Network on Pesticide Steering

Minutes of the 17th meeting

Held on 11.11.2014 – 12.11.2014, Parma
(Agreed on 10 February 2015)

Participants

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

Country	Name	Country	Name
Austria	Sonja Ecker	Lithuania	Kristina Valioniene
Belgium	Herman Fontier	Malta	Joanne Borg Galea
Bulgaria	Iva Romanova	Norway	Abdelkarim Abdellaue
Croatia	Rajka Turk	The Netherlands	Hanneke Westland
Czech Republic	Martin Prokop	Poland	Robert Bańkowski
Estonia	Jan-Roland Raukas	Portugal	Bento De Carvalho
Finland	Kaija Kallio-Mannila	Slovakia	Bronislava Škarbová
Germany	Herbert Köpp	Slovenia	Milena Koprivnikar Bobek
Greece	Danae Pitarokili	Spain	José Luis Alonso Prados
Hungary	Tamás Griff	Sweden	Katarina Lundberg
Ireland	Aidan Moody	The United Kingdom	Susy Brescia
Latvia	Vents Ezers		

- **Panel Members**
  - Bernadette Ossendorp, chair of PPR Panel, participated in agenda point 5.6, on nanopesticides guidance
- **European Commission and European Institutions:**
  - Wolfgang Reinert (DG SANCO)
  - Jani O. Honkanen (ECHA)
- **EFSA:**

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- Pesticides Unit (José V. Tarazona, Head of Unit, Chair)
- Pesticides Unit (Luc Mohimont, Deputy Head of Unit)
- REPRO Department (Per Bergman, Head of Department), participated in agenda point 5.4
- Pesticides Unit (Bruno Dujardin, MRL team)
- Pesticides Unit (Jean Pierre Cugier, Peer Review and Art. 10 team)
- Pesticides Unit (Christopher Lythgo, Fate and Behaviour Team)
- Pesticides Unit (Bénédicte Vagenende, Coordination Team)
- Applications Desk Unit (Tom Meyvis, APDESK Unit)
- Pesticides Unit (Tunde Molnar, Coordination Team)
- Pesticides Unit (Dimitra Kardassi, Coordination Team)
- Pesticides Unit (Stefania Barmaz, Coordination Team)
- Pesticides Unit (Hermine Reich, MRL team), participated in agenda point 5.6
- Pesticides Unit (Manuela Tiramani, Toxicology team), participated in agenda point 5.6
- Pesticides Unit (Anja Friel, Peer Review and Art. 10 team), participated in agenda point 5.6
- Pesticides Unit (Mark Egsmose, Fate and Behaviour team), participated in agenda point 5.6
- Pesticides Unit (Franz Streissl, PPR team), participated in agenda point 5.6
- Pesticides Unit (Ragnor Pedersen, Coordination Team), participated in agenda point 5.7
- Legal and Regulatory Affairs Unit, (Citlali Pintado, Legal officer), participated in agenda point 5.10

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted with the addition of the two additional points under any other business, from the UK and the NL.

3. Declarations of interest and new EFSA Policy on independence

The Chair informed the participants on the new implemented rules following the ED decision from 2014. In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes regarding Declarations of Interests (DoIs) and the Decision of the Executive Director implementing this Policy[1], members of networks, peer review meetings, networking meetings and their alternates shall be invited to complete and submit an Annual Declaration of interest (ADoI). The responsibility for the appointment or nomination of

[1] http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf

representatives of the Member State(s) or of its authorities rests exclusively at all times with their respective Member State(s).

EFSA invites members of Networks to complete and submit an ADoI for transparency reasons, without screening. EFSA shall publish the submitted ADoIs in accordance with Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data. No Specific Declaration of Interest (SDoI) or Oral Declaration of Interest (ODoI) are requested.

4. Agreement of the minutes of previous Pesticide Steering Committee

4.1 Minutes of the 16th meeting of the Pesticide Steering Committee held on 18 - 19 February 2014:

The minutes were agreed with some minor amendments. The minutes have been published on the EFSA website (http://www.efsa.europa.eu/en/events/event/140218a.htm).

4.2 Update on the PSC dedicated meetings on bees

The Chair gave an update on the outcome of the Pesticide Steering Committee dedicated meeting on bees. It was explained that following the action point for EFSA agreed at the February meeting, expert groups have been created dealing with the peer review of bee study protocols, the validation of the bee calculator tool supporting the EFSA guidance document on the risk assessment of plant protection products on bees and the restructuring of the same guidance. The Technical Reports on the study protocols were finalized in May 2014 and version 2 of the bee calculator tool was issued in November 2014.

On a similar matter, the Chair informed that the Commission mandated EFSA to perform the risk assessment for bees for all uses other than seed treatments and granules (including foliar uses) for 3 neonicotinoids (clothianidin, imidacloprid and thiamethoxam). The Chair informed that the risk assessment will follow the EFSA Guidance Document on the risk assessment of plant protection products on bees. A postponement of the deadline for the delivery of the Conclusions was officially requested by EFSA. The new deadline will be communicated following confirmation received from COM.

4.3 Update on the PSC dedicated meetings MRL

EFSA organised a dedicated meeting on the MRLs procedures which was held on 19-20 June 2014. The agreed minutes of the 1st meeting on the MRLs procedures can be found on the EFSA website.

EFSA gave an overview of the streamlined procedures under Art. 10 and Art. 12 of Reg. (EC) No 396/2005.

In order to improve and simplify MRL reviews under Art. 12 of Reg. (EC) No 396/2005, EFSA proposed a new streamlined process (future process). Considering that data have been already submitted for many active substances, the need of a transient process (interim process) has been agreed for phasing out the current process. It was mentioned that for the interim process, GAPs and trials should be reported by the authorising country (not the RMS), GAPs and trials should be submitted by MSs at the moment of the call for data. The RMS has 2 months or more for the preparation of the evaluation report; in the future process the comments will be submitted at an earlier stage and a complete coordination with the MSs from the start of the procedure is foreseen as part of the procedure. It was clarified by EFSA that all AIR III a.s. should be considered under the future process since the renewal process could have impact on residue definitions or on the toxicological reference values,

with major implications on the authorisation of the a.s. In these cases we should wait the AIR III peer review to be finalised before Art. 12 review is initiated. However, if there is a consumer intake concern for AIR III substances these would be considered under the interim process since those are needed to be handled under high priority.

In order to adopt a streamlined approach for the drafting of the EFSA Reasoned Opinion on MRL applications (as it was done for the EFSA Conclusions), EFSA intends to publish the Evaluation Reports (ER) as "background document" to the Reasoned Opinion. The 2 months period is adequate for the RMS in order to comment or amend the ER before publishing. EFSA highlighted that confidential information should be avoided in the ER (e.g. avoid mentioning author names of vertebrate studies as this information is considered to be treated as confidential in accordance with Art. 63 of Reg (EU) No 1107/2009). EFSA will follow a similar approach for the Evaluation Reports on MRL Review (Art.12 of Reg (EC) No 396/2005) that will be dealt with under the interim process. However, this will be communicated when EFSA invites all Member States to submit additional data. Following a comment from a MS, EFSA clarified that in case there is a difference of opinions between RMS and EFSA this should be clearly indicated in the Reasoned Opinion (as it is done for the EFSA Conclusions).

Regarding MRL applications under Art. 10, EFSA informed that certain documents have been developed and uploaded to the EFSA Document Management System in order to harmonise the different procedures i.e. handling import tolerances, animal burden calculation spreadsheet, MRL calculation in food of animal origin according to the OECD documents etc. The comments collected and the documents amended/corrected according to the MS comments will be presented in the next PAFF Standing Committee on Residues to be held in February 2015. EFSA proposed the new data requirements (validation of analytical methods, crop matrices classification etc) to be discussed in small working groups.

It was stressed that for the new active substances the assessment of MRL applications is already included in the Draft Assessment Report. If CXLs are already available for the active substance under consideration, these should be presented and discussed in the Draft Assessment Report.

Member States were informed that a guidance document on the interpretation of the transitional measures for the data requirements for active substances and plant protection products according to Regulation (EU) No 283/2013 and Regulation (EU) No 284/2013 is under discussion at COM level. The new data requirements (Regulation (EU) No 283/2013 and 284/2013) are applicable to new a.s. for which the dossier was submitted on or after the 1st January 2014. For the "existing" active substances, the new data requirements are applicable to the active substances whose approval expires on the 1st January 2016 or later. The "old" data requirements (Regulation (EU) No 544/2011 and 545/2011) are therefore applicable to the AIR II a.s. In contrast, the "new data requirements" will be applicable to the renewal of the approval of the AIR III a.s.

Following a comment it was clarified that for Art. 10, as soon as EFSA receives the mandate from COM, will start the completeness check; 'clock stop' will be set when information is missing, at the very early stage. Opportunity is given to the MSs in order to amend the ERs.

EFSA informed the Network that EFSA is considering a project for compiling all the list of End Points (LoEPs) to a single database which will cover also MRLs. This consolidated database will contain all the information retrieved from EFSA pesticides outputs on active substances.

MSs welcomed the initiative for a centralised database on LoEPs; however, some MSs expressed their concern regarding the update of the database and possible difficulties on tracking information after several amendments/changes. A comment was received from a MS that in some cases the end points are changed following Standing Committee decisions (without EFSA involvement), therefore it would be useful these changes to be included in a

single database. COM and EFSA will further explore this possibility in a bilateral discussion. The aim is to create one point of reference for the final approved endpoints.

Action point:

- MSs to provide comments on the Art.10 documents. The documents will be presented in the next PAFF Standing Committee on Residues.

5. Topics for discussion

5.1 Work programme for new substances, state of play

EFSA gave a presentation on the status of the work programme for new active substances. The last substance falling under Commission Regulation (EU) No 188/2011 is currently under the peer review. The EFSA conclusions on the risk assessment are expected by May 2015. EFSA have, so far, finalised the conclusions on the risk assessment for 6 substances falling under Regulation (EC) No 1107/2009. By the end of 2014, the peer review will be finalised for further 3 substances and by the end of 2015 for 11 substances.

The submission of 2 new DARs is expected by the end of 2014. 9 new DAR submissions are expected in the course of 2015. MSs were reminded that for all the new active substances the MRL application form needs to be submitted.

EFSA is expecting 4 applications for amendment of the approval conditions under Art.12 of Regulation (EC) No 1107/2009.

MSs were reminded to inform EFSA of any stop of the clock or delays during the preparation of DARs to facilitate planning of the upcoming work programme.

Action point:

- MSs to inform EFSA of any stop of the clock or delays during the preparation of DARs. MSs were asked to update the EFSA planning tables available in the EFSA DMS with their proposed submission dates.

5.2 Work Programme for renewals

- EFSA gave a presentation on the work programme for renewals. 19 AIR II substances out of 29 will be finalised this year and the rest will be finalised in 2015. The EFSA procedure on AIR III renewals was explained. The challenges were stressed: timelines altogether 5 months following end of commenting period + clock stop (max 3 months), no additional time granted in case expert consultation is necessary. Compilation of the Reporting Tables and kick off teleconference, i.e. ca 6 weeks, is consumed from the overall timelines. Due to the tight timelines it is expected that for many substances a physical meeting may not be feasible, and instead more teleconferences may be organized. The commenting period will start only after the RAR is made publicly available. Challenge was identified concerning multiple applicants: confidentiality, necessity to create separate confidential Reporting Tables, Evaluation Tables, pre-sanitisation of documents shared with applicants during / after the peer review (e.g. Peer Review Report + Final addendum).

It was highlighted that according to the AIR III GD (rev July 2014)[2] studies used for setting of endpoints during the original approval of the substance should be checked and it should be ensured that the endpoint is still valid; this should be reported in a transparent way in the

[2] Not yet taken note

dRAR. Although the re-evaluation of old studies is not required on a routine basis on all studies, but on a case-by-case basis, it is important to transparently demonstrate in the RAR that the previously accepted endpoints are still reliable for risk assessment purposes. EFSA will comment if this is not the case.

Regarding representative uses vs real uses the AIR II/III GD says: 'The range of supported uses should reflect a representative use pattern and including whenever possible the uses evaluated for Annex I inclusion / first approval.' Similarly to the approach followed for AIR II substances, EFSA will comment if there are significant changes to the representative uses supported in the context of the renewal compared to what was supported in the original approval/real uses supported in Art.12 MRL Review and flag any issues of concern in the Conclusion that may arise from the change in the representative uses.

It was pointed out that for a proper planning, feedback is needed from MSs including possible delays in the RAR submission dates (AIR III submission table available in the EFSA DMS).

The mandatory scientific peer-reviewed open literature was flagged. The RMS should provide a transparent evaluation on how the literature search was carried out and if they can agree with the justifications given by the applicant. It was also highlighted that summaries alone are not sufficient and the full articles should be submitted by the applicants. Regarding MRL application, an MRL application should only be submitted in case a setting of an MRL for a new use or a change of an existing MRL is requested. The assessment of these MRLs will be included in the RAR as prepared by the RMS and peer-reviewed by EFSA in the conclusion. No separate Art.10 Reasoned Opinions (RO) will be adopted.

A mandate from COM is not needed by default. COM should inform EFSA in case a conclusion is not necessary; however, it is not foreseen that this provision will be used on a regular basis.

Some MSs expressed their concerns regarding re-opening discussion on "old" studies and LoEPS, more burden will be put to RMS, lack of resources was pointed out as main issue. Extensive discussion took place. Apparently there are different practices between MS as regards re-evaluation of old studies and there is the general view not to re-open old discussions for issues already concluded and agreed in the past. Clear criteria were sought. EFSA clarified that all lines of evidence should be taken into account for the selection of studies for endpoints and then, if needed, to reconsider existing endpoints based on weight of evidence the new and old information is important in order to consider the weight of evidence. As highlighted, many criteria of approval have been changed (i.e. those based on the new CLP criteria), the old studies should be checked when they are relevant to the approval criteria. COM reminded that the aim of the reassessment process is to aid risk managers to make decisions.

Action point:

- MSs to inform EFSA of any stop of the clock or delays during the preparation of RARs. MSs were asked to update the EFSA planning tables available in the EFSA DMS with their proposed submission dates.

Post-meeting note: the flowcharts outlining the main steps and timelines of the AIR III procedure have been made available in EFSA DMS after the meeting.

- EFSA (APDESK Unit) gave a presentation on the practicalities related to the AIR III and to the sanitisation procedure. In this context, it was highlighted that EFSA should always be informed on the completeness check of the application and the admissibility of the application (in practice supplementary dossier). EFSA also proposes to be put in copy when

the RMS provides their comments on the justification form for the sanitisations to the applicant. An overview of all documents including the preferred format and the associated timelines, is sent to the applicant on first contact and is also available on the APDESK web pages (both for NAS and AIR III). Regarding the sanitisation EFSA highlighted the existing differences in the content of the confidential volume of the applications and questioned if the volume can be simply disregarded for public access or should be sanitised and made available. As to the guidance document (Guidance Document on the renewal of approval of active substances to be assessed in compliance with Regulation (EU) No 844/2012, Rev.3), EFSA informed that this will be possibly taken note at the next Standing Committee. It includes important practical arrangements for the AIR III procedure as regards sanitization.

Concerning the first series of AIR III substances (dRAR submission to EFSA on 31/01/2015), EFSA raised the attention to the fact that for some substances EFSA did not receive any information on the admissibility decision and this information would need to be received ASAP so that the supplementary dossiers can be requested from the applicant and the sanitised version is made public before the dispatch of the dRAR. RMS is requested to always send the admissibility decision to EFSA as well.

The main changes between the AIR II and AIR III procedure were described. One of the main changes regards the commenting period; in the case of the AIR III, member states, applicant(s) and public commenting rounds will be run simultaneously. As a result, EFSA is currently reviewing its DAR and RAR dispatch procedures.

The sanitisation procedure of the assessment reports is also partially changed e.g. the sanitisation of the DAR is now performed directly by the applicant and subsequently verified by EFSA. The evaluation of the confidentiality claims for the supplementary summary dossier is performed at RMS level. EFSA will undertake only a rough check before making it available to the public. EFSA raised the attention to the fact that, when the sanitisation is performed by electronic means, the correct software should be used; the information should be actually removed from the documents and not just covered by a black box.

EFSA informed that some clarifications were sought from Member States on the confidentiality of microorganisms' metabolites. In general, metabolites are not considered confidential information.

One member state suggested that the RMS should check in more detail that only confidential information is put in the confidential part of the application. One Member state suggested that a practical guidance on sanitisation may be useful. On the microorganisms' metabolites, the expert group on Biopesticides may be consulted.

Some concerns were raised as to the changes implemented in the sanitisation process; it is important to ensure that the version of the RAR as provided by the RMS and sanitised by EFSA is published.

Action point:

- EFSA to issue some guidance on sanitisation technicalities
- EFSA to take on the discussions on the possible risks from the fact that the DAR is directly sanitised by the applicant for changes applied to the DAR

Post-meeting note: The Working Group on Biopesticides agreed with the EFSA view that **metabolites of microbial pesticides would *a priori* be non-confidential information**. This is also substantiated by the fact that in general when information on (secondary) metabolites is requested applicants use justifications based on the fact that related fungal species have one or more (secondary) metabolites in common and that these metabolites are not related to any known (human) pathogen. Only in cases when a metabolite is

produced at very specific conditions confidentially may be claimed. In that case, all relevant data requirements should be addressed for this metabolite.

5.2.1 Planning of coming work on renewals, SE proposal

Sweden presented a document which gives an overview of the work planning on renewals. SE is of the view that a new work program for the coming years should be initiated so that planning of work and resources can be made at an early stage. To get an idea of the work-load for the coming years KemI compiled a list of active substances in PPP with expiry dates over the years 2019-2022; however the evaluation of these actives has not been allocated to Member states yet. COM was asked to consider whether there are any plans to allocate the evaluation of these "renewals" to Member States. A brief discussion took place. COM is working on this issue and will inform MSs as soon as possible.

5.3 EFSA Applications Desk: Services to applicants

EFSA gave a presentation on the state of play of the customer service initiatives taken for Regulated Products' applications. The focus of the presentation was on the activities in support of applicants (and other stakeholders) in the areas of Regulated Products. It was highlighted that a REPRO Task Force Customer Oriented Approach is taking care of the development of a set of services for applicants. The set of services was identified starting from EFSA and EU Agencies' experience and from the feedback collected from the applicants. The EFSA Survey on Stakeholder needs and on Stakeholder satisfaction were also taken into account. A catalogue of the services for applicant has been prepared.

An overview of the services in place during the pre-submission, evaluation and post-adoption phases was provided. These include some new services developed during 2014 such as the submission of applications by electronic means, technical hearings and the possibility for applicants to request clarifications via telephone conferences. EFSA clarified that not all services are relevant for the peer-review of pesticides a.s.

5.4 MATRIX project

The MATRIX project namely the electronic management of regulated products applications lifestyle was presented by the head of REPRO Department. Matrix is a project aiming to optimize the "electronic lifecycle management of applications" that EFSA receives for evaluation in the regulated products area. The project is consisting of three components: streamline of the format in which the regulated products' applications are submitted to EFSA, design of data submission templates and revision of the current regulated products' applications workflows within the scope of existing legal framework. The final aim of the project is to integrate the revised workflows, data requirements and new IT technologies. Until the end of 2014 the project will focus on the analysis of the scientific data requirements, and the workflows of regulated products applications. It was noted that a Stakeholders Benefits Survey sent to all EFSA Stakeholders groups to identify the expected benefits of an online tool for the management of applications of regulated products was not yet distributed to this network. The survey will be "on air" until 5th December. Upon the finalization of the Benefits Analysis, a detailed plan will be made to design the implementation steps of the electronic lifecycle management of applications. Following a question it was clarified that this project will be compatible with the systems that are in force for pesticides now and with the new OECD developments.

Action point:

- EFSA to distribute the survey to the network members

5.5 Classification and labelling alignment

5.5.1 Presentation by ECHA on follow up of the June workshop

ECHA gave an overview of the activities undertaken so far concerning the alignment of the harmonised classification and labelling (CLH) process with the active substances evaluation procedures. The starting point of the alignment is that the C&L of active substances is part of the approval criteria.

The outcome of a workshop on the CLH for Pesticides (and Biocides) held on 10-12 June 2014 in Helsinki was presented. The aim of this workshop was to improve the co-operation and communication between all parties involved (Member States, EFSA, ECHA, Commission and Industry) and to exchange views and ideas on how to create a transparent and efficient alignment process.

One important aspect under discussion regarded the limited resources available at Member States (MS) level. The main goal of the alignment is to have the Risk Assessment Committee (RAC) opinion on the CLH for pesticides adopted before the EFSA peer review expert meetings. This implies that the CLH report needs to be submitted to ECHA 1-3 months before the DAR/RAR submission to EFSA. MS are therefore supposed to prepare in the same timeframe the DAR/RAR and the CLH report and this results in high workload. The possibility of harmonising the hazard assessment sections in CLH and pesticides reports was identified as one of the main items to be further investigated.

As a follow up of the workshop, ECHA is assessing the feasibility of the organisation of pre-submission meetings with the parties involved. ECHA is promoting the use of the registry of intentions by MS and is investigating whether the contact details of MS involved in pesticides and CLH processes could be disseminated in order to facilitate the communication flow. The possible involvement of industry in the preparation of draft CLH reports, to be submitted to MS for further revision is also under investigation. The ECHA support in the preparation of the CLH report will be further advertised.

Two pilot cases for the alignment were already finalised (flumioxazin and sulfoxaflor) and a third one is currently running (benzovindiflupyr). ECHA reported that, for many pesticides currently under EFSA peer-review, the CLH report was not yet submitted. In this context, it was highlighted that in the absence of the RAC opinion, Commission may not be in the position to take a decision on the approval. In this context, the role of the EFSA proposal for C&L was briefly discussed. EFSA clarified that in absence of a RAC opinion, EFSA recommendations for C&L will be used in the EFSA conclusions. If a RAC opinion is under discussion, potential divergences are expected to be clarified between both agencies during the process and the RAC opinion, if adopted before the EFSA adoption, will be explicitly mentioned in the EFSA Conclusion. Differences, if any, between the EFSA conclusion and the RAC opinion will be clarified according to the agreed mechanisms between EFSA and ECHA for dealing with conflicts of scientific opinions.

ECHA highlighted that the effort to align the two processes will continue nevertheless the timely alignment may not be achievable in all cases. In order to facilitate the alignment, the timelines for some steps in the CLH process (i.e. accordance check) will be shortened. Also, to warrant consistency in the data set under the two processes, ECHA will intensify the contacts with dossier submitters in order to get access to the additional data requested under the EFSA peer review process. The need to harmonise the substance identity under the CLH and pesticide procedures was identified. During the discussion, it was clarified that the substance identity under Regulation (EC) No 1107/2009 may differ from the substance to be considered for harmonized C&L under the CLP. The implications of potential differences in the substance identity relevant for the classification and labelling should be further

investigated.The presentation from ECHA triggered a discussion and the following points for further consideration were raised:

- The harmonised classification and labelling dossiers submission may need to be implemented as a requirement under the Regulation (EC) No 1107/2009. This would give a legal status to the alignment.
- The involvement of industry in the preparation of the CLH dossiers is being investigated by different Member States. Further discussion on this, considering also the possible feedback on recent cases, is needed.
- The most important action to increase the efficiency and reach alignment in the two processes would be to include the comparison with the CLP criteria and other relevant parts from the CLH report format in the DAR/RAR so that the DAR/RAR can serve as a CLH report as well. In this way, the time consuming and unnecessary work to transfer the information to another format could be avoided.
- The comparison with the CLP criteria may need to be included in EFSA conclusions for those active substances for which an entry in Annex VI to Regulation (EC) No 1272/2008 (harmonised C&L) is not yet available or when changes in the current classification are proposed. In these cases the C&L needs to be discussed during the peer review meetings.
- The high workload of MS is due not only to the preparation and submission of the CLH report but also to the following steps in the CLH process (preparation of the responses to the public consultation comments)
- Further coordination between MS is needed in the case of substances under renewal where the RMS may be different from the RMS which was dealing with the approval.

The need for further increasing the coordination between both processes was agreed. The PSN was considered the relevant forum for discussing these issues.

5.5.2 UK proposal on needs and priorities regarding Guidance Documents

UK presented a proposal for targeted alignment. This proposal foresees that the alignment of the two processes is prioritised for new or renewal substances with no harmonised C&L in Annex VI to CLP that meet or have the potential to meet the criteria for classification as CMR 1A, 1B or 2. In the case of the substances with a harmonised C&L in Annex VI to CLP, the alignment should be prioritised if there are new data which have the potential to trigger classification as CMR 1A, 1B or 2.

The assessment on whether the criteria for classification as CMR 1A, 1B or 2 are met should be done at the admissibility check or during the DAR/RAR preparation by the RMS. At that stage MS could estimate whether the CLH dossier submission need to be prioritised and could inform ECHA accordingly. In this respect, the DAR/RAR would need to always include a comparison with CLP criteria.

It was clarified that the CLH dossier should address all hazard classes, not just the CMR categories.

Action points:

- ECHA/EFSA to clarify bilaterally the harmonisation of the substance identity under the two processes, and to discuss with COM the implication of differences in the substance identity relevant for the C&L process (e.g. differences between the classification of the pesticide a.s. according to the technical specifications including

isomer rates and impurities and the harmonised classification of the substance following the substance identity under the CLP recommended by ECHA)

- ECHA/MS/COM and EFSA (as observer) to continue the discussion on the CLH and DAR/RAR format harmonisation
- UK proposal to be further discussed e.g. at CARACAL meeting and COM to clarify the way forward when no proposal for harmonised C&L has been submitted to ECHA.

5.6 Guidance documents

5.6.1 Update on the development process of Guidance Documents.

This point was postponed to the next meeting due to lack of time. The Chair highlighted that according to the new mandate, the network has new roles regarding guidance development. The network is expected to contribute to further improvements regarding the practicability and fit for purpose of the EFSA guidance documents.

5.6.2 PSN involvement during development of EFSA guidance: updated PSN mandate

EFSA gave an overview on the preparation of the Guidance Document of the PPR Panel on the establishment of the residue definition for dietary risk assessment – which is a self-tasked activity in accordance with Article 29 1(b) of Regulation (EC) No 178/2002. The guidance will be based on the EFSA PPR Opinion of 2012 on Evaluation of the Toxicological Relevance of Pesticide Metabolites for Dietary Risk Assessment and should become a practical instrument for risk assessors, using new scientific tools and approaches described in the said opinion. The guidance will help to more consistently identify which compounds need to be included in the residue definition for dietary risk assessment and where further experimental data (tox) are really necessary. Public consultation of the EFSA Draft Scientific guidance is expected around end of June 2015, and the finalisation by the end of 2015. The compilation of a database, specific for the pesticide active substances and their metabolites, comprising the different genotoxicity end points i.e. point mutations, structural and numerical chromosome aberrations (grant agreement) has been commissioned. Even though Member States may initially have to allocate resources in order to get used to the application of the new tools never used before systematically in regulatory consumer risk assessments, long-term efficiency gain in assessment and review process (RMS evaluation reports, expert consultations) is expected. Specific training might be offered on how to use this guidance.

The members appreciated the work and welcomed the EFSA offer for providing specific training on the tools to be used.

5.6.3 EFSA proposal on prioritisation

EFSA presented a document comprising a proposal for prioritization of ongoing and possible activities for consideration. MSs welcomed this initiative; however, they identified the need to comment on the proposal in their own countries. It was stressed that MSs are free to submit comments in the list of priorities; the mandate to EFSA for these activities should be tasked by COM. MSs would further appreciate a justification for the prioritisation list.

Action point:

- Member States are invited to comment on the prioritisation list.

5.6.4 Discussion on specific proposals

EFSA gave an overview of the activities supporting the development of guidance documents.

- Isomers

EFSA presented its proposal on isomer guidance. The current data requirements for plant protection products establish that the active substance tested should match the technical specification (including its isomeric composition) and that formation and effects of metabolites, degradation and reaction products should be investigated. This does not exclude the case when metabolites / transformation products are isomers of the active substance / are constituted by active substance components of a different isomer ratio to that defined by the technical specification. The information provided must be sufficient to permit an evaluation to be made on the nature and extent of the risks for man, an assessment of the fate and behaviour of the active substance in the environment and the identification of non-target species likely to be at risk from exposure to the active substance, its metabolites, degradation and reaction products, where they are of toxicological or environmental significance.

EFSA in its conclusions on pesticide active substances and reasoned opinions on setting or modifying MRLs, currently identifies the concern that assessments are not finalised/remain open, where further information is considered necessary on the behaviour of stereoisomers in plants, animals and the environment and or effects on non target organisms. This is concluded when this information is essential to better characterise the risk to humans and other non target organisms, because there are insufficient margins of safety in the available risk characterisation/s. When making EU approval decisions on active substances, where the EFSA risk assessments identify this concern, there are several examples where risk managers have decided to keep the substance on the market, but indicated applicants must generate studies on this, that must be submitted as confirmatory data within two years after the adoption of a specific guidance document on evaluation of the impact of isomers on the pertinent risk assessments. Therefore the information necessary to address this concern that is highlighted by EFSA, will only ever be addressed after a specific guidance document is made available. This is why EFSA considers that making this guidance available should be a priority.

MSs very much appreciated the justification provided for the proposed guidance document.

Action point:

- EFSA will prepare draft ToRs for consideration. COM should consider to mandate EFSA after the ToRs are agreed.

- Focus surface water

EFSA presented a discussion note for repair action of FOCUS surface water scenarios

The Guidance of the PPR Panel on tiered risk assessment for aquatic organisms in edge-of-field surface waters was adopted in July 2013. The guidance revised the effect assessment for aquatic organisms in edge-of-field surface waters. A number of MSs (DE, NL, SE, FI, AT) expressed the opinion that the exposure assessment as an integral part of the aquatic risk assessment should be revised as soon as possible. DK also asked EFSA to reconsider the FOCUS surface water report in the PSN meeting in February 2014. The problem is that surface water concentrations are much more event driven than the respective ground water simulations. Currently TOXSWA only runs over 16 months, the consequence is that similar pesticide applications could lead to totally different entries into surface water even when applied in the same season.

Also several experts have identified deficiencies in the current FOCUS scenarios for which a repair action could be running the FOCUS step 3 scenarios over a period of 20 year instead of the 16 months the TOXSWA model currently applies. Issues were identified also

concerning runoff events in the FOCUS surface water runoff scenarios for where long periods between the pesticide application and the first runoff event are unlikely to represent realistic worst case runoff conditions for EU pesticide registration. It was acknowledged that runoff events were very much dependent on the application window. By extending simulation period over 20 year an underestimation of surface water runoff events based on the unusual events, when the application window is very small, could be avoided. It was proposed that this would be a repair action in the FOCUS GD and not a full revision of the scenarios (long-term action).

The Members of the Network agreed that EFSA should initiate a repair of the FOCUS surface water scenarios to introduce a 20 year weather period instead of the current 16 months weather period. For the repair action the proposals from UK, SE and AT submitted before the meeting will be considered for the preparation of the draft ToRs. Proposals for a full revision of the FOCUS scenarios (beyond a repair action) will be captured in the document for proposals for priority list for guidance.

Action point:

- EFSA will disseminate the draft ToRs for repairing the FOCUS surface water scenarios to the MSs for consideration. COM should consider to mandate EFSA after the ToRs are agreed.
- MSs are invited to make additional proposals for possible repair actions to the FOCUS surface water scenarios.

- Guidance on the assessment of exposure of operators, workers, residents and bystanders

It was briefly presented the Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products, published on 23 October 2014[3]. In 2010, the EFSA Panel on PPR prepared a Scientific Opinion on "Preparation of a Guidance Document on Pesticide Exposure Assessment for Workers, Operators, Residents and Bystanders", highlighted some inconsistencies between the approaches adopted by regulatory authorities and proposed a number of changes to those practices. An ad hoc EFSA working group was established to prepare a GD and the related calculator.
The guidance, which was recently published, introduces the concept of an acute risk assessment in addition to the long term risk assessment. It also suggests the use of 95th percentile of relevant datasets for acute risk assessments for operators, workers and bystanders for acutely toxic PPPs whereas the use of 75th percentile is applied for chronic assessments. The resident exposure assessment is also introduced (limited database).
A tiered approach to exposure assessment is proposed and the deterministic method is still suggested in routine risk assessment for individual PPPs, because of the limitations of the currently available data. The GD includes a number of recommendations, as well as a list of data gaps.
In particular, EFSA highlighted the need of appropriate reference values for the risk assessment (acute and long term): the UK volunteered to lead on the elaboration of appropriate methodology to derive such reference values with the possible collaboration of Germany. EFSA welcomed this offer.

[3] EFSA Journal 2014;12(10):3874

Action point:

- EFSA and COM to discuss the ToRs regarding a possible mandate to EFSA for addressing this issue.
- EFSA to engage with UK and Germany after receiving the mandate.

- Bee Guidance Document

A short overview of the possible activities on the integration of the BEEHAVE model in the Guidance Document on the risk assessment for bees was presented. In 2015 an evaluation of the BEEHAVE model including suitability check of the model (e.g. based on the PPR Panel Guidance document on Good Modelling Practices) for its potential use in a regulatory context and for the RA on multiple stressors in honeybees at the landscape level (strengths and limitations, data needs, recommendations on possible implementations) will be performed and reported as a statement of the PPR Panel. Following a question, it was highlighted that other models addressing multi-stressor situations will be also taken into consideration.

- Birds and Mammals Guidance Document

The need for harmonising the approaches used for risk assessment refinement and the consequent revision of the EFSA Guidance on birds and mammals of 2009 has been already identified by Member States both at the Pesticide Steering Committee and at the Peer review Experts' meeting.

A call for proposals and a grant have already been launched on data collection and harmonisation of the available focal species ecological data, diet composition data obtained in the treated areas (PD); data from residues trials including both residue levels and residue decline to be used for risk assessment of birds and mammals under the regulatory framework of 1107/2009. The final deadline for submission of proposals is 28 November 2014.

Action point:

- EFSA will prepare draft ToRs for consideration. COM should consider to mandate EFSA after the ToRs are agreed.

- Revision of PRIMo

The update of PRIMO model as an ongoing and future activity was briefly discussed. The version 3 of PRIMO model is available; however, the document which describes the version 3 will be released next year (after the Codex meeting). Exposure calculations for processed commodities will be introduced for more refined calculations. EFSA informed that the version 4 of PRIMO model is under consideration, the raw data from Comprehensive Consumption Database will be used instead (MSs will no longer convert their own data to a format compatible with PRIMO model).

- Nanopesticides

The Chair of EFSA PPR Panel presented the state of play. It was stressed the need for linking the EFSA Scientific Committee (SC) activities on nanomaterials with the assessment on pesticides. EFSA considers that the relevance is mostly on the assessment of PPPs not on active substances thus mostly a MS issue; however the need for a PPR Panel opinion as a first step should be discussed. The work on nano-particles has been started in EFSA in Food Contact Materials and Food Additives areas, it was acknowledged that new things are

going on in research; other organisations and counties (USA, ECHA, Australia) have already implemented rules. It was acknowledged that the main involvement of nanopesticides will be put on the formulations and not on the active substances as such. The Member States were informed that a specific working group within SC has been created to deal with these issues. Most of the MSs responded that they have limited (NL, UK, IRL) or hardly any expertise in place but they support the initiative of SC into joining forces on this area. Some MSs expressed concerns that the science is developing very fast and that the EU should take immediate action.

In general the initiative of SC to cover nanopesticides as well as nanoformulations in this resource intensive task was very much welcomed.

5.6.5 Discussion and agreement on priorities and timelines

Action point:

- Member States are invited to comment on the prioritisation list.
- Following the comments of the MSs EFSA will amend the list of priorities if needed.

5.7 Assessment of endocrine effects in the EFSA conclusions

EFSA informed about the recent developments concerning the assessment of the endocrine effects in the EFSA conclusions. During the peer review meetings 114 (mammalian toxicology) and 115 (ecotoxicology), EFSA proposed a possible approach. Following the peer review meetings a commenting round was organised which ended in June 2014. The comments received were circulated to the participants and via CIRCABC. In this context, it was suggested that this issue is further addressed in a joint meeting of toxicology and ecotoxicology experts aimed at discussing specific active substances for which the evaluations are on-going. MS were invited to submit possible case studies by the end of June 2014; so far one proposal was received.

Although adopted scientific criteria for the determination of endocrine disrupting properties are not available, for the hazard assessment of endocrine disrupting properties interim criteria, based on classification and effects on endocrine organs, are already in place. The development of specific criteria for the determination of endocrine disrupting properties is under responsibility of COM. Nevertheless, EFSA, together with the member states, have to conduct an overall risk assessment and conclude on each active substance in a consistent manner. In this connection, Reg. (EC) No. 283/2013 introduces a new data requirement according to which if there is evidence that an active substance displays ED properties specific studies should be required.

Considering the above EFSA is refining the approach in the EFSA Conclusions which now covers both the hazard assessment of the endocrine properties (interim criteria) and the risk assessment of endocrine effects with regards to the overall approval criteria. This is in line with the EFSA Scientific Committee (SC) opinion on the hazard assessment of endocrine disruptors. EFSA Conclusions aim at presenting a clear view on the risk assessment of possible ED which includes also the indication of data gaps and the indication of concerns (e.g. issues not finalised, key areas of concern and/or concerns for the representative uses). The concerns are presented on a case-by-case basis and may cover mammalian toxicology and ecotoxicology.

As to the ED assessment from an ecotoxicological point of view, the EFSA SC opinion on the hazard assessment of endocrine disruptors highlighted that rather limited tests are available. For this reason a grant on the ecotoxicological assessment of ED effects was proposed by EFSA to seek for scientific support and practical recommendations on how to use available data (e.g. pesticides dossiers, DARs, additional information requested and peer-reviewed literature) to identify the relevant effects for further consideration in the risk assessment. The specific objective of the grant would be the identification of the lines of

evidence linking the effects with the concerns relevant for ecotoxicological assessment to be integrated into the current regulatory context.

A MS indicated the need for coordination with the ECHA WG on endocrine disruptors. EFSA clarified that one EFSA expert is participating to the ECHA expert group as observer. Further coordination with ECHA is not considered necessary for the time being.

5.8 Establishing the effects of water treatment on surface water

The UK presented a document describing the proposal on addressing water treatment requirement.

The issue is that the current risk assessment procedures for plant protection products do not take into account the impact of water treatment processes on pesticide-derived residues in either ground- or surface water. However, article 4(3)(b) of Regulation (EC) No 1107/2009 clearly states that approval of pesticide active substances should also take into account substances resulting from water treatment.

Previous UK experience with potential formation of nitrosamines from water-borne residues of the pesticide and biocide active substances indicated that nitrosamine formation could not have been predicted from standard route of degradation studies in soil or water as the nitrosamine was formed from a part of the structure that would not be routinely radiolabelled. In addition, it was indicated that a specific sequence of water treatment methods were required to produce nitrosamines from these particular substances.

UK presented two options for implementing Art. 4(3)(b) of Regulation 1107/2009. Option 1 would need to be deployed only if concerns about the possible effect of water treatment arise in any particular case. If they do, Art. 4(3)(b) could be used to amend or withdraw the approval in order to address those concerns. Option 2 would be to regard it as a condition to be satisfied by every active substance as part of the approval process. Taking this approach, information would need to be generated and submitted to allow Regulators to judge the impact of water treatment processes on water-borne residues of active substances and metabolites, i.e. the capability of water treatment processes to form potentially harmful substances when degrading the water-borne residue. In case option 2 is pursued, the UK presented a more simplified approach.

In the discussion which followed the UK expressed preference to the option 1. The majority of the MSs and COM were favourable to the option 2 approach.

EFSA expressed the opinion that on this issue the initial responsibility is lying on the applicant. It was highlighted that EFSA is systematically commenting on the DARs and, if necessary, identifies relevant data requirements for the applicant since EFSA should provide a view in its conclusions on the approval criteria. In case the applicant has not provided enough information, this point might be considered as a data gap for consideration by risk managers. COM pointed out that the relevance of the data gap may be different from substance to substance. Such information could therefore be included in the Conclusion to facilitate decision-making. It is acknowledged that a guidance document on this issue is not needed, as the applicant is expected to have sufficient knowledge on the properties of the substance including its reactivity potential, and the need for specific testing should be assessed case by case. Applicants may choose to provide sound argumentation based on available information or make a case which may also fulfil the data requirement.

It was also stressed that during the pre-submission meetings with applicants these data requirements would be better communicated to the applicants; it is up to the RMS to ask for additional information at first place.

NL informed that they have a model for calculating concentrations for a.s. and metabolites at the point of abstraction of surface water for drinking water. EFSA invited NL to present this model at the next meeting.

5.9 Status of the list of decisions from the peer-review expert meetings

The Chair informed that the list of decisions from the peer-review expert meetings is now made available via the EFSA DMS. This list is a collection of decisions taken in the context of the peer review expert meetings and is prepared to warrant consistency in the assessment and to facilitate the discussions. The list is for MS experts only and not intended to be a guidance for applicants, elements relevant for the applicants may be considered for future guidance updates.

5.10. Received requests to access to full dossiers and study reports

The LRA Unit of EFSA gave a presentation on public access to documents, in particular full dossiers and study reports. The presentation introduced the principles of openness and transparency as established by the Treaty on the Functioning of the European Union, Charter of fundamental rights of the European Union and Secondary legislation. They are considered essential aspects of the system of checks and balances that ensures the accountability of the European Union to European citizens and Member States alike. According to the statistics the requests for public access increased in the previous years. Regulation (EC) No 1049/2001 establishes the procedure for handling public access requests. Under this legal framework all documents prepared or handled by EFSA can be subject to disclosure including internal notes; preparatory documents (e.g. draft opinions); internal and external correspondence; documents of Member States. Common awareness of the possible accessibility of all documents is needed. Few exceptions to the disclosure are provided by the legislation, but strictly interpreted by Union Courts. The burden of proof to demonstrate that an exception applies relies on EFSA (i.e. why a document cannot be disclosed). In case of MS documents a consultation is undertaken with the concerned MS in order to clarify the confidential status of requested documents. In case of access to environmental information, the Aarhus Regulation (EC) No 1367/2006 applies. Under this Regulation, a restrictive interpretation of exceptions exists for protecting documents against disclosure (under PAD Regulation), in particular when this information qualifies as “emissions into the environment”. A case concerning a pesticide substance, pending before the Court of Justice of the EU, was mentioned as an example.

Following questions from MS regarding the disclosure of documents originating from MS, it was clarified that, in accordance with the legislation, systematic consultation with the MS, owner of requested documents, is done by EFSA. Documents from MS are disclosed following a full screening and only after having clarified with the MS whether an exception for disclosure should apply.

It was mentioned that for this particular meeting a request was received for access to the documents shared at the meeting. The MS representatives agreed that access to their documents could be provided only after the meeting (and not before).

The minutes will indicate that documents, excluding confidential documents and preliminary documents for discussion, distributed during the meeting are available under requests. Members are requested to indicate clearly in their submission the documents they consider should not be distributed to third parties.

Action point:

- EFSA to indicate in the minutes that documents with the abovementioned exeptions are available upon request
- Member States to indicate in the submission the documents that should be consider confidential or preliminary documents for discussion not to be distributed to third parties.

5.11: Case studies for the application of the Guidance of EFSA on Submission of scientific peer-reviewed open literature: Presentation from AT

AT presented the results of a case study on the application of the EFSA Guidance 'Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009'. This project was founded by an EFSA grant.

The aim of the project was to assess the usability of the EFSA guidance. AT reported that three case studies were selected. For each case study, the search strategy and the relevance and reliability criteria were established beforehand. The terms used in the search were derived directly from the pesticides' data requirements. Two experts were allocated to each relevant section. The databases searched comprehended a free of charge database and three additional databases (subject to fee payment).

As a result of the project, AT highlighted that some refinements are needed. Some concerns were raised as to the tools to be used to assess the reliability of the studies. According to AT tools are available only in the case of toxicological studies. On this point, EFSA clarified that the Klimish score can be used but the GLP status in the case of open literature cannot be used as reliability criteria; the focus should be on the reporting of the method and of the results. As to the relevance criteria, AT highlighted that it is utmost important to always document which criteria are used. In the case studies, the relevance criteria were established starting from the relevant OECD Guidelines. In this connection, AT highlighted that some of the relevance criteria in the EFSA guidance may need to be included as reliability criteria.

AT reported that with some databases the search was hampered by a lot of noise which did not allow scoping the search with keywords. This happens for instance by using trade names as keywords. AT recommended not using trade names unless they are commonly used names for pesticide products. In the case of the literature search for metabolites, it was recommended that this is done separately for well-known metabolites. AT highlighted that the selection of the appropriate database is crucial; depending on the topic of the literature search some databases may be more suitable than others.

EFSA reported that an initiative to improve the quality of the scientific papers will possibly start. The aim of this initiative is to raise the awareness of the scientific community and journals' editors on the need to assess the quality of the information and its relevance during the peer review pre-publication process for improving the usability of the scientific papers in the regulatory context.

Overall, the case studies proved that the guidance is workable.

5.12 Improving the efficiency of peer-review expert meetings

A reduction to the number of experts in peer-review expert meetings was proposed in order to improve efficiency and deal with the budgetary restrictions. The priority for participation to peer-review expert meetings will be given to experts from RMS, MSs that have commented (even 'no comments' as this is regarded as agreement after assessment), experts with relevant expertise etc. If an expert is not invited to the meeting, he or she could attend the

meeting on his own expense or join the discussion via teleconference. Integration of an expert who never participated before or with new area of expertise in the expert meetings will be taken into account in the selection of experts.

In order the experts to fully participate in the expert meetings, EFSA proposed its staff to chair the meetings on a more regular basis.

6. AOB

6.1 The UK expressed its concern since they consider that their comments (as RMS) are not taken into consideration when commenting on the draft Conclusions.

It was clarified that EFSA publishes the comments received from RMS/ MSs in all steps of the peer-review process on the EFSA website as background documentation to the EFSA Conclusion. The factual comments that are identified from MSs are corrected in the final Conclusions, however, the scientific comments cannot always be considered at this very last stage, particularly in case of diverging views on scientific issues when consensus was not achieved during the expert meeting. When there is a disagreement between EFSA and RMS, this discrepancy is clearly depicted in the EFSA Conclusions.

EFSA agreed to better report in the Conclusions the divergence of views when expressed in the expert meetings.

6.2 NL requested a clarification on the procedure to be followed when the notifier requests for an amendment of an endpoint.

Commission reported that in principle the endpoint needs to be updated only in those cases in which the change of endpoint may affect the outcome of the risk assessment. Further discussion is needed in order to ensure that a harmonised approach is applied at MS level.

7. Next meeting

Next meeting of the Pesticide Steering Network: 10 February 2015 (full day).

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