Network on Pesticide Steering

Minutes of the Teleconference 01

Held on 17.07.2015
(Agreed on 14 September 2015)

Participants

- **Network Representatives of Member States (including EFTA Countries):**

Country	Name	Country	Name
Austria	Sonja Ecker	Hungary	Tamás Griff
Belgium	Philippe Castelain	Ireland	Aidan Moody
Czech Republic	Martin Prokop	Italy	Pasquale Cavallaro
Denmark	Nina Sorup Hansen	Latvia	Vents Ezers
Estonia	Jan-Roland Raukas	The Netherlands	Hanneke Westland
France	Thierry Mercier	Portugal	Bento De Carvalho
Germany	Herbert Köpp	Spain	José Luis Alonso Prados
Greece	Danae Pitarokili	The United Kingdom	Susy Brescia

- **European Commission and European Institutions:**
  - Jani O. Honkanen (ECHA)

- **EFSA:**
  - Pesticides Unit (José V. Tarazona, Head of Unit, Chair)
  - Pesticides Unit (Bénédicte Vagenende, Coordination Team)
  - Pesticides Unit (Christopher Lythgo, Fate and Behaviour Team)
  - Applications Desk Unit (Tom Meyvis, APDESK Unit)

1. Welcome and apologies for absence

The Chair welcomed the participants.

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2. Adoption of agenda

The agenda was adopted without additional points. However, a change in the order of the agenda points was requested by ECHA so agenda point 5.4 and 5.5 were discussed first.

3. Discussion on ECPA proposal for a technical workshop on higher-tier environmental risk assessment for active substances

EFSA proposed 18 or 19 November 2015 as possible dates for the ECPA workshop on higher-tier environmental risk assessment and introduced the ECPA proposed case studies for the different issues as follows:

- Higher-tier data –Mesocosm studies
    - Esfenvalerate
    - Imidacloprid
- Higher-tier data – Groundwater modelling
    - Chlorantraniliprole
    - Acetochlor
- Review of risk mitigation measures
    - Oxyfluorfen

UK mentioned that reimbursement by ECPA for 2 or 3 experts per MS would be needed.

ES questioned what the expectations are from this workshop and what is requested from the RMS regarding the proposed case studies.

EFSA explained that industry raised a concern 'higher tier studies for the environment are not sufficiently covered by the RMS in the DAR and in the EFSA conclusion'. The aim of the workshop is to allow industry to present their concerns using examples, not to reopen closed a.s. assessments. In case justified comments are identified in the workshop, those will be further discussed in fate and/or ecotox expert meetings. It is crucial that the RMS of the proposed case studies is joining the workshop. EFSA will present the EFSA view expressed in the respective conclusions.

BE agreed with the proposal to select closed assessments but expressed its concerns on the possible risk that this kind of workshops would need to be organised on a regular basis and its impact on the workload. It is important that all MS, EFSA and EC are clear on the scope of this workshop.

Several MS expressed their concerns and requested more details on ECPA's proposals and expectations. Furthermore, concerns were expressed that accepting this workshop might trigger further requests from other organisations and there is a lack of resources in MS to respond to these requests.

UK is in favour of the workshop as it enhances transparency and is a good forum to listen to the concerns of our stakeholders.

AT and DE proposed to organise a pre-meeting between MS and EFSA in order to be prepared and aligned before the workshop takes place. DE proposed to postpone the workshop to early 2016 because of lack of resources.

The following was agreed:

- EFSA will propose to ECPA to postpone the workshop to early 2016.

- EFSA will invite ECPA to submit full documentation supporting the case studies by end September 2015.
- EFSA will organise dedicated fate and ecotox TC by the end of 2015 to discuss with the MS the details of the case studies.
- EFSA will request ECPA to check the availability of the RMS' experts for the proposed case studies as the participation of the RMS is crucial.
- EFSA will request ECPA to delete the proposed case study on acetochlor as MT is currently preparing a DAR for approval of acetochlor as NAS. As the DAR is expected to be finalised by December 2015, consultation on the DAR will be on-going at the time of the workshop and thus acetochlor cannot be considered as a closed assessment.

4. Discussion on the services provided by EFSA and RMSs to Applicants

EFSA (APDESK Unit) gave a presentation on the catalogue of services provided to applicants. The catalogue contains quite some exceptions for Pesticides as EFSA is not involved in the initial assessment. However most of the services in the catalogue are available to the applicants through the MSs. Therefore EFSA would like to propose the creation of a catalogue dedicated to the Pesticides area, that covers both MS and EFSA services and would provide a much completer and clearer picture of the services offered to applicants in the Pesticides area.

NL highlighted the need for sharing the finalised reporting table with the applicant in addition to the clock-stop letter. EFSA explained the confidentiality issues in case of multiple applicants as no sanitised versions of the reporting table are provided to EFSA. DE informed that they provide the applicant with an extract of the reporting table restricted to the data requirement points only. EFSA will further reflect on possible solutions for this issue.

EFSA asked the view of the MS on the proposal of preparing one harmonised catalogue for applicants, covering both the RMS and EFSA parts of the procedure and invited MS to participate in the drafting of the catalogue. EFSA clarified that the drafting of the catalogue should be done by MS as they have the best knowledge of their part of the procedure, EFSA will coordinate the working group. DE agreed to have one harmonised catalogue and will most likely participate in the drafting of the catalogue. Several other MS also agreed to produce one harmonised catalogue.

EFSA informed that industry associations will be invited to the next PSN meeting (27-28 October 2015) for a technical hearing. One of the agenda items will be on the services provided to applicants.

Action point:

- MS to nominate experts by the end of September to participate in the working group for drafting the harmonised catalogue

5. AoB

5.1 PSN involvement in the development of the guidance documents on non-target terrestrial plants and arthropods

EFSA informed that an initial proposal will be prepared by EFSA and send to all members of the PSN for commenting. A dedicated sub-working group of the PSN will be created for setting the basis for developing EFSA guidance documents based on the PPR Panel opinions. All MS are invited to nominate experts.

Action point:

- EFSA to circulate the initial proposal of the GD to all members of the PSN for commenting.
- MS to nominate experts to participate in the dedicated sub-working group supporting the GD development

5.2 PSN consultation on the PPR guidance on residue definition

EFSA informed that the adoption of the PPR guidance on residue definition has been postponed to February – March 2016. According to the change in the terms of reference of the PSN, a consultation on the draft GD will be organized for ensuring that the guidance is fit for purpose and to facilitate the implementation. If considered useful, a dedicated meeting and/or info session could be organised presenting the draft GD to MS. MS are invited to provide feedback on the best way for commenting/interaction. PT requested EFSA to clearly indicate in the call for comments what exactly is required from MS.

Action point:

- MS to provide feedback on the best way for commenting/interaction
- EFSA to consult members of the PSN on the draft PPR guidance on residue definition

5.3 Technical report compiling the assessment of endocrine effects in the EFSA Conclusions

EFSA is preparing a compilation in the format of a Technical report of all assessments of endocrine effects in the EFSA conclusions that will be distributed to MSs for information before publication. There is no new information in this document, however it was created to enhance transparency in how EFSA is assessing endocrine effects in its conclusions. The document will be published in September 2015.

Action point:

- EFSA to distribute the Technical report to all members of the PSN for information. *Post-meeting note: the Technical report was distributed on 20/07/2015.*

5.4 Progress of the expert group for the alignment of the DAR and the CLH report

EFSA informed that the first TC of the expert group took place in July 2015 and the following items were discussed :

- Integrating the CLH content in the DAR Template
- DAR will be the starting point, current headings would not be modified (subheadings could be added).

ECHA and EFSA will prepare a draft during summer that will be distributed to all MS and discussed at the next PSN.

IT welcomed to have one template covering both processes and asked about the timelines for the implementation of this new template. EFSA clarified that the template will be discussed at the next PSN (27-28 October 2015). Once the template is finalised and agreed, it would need to be implemented without delay.

NL and ES highlighted difficulties in meeting the deadlines as two different competent authorities (CA) are dealing with PPP and CLH and thus should be consulted. EFSA explained that at least the proposed CMR classification should be agreed between the CAs

before finalising the DAR/RAR. If needed, more than one expert (one for PPP and one for CLH) could be invited to the mamtox expert meeting.

PT requested to keep the numbering in the DAR template as much as possible unchanged as the DAR template is corresponding to the dossier structure.

UK questioned if the RMS would need to add the complete CLH report as Annex to the Vol 1 of the DAR and thus would not submit a CLH report to ECHA, or is the aim to add only relevant parts of the CLH report to the Vol 1 of the DAR and the CLH report would need to be submitted anyhow to ECHA.

ECHA explained that the overall idea is to reduce the workload of the MS and to have both procedures (a.s. approval and CLH) started at the same time. However, there are still uncertainties on how all this will be implemented in practice. It will be considered if one public consultation could cover both processes (and avoid 2 parallel public consultations). Further discussions with European Commission are needed as the timelines are different for both procedures.

AT questioned if ECHA would start the CLH process at the same time of the DAR (incl CLH) submission to EFSA. EFSA responded that this would be the case.

5.5 CMR assessments in the DAR/RARs

EFSA explained that in the July PAFF meeting, it was clarified by EC Legal services that the peer review C&L proposals in the EFSA Conclusions are the basis for the interpretation of "has to be classified". ECPA has requested a meeting with EFSA during August to discuss this further. Applicants and RMS are requested to include (in the dossier and DAR/RAR respectively) explicitly the comparison with the CLH criteria. All MS are invited to comment on the C&L proposals during the consultation on the DAR/RAR. Furthermore, EFSA has requested ECHA a higher involvement during the commenting rounds for ensuring consistency; this is still under discussion between the 2 Agencies.

AT questioned if the new template will replace the CLH report. ECHA clarified that if all elements needed for C&L are covered in the DAR, there is no need for copying the same information in a different format. A different cover page might be needed but this is still under consideration and discussion by the expert group for alignment of both templates.

IT asked if the procedures will change. EFSA clarified that the procedures will not change but the importance of C&L under the peer review process is higher, including a more detailed commenting on C&L proposals, in particular for CMR properties.

PT questioned if EFSA will communicate these changes clearly to the applicants. EFSA explained that a meeting with ECPA is taking place in August to clarify the information that should be presented in the dossier (especially when no classification is proposed) and to discuss how to deal with on-going, already submitted dossiers. EFSA will inform the members of the PSN of the outcome of the meeting.

ES questioned what is exactly expected from the RMS. EFSA clarified that the RMS should include in the DAR their proposals for classification, the comparison against CLP criteria and a justification why (no) classification is needed. The proposal should formally also cover the environmental classification however in view of the approval criteria, the DAR should contain at least the CMR proposals.

UK welcomed the fact that there is finally an EC view on this issue but expressed the importance of both processes; a clear comparison of the data against the criteria is often lacking and is considered crucial. EFSA explained that ECHA is invited to comment during all stages of the peer review and is also invited to the peer review meetings. EFSA agreed that there is a need to improve the way classification is discussed in the mamtox meetings.

BE agreed with EFSA and ECHA: classification proposals, incl clear justification, should be added to the DAR. In case uncertainties on classification are expressed in the DAR, the proposal should be discussed in a mamtox expert meeting.

UK questioned what will happen in case of disagreements. Furthermore, they highlighted a lack of experience on classification of the mamtox experts as they are not aware of previous RAC decisions. EFSA clarified that possible disagreements/divergent opinions will be presented in a transparent way in the meeting report.

EFSA explained that ideally the aim is to have the RAC opinion published before the EFSA conclusion and to have only one discussion on C&L instead of having separate discussions in ECHA and EFSA. In case of different substance identity (refer to PSN 18), there might be differences between the harmonised classification and the EFSA proposed classification.

NOTE: Documents distributed during the meeting, excluding confidential documents and preliminary documents for discussion only, are available upon request to pesticides.peerreview@efsa.europa.eu