NETWORK ON PESTICIDE STEERING MEETING

MINUTES OF THE 24TH MEETING

Held on 09-10 April 2019, Parma

(Agreed on 06 May 2019)

Participants

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

  Alf AAGAARD (Denmark)
  Anko ARISSEN (The Netherlands)
  Katja BIDOVEC (Slovenia)
  Liga BRENCE (Latvia)
  Agathi CHARISTOU (Greece)
  Sonja ECKER (Austria)
  Darren FLYNN (The United Kingdom) (participated through TC)
  Herman FONTIER (Belgium)
  Eva GOCLIK (Germany)
  Sarah GODSON (The United Kingdom) (participated through TC)
  Tamas GRIFF (Hungary)
  Kaija KALLIO-MANNILA (Finland)
  Mitsuko KOMADA (Norway)
  Katarina LUNDBERG (Sweden)
  Thierry MERCIER (France)
  Aidan MOODY (Ireland)
  Danae PITAROKILI (Greece)
  José Luis Alonso PRADOS (Spain)
  Pawel STRUCINSKI (Poland)
  Kristina VALIONIENE (Lithuania)
  Lucie VANOVA (Czech Republic) (participated through TC)

- European Commission representatives:

Karin NIENSTEDT (DG SANTE)

- EFSA:

  Pesticide Peer Review Unit (Manuela TIRAMANI, Head of Unit, Chair)
  Pesticide Peer Review Unit (Bénédicte VAGENENDE, Coordination Team)
  Pesticide Peer Review Unit (Dimitra KARDASSI, Coordination Team)
  Pesticide Peer Review Unit (Tunde MOLNAR, Coordination Team)
  Pesticide Peer Review Unit (Jürgen STURMA, Coordination Team)
  Pesticide Peer Review Unit (Chloé DE LENTDECKER, Coordination Team)
  Pesticide Peer Review Unit (Andrea TERRON, Mammalian Toxicology Team)
  Pesticide Peer Review Unit (Juan Manuel PARRA MORTE, Mammalian Toxicology Team)
  Pesticide Peer Review Unit (Frédérique ISTACE, Mammalian Toxicology Team)
  Pesticide Peer Review Unit (Arianna CHIUSOLO, Mammalian Toxicology Team)
  Pesticide Peer Review Unit (Domenica AUTERI, Ecotoxicology Team)
  Pesticide Peer Review Unit (Maria ARENA, Ecotoxicology Team)
  Pesticide Peer Review Unit (Laura VILLAMAR, Ecotoxicology Team)
  Pesticide Peer Review Unit (Chris LYTHGO, Chemistry and Environmental exposure Team)
  Pesticide Residues Unit (José TARAZONA, Head of Unit)
  Pesticide Residues Unit (Luna GRECO)
  Evidence Management DATA Unit (Jane RICHARDSON)

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Bento CARVALHO (Portugal) and Pasquale CAVARALLO (Italy).

2. Adoption of agenda

The agenda was adopted with an addition (AT added an AOB point on the amendment of the disclaimer on the minutes of pre-submission meetings. The point was discussed under item 3.3).

3. Topics for discussion

3.1. MATRIX project

The project aims to standardize and structure the dossiers, to have a single access point for the dossiers of all regulated products, to check and communicate the status of the application and to have a cohesive channel for communication.

EFSA would like to have a more transparent and traceable approach of the scientific risk-assessment that would be more data-driven.

OECD is currently preparing a revision of the Globally Harmonised Submission and Transport Standard for the dossiers.

DG SANTE's FSCAP system has been developed to submit, manage and follow up applications for novel foods. The same system will be available by the summer for food additives.

The planning tool in FSCAP system allows EFSA to keep track of the progress status of the applications. Though not directly relevant to pesticides, this system shows ways to improve the management applications.

During the fitness check of the general food law, a certain lack of transparency was perceived by the civil society regarding the confidentiality rules around industry studies.

Therefore, changes were proposed in order to have more transparency. Changes needed to be done in different fields:

- Register of studies: the goal is to prove that studies have been registered by making them available at an earlier stage of the process. This change should be managed by the IT system.
- Confidential information: a specific discussion is running in conjunction with EFSA stakeholders.
- Access of studies in e-format: IUCLID comes with a very advanced tool with international standards. Although, it is not decided whether IUCLID could be the solution to build and transport the dossiers.
- More structured data in the format of e.g. OHTs (OECD Harmonised Templates): confidentiality will be manageable at a smaller level with OHTs. The tool will allow to produce reports and summaries. There would be an overview of the endpoints of each study. The information will be used more effectively for analysis.
- Risk assessment: the goal would be to record how the information is assessed.

An EP feasibility study sponsored by the EU Parliament was launched exploring possibilities for a common platform for chemical substances and regulated products (common platform with ECHA and EMA).

Next steps

- On Friday 12 April 2019, a meeting between EFSA and ECHA will take place to discuss the joint strategy in terms of IT tools through the REACH process for ECHA and find common ground on how to work together.
- A discussion group on confidential information is ongoing to focus on the aspects mentioned during this PSN.
- End2end science project: endpoint selection criteria.

SE raised a concern for the vision on active substances process and the timelines for the new aspects under the proposed amendment of the general food law. EFSA would like to involve MSs in a better way. The amendment of the founding regulation will be voted soon and published in the summer. It will be supported with a series of implementing acts agreed with the MSs including an amendment of 844/2012 that will address also this issue of e-submission of the dossier. The IT systems should be adapted by that time. It was acknowledged that the timelines are challenging. It would be interesting to share experiences with MSs involved in the biocides working group with ECHA.

MSs were also interested in knowing how they will get informed on the implementation schedule and the timelines. EFSA underlined that discussions are ongoing; not on the content of the dossier to be submitted but on the way it will be submitted. Indeed, application dossiers already have a defined structure and pesticides processes are well advanced on this subject compared to other food sector areas within EFSA. However, the e-system (GSTHS, IUCLID, other) will be developed also with regard to the applicability in other areas of regulated products and not only for pesticides.

MSs were interested on the GSTHS system developed by the industry. EFSA is represented in the relevant OECD Working Group, but MSs representation is very limited.

The MSs would like to be informed as soon as possible on the implementing schedule related to the developments on the MATRIX project. EFSA would like to have feedback on existing systems in the MSs. It would be very useful to understand specific issues in particular on the impact on IT systems at national authorities.

Action point: EFSA is exploring the possibility for launching a short survey regarding MSs experience with biocides, OHTs, current systems and plans. More details will be sent at a later stage. MSs could already share with EFSA further comments or useful information via email (e.g. documents available, contact points from competent Authorities working already with IUCLID or other systems).

3.2. Update ongoing discussions and proposals General Food Law and pesticide specific issues

Commission gave an update on the amendment of the General Food Law introducing new rules on the "transparency and sustainability of the EU risk assessment in the food chain". The proposal will be voted in plenary in the next weeks. The new rules expected to be published in the Official Journal over summer and enter into application in early 2021.

Four pillars were identified:

- Quality and reliability of studies: general pre-submission advice to applicants (by RMS/EFSA), notification of commissioned studies and public consultations.
    - For renewals only, the public consultation of planned studies will be introduced at the pre-submission phase; for all submitted studies, public consultation will take place during the risk assessment phase.
    - Fact-finding missions by Commission to laboratories carrying out studies (in EU and in 3rd countries where relevant agreements) to take place within 4 years after entry into application. Based on the outcome, a possible legislative proposal may be introduced.
    - Possibility to mandate EFSA to carry out verification studies in exceptional circumstances of serious controversies or conflicting results.
- Transparency of the risk assessment: the new rules foresee that studies/data are to be made public proactively and automatically, in an easily accessible format through EFSA's website, early on in the risk assessment process (i.e. when an application is found valid or admissible) except for duly justified confidential information. The standard format of the studies will make it easier (cfr. MATRIX project). There will be closed positive lists of information that may be treated as confidential, upon verifiable justification proving significant harm to commercial interests. However, no change for pesticides since rules on confidentiality claims already apply in the legislation.
- Improve risk communication: it includes appropriate mechanisms of coordination and cooperation amongst risk assessors and risk managers and appropriate mechanism for open dialogue amongst interested parties.
- Sustainability and governance of EFSA: more MSs will be included in the EFSA Management Board as well as civil society, EU Parliament and food chain relevant parties. An active involvement of MSs to stimulate experts in contributing to EFSA's work (promotion of EFSA's call for experts to Scientific Panels and Scientific Committee) is foreseen.

Other elements:

- Transitional measures: the new rules will not apply to applications under Union law and requests for scientific outputs submitted to EFSA before its entry into application (most probably early 2021).
- Review clause: regular review of the GFL Regulation is foreseen. Every 5 years, Commission will review EFSA's performance.
- An increase of budget for EFSA with 62.5 million euros and 106 additional posts.

The GFL will enter into force 20 days after its publication in the OJ and it will be applicable in early 2021. It will take 18 months for the entry into application. During that period, preparatory work must be carried out both by EFSA and by Commission. An amendment of the Commission Implementing Regulation (EU) No 844/2012 and for new active substances is foreseen to take into account the general plan on risk communication and the standard data formats for applications.

3.3. Improving cooperation between EFSA, Commission and MS: Overview initiatives undertaken to improve efficiency peer review and ensure EFSA Conclusions are fit-for-purpose

In June 2016, a brainstorming session with MSs took place. The aim was to determine where the peer review process could be improved.

An action plan with various initiatives for improving the peer review process was published on 08 December 2017.

EFSA collected feedback on the initiatives already implemented if MSs considered them useful.

Some initiatives introduced following the high-level meeting MS/SANTE/EFSA in September 2018

Pre-submission meetings with applicants: the initiative is appreciated and more meetings were organised. EFSA provides pre-submission advice, supporting the RMS during the risk assessment phase. There are increasing written requests for advice from RMS, if EFSA is directly contacted by the applicant (APPL), the response will be copied to the RMS. It is noted that the support that EFSA provides during an APPL-RMS-EFSA teleconference (TC) is without prejudice to upcoming peer review.

The implementation of the ED assessment increased the number of requests for these meetings.

EFSA is only participating for particular questions via TC.

AT showed appreciation for EFSA's participation in the pre-submission meetings. The request of these meetings came from applicants. In Austria, they decide on the topics for which they will consult EFSA. EFSA is involved at an early stage for complex scientific issues to avoid them being raised too late in the peer review. It was noted that in case of recurring complex questions, the issue might also be discussed in a peer review expert meeting.

The RMS is encouraged to request support/advice from EFSA for complex issues in the pre-submission and/or risk assessment phase. EFSA should be informed well in advance about the meeting (3 - 4 weeks) to be prepared, as several experts may be involved in the discussion.

Disclaimer from AT on the minutes of the pre-submission meetings (item added to the agenda by AT)

AT proposed an amendment to the disclaimer noting that the decision is based on the information available on the meeting.

The amendment was agreed during the meeting.

In addition, EFSA explained that a Q&A file is shared on the DMS. Written questions on pre-submission meeting are included in the file. It is aimed to help RMSs on similar questions during pre-submission meetings. A pre-submission folder, where relevant, is available on DMS for respective active substances. RMSs are encouraged to consult similar cases or contact the PREV unit if additional information is needed.

Follow-up actions from SANTE

Some initiatives are ongoing for biopesticides:

- Guidance on antimicrobial resistance

The guidance is currently developed by Commission.

The main questions for biopesticides are on the mode of action and the production of secondary metabolites and/or toxins. The guidance already offers a few clarifications on how to handle these questions.

- Working group on biopesticides

A lot of MSs are involved and the group is growing.

- BTSF (Better Training for Safer Food) trainings (point anticipated by Commission)

The EU Commission is starting a project on biopesticides trainings. It is currently in the planning phase.

Action point: Commission is inviting MSs to communicate on which topics they would need training. MSs to provide to SANTE/EFSA, topics for which training would be needed for the assessment of biopesticides/microorganisms (to be organised as BTSF training) **by 30 April 2019**.

Overview and status of different initiatives

- Peer Review expert meetings

The experts' active participation is increasing. The allocation of the substances to specific experts and the collection of comments prior to the meetings is fully implemented. The initiative has a positive outcome and was well received by the respective teams in PREV Unit and experts.

- Invitation of applicants

For specific discussion points, the applicant may be invited to participate to the expert meetings either as a hearing expert or on call duty. The scope is to clarify complex issues for specific discussion points during expert meetings, if the experts consider the need during the meeting.

- Draft EFSA conclusion with RMS additional commenting

EFSA will launch a new consultation step on the draft EFSA conclusion with RMS. The aim is to solve divergent views between the RMS and EFSA. Furthermore, the intent of this consultation is also to bilaterally clarify open issues after the expert meeting and flag possible changes in the EFSA conclusion compared to what was agreed in the expert meeting. This additional step should also strengthen the role of RMSs in performing a thorough quality check of the draft EFSA conclusion. Commenting boxes with specific requests to RMSs would be included in the conclusion to facilitate the process. The same commenting table would be used by the RMSs for this step. The RMSs will be given 1 week for providing written comments and/or request for an ad-hoc TC in a specific area. EFSA will respond to comments, amend the conclusion where needed and launch the normal 2-week commenting with all MSs.

In case of continued divergency, this will be transparently reported in the conclusion. The first RMS additional consultation will be launched soon. MSs raised concern that one week is short to address comments. The Coordination team will make sure that the RMS will be informed at an earlier stage on the upcoming RMS 1-week consultation on the draft Conclusion.

- Administrative guidance and its implementation

The administrative guidance on submission of dossiers and assessment reports and 4 amended Guidance documents were presented for note taking in March PAFF meeting. The administrative guidance and the accompanied Appendices were published on 8 April on EFSA's website[1].

The implementation schedule has been agreed upon: from 1st October 2019 for the submission of (supplementary) dossier and from 1st October 2020 for the submission of the Assessment Reports.

[1] https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2019.EN-1612

In order to ensure an efficient peer review, applicants and Member States are encouraged to use the EFSA guidance or at least parts of it, as from now. The short-term Completeness Checklist for Assessment Reports (Appendix B1 of the Administrative guidance) is directly applicable and should be submitted together with DARs/RARs sent to EFSA after 1 April 2019.

The full Completeness Checklist for Assessment Reports (Appendix B2 of the Administrative guidance) should be submitted together with DARs/RARs sent to EFSA after 01 October 2020.

The completeness checklist is listing the criteria that will be used to possibly reject a DAR/RAR. In case of issues on format, overall quality or missing documents etc, these issues should be amended before launching the public consultation.

DE raised an issue with appendix J due to a mistake and proposes an amendment as soon as possible.

This topic will be discussed bilaterally with DE because this comment seemed to be already addressed in the previous commenting round.

- Data gap categorisation in EFSA Conclusion

As a follow up of EFSA-SANTE discussions on September 2018, a re-structuring of the section on data gaps introducing different categories for qualifying the data gaps was proposed aimed on a better understanding of their impact on the risk assessment and their consequences for the decision-making. This will increase the clarity and transparency for both risk managers and the general public.

A pilot exercise on Benalaxyl and Milbemectin with SANTE and EFSA was carried out.

The scope of the exercise was to improve the presentation of the data gaps in the new structure to better visualise the connection between the data gaps and the concerns.

Commission and EFSA compromised on the structure: the proposal is that data gap of section 7 will no longer appear and data gaps will be split in 3 sections: data gaps linked to issues not finalised, data gaps linked to critical areas of concern and a third list of other outstanding issues (data gaps not expected to lead to concern but necessary to comply with the data requirements, relevant only for the representative uses assessed at EU level). It should be clear indication if this data gap is linked to guidance/test guideline not being available. A new appendix was introduced (Appendix B) on request from SANTE in line with the BPC (Biocidal Products Committee) opinion as summary table with the Annex II cut off criteria: CMR, ED, PBT, POP. EFSA proposes that details on persistence will only be included when all three criteria are met and the substance may be PBT.

An explanatory paragraph was introduced as well.

The Table 5 was amended to be more self-explanatory and more transparent for risk managers.

Action point: MSs are invited to comment on the data gap categorisation using the commenting table template **by 30 April 2019**. Focus should be given on the new structure and presentation of data gaps, not on content/reopening discussion on agreed approach for ranking. Also, attention should be given whether the new proposal is fit-for-purpose for national authorizations.

The case of benalaxyl was considered in this exercise. Changes were highlighted in turquoise. The data gaps are added close to the concern in section 8.

In general, there was a positive feedback on the amendments from MSs. The new presentation is expected to facilitate decision making/ risk communication.

- Commenting table

A new Excel commenting template will replace the reporting table, evaluating tables and written procedure on additional information. A pilot was run on active substance pydiflumetofen (NAS) with France as RMS with a good feedback.

New improvements were done. Two files were created for commenters: one for chemicals and the other for microorganisms. A third file was created for compiling.

The next step will be to run a mini-pilot with garlic extract launched for public consultation by end of April.

Action point: Comments from RMS are welcomed **by 30 April 2019**, using the appropriate commenting table template.

The table offers new functionalities and allows sorting and filtering which facilitates extraction of subsets of comments for different purposes (e.g. different APPL). Protection to the table will be provided to avoid unintentional changes.

- Risk mitigation measures

One issue identified from the discussion EFSA/Commission/MSs was the possibility to incorporate risk mitigation measures in the peer review process. If an MS already has a scenario which proves that a risk can be reduced this could already be taken into account in the EFSA conclusion. This is also important for decision making.

A list of risk mitigation measures has been prepared by SANTE and presented in the standing committee of March. A living document approach is proposed with the aim to be used in the peer review, decision making or even in pre-submission discussions. This will increase the consistency of the risk mitigation measures used in different sections and finally the consistency of the outcome. The list is open for comments in the PAFF meeting.

Commission indicated that the early discussion on the data gaps will reduce the number of data gaps in the dossiers.

- Needs and activities as regards microorganisms

Commission advises MSs to pay attention on key issues popping up in the dossiers such as the quality of the dossiers, the strain identification, the analytical methods available, the lower risk criteria, secondary metabolites…

For microorganisms, the understanding of the mode of action is needed to refine the risk assessment.

Commission is currently updating the data requirement and guidance document for microorganisms. Commission is also aware of difficulties as regards testing. BTSF trainings could include this topic if needed.

Action point: MSs to provide their needs of training **by 30 April 2019** (already indicated in previous point).

3.4. Guidance documents

Guidance on drinking water

The first step is to define which water treatment processes should be addressed. Then, a scope should be agreed on the task related to decision making. Commission will mandate EFSA to have an

overview of what is available and to see if other sectors (e.g. ECHA, DG environment, JRC) have something existing regarding the processes. A discussion between EFSA and MSs should take place to have the first guidance document available in a reasonable time. ECHA Biocides have a similar requirement but do not have a guidance yet.

It could be a solution to draw a survey out of the water treatments available as a first step. Information should be obtained from different member states/ECHA/water industry trade associations. A proper implementation period should be set to address this issue. Commission is best placed for contacting water industry trade association(s) via DG environment.

FR raised a concern on the data coming from monitoring, with the presence of metabolites and difficulties to estimate the consequences of water treatment. Consumers' non-exposure cannot be excluded and the guidance should cover ground and surface water treatments.

ES mentioned the existence of a background document that is available from a former call for interest with ES, NL and UK's involvement.

<u>Guidance initiated by Member States or Commission working groups that then needs to be finalised and changed to EU risk assessment guidance</u>

A group of MSs have compiled documents that are designed to become risk assessment guidance. Two examples (one on seed treatment products and a second on soil photolysis groundwater exposure estimations) had been presented at the last standing committee. How to proceed with this topic needs to be discussed further by EFSA. For these examples, a public consultation has not yet taken place and then the finalisation of the guidance could be progressed. For the seed treatment example, some action was still needed to split the existing document into to two: one covering management issues and the second on exposure and risk assessment being that might then be progressed by EFSA. Commission will mandate EFSA to finish the guidance. The exact process should be further discussed with EFSA. The aim would be to share responsibilities and work between EFSA and MSs, when for instance a guidance needs some refinements.

3.5. ECHA/EFSA alignment peer review and classification

At the last PSN, the alignment document on the ECHA/EFSA processes was shared followed by a commenting period. It was agreed to revisit the document by clearly separating issues relevant only for the internal coordination between EFSA and ECHA and focussing the document on the role and input of MSs. Therefore, an extract with clear instructions and actions tailored to MSs was prepared.

The new version of the document was shared with CARACAL in November 2018. Overall, the initiative was welcomed. However, concerns were raised on the feasibility of the timelines for the accordance check.

In the meantime, Commission has restarted the work on the amendment to Regulation 844/2012, laying down the legal framework for the mandatory submission of CLH dossiers in the context of the renewal of active substances under the peer review process. The proposal for the draft regulation was presented at the January 2019 ScoPAFF meeting, followed by a commenting round with risk managers. The draft amendment of Regulation 844/2012 was subsequently discussed in a trilateral TC between EFSA/ECHA/EC (with involvement of DG SANTE, GROW and ENV) in March 2019.

The regulation is still a draft and is now at Commission level. The draft amendment is considered a big step forward in the alignment. It specifically prescribes that the RAC opinion should be available in time and taken into account in the EFSA conclusion, and subsequently during the decision-making phase. According to the current proposal, the submission may include:

i) New classification proposal

ii) Proposal for revision to the existing classification

iii) Re-confirmation of the existing classification: for hazard classes already covered by an existing opinion, the RMS justification is needed for the existing classification to remain valid.

In order to fit in the regulatory process, the accordance check (in parallel by EFSA and ECHA) should be completed within a period of maximum 3 months (cfr Art 12(1) of amendment to Reg 844/2012) and therefore the timelines should be revised.

The proposal is the following:

- ➔ For ECHA/EFSA: **5 weeks** to check the initial AR/CLH documents.
- ➔ For RMS: **5 weeks** to update and resubmit the documents accordingly.
- ➔ For ECHA/EFSA: **2 weeks** to check the updated documents.

As the only possible way to comply with the legally binding timelines, a formal withdrawal step of the AR/CLH report is proposed to be introduced. MSs may choose to withdraw the report if the documents cannot be updated within the agreed timeframe (5 weeks) or if they are not found in accordance after the re-submission.

FR is worried that the RMS has to face a double accordance check and that this formal withdrawal would delay the evaluation of some substances for which there is already a concern. For the NAS, it would be a disadvantage for the notifier in terms of availability of the products on the market. Indeed, it is acknowledged that this option may trigger delays in the overall timelines, the decision-making process and the potential need to extend the expiry dates; nevertheless, this was considered as the only feasible option. It is suggested to put efforts in the work upfront in particular with the implementation of the administrative guidance in order to limit the risk of occurrence of withdrawal. For the time being, it is the best compromise. Any other proposal is welcomed on this topic.

The next step will be for ECHA. The agency will present the revised flowchart for the accordance check to CARACAL. In addition, there is an ongoing discussion at ECHA related to the provisions of confirmation of the existing classification. Currently, no process is in place at ECHA to assess RMS justifications, while ECHA/RAC input would be needed to underpin the EFSA peer review in case the proposal by the RMS to maintain the existing classification may be challenged during the EFSA process.

Concerning current practicalities, EFSA follows the RAC discussions but do not proactively comment on the public consultations on CLH proposal due to resource issues unless it is an alignment case. In any case, all the documents are shared between both agencies to allow having the same level of information.
If it is an alignment case, no discussions occur in the EFSA peer review on the classification part and the corresponding comments should already be addressed in the RAC process. Once the amendment of the Regulation 844/2012 will be in place, this will be a standard practice since applicants will have to submit their dossier to both agencies, ECHA and EFSA.

EFSA mentioned that additional data arriving through both processes are considered by both agencies. Indeed, in the EFSA clock-stop letter, EFSA strengthens the need for applicants to submit the requested additional data also to ECHA for the alignment cases in order to facilitate timely integration of relevant data into the RAC discussions where needed.
Similarly, in case new information is available from ECHA, this should be considered in the updated RAR (e.g. mancozeb).

3.6. Stakeholder involvement in Pesticides Steering Network

Requests were received from stakeholders - NGOs and others - to attend the PSN forum.

How does EFSA treat interactions with stakeholders? According to the EFSA Stakeholder engagement approach, for any involvement and contribution to EFSA's work, stakeholders are invited to enrol in the list of EFSA's Registered Stakeholders. There is no interaction with single stakeholders. The organisations must be legally established in the EU. There are different ways to interact with the stakeholders for equal opportunities: permanent platforms (Stakeholder Bureau, Stakeholder Forum) and targeted platforms (more flexible tools to have feedback and proposals e.g. scientific colloquia, discussion groups, round tables, communication labs and info sessions).

EFSA is thinking of an organised way to interact with the stakeholders wishing to participate in the PSN. Potentially, for the next PSN, an open session could be scheduled. If this option is chosen, the PSN would be open to all relevant stakeholders.

MSs were interested to explore the frequency and what the PSN could offer to stakeholders. EFSA proposed to potentially start with one session next year to see how it will go and learn from that first experience. Overall, MSs felt that the PSN may not be the right context.

For AT, there is a necessity to clarify the subject of these open sessions. Maybe stakeholders could submit questions in advance on what they would expect from these meetings.

MSs considered that inviting all stakeholders to the PSN would be too ambitious, the number of participants should be limited. Limits and instructions need to be clarified before launching these open sessions. BE also thinks that experience could be drawn from other networks where stakeholders were involved.

Mainly, the MSs are sceptical on the necessity and efficiency of these open sessions that might be too general, and overall considered these of limited value.

For ES, dealing with stakeholders on a case by case basis would be a better option.

Action point: MS to share their view on possible stakeholder involvement in upcoming PSN (frequency, length of meeting, topics for discussion, etc) **by 30 April 2019**.

3.7. Updates on PPR Panel

Two Panel coordinators were identified: Arianna CHIUSOLO and Maria ARENA respectively for Mammalian Toxicology and Ecotoxicology teams. The purpose of this year is to identify areas for involvement where the Panel experts in the peer review process on specific areas or concerns. Discussions are currently ongoing to elaborate procedures and ways of involvement (e.g. as working group members or individually based on personal capacity for specific issues).

3.8. Update on development activities mammalian toxicology

Developmental neurotoxicity project (DNT)

Two activities:

- Development of an OECD Guidance for the use and interpretation of a DNT in-vitro testing battery and alternative models. An expert working group has been set up at OECD level chaired by EFSA and US EPA. This expert working group is expected to develop a guidance which will be largely based on different IATA case studies dealing with different regulatory problem formulations. Experimental work supported by EFSA, US EPA and Danish EPA is ongoing for scientific validation of the DNT testing battery. Additional experimental work is planned for the evaluation and possible inclusion in the guidance of alternative models like the zebra fish model.
- EFSA case study: the plan for the working group would be to select 3 chemicals, elaborate the problem formulation an develop IATA case studies. All the available information on DNT

will be used to develop the IATA case studies and the impact of the *in vitro* DNT testing battery will be assessed by inclusion of a comparative uncertainty analysis. The expectation is that the battery will improve the mechanistic understanding of the DNT hazard and consequently improve the DNT hazard characterization.

Commission wanted to know whether the proposed assays will undergo re-testing. EFSA answered that a "green list" of chemicals has been already published and for this some testing results are available. The proposed in vitro testing battery is undergoing scientific validation by assessing the assays performance including the results of multiple labs in a single database and produce a heat map describing the assay performance by comparing the different outcomes against known-human-DNT substances, known negative and substances for which *in vivo* experimental data exists. The assays will be performed following the OECD guidance 286 on good *in vitro* method practices.

An observation was made by Commission concerning the selection of the 3 chemicals. It should be clearly stated in the opinion if the substances selected for the IATA case studies are still on the market or not.

SE wanted to know if in the long term the aim is to replace the present *in vivo* DNT test and timeframe for this. EFSA replied that thinking that *in vitro* testing will quickly replace the *in vivo* ones would be very optimistic. The expectation is that the availability of an integrated *in vitro* testing battery will be critical and strategic for the development of a DNT tiered approach. The battery will represent a mechanistic shift in understanding DNT and the current work should be valuable to scientifically validate its prediction ability. It should however be noted that the proposed *in vitro* testing battery has metabolic limitation as it is not able to assess DNT effect consequent to endocrine disruption.

UK was interested to know if the guidance would cover uncertainties. For now, they will see how the testing battery will evolve and on which DNT endpoints it is focusing on. EFSA replied that the uncertainties analysis is however a critical step in any IATA case study.

<u>Development of adverse outcome pathways and relevant identification of substances that are ED</u>

The practical implementation of the EFSA/ECHA ED guidance is facing two main scientific issues:

- identify the most robust dataset necessary to support the biological plausibility linking an endocrine mediated adverse effect with an endocrine activity through a coherence analysis and consequently postulate and develop a MoA as requested by the criteria for the EATS modalities
- identify (the most common) MoAs covering the non-EATS endocrine modalities.

Development of Adverse Outcome Pathways (AOPs) for both EATS and non-EATS endocrine adverse outcomes using a top-down approach, can provide a practical answer for the two main scientific issues and will represent a regulatory valid approach for the scientific implementation of the ED EFSA/ECHA guidance.

The postulated AOPs will consider first the adverse effect (outcome) as evidence retrieved from the pivotal studies used for the authorization process, followed by the identification of the intermediate key events (KES), including the dysregulated endocrine activity and of the molecular initiating event (MIE). Adverse effects dependent by multiple MIE/pathways, will be considered through the development of an AOP network. The AOP is chemically agnostic and can therefore be applied to any substance. Each AOP will be submitted to public consultation in order to have an immediate feedback from the stakeholders. Then it will go through the standard process of the OECD.

SE was interested in the flexible working group PPR panel timeline. EFSA: The scoping document has been accepted and the chartering of the project is ongoing. This would be likely launched by the

beginning of summer. The aim is to develop 3 or 4 AOPs for a specific target organ which can be potentially affected by ED chemicals. It should take approximately 2 years in total.

SE also wanted to know if MSs would be regarded as stakeholder in this case. EFSA confirmed that public consultation also includes MSs.

In vitro comparative metabolism studies project

In vitro comparative metabolism studies are requested by European Union regulation on pesticides, but no OECD guidelines are yet available. The timelines of the project are:

- Work Package (WP) 1: a workshop with stakeholders took place on November 2018. The event report has been published recently, http://www.efsa.europa.eu/en/supporting/pub/en-1618. The event report will be used for the guidance.
- WP2: draft EFSA Guidance to be developed between September 2019 - November 2020 and it will be followed by a public consultation.
- WP3: EFSA Guidance and Technical Report by March 2021.

Update of EFSA guidance on non-dietary exposure assessment

New data to be taken into account: new greenhouse model in Germany, BROWSE project (planned to be discussed in next June), BROV WG activities (work at MS level not finalised) and seed treatment (old and new data under assessment by the Seed Tropex Task Force).

An open call was launched last year until December 2018. New data from workers, new application equipment and new scenarios for operators were sent. A lot of comments were received on new approaches and suggestions.

The calculator will be updated as a new web tool. It will include additional options for use in national authorisations. It will be more transparent and user-friendly.

The revision of guidance will be until December 2020 and the final publication is planned for September 2021.

ES asked details on the inclusion of risk mitigation measures. This was discussed in the working group and appropriate mitigation measures supported by available data will be included in the calculator.

Commission mentioned that risk mitigation started to be discussed at the standing committee and that the working group should stay in link with Commission to make things consistent.

Update on the OECD project on dermal absorption

The EFSA guidance on Dermal Absorption developed in 2012 has been recently revised based on the analysis of a large dataset of studies on human in vitro dermal absorption with pesticides. The revised EFSA guidance on Dermal Absorption, published in 2017, was voted for its implementation starting from 25 August 2018. In the guidance document, a collection of the discrepancies between guidance documents on dermal absorption (e.g. OECD Guidance Notes 156, OECD Guidance 28, OECD TG 418, EFSA and SCCS guidance documents) is presented in the EFSA guidance (2017), evidencing the need for updating the OECD guidance documents on dermal absorption. Based on this, EFSA supported by BFR, submitted the project proposal (SPSF) to OECD, that was approved by the WNT and included in the OECD workplan for test guidelines programme in 2018. Up to now, two web meetings were held by the OECD Expert Group (EG) on dermal absorption, to revise the OECD Guidance Notes 156, primarily focused on establishing dermal absorption values for pesticides and

biocides. Based on the comments to the draft revised documents, the EG recommended to expand the scope to other sectors (e.g. cosmetics) and to start the project with the revision of the OECD TG 428 as priority. These proposals, implying a reconsideration of resources, have been captured in a document presented to the WNT Annual Meeting in April for feedback on the way-forward. DG SANTE, informed about the recommendations from the EG, confirmed the support to the project.

3.9. Update on development activities ecotoxicology

Statements on bats

This statement was a self-task and was initiated in the context of the mandate for the revision the guidance for birds and mammals. The outcome of the statement will be considered by the scientific working group on birds and mammals.

The main focus is on oral exposure and the working group is comparing the exposure of bats with the exposure scenarios available in the current guidance on birds and mammals.

Birds and mammals

The guidance will be developed by a working group composed with EFSA and external experts, including experts from MSs, academia and panel members. It should be adopted in July 2020, pending on the input needed from Commission and risk managers on the specific protection goals.

Reoccurring issues in ecotoxicology

A technical report covering the general issues was written following a meeting in October 2018. It is now under written procedure and the deadline is the 22 April 2019.

Metals

Commission mandated the PPR Panel to develop a methodology for ERA of transition metals for all the relevant environmental compartments: this should include bioavailability, homeostatic mechanisms and bioaccumulation, etc.

Bees

EFSA received a mandate form the Commission to update the current guidance i.e. EFSA, 2013. To address the mandate, EFSA will establish a scientific working group. Expertise from MSs is very relevant and EFSA is considering to launch a call for expression of interest for all MSs in order to identify and select the relevant experts.

DK was interested to know when the final technical report for general issues will be finished. The current phase is for collecting comments via written procedure by 22 of April. Then the output will be published after addressing the comments. There is no clear deadline but it will be done as soon as possible. DK also wanted to know if other metals would be covered by the statement. EFSA stated that the aim is not to develop a specific methodology for copper but a framework covering metals used in plant protection products.

DE was interested to know why the aquatic guidance and terrestrial guidance are not scheduled for this year. EFSA answered that the activities were planned for updating both the aquatic and the terrestrial guidance documents. The terrestrial guidance will include several guidances. For the

aquatic guidance, a lot of comments were collected from MSs. The activities were postponed because of other priorities (e.g. the revision of the bee guidance). Therefore, it limits resources to cope with all those activities. EFSA also clarified that Specific Protection Goals (SPGs) have to be agreed before initiating the guidance revision. Commission informed on its initiative for the SPGs and it specified that some activities were on hold for clarifications and feedback. A tentative action plan for SPG was drafted during the standing committee but due to the complexity of the activities, it will be a step by step approach. The idea would be to have several workshops with stakeholders in the summer. The invitation will be sent to MSs. For each country, there will be 2 experts: one who is regularly coming to the standing committee and the other one specialized in toxicology or ecotoxicology to mix the expertise.

3.10. Peer Review as regards new criteria to identify Endocrine disruptors

The new scientific endocrine disruptor (ED) criteria are applicable since 10 November 2018. It triggered a lot of discussions and procedure changes internally.

For the renewals, there is a specific amendment to the Regulation 844/2012 (Regulation 2018/1659). Based on the ED assessment updated in line with the EFSA/ECHA (2018) guidance, different cases and scenarios are possible:

- ED criteria are not met
- ED criteria are met
- not enough data to exclude ED.

The applicant should decide on the testing strategy even though EFSA can propose one.

Extensive templates and flowcharts were developed to detail the procedure.

The amendment of the Reg 844/2012 does not apply for NAS. The clarification from SANTE via a letter last year stressed that there is no option for a second clock-stop for NASs. EFSA should finalize the conclusion highlighting the missing data on ED, with indication of the timeframe to provide the missing information. After the finalization of the EFSA Conclusion SANTE might consider sending an ad-hoc mandate.

Final flowcharts procedures

The ED flowcharts have been simplified following the previous consultation with PSN. They will be published on the EFSA website in a slightly different format, together with some explanatory notes.

An internal document was developed by the Mammalian Toxicology team. It is a 12-question document to conduct the assessment on the ED criteria during the scientific check. It aims to facilitate the assessment until more experience is gained.

Templates DAR/RAR on how to present the endocrine assessment

Appendix I of the the administrative guidance contains a template to present the ED assessment in the assessment report. Further instructions are also available in Volume 1 of the assessment report including an ED assessment report template (chapter 2.10) which was recently published on the Commission website. Appendices E of the ECHA/EFSA (2018) guidance (excel file for compilation of studies) has also been republished to solve some bugs encountered.

All newly submitted applications should include an ED assessment. The Appendix E should be verified by the RMS.

Feedback on applying the new criteria and use of ECHA/EFSA GD

EFSA is exploring the possibility to create a specific internal working group on ED to establish cooperation and harmonize the work with the ECHA ED working group.

NL had a question from an applicant about a tiered approach. It was reiterated that the timelines given in the legislation are quite short to fit with this approach.

NL also raised a concern on the actions to be taken for cases with several applicants. If 3 applicants are applying for the same substance it may happen that they propose 3 different strategies. Commission has not yet considered how such situations should be handled, especially on a legal level. The approach is to wait and see until a concrete case occurs and handle it case by case.

FR is currently assessing substances that are in the process. The guidance is applicable which is time-consuming and increases the workload. Experience needs to be gained with time. With the BREXIT adding to that for certain substances, the workload further increases.

SE wondered if for substances on which there is not enough data to exclude ED properties, the derogation is legally justified? Commission stated that the applicant has the right to include article 4(7) assessment in the pending dossiers for which a substance is likely to be an ED. Opportunity needs to be given to applicants to provide additional information to follow up the ED assessment and/or to submit Art 4(7) derogation/negligible exposure assessment.

UK supported NL's comment on the tiered approach.

Even though the use of Appendix E is not mandatory, EFSA reiterated that the excel spread sheet is highly recommended in order to have an objective way of presenting the data in a tabular form allowing a harmonized assessment of the data by the evaluators.

UK asked how to evaluate the effect on the thyroid. EFSA replied that a dedicated appendix on thyroid is in the guidance and includes definition of adversity for thyroid effects, how thyroid effects mediated by liver induction should be contextualized, how to develop specific MOA and how to consider these data in the WOE.

AT had a good experience with the guidance document and asked how to consider changes in the endpoints that might be triggered after the ED data are submitted. This might be the case for toxicology and ecotoxicology. In certain cases, this is unavoidable and in such situations after the second clock-stop, a second meeting might be needed.

DE mentioned the increasing workload in relation to the ad hoc EFSA assessments. They encountered difficulties with the timely commenting on the EFSA ED assessments for the first 6 substances which were launched recently. EFSA takes note of this comment and will try not to launch the commenting period simultaneously whenever possible, depending on the availability of the reports and the flexibility in the timeframe.

BTSF trainings

This was already mentioned by Commission in point 3.3.

3.11. Update from the PRES Unit and organisation of a dedicated PSN meeting on residues

The PRES HoU informed the network on the competences of his new unit. Following the transfer of the annual report on pesticides residues, covering post-marketing monitoring of data to the DATA Unit; PRES is responsible for all pre-marketing assessments regarding pesticide residues and consumers risks. This cover the assessment of residues for the peer review processes, MRL applications, MRL Art 12 reviews, MRL Art 43 ad-hoc assessments, and the support to SANTE to Codex activities in the area of pesticides residues (CCPR). The unit also covers transversal and residue specific developmental activities, including the cumulative risk assessment of pesticides residues in food.

The PRES Unit is provisionally divided in 3 different processes with allocated Process Leaders, and the organisation of the unit in teams is ongoing. The current process (and potential teams) are:

- MRL applications
- Residue Peer review
- MRL reviews

There are several challenges in the area of pesticides residues, covering both, the need for further leaning and efficiency gains in each process and to further explore the link between the renewal process and the MRL assessments. Just as an example, the case study on benalaxyl described under point 3.3 was mentioned. The peer review conclusion informs risk managers that the residue definitions proposed in the EFSA Reasoned Opinion on the MRL review is no longer scientifically supported, but the focus is on the representative uses, which do not cover all crop groups. The example indicates the need for getting agreement among risk assessors in the MSs and EFSA for ensuring that the peer review Conclusions offer the required information for risk managers regarding not only the renewal for the a.s. approval but also the MRL setting and MS authorisation. The PRES unit is proposing a dedicated meeting of the PSN on pesticide residue processes, to be held on Q4 2019, for getting alignment between MSs and EFSA experts, similar to the one held in 2014.

3.12. Improvement initiatives for the MRL processes

Improvement MRL application process

As already planned under PRAS, once the peer review improvement initiatives have been implemented and the practical guidance noted by the PAFF Standing Committee, the PRES Unit is envisioning the application of a similar process for improving efficiency in the MS and EFSA assessment of MRL applications, developing with the MS a proposal for an administrative guidance for MRL applications.

EFSA proposed to apply the same principles that have shown to be effective for the peer review process. The process will cover the format of the MRL dossier, the MRL Evaluation Report and the EFSA Reasoned Opinion. EFSA proposed a brainstorming with MS residue/MRL experts at the dedicated PSN meeting in Q4 2019, using the residues part of the peer review practical guidance as background, following by the preparation of a draft practical guidance for MRL process with a set of MS volunteers to assess the additional specific needs. The draft will be revised following a commenting round with MSs and then submitted for discussion by the Residue Section of the PAFF. EFSA will in parallel discuss with DG SANTE if the MRL part should be integrated in the administrative guidance or prepared as a standalone document. EFSA will guarantee full consistency between the peer review and MRL parts.

It is reminded that in case an MRL application is submitted with the RAR, then both applications can be merged, even if the MRL application form is not on the representative uses. This means that the

MRL application will be included in the peer review process. The MRL application can also be assessed separately depending on the need of additional information.

Update on the MRL review process

EFSA informed that the decision tree used for deriving MRL recommendations and included as an Appendix to the reasoned opinions prepared under Article 12, has been revised.

In the past few years EFSA faced situations where it was not even possible to perform an indicative risk assessment considering the existing MRL. In all these situations it was simply reported in the footnote of the MRL recommendation that this case was not reflected in the decision tree.

It was now decided, for transparency reasons, to include also this option in the decision tree. The new decision tree is not expected to have an impact on the way the assessment is performed, nor on the procedure agreed by the PSN in 2014. The revised decision tree was already discussed with SANTE. It will be introduced in the next published reasoned opinion of EFSA.

Proposal for a dedicated PSN for Residues

EFSA proposed the organisation of a dedicated PSN in the last quarter of 2019. The proposal and timing have been pre-discussed with DG SANTE, as for EFSA the participation of EC is essential. It will cover all MRL processes and the link between the residue peer review and MRL processes. A draft agenda will be distributed and EFSA will prepare background documents for facilitating the discussion. MSs will have also the possibility for submitting agenda items. All MSs agreed with the EFSA proposal.

The nomination of specific Residue experts among MSs needs to be done in order to know in advance who will attend the dedicated PSN.

It was mentioned that in certain countries, the MRLs are under different authorities than the plant protecting product assessments. MSs should consider the points for discussion at the dedicated residue PSN meeting in order to nominate the relevant person and the institutions that should be consulted. The experts/organisations participating at the 2014 PSN dedicated meeting could be used as a starting point for the MSs. MSs are invited to submit their proposals for the agenda, then EFSA will identify the key topics and send the invitations through the MS contact points.

Update on PRIMo

EFSA informed that the new version of the model (v3.1) was published on 29 March 2019. Following a request from BU, MSs are invited to inform EFSA in case they see needs for training of MS experts for PRIMo v3/v3.1.

The next version of PRIMo would be version 4 and will represent a significant change as the model will be based on the EFSA comprehensive consumption data and the tool published by EFSA in early 2019 for linking consumed food with raw primary commodities. Developing a new model will take 2 or 3 years and EFSA will involve MSs through the full process. A brainstorming already took place with MSs. Now PRES is preparing a questionnaire on the features MSs would like to have on the new version.

Update on cumulative risk assessment

EFSA updated MSs on the status of the cumulative risk assessment project and the expected publications in 2019.

MSs wanted to know if it is possible to have trainings to implement this cumulative risk assessment. It will be possible but not now because it is too early in the process. Currently, EFSA is focussing on the improvement and validation of the exposure tool, MCRA, developed by RIVM and offered to MS for their assessments.

FR said that in their monitoring data, there is an exposure data to other chemical substances inducing effects on the nervous system; therefore, the whole exposure is not known. EFSA acknowledged the comment and clarified that currently there are two connected activities in EFSA. One specifically on pesticides presented to the PSN, and another general one on the risk assessment for mixtures lead by the Scientific Committee, which has recently published a guidance document and some tools.

Action point: MSs to inform EFSA if they have training needs on PRIMo v.3.1 (published on 29/03/2019) and to provide their input on which points should be discussed in a PSN dedicated to residues, **by 30 April 2019**. MS are requested to ensure that the relevant organisations covering MRL issues and consumer risk assessments in the MS are informed and involved in the selection of the experts.

4. Any Other Business

4.1. Discussion on development of "terms of references" for the expert meetings (proposed by DE)

This topic was discussed at the last meeting. It would be good to have fixed numbers of MSs taking part in the expert meetings and a date for presenting documents. EFSA stated that this information is available in the document that was developed to define the role of experts.

Some experts have problems with the documents being sent with short notice before expert meetings. They would prefer to have them 14 days prior. For a teleconference, they would like to have them 1 week earlier. EFSA stated that it depends on when the revised documents are submitted by the RMS. It is a shared responsibility. EFSA is open for suggestions to improve the situation.

Action point: EFSA proposed that DE shares their suggestions on the document defining the role of experts and then can be shared with the MSs.

4.2. Request APPL to include reference lists (Docs LCA/LCP) in response to EFSA additional information (proposed by DE)

DE has some difficulties to understand the correspondence between the points listed in the letter and the documents sent by the applicant.

Action point: EFSA will include this proposal in the clock-stop letter from now on.

4.3. Draft Guidance on isomers: update on public consultation

This is implementing the priority identified by the PSN and the follow up mandate received 2 years ago. The draft guidance document will be launched for public consultation soon. It is a transversal document covering all pesticides areas and drafted by EFSA scientific staff. MSs are invited to submit their comments during the public consultation. If needed a dedicated assessment of the received comments could involve the PSN.

5. Date for the next meeting

The next PSN is scheduled on **24-25 March 2020**. These dates need to be confirmed depending on next year's PAFF meeting dates.