Network on Pesticide Steering meeting
Minutes of the Teleconference 02

Held on 21 June 2017

(Agreed on 19 July 2017 via written procedure)

Participants

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

Country	Name
Austria	Sonja ECKER
Belgium	Herman FONTIER
Czech Republic	Jana JEZKOVA
Denmark	Alf AAGARD
Finland	Kaija KALLIO-MANNILA
France	Thierry MERCIER
Germany	Herbert KÖPP
Hungary	Tamás GRIFF
Ireland	Aidan MOODY
Latvia	Līga BRENCE
Lithuania	Kristina VALIONIENE
Netherlands	Hanneke WESTLAND
Poland	Pawel STRUCINSKI
Portugal	Bento DE CARVALHO
Spain	José Luis ALONSO-PRADOS
Sweden	Katarina LUNDBERG
United Kingdom	Susy BRESCIA

- **European Commission DG SANTE:**

Wolfgang REINERT

- **EFSA:**

Pesticides Unit (José V. TARAZONA, Head of Unit, Chair)

Pesticides Unit (Bénédicte VAGENENDE, Coordination Team)

Pesticides Unit (Dimitra KARDASSI, Coordination Team)

Pesticides Unit (Tunde MOLNAR, Coordination Team)

Pesticides Unit (Alessia VERANI, Coordination Team)

Pesticides Unit (Angela SACCHI, Coordination Team)

Pesticides Unit (Jürgen STURMA, Coordination Team)

Pesticides Unit (Chloé DE LENTDECKER, Coordination Team)

1. Welcome and apologies for absence

The Chair welcomed the participants and presented the scope and objectives of this teleconference.

2. Adoption of agenda

The agenda was adopted without any changes.

3. Follow-up on the workshop on improvements in the peer review process

3.1 Update by EFSA on status/implementation agreed action points and MS feedback on EFSA initiatives

EFSA presented the different actions undertaken by EFSA related to the action points agreed in the February PSN meeting (http://www.efsa.europa.eu/sites/default/files/event/170214-m_0.pdf)

Specific discussion took place on the following topics:

- EFSA reminded that the RMS could request support/advice from EFSA (via email or ad hoc Teleconference to be organised) in case complex situations are encountered at any time point prior to submission of DAR/RAR (eg pre-submission phase, DAR/RAR preparation phase).

- EFSA presented the FAQ document that is shared with MS on the EFSA document management system and updated on a daily basis when new questions are received. MS were invited to provide comments and suggestions on this document.

- E-consultation groups on the EFSA documents management system: EFSA informed that a pilot forum has been created **on microorganisms**. MS were invited to contact EFSA in case a new discussion group on a specific topic should be created. It was agreed to create another forum on botanicals and plant extracts. EFSA clarified that notifications can be set by experts interested in a specific forum in order to receive automatic alerts when new issues are posted in the forum. EFSA referred to the user manual for more details.

- Concerning the organisation of peer review meetings on general and recurrent issues, EFSA invited MS to send topics for discussion at any time point. EFSA will collect the topics and will organise a dedicated meeting if

sufficient material is available. A meeting on mammalian toxicology will still be organised at the end of this year.

- 'Accordance check' of the summary dossier: MSs/EC are invited to nominate experts by 15 July 2017 to participate in the working group on the accordance check and to share any completeness checklists or other documents that are used at MS level and could be useful as starting point by the WG. Following nominations, the first TC will be organised in September. A discussion took place on the quality of the dossier and if more detailed guidance is needed on what information should be submitted by the applicant and how this information should be presented (especially for renewal dossiers). The UK clarified after the TC that problems arise later on, during evaluation, because the admissibility checks of applicants' dossiers performed by MS focus only on the presence of information/waiver being provided for each endpoint, not on the quality of that information/waiver. It was highlighted that the dossier structure is also discussed in the context of the on-going MATRIX project and that OECD OHT for study summaries are well established. EFSA informed that a grant is currently on-going to prepare study summaries (especially on carcinogenicity and genotoxicity, with the possibility to be extended to reprotoxicity) in order to build specific examples for a proper reporting of the data. The issue of timelines should be clarified in case this additional task of accordance check would be included into the process.

- Concerning the risk assessment of microorganisms and the need of training, it was highlighted that no nomination for trainers was received from MS and EFSA clarified that they currently do not have the capacity to take the lead on this. However, MS were invited to make use of the existing microorganism e-consultation forum and if needed request support from EFSA at pre-peer review phase. Furthermore, when expert consultation will be scheduled for AIR IV microorganisms (eg Bacillus group), EFSA proposes to foresee more time to discuss general issues (but still linked to practical examples as otherwise risk of very long general discussions not leading to specific outcome, cfr past long expert meetings on microorganisms with few specific conclusions) and eventually draft a technical report with more general recommendations on m.o. assessments. RMS for AIR IV microorganisms were invited to highlight in the AIR IV RAR (different colour or separate document containing specific list) which data requirements they consider as more relevant for the risk assessment. This could be the starting point for establishing a list of most important data requirements relevant for the risk assessment of microbial active substances and considered to be of high importance for decision making.

- EFSA informed MS that launching of new peer reviews would be limited to 4 new DAR/RAR per month in order to ensure a proper peer-review and sufficient commenting by MS and EFSA.

- The new way of commenting was presented by EFSA: An excel template has been developed in order to streamline the commenting during the different steps of the peer review. This excel template will replace the commenting tables on DAR/RAR, the reporting table, the evaluation tables and the written procedure on additional information report. So a 'living' document approach is proposed with one table that will 'grow' during the different stages of the peer review. Different colours in the headers are used in order to visualise the different stages of the peer review. Following the commenting round, EFSA will sort the comments according to the section number, so as a separate excel file will be created for each section. This living document approach should reduce the current manual editing and increase the transparency as the overall evolution of comments through the process could be followed.

  MS expressed some concerns on the proposed excel format as long comments, tables and graphs would not fit in excel cells. Furthermore, the need for printable formats was highlighted, as well as the need for freezing the document at different stages of the peer review. In view of the sanitisation before publication, a pdf format is needed and will be developed.

  MS are invited to upload their comments by 15/07/17 in the commenting table on DMS (https://dms.efsa.europa.eu/otcs/llisapi.dll/link/17931369). Following the commenting round, EFSA will further amend the excel file. MS are invited to indicate if they would be interested to participate in a pilot for testing the new excel file with a recently submitted DAR/RAR that will start peer review in September.

- EFSA clarified that a document summarising the expectations from experts attending peer review meetings or teleconferences has been prepared by EFSA. Furthermore, the call for nomination of experts for the peer review meetings has been amended and MS are invited to indicate active substances for which they would like to support the RMS in the discussions. All these documents have already been used in the call for nominations for the June-July expert meetings and substances have been allocated to participating experts. EFSA shared the first experiences following this new approach. The substances under discussion will continue to be distributed between the attending experts. The experts are invited to upload their preliminary comments on the allocated a.s. at the latest 3 working days before the meeting in the template available in the respective meeting folder on DMS. A discussion took place if it is more efficient the expert who prepared the DAR/RAR is attending the meeting, or if there is continuity guaranteed by the same expert attending all meetings (cfr ECHA RAC and biocide model). EFSA clarified that the former is the choice of the MS.

3.2 Continued discussion on outstanding issues for which no agreement was reached in February PSN meeting

Assessment of representative uses and other uses:
EFSA clarified that all the studies that are properly assessed and presented in the DAR/RAR, even if not relevant for the representative uses, will be peer reviewed. In addition, EFSA, if requested, would support the MS (following a mandate) for the assessment of complex zonal studies on an ad-hoc basis.
The majority of MS agreed that a maximum of endpoints should be agreed at EU level however this should be further discussed and agreed by the PAFF. All MS agreed that for the residue section all studies (beyond those supporting the representative uses) submitted by the applicant should be included in the DAR/RAR in order to establish a proper residue definition that will facilitate the MRL setting process.

3.3 Discussion and agreement on next steps – Action plan

EFSA will prepare a technical report presenting the entire process on improving the peer review procedure (from June 2016 until today) and the main outcomes. The draft technical report will be circulated for comments to the PSN members in the second part of September and most likely be presented to the PAFF meeting in October 2017.

4. AOB

4.1 Update status MATRIX project

EFSA gave a short update on the status of the MATRIX (e-submission and electronic workflows) project. A first pilot phase will take place over July – September. A discussion group has been established with different stakeholders, including 2 MSCA for pesticides.

MS asked EFSA to provide more general information on MATRIX project (eg high level project plan).

A more detailed discussion on MATRIX is foreseen to take place in the October PSN meeting (including outcome of pilot and scope of the dossiers (a.s. versus PPP).

4.2 Update on the "new" procedure in the framework of Article 12 MRL Review

The new procedure and work programme have been extensively discussed in the dedicated residue expert meeting in May 2017 and the PAFF residues meeting in June 2017. EFSA would like to highlight the following points:
- In the current interim process, the delay is 8 wks for "GAPs and trials" collection, so the overall time to compile data will not really change;
- Residue trials data are collected which were in theory already assessed by MS as the GAPs reported should also be GAPs that are already authorised (no new data or GAPs should be submitted during this exercise);
- The format for the trials is the same than before (OECD tables); only the format for the GAP will change (and is more user friendly).

The work programme is now publicly available on http://www.efsa.europa.eu/sites/default/files/pesticides-MRL-review-progress-report.pdf and will be updated on a quarterly basis.
Following the pilot case on glyphosate, the new process has been launched for other MRL reviews in May 2017.

4.3 Update on Guidance on Endocrine disruption

EFSA provided an overview of the different stages and consultations foreseen during the development of the ECHA/EFSA Guidance on Endocrine disruption. Following a MS comment on the applicability of the guidance for all assessments, EFSA clarified that the next version will better address procedural issues and will take into account the comments received during the first consultation of the stakeholder consultation group.

MS are invited to inform EFSA by 15/07/17 on possible case studies they would like to present as RMS in the workshop that will be organised by EFSA and ECHA at the end of the public consultation (currently planned for Q4 2017).

4.4 Update on time lines Art.21 reviews of neonicotinoids

EFSA clarified that MS consultation on the draft conclusions and expert meetings will take place in September – October 2017. The final deadline for providing the EFSA conclusions is on 30/11/2017.

4.5 Mandate PSN: 3 yrs mandate will expire in July. Discussion on need for update.

EFSA proposes to not change the current mandate (Terms of Reference will remain unchanged), with the exception of the preparation of an annual report on the activities of the PSN, as this is a duplication of the minutes that are anyhow published. MS to send by 30/06/17 any further comments or proposals for changing the mandate. If no comments are received, the mandate will be renewed as proposed by EFSA for the next 3 years.

Next meeting: 24-25 October 2017. MS are invited to send their agenda items by 08/09/17.