quarter of 2011.

Action point:

1. Member States to contact DE (Herbert Köpp), if they would be interested to contribute to the discussion paper.

9.c Guidance on scientific peer reviewed open literature (Art. 8(5))

A public consultation on the draft guidance document has taken place and EFSA is considering the comments. Feedback from the PSC will be provided to the working group. The final guidance is expected to be available by the end of the year.

9.d Consultation of EURLs (Art 12(3))

Presentation from EFSA. It was agreed that there would be benefit in systematically consulting EURLs (European Reference Laboratories) with regard to the residue definition and the related methods of analysis proposed in the assessment report. It was agreed that such consultation should be organised early in the process, and preferably in parallel with the commenting phase on the assessment report. According to the regulation EFSA may ask COM to consult the EURLs, and a streamlined approach will be developed for this step. Further consideration should be given to the need to consult the EURLs in relation to MRL setting, and in particular to whether this should be undertaken at the level of the evaluating Member State, taking into account the tight legal timelines for delivery of the EFSA Reasoned Opinion.

Action points:

1. COM and EFSA to agree on a streamlined procedure for the systematic consultation of EURLs during the peer review process.
2. EFSA and COM to further consider the need for consultation with EURLs in the context of MRL setting.

## 10. Isomers

Presentation from EFSA. With reference to specific examples, EFSA gave an overview of the issues that may arise for isomeric compounds, such as preferential degradation, conversion, differing toxicological properties etc., highlighting the need to fully consider these in a robust scientific risk assessment. In EFSA's view the current data requirements clearly foresee that data to address these issues should be provided where relevant. EFSA explained the approach taken in the absence of sufficient data.

It was agreed that there is a clear need for guidance in this area, as also identified in the EFSA survey on needs and priorities of guidance documents, which will be discussed by the panel on Plant Protection Products and their Residues. Terms of reference for a guidance document have been drafted by ES, AT and BE, and submitted by ES to EFSA. EFSA will circulate the terms of reference to Member States for comments.

Action points:
1. EFSA to circulate the terms of reference as soon as possible.
2. EFSA and Member States to submit comments on the terms of reference.

## 11. Workshop on cooperation in the area of C & L

It was noted that a first meeting of the organisation committee took place in October 2010 to discuss the scope and organisation of the workshop. A preliminary workshop programme and draft outline papers for the proposed break-out groups are available on CIRCA. Comments are welcome by 6 December 2010.

Formal invitation letters will shortly be issued by COM, and the Member States are requested to provide the relevant contact details for the competent authorities dealing with pesticide risk assessment and classification & labelling.

A Member State volunteer is sought for the introductory lecture "Document formatting for dossiers and DARs according to Regulation (EC) No 1107/2009"

Action points:
1. Information on the contact points should be sent to COM (Patrizia Pitton) as soon as possible.
2. Written comments on the draft documents to be submitted by 6 December 2010 to Herbert Köpp, Roland Solecki and Herman Fontier.
3. Member States volunteering for the introductory lecture "Document formatting for dossiers and DARs according to Regulation (EC) No 1107/2009" to inform Roland Solecki.

## 12. List 4 'green track' active substances: next steps

Presentation from EFSA. It was noted that the commenting phase for the first batch of 11 active substances was launched in October 2010. It was agreed that a second batch of 11 active substances will be distributed for commenting in mid December 2010, with a third batch to be launched by mid February 2011.

In accordance with the mandate recently received from COM, the scope of the peer review should be defined during a teleconference between EFSA, COM, and the RMS. The PSC agreed to the EFSA proposal to discuss a group of active substances in one teleconference involving all relevant RMSs.

Action point:

1. RMSs to provide EFSA with the contact details for the teleconference.

## 13. Written procedure on the draft conclusion

Presentation from EFSA. In the interests of transparency, from now on EFSA will document comments received on the draft conclusion in the format of a commenting table, where EFSA will respond to each comment. The commenting table will then be publicly available as part of the Peer Review Report.

Action points:

1. EFSA to provide Member States with all necessary background documents for the written procedure on the draft EFSA conclusion.
2. Member States to submit any proposals for amendment of the commenting form by the end of the week (3 December 2010).

## 14. OECD global joint reviews

OECD has made available a draft guidance document on global joint reviews. Comments are welcome by 3 January 2011. EFSA advised that it is willing to discuss any possible participation in future global joint reviews.

Action point:

1. Member States to submit comments to OECD on the draft guidance document by 3 January 2011.

## 15. Any other business

15.a EFSA expert compensation guide

EFSA informed the PSC of some important changes that have recently been made to the rules for expert compensation. A copy of the revised expert compensation guide will be made available on CIRCA. The new rules are applicable as from November 2010.

15.b Proposal for a “living dossier” concept

It was noted that ECPA recently made further proposals in relation to the “living Dossier” concept. This issue is also under discussion in several forums, including a small IT group under the leadership of COM. It was agreed that issues of transparency and independence should be carefully considered.

15.c Change of the specification under the resubmission procedure

It was noted that according to Art 15 (1a) of Commission Regulation (EC) No. 33/2008 the specification may only be changed in so far as it is necessary in light of the reasons that gave raise to the non-inclusion decision.

## 16. Guidance documents discussion on priorities

The PSC was informed of the progress since the last meeting regarding guidance documents (GD) to be developed or revised. In particular:

1. The development of GD on local effects caused by dermal or respiratory exposure is not supported anymore.
2. A letter has been sent by EFSA to the Commission on a list of risk management issues to be discussed to ensure coherence between risk assessment and risk management in the development of cumulative risk assessment methodologies.
3. The update of the revised (2009) GD on risk assessment for birds and mammals was included in the list of needs. The report from the Joint WG (Commission, Member States and PPR Panel) will be used as a starting point. Member States are invited to send comments on additional scientific issues that would need to be addressed as well as on bugs or problems encountered with the calculator tool by the end of January 2011.
4. NL, FR, DE and EFSA will cooperate to draft terms of reference on the basis of the Dutch proposal for further discussion in the PSC.
5. The FOCUS GD on persistence and degradation kinetics will be updated to ensure consistency with the recent guidance of the PPR Panel on the evaluation of results of field persistence and soil accumulation studies for exposure assessment of soil organisms.
6. The update of the MED-RICE GD was included in the list of needs. IT and GR will cooperate to draft terms of reference.
7. ES in cooperation with BE and AT have drafted terms of reference regarding the risk assessment of isomer mixtures. Member States are invited to send comments in view of further discussion in the PSC.
8. The PPR Unit will outsource preparatory activities in 2011 as support to development or revision of GDs regarding the setting of the ADI and on the setting of the AOEL.
9. Three outputs relevant for the list of needs have been published by EFSA (Report of the internal task-force on endocrine active substances (SC), report of the first public consultation on the GD on the use of probabilistic methodologies in dietary exposure assessment (PPR) and opinion on protection goals (PPR)).

The PSC was also informed of the activities planned by the PPR Unit and the PPR Panel in 2011 in the area of guidance documents. The PSC agreed that the risk assessment of isomer mixtures was a priority that should be considered for possible inclusion in the PPR programme of activities in 2011.

## 17. Technical hearing with stakeholder representatives

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. ECPA and IBMA expressed their wish to establish a regular dialogue with the PSC on an annual basis.

Action point:

1. Industry representatives to indicate by July/August 2011 any topics for possible discussion in a session of the PSC at the end of 2011.

## 18. Date of next meeting

22 – 23 March 2011 (tbc).