



Network on Pesticides Steering Minutes of the 25th meeting

Held on **16-17 March 2020, TELE-conference**

(Agreed on 7 April 2020)

Participants

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

Country	Name ¹
Austria	Sonja Ecker, Klaus Leder
Belgium	Philippe Castelain
Czech Republic	Lucie Vanova
Denmark	Alf Aagard
Estonia	Eva Lind
Finland	Kaija Kallio-Mannila (only on 16/03/2020)
France	Thierry Mercier (only on 17/03/2020)
Germany	Eva Goclik
Greece	Agathi Charistou, Danae Pitarokili
Ireland	Sadhbh O'Dwyer
Latvia	Liga Brence
Lithuania	Kristina Valionė
Netherlands	Hanneke Westland
Portugal	Bento De Carvalho
Slovakia	Marta Galusova (only on 17/03/2020)
Slovenia	Polona Slokan
Spain	José Luis Alonso-Prados
Sweden	Katarina Lundberg

- **European Commission:**

Karin Nienstedt (DG SANTE)

- **EFSA:**

¹ Indicate first full name and them surname (John Smith) throughout the document

Pesticide Peer Review Unit (Manuela Tiramani, Head of Unit, Chair)

Pesticide Peer Review Unit (Tunde Molnar, Coordination Team)

Pesticide Peer Review Unit (Dimitra Kardassi, Coordination Team)

Pesticide Peer Review Unit (Chloé De Lentdecker, Coordination Team)

Evidence Management (DATA) Unit (Jane Richardson, Lead Scientist on Open Scientific Data)- participated in agenda point 3

Legal & Assurance Services Unit (Dirk Detken, Head of Unit)- participated in agenda point 8

Pesticide Residues (Luc Mohimont) - participated in agenda point 4

Pesticide Peer Review Unit (Mark Egsmose, Environmental Fate & Behaviour Team)-participated in agenda point 4

Pesticide Peer Review Unit (Domenica Auteri, Ecotoxicology Team)-participated in agenda point 4

Pesticide Peer Review Unit (Juan Parra, Mammalian toxicology Team)- participated in agenda point 4

Pesticide Peer Review Unit (Frederique Istace, Mammalian toxicology Team)-participated in agenda point 4

Pesticide Peer Review Unit (Federica Crivellente, Mammalian toxicology Team)-participated in agenda point 4

Pesticide Peer Review Unit (Andrea Terron, Mammalian toxicology Team)-participated in agenda point 7

Pesticide Peer Review Unit (Maria Arena, Ecotoxicology Team) - participated in agenda point 7

Pesticide Peer Review Unit (Carla Huizing, Coordination Team)

Applications Desk Unit (Karine Lheureux, Head of Unit)

Applications Desk Unit (Sara De Berardis)

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted with two additional points added under AOB as regards ecological modelling and field applications by drones.

The update of the Matrix project has been cancelled.

3. IUCLID implementation in pesticides

EFSA gave an overview of the Pilot phase 1 run until now:

- Participants: 2 Industry associations, 1 contractor, 5 Rapporteur Member States, the Commission's Directorate-General for Health and Food Safety (DG SANTE), the European Chemicals Agency (ECHA) and EFSA

- 5 Dataset types created (plant protection products (PPP) mixture, active substance, basic, Micro-organism, relevant metabolite/impurity)
- 77 Organisation for Economic Co-operation and Development (OECD) Harmonised templates, 65 Summary templates, > 9,000 data elements
- Draft dossier creation manual available
- 9 Training sessions on different aspects of International Uniform Chemical Information Database (IUCLID)
- 102 questions answered
- 353 issues identified
- Proof of Concept (POC) for new active substance and renewal

The expected benefits are numerous:

- The proof of concept of a structured pesticides dossier using all relevant OECD templates. The new active substance and renewal POC were created and in the next phase of the project, this would be extended to the micro-organisms.
- A harmonisation of the dossier management and an improved collaboration between EFSA and rapporteur Member State (RMS) sharing a common IUCLID and the use of tools like 'Report Generator' and 'Annotation' is stimulating collaboration between the regulatory agencies and alignment of processes. It is noted that the re-use from biocides is also creating synergies across the regulations. The 'Information Lifecycle' needs further discussion to identify the IUCLID adaptations to support process alignment.
- An improved traceability of the dossier life cycle since IUCLID allows new versions of the dossier to be submitted and the 'Comparison' tool visualises all changes between versions. Since a dossier cannot be amended by a recipient the use of annotations separates applicant changes from evaluator comments and decisions (RMS's view vs applicant's view). Further discussions are needed to ensure that the final validated endpoints of the evaluator are stored and retrievable.
- An automated validation of dossier content and filtering of confidential information. The 'Filtering' tools are being tested and the 'Validation assistant' testing will begin in March. In the next phase of the project, the pesticide specific rules for validation and filtering should be defined and agreed.
- An understanding of the ECHA project and Change Advisory board and ECHA IUCLID team roles that would ensure an effective collaboration after the pilot phase. The participants in the project are now aware to the IUCLID release schedule and the role of OECD in the governance of changes to templates and IUCLID. In the next phase, the requests for change should be submitted to the IUCLID backlog.

A questionnaire was shared with the EFSA Technical Group members and out of 10 members who replied, 100% would recommend IUCLID for Pesticides applications, if all the problems raised during the first pilot phase are solved.

Many activities have been identified to be further considered like the development of templates/formats for information other than OHTs; to allow PDF attachments for content that is currently not structured and ramp up to more structured data over time; regarding QSAR, the structural information should be implemented at a prominent spot in the dossier; the concept of IUCLID to transport needed information for metabolites; the OHT improvement and definition including reduction of Rich Text Fields; the cross-reference to other data points; a central submission point to ensure that all entities are working with the same dossier version; to improve the documents to handle extensive risk assessments, Vol.4, efficacy and open literature data; to improve table of contents to match 1:1 with SANTE templates to IUCLID, without cross-references etc... Already some of these topics are planned to be discussed at the weekly meetings of the EFSA Technical Group on IUCLID.

It has been confirmed by EFSA that IUCLID will be used for Pesticides applications from March 2021. Therefore, IUCLID will be included in the legislation. A revised Regulation (EU) 844/2012 to apply after the 27th of March 2021 will include the requirements of the Transparency Regulation (relevant amendments in the General Food Law and in the PPP Regulation) e.g. references to pre-submission process, notification of studies requirements and dossier format. The regulation will still be in place for renewals submitted before 27/03/2021. The aim would be the adoption of the new regulation in July or September Standing Committee on Plants, Animals, Food and Feed (PAFF committee) meeting.

The IUCLID Minimum Viable Product (MVP) prepared by ECHA, to be delivered by March 2021, was presented. The authorities/RMS will get a large number of functionalities such as the automated actions on the dossiers e.g. dossier validation, cross checking with related data (from different substances), notifications (updated dossier available for instance) and dossier public data readied for publication. Assessment tools will also be available such as dossier dashboard, commenting/annotation and to contextual the menu for operations.

The next phase is now to refine the format changes and to adapt IUCLID to reach in April 2020 the IUCLID release. An updated version of IUCLID is expected in October 2020 with the release of documentation, webinars and manuals and the organisation of trainings on IUCLID to be ready by March 2021 when the amended General Food Law will enter into force.

ECHA Cloud Service will be available for Pesticides and it was clarified that IUCLID will be cloud-based, therefore, no specific IT tools are needed for the applicants or member states.

An open call to express interest via Advisory Forum was launched to all EU countries to become a member of the EFSA Technical Group on IUCLID focusing on specific experience and knowledge on micro-organisms applications. The deadline was the 16th of March 2020. Commission mentioned that an update of the data requirements is on-going that will likely impact the data format.

After the presentation, it was discussed whether IUCLID is an appropriate tool for assessment report generation and especially in terms of quality compliance and considering the proposed timeline for its implementation. EFSA clarified that many areas will be automatically generated, especially the summaries that is quite straightforward. The automation is however not mandatory and the generation of the report can be done manually if more convenient.

IUCLID is copied from the current template of the assessment report but afterwards in case changes would be needed, it can be amended accordingly.

For the renewal dossiers, the idea expressed by the Member States (MSs) would be to start the renewal assessment report from the draft assessment report (DAR). It was mentioned that the same functionalities already developed for Biocides have been used for Pesticides as well and some improved actions developed now for Pesticides will be applied to Biocides.

It was also reiterated that the system will not be completely finalised by March 2021 (Cf MVP).

EFSA mentioned that the need expressed during the previous PSN meeting to present the data in a more structured manner was the starting point for drafting the Administrative guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substance². In this context, several templates were developed and included in the Administrative guidance. Moreover, the need to develop template and structured format for the endpoints for which no OHT is available was already raised and is still applicable. It was also clarified that the aim of the IUCLID implementation is not to change the current practice (at least in a short-term perspective) but to apply and continue the work that has been started last year from the previous PSN meeting. Therefore, the development of additional templates should be done and would be included in IUCLID. The proposal would be to work in small groups to develop the useful templates that are still missing and are needed to improve the assessment.

Commission added that IUCLID is already used in Biocides and REACH areas and that discussion at national level may be useful across the regulations in order to boost the understanding of IUCLID among PPP experts.

DE does not support IUCLID to be implemented by March 2021 since too many issues are left to be solved. A higher workload to ensure the quality of assessment reports is expected. Furthermore, DE questions the compatibility with the existing procedure in the context of processing and archiving in Germany.

Action points:

- MS to contact EFSA for information on how to access the proof of concept of a pesticide dossier used in the IUCLID project in pesticides by **27 March 2020**.

4. Update on developmental activities (DG SANTE)

4.1 Update on ongoing activities at DG SANTE.

DG SANTE gave an update on the Regulatory Fitness and Performance programme (REFIT) of the EU Pesticides legislation. The Commission Report and accompanying Staff Working Document is under Inter Service Consultation (ISC) and the publication is expected soon, as package with the Sustainable Use Directive (SUD) report and Farm to Fork Communication. Feedback from the consultation during evaluation (across all stakeholders) is that current framework is adequate, but

² <https://www.efsa.europa.eu/en/supporting/pub/en-1612>

better implementation should be envisaged. Key issues identified: delays, need for more transparency and need for more low risk alternatives.

The better implementation of "cut off" criteria is one of the actions to reduce delays and is based on the **Commission Implementing Regulation (EU) 2020/103³** of 17 Jan 2020 amending Implementing Regulation (EU) No 844/2012 as regards the harmonised classification of active substances, C/2020/93. Now **MSs have to submit systematically** and early in the evaluation process **proposals for harmonised classification and labelling under classification, labelling and packaging (CLP) Regulation⁴**. The new regulation applies to renewal procedures of those active substances for which the approval period expires on or after 13 May 2023.

On-going discussions on how to make the risk assessment process more fit for decision making are taken place in PAFF, PSN and between SANTE/EFSA. Regarding the authorisation of Plant Protection Products (PPPs) the actions taken to reduce delays include: continuing supporting the Member States for authorisation of PPPs (Post approval Issues WG) financially supporting the minor uses facility, developing the Plant Protection Products Application Management System (PPPAMS) to enable notifiers to create applications for PPPs and submit these to EU countries for evaluation.

Regarding the actions to increase transparency DG SANTE noted the following measures:

- Publication of Emergency Authorisations (notifications under Art. 53 via PPPAMS) since February 2020
- Publication of draft acts and draft review reports under Section B for vote) and Section C (for discussion) of the Standing Committee meetings via Comitology Register
- Amendment of General Food Law on Transparency⁵
 - Aim: notification and publication of scientific studies supporting risk assessment
 - Implementation: replacement of Regulation (EC) No 844/2012 is in preparation
 - Implementation: EFSA to develop IT tools

The new Transparency Regulation enters into application **27 March 2021** with the exception of the new EFSA MB and appointment of experts in panels: as of 1 July 2022. Transitional measures: The new rules will not apply to requests for scientific output submitted to EFSA before its entry into application. Next steps will include the alignment of the existing Commission guidance/implementing acts in sectoral legislation to the new rules, this alignment needs to be coordinated with the alignment of EFSA procedures and guidance by end of March 2021. In addition a

³ Commission Implementing Regulation (EU) 2020/103 of 17 January 2020 amending Implementing Regulation (EU) No 844/2012 as regards the harmonised classification of active substances. OJ L 19, 24.1.2020, p. 1-4

⁴ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, p. 1-1355

⁵ Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC. OJ L 231, 6.9.2019, p. 1-28

general plan on risk communication will be adopted and standard data formats for applications are envisaged to be developed. The Commission should also be prepared to carry out the fact-finding missions (within 4 years following entry into application), the findings to be presented in an overview report. With regard to the implementation in the PPP area, the existing Commission guidance/implementing acts in sectorial legislation should be aligned to the new rules. This will include the **amendment/replacement of Commission Implementing Regulation (EU) No 844/2012** and the update of Commission's Guidance Document on the renewal of approval of active substances to be assessed in compliance with Regulation (EU) 844/2012 and other relevant guidance documents. EFSA has developed **practical arrangements** to ensure the consistency of confidentiality assessments by MS in case of approvals for active substances and of confidentiality assessments by EFSA in case of renewals.

Regarding the amendment/replacement of Implementing Regulation setting out the procedure for the renewal of active substances, the pre-submission phase will include: notification(s) of studies, pre-submission advice and public consultation on planned studies. The notification of planned studies could happen at least **5 years before the application for renewal** and the application could include the submission of the renewal dossier and it will happen **3 years before the expiry date** of the active substance. The IUCLID software package could be used for the submission of the dossier in the PPP area, EFSA and ECHA are working together on this project. The aim is to vote on the draft Regulation in **July or September PAFF Committee meeting**.

Regarding the implementation of Article 63 Regulation 1107/2009, the list of the information that can be treated as confidential has not changed, some elements have been moved to the Transparency Regulation as of horizontal application, **however**, there is a change as regards the **level of proof** required: applicants would now need to demonstrate that disclosure of the information concerned would potentially harm its interests to a significant degree. It was stressed that the confidentiality for renewal of the active substances will be assessed directly by EFSA according to the new provisions.

DG SANTE stressed the need of more low risk substances as alternatives in the longer term. Commission took actions to boost the low risk alternatives, it was mentioned the Commission Notice concerning a list of potentially low-risk active substances approved for use in plant protection (2018/C 265/02) **and the review** of the data requirements for microorganisms currently on-going. Also the Better Training for Safer Food (BTSF) training for microorganisms organised by DG SANTE aimed to increase the expertise in MS in terms of evaluation of those substances.

Beyond active substances it was noted:

- List of unaccepted co-formulants (vote foreseen at next PAFF)
- Safeners and synergists (survey at MS initiated)
- Increased scrutiny on the repetition of emergency authorisations
- Preparing AIR 6 programme
- Efficient risk mitigation (discussions at PAFF and workshop 17 January 2020)
- Defining Specific Protection Goals (SPGs) for updating Environmental Risk Assessment (ERA) Guidance Documents (GDs)

Regarding SPGs for updating ERA GDs several workshops took place recently (June 2019, September 2019, February 2020). Different scenarios were developed, and the report is in progress.

The following guidances are in progress at Commission level: EFSA GD on isomers (discussion at PAFF on-going), antimicrobial resistance, secondary metabolites, emergency authorisations, seed treatments (split of risk management and risk assessment). Other mandates to EFSA are also on-going.

4.2 Guidance Documents after Brexit

AT proposed to discuss and possibly decide on further proceeding with draft guidance documents which have been in charge of the United Kingdom.

AT noted the following guidances as having high priority:

- i. Guidance on Time Dependent Sorption of Pesticides to Soil. This document seems to be finalised from a technical point of view and Commission was asked to consider it at PAFF level.
- ii. Amendments to the kinetics guidance - some further work necessary.
- iii. Guidance document for physical, chemical and technical properties of PPPs under Regulation (EC) No. 1107/2009: This was taken over by AT, there was already communication between AT and Commission

Action point:

- Guidance on Time Dependent Sorption of Pesticides to Soil - AT to discuss with SANTE to consider including discussion on the guidance in the following PAFF meetings
- Amendment to the kinetics guidance- It is proposed that MS should be encouraged to take over and continue the work of UK on this GD

4.3 Guidance on aged sorption of pesticides for groundwater leaching assessments

The (Forum for the Co-ordination of Pesticide Fate Models and their Use) FOCUS ground water report (2015) provides guidance for the assessment of leaching to groundwater. The FOCUS report provides some short general guidance on refinement of assessment using aged sorption parameters. When applicants use the aged sorption (time dependent sorption) approach it resulted in long discussions. A **workshop** on aged sorption of pesticides in soil was organised by the Chemicals Regulation Division (CRD) for developing a GD in 2010. The CRD prepared a draft GD and the PSN was consulted and proposed that the PPR Panel reviewed the guidance. Following the recommendations of the Panel on Plant Protection Products and their Residues (**PPR Panel**) the aged sorption guidance was updated and finalised in 2019. The CRD submitted in 2019 the finalised aged sorption guidance to DG SANTE for consideration for regulatory use. The finalised guidance (2019) provides a more detailed, robust and reproducible approach⁶. See also action point under point 4.2.

⁶ <https://www.hse.gov.uk/pesticides/pesticides-registration/data-requirements-handbook/fate/proceedings.htm>

4.4 Development and revision of GDs for the environmental exposure assessment

The following were briefly presented:

- Request from the EC for a statement on a framework for conducting the environmental exposure and **risk assessment for transition metals** when used as active substances in plant protection products (PPP). The Statement to provide advice/recommendations for ERA of transition metals e.g. Cu and Fe compounds used as PPPs is on-going, public consultation foreseen in July 2020 and adoption of statement by February 2021.
- **EFSA scientific report on FOCUSsw “repair”**: EC mandate on the “repair action” of the FOCUS surface water scenarios. Major change in temporal exposure assessment from 16 months to 20 years. The new procedure will provide more robust surface water predicted environmental concentrations (PECs) than the current process. Risk managers will be consulted on exposure targets. EFSA scientific report and stakeholder report will be published by June 2020.
- **EFSA PECs in soil guidance**: The EFSA PECs in soil GD and the supporting Persistence in Soil Analytical Model (PERSAM) software are publicly available. The supporting Pesticide Emission Assessment at Regional and Local scales (PEARL) and Pesticide Leaching Model (PELMO) models are in FOCUS version control for checking before release for regulatory use. Spatial and temporal aspects of soil, weather and crops in Europe are taken into account in the new procedure. The new PECs in soil guidance provides a more scientifically justifiable approach compared to the current PECs in soil procedure from 1997.
- **Member State (MS) guidance on photodegrades**: Germany together with MSs has prepared a draft guidance for parameterisation of photodegrades from substances which could reach groundwater from use of PPPs. European Commission (EC) has mandated EFSA to launch a public consultation on the draft GD. EFSA shall finalise the GD together with MSs 18 months after accepting this mandate.
- **EFSA/ECHA guidance on drinking water**: EC mandated EFSA and ECHA for developing a GD on the impact of drinking water treatment processes on residues of substances in water abstracted for use as drinking water. Consultation with the appropriate stakeholders involved in the treatment of drinking water should be considered. EFSA and ECHA have been given 2 years for preparing this guidance.

All mandate requests and acceptance letters can be found here:

<http://registerofquestions.efsa.europa.eu/roqFrontend/ListOfQuestionsNoLogin?2>

4.5 Cumulative risk assessment update

The pilot project was briefly presented by EFSA. In particular, the acute effects on the nervous system (AChE inhibition, functional alteration of the motor division) and the chronic effects on the thyroid (hypothyroidism, C-cell hypertrophy, hyperplasia and neoplasia) were considered in two pilot retrospective assessments of the cumulative effects of pesticide residues in food.

19 organisations have commented during the public consultation on the pilot project; regulatory organisations such as U.S. Environmental Protection Agency (US EPA) and Health Canada Pest Management Regulatory Agency (PMRA), non-governmental organisations (NGOs), industry, food producer and academic/scientific bodies. The main comments targeted the problem formulation, the cumulative risk assessment group, the clarity of the assessments, the perception of biased assessment and the communication/wording of an overarching conclusion. It was noted that changes to the scientific reports consists in clarifications not impacting the assessment process and the outcome

The development of a prospective cumulative risk assessment (CRA) it is planned for the future; case studies are under development (the Dutch National Institute for Public Health and the Environment (RIVM) partnership).

MS are invited to provide input in a meeting of the PAFF WG on cumulative risk assessment in April and the discussion of a tiered approach is envisaged to take place in November within the same working group (WG). Next retrospective CRAs are envisaged including chronic Inhibition of AChE (exposure/risk) in 2020 and cranio-facial malformation (hazard/exposure/risk) in 2021. Longer term implementation plan for CRA will be discussed between EFSA/SANTE by end 2020.

4.6 Update on the bee guidance and the guidance for birds and mammals

The review of the Bee guidance is on-going. In particular, as regards the bee background mortality, EFSA is now finalising the stand-alone document that it is part of the Terms of Reference (ToRs) of the mandate, based on the protocol developed and consulted with MSs in October 2019.

It was noted that on 20 March a new consultation will be launched on the draft protocol regarding the review of the list of bee-attractive crops and on the review of the current risk assessment methodologies for revising Tier 1 schemes (ToR 3 and ToR 4 of the mandate).

The review of the requirements for higher-tier testing will be subject of a separate sub-project that will be carried out within this mandate at a later stage of the review process. The work on these aspects will start when agreed SPGs are available and frameworks for Tier 1 and Tier 2 risk assessments schemes are advanced. The public consultation of the GD is expected in October.

The work on the revision of the GD on the risk assessment for birds and mammals has slowed down due to the pending activity on the finalisation of the SPGs. Nonetheless, the WG continues the work in the parts of the guidance that are not affected by the discussion on SPGs. In addition one member of the WG needs to be replaced due to the Brexit causing delays.

Action point:

- PSN members and the Stakeholder Group will be consulted on the approach for revising Tier 1 schemes for the new EFSA guidance on the risk assessment of plant protection products on bees. Comments to the document will be topic for discussion during the online workshop scheduled on Monday 20th April.

4.7 Update of the EFSA guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products

The work is on-going. EFSA reported that there was lack of data submission during the open call for new scientific information/data related to the assessment of exposure of operators, workers, residents and bystanders and that not all the recommendations will be addressed. However, there is new data for new scenarios (i.e. greenhouse) as well as to refine existing scenarios (workers, residents and bystanders) and to refine the current default values. Literature data are reviewed in the last case.

The update of the calculator is on-going; for this purpose an online calculator will be developed, more user-friendly and also suitable for national authorisations including different options based on the risk mitigation measures available to MSs.

The deadline for delivering this project has been postponed to end 2021 in order to take into account the new information.

4.8 Guidance on In vitro comparative metabolism studies

In vitro comparative studies are part of the data requirements for pesticides active studies, however, no Guidance is available on how to perform these studies and how to interpret the results obtained.

As a consequence, either these studies are not provided by the applicant because of lack of guidance or the studies are conducted using different experimental layouts making it difficult to evaluate the data.

EFSA organised a workshop for stakeholders involved in the peer review of pesticides and with experts in the field of *in vitro* metabolism studies in November 2018. Based on the outcome of the workshop an EFSA guidance on use and conduction of *in vitro* comparative metabolism studies deemed necessary to be developed. The Guidance is expected to be finalised in March 2021.

EFSA will run a Member State consultation through the PSN after the Working Group 3, between May and July 2020, to receive major comments on the draft Guidance. MSs will have again the opportunity to comment during the public consultation that will take place after November 2020.

4.9 Issues discussed during the Pesticide Peer Review meeting on general recurring issues in mammalian toxicology

The meeting took place in Parma in October 2019 with MSs representatives with expertise in toxicology. The aim was to discuss issues identified during the peer review of active substances to enhance the harmonisation of risk assessment. Recommendations were compiled on the basis of the discussions and conclusions achieved. These recommendations will be applied during the EFSA peer review of the active substances and are expected to provide additional clarifications to applicants and rapporteur Member States regarding the scientific interpretation of the relevant guidance documents when preparing the dossiers and the assessment reports. The Technical Report of the meeting will be published in March-April.

In the meeting EFSA presented the experience gained on the assessment of ED properties applying the recent ECHA/EFSA guidance (2018) and the feedback

received from stakeholders. The endocrine disrupting (ED) assessments done within the peer review process was also presented (43 substances at the time of the meeting). A list of relevant points for potential update of the Guidance was discussed and recommendations and agreed actions provided.

The issue of the guidance on the assessment of the relevance of impurities from ECHA biocides was also presented and discussed. Currently the toxicological relevance of impurities in pesticides risk assessment is performed by following the EC guidance document on the assessment of the equivalence of technical materials (European Commission, 2012⁷). ECHA developed a guidance document (not published yet) for the assessment of relevant impurities. It was discussed the possibility to apply the ECHA Guidance for the assessment of the toxicological relevance of impurities for pesticides. No recommendations could be made during the meeting since the process of testing the applicability of ECHA Guidance for pesticides is still ongoing.

The EFSA Guidance on risk assessment for active substances of PPP that have stereoisomers as components or impurities (EFSA, 2019⁸) was presented and discussed during this meeting. Recommendations were provided on how to best address and assess the data requirements for active substances containing stereoisomers.

With regard to the groundwater metabolites, the guidance document on the assessment of the relevance of metabolites in groundwater proposed an *in vitro* test battery consisting of an Ames test, an *in vitro* mammalian gene mutation assay and an *in vitro* chromosome aberration assay (European Commission, 2003⁹). This test battery is not properly assessing aneugenicity potential according to the current scientific knowledge (EFSA Scientific Committee, 2011¹⁰). An *in vitro* micronucleus test (MN) instead of an *in vitro* chromosome aberration test to properly cover aneugenicity would be needed.

Regarding the genotoxicity of mixtures, it was discussed and agreed to use the statement of the Scientific Committee (EFSA Scientific Committee, 2019¹¹) on how to assess the genotoxic hazard of substances in chemical mixtures present in food and feed during approval or renewal of approval of pesticide active substance mixtures. It was clarified that the Guidance is not applicable to PPPs.

The outcome of the outsourced project on the evaluation of the applicability of *in silico* models (Quantitative structure activity relationships (QSARs) and read-across) for predicting the genotoxicity of pesticides and their metabolites was also discussed. Good performance was demonstrated in the case of prediction of point mutations, but poor in the case of prediction of other genotoxicity endpoints. Experts agreed that, in case of positive predictions, testing should be done; in case

⁷ European Commission, 2012. Guidance document on the assessment of the equivalence of technical materials of substances regulated under Regulation (EC) No 1107/2009. SANCO/10597/2003-rev. 10.1, 13 July 2012.

⁸ EFSA (European Food Safety Authority), Bura L, Friel A, Magrans JO, ParraMorte JM and Szentés C, 2019. Guidance of EFSA on risk assessments for active substances of plant protection products that have stereoisomers as components or impurities and for transformation products of active substances that may have stereoisomers. EFSA Journal 2019;17(8):5804, 33 pp.

⁹ European Commission, 2003. Guidance Document on Assessment of the Relevance of Metabolites in Groundwater of Substances Regulated under Council Directive 91/414/EEC. SANCO/221/2000-rev. 10 final, 25 February 2003.

¹⁰ EFSA Scientific Committee, 2011. Scientific opinion on genotoxicity testing strategies applicable to food and feed safety assessment. EFSA Journal 2011;9(9):2379. <https://www.efsa.europa.eu/en/efsajournal/pub/2379>.

¹¹ EFSA Scientific Committee, 2019. Genotoxicity assessment of chemical mixtures. EFSA Journal 2019;17(1):5519. <https://www.efsa.europa.eu/it/efsajournal/pub/5519>.

of negative predictions, a case-by-case approach should be applied. Overall, general acceptance of the *in silico* models for risk assessment is considered still pending.

With regard to the toxicological assessment of metabolites found as residues, the PPR guidance on the establishment of the residue definition for dietary risk assessment (EFSA PPR, 2016¹²), although not taken note of by the European Commission and MSs, is currently used for some of the scientific elements. However, so far the data included in the dossiers have not been consistently and/or sufficiently reported. EFSA presented and proposed to use a template for assessing QSARs reports in the draft assessment report (DAR)/renewal assessment report (RAR) to allow an independent peer review together with a table summarising and integrating all available data (experimental and QSAR analysis) on genotoxicity of metabolites; MSs proposed to ask the Applicant to use such templates.

Furthermore, the use of benchmark dose instead of (No observed effect level) NOAEL was discussed. The discussion focused on some examples from the peer review process where benchmark dose (BMD) has been already applied, in parallel to the setting of NOAEL/low observed adverse effect level (LOAEL). It was agreed to use the BMD analysis in the case no NOAEL is set for a specific parameter and a LOAEL is set instead, or also on critical endpoints used to derive toxicological reference values. MSs and EFSA identified the need to exchange practical experience in a dedicated workshop.

During the Pesticide Peer Review meeting EFSA also provided some updates on the following on-going developmental activities: *in vitro* metabolism comparative metabolism, OECD project on dermal absorption, developmental neurotoxicity, development of an adverse outcome pathway (AOP) relevant for the identification of substances having ED properties, top dose selection. Finally, some experts indicated as emerging issues the exposure of children to alkyl phosphates (associated with higher risk of neurological impairment in children) and the need of a clear guidance on the use of historical control data.

After the presentations and along the discussions the need to harmonise the way the EFSA guidance documents/other documents are dealt with by the PAFF was identified. It was suggested EFSA to discuss internally and with SANTE on suitable approach to communicate the EFSA outputs. It was also discussed that EFSA and SANTE should consider prioritisation of different activities in relation to development and revisions of guidance documents especially in ERA (e.g. the aquatic GD that is not adequate for non-target plants so that DE proposed an interim solution to be developed; the terrestrial GD that does not fit to the current state of the art e.g. for soil organisms). Commission aims to define SPG before prioritising the work on outstanding GDs or their revisions. Furthermore, EFSA should further reflect on the best way to communicate on the proposals and recommendations formulated during the general Pesticide Peer Review meeting on general recurring issues in mammalian toxicology. Concerning genotoxicity testing the problem was raised by DE that are only a few lab capacities worldwide to perform *in vitro* micronucleus tests so that it will be difficult for applicants to submit these studies as requested. Therefore, timelines should be reconsidered.

Concerning CRA, DE asks for a feasible implementation for the risk assessment.

¹² EFSA PPR Panel (European Food Safety Authority Panel on Plant Protection Products and their Residues), 2016. Guidance on the establishment of the residue definition for dietary risk assessment. EFSA Journal 2016;14(12):4549, 129 pp. doi:10.2903/j.efsa.2016.4549.

Action points:

- Action point for EFSA to discuss internally and with SANTE on suitable approach dealing with communicating different EFSA outputs.
- EFSA and SANTE to consider prioritisation of different activities in relation to development and revisions of guidance documents in ERA
- EFSA to further reflect on the best way to communicate on the proposals and recommendations formulated during the general Pesticide Peer Review meeting on general recurring issues in mammalian toxicology meeting (October 2019).
- The need of a clear guidance on the use of historical control data was shared by the audience.

5. MS initiative for harmonised use of groundwater monitoring data in EU regulatory pesticide risk assessment

AT presented the initiative for a harmonised use of **groundwater monitoring** data in European Union (EU) regulatory pesticide risk assessment. AT noted the need for the definition of a specific protection goal for groundwater with respect to pesticide risk assessment in the EU and further guidance how to design and conduct targeted groundwater monitoring studies and how to assess monitoring data from both targeted monitoring studies and publicly available monitoring data in pesticide risk assessment.

Currently the groundwater risk assessment for pesticides in the EU is based on modelling estimates at a depth of 1m below the soil surface (lower tiers). Spatial and temporal aspects of the general protection goal for groundwater are not clearly defined in European regulation. In general there is a lack of a specific protection goal for groundwater in the EU. This hampers the development of applicable harmonised guidance for the design, conduct and assessment of groundwater monitoring studies, which is recommended by FOCUS as highest possible tier in groundwater risk assessment.

However, groundwater monitoring data are increasingly provided by applicants and need to be assessed by regulators. Currently, there are no decision criteria for the interpretation of monitoring data in relation to groundwater risk assessment in the EU, therefore, a harmonised regulatory decision making is not straightforward.

Defining decision criteria would also facilitate to use publicly available monitoring data in future EU risk assessments.

New scientific recommendations from a Society of Environmental Toxicology and Chemistry (SETAC) publication (Gimsing et al., 2019)¹³ are available, how to assess monitoring data based on examples of different groundwater exposure assessment options. AT noted that those examples and recommendations are considered to be a suitable basis to start a process of defining a specific protection goal for groundwater in the EU.

¹³ Gimsing A L, Agert J, Baran N, Boivin A, Ferrari F, Gibson R, Hammond L, Hegler F, Jones R L, König W, Kreuger J, van der Linden T, Liss D, Loiseau L, Massey A, Miles B, Monrozier L, Newcombe A, Poot A, Reeves G L, Reichenberger S, Rosenbom A E, Staudenmaier H, Sur R, Schwen A, Stemmer M, Tüting W, Ulrich U (2019): Conducting groundwater monitoring studies in Europe for pesticide active substances and their metabolites in the context of Regulation (EC) 1107/2009 – Journal of Consumer Protection and Food Safety (2019) 14 (Suppl 1):S1–S93 (<https://doi.org/10.2903/j.efsa.2016.4499>)

Several MSs (AT, FR, DE, NL, SE) asked the EC to mandate EFSA to organise a public consultation on the SETAC EMAG+Pest GW publication (Gimsing et al., 2019) and to deliver an EFSA Scientific Statement on that regard. The EFSA Scientific Statement should consider the scientific and technical aspects on study designs and procedures as well as decision criteria on the assessment of groundwater monitoring data to be used in the EU regulatory risk assessment of pesticides. Risk managers would need to be consulted regarding the definition of possible options for groundwater protection goals in the EU and to agree on one option.

Action points:

- SANTE to consider mandating EFSA to initiate a public consultation of the SETAC EMAG-Pest GW paper with the objective to (i) deliver at the end an applicable guidance for the use of monitoring data in groundwater risk assessment and (ii) simultaneously initiate the discussion on a specific protection goal with risk managers. This will be considered based on the prioritisation exercise of different activities in ERA.
- EFSA to further discuss internally and with AT on the possible tiered approach proposed i.e. organise the peer review of the SETAC publication and then further consider the way to proceed.

6. Initiatives to improve efficiency peer review

EFSA gave an update on the status of initiatives concerning the improvement of the efficiency of the peer review, leading to amendments in the EFSA Conclusion template. EFSA shared with PSN the **consolidated updated Conclusion template** as a result of all changes occurred, containing the following improvements:

1) New structure for data gap categorization as a follow up of the pilot exercise:

The pilot exercise, based on the practical example of benalaxyl, started in November 2018 with the aim to improve the presentation of data gaps in a new structure, in order to allow a better understanding of their impact on the risk assessment and their consequences for the decision-making. It was however not intended to change the current criteria or reopening discussion on the agreed approach for listing items under concerns.

Following feedback from SANTE last year, an initial proposal for a new structure was already presented at the last PSN in April 2019. Following a subsequent commenting round with MSs, there was a need to undertake some minor changes (refinement of wording of some introductory paragraphs), however the overall structure remained the same, as presented in the last PSN:

- data gaps are split into 3 groups:
 - a. data gaps linked to issues not finalised are directly reported under the specific issue to which they are related (**section 9.1**)
 - b. data gaps linked to critical areas of concern are directly reported under the specific issue to which they are related (**section 9.2**)
 - c. List of other outstanding issues (**section 10**) as a new stand-alone section, containing the data gaps which are not expected to lead to concerns, however necessary to comply with the data requirements;

these data gaps are relevant only for the representative uses assessed at EU level

- Explanatory paragraphs have been introduced to increase clarity and transparency under **section 8 (particular conditions)** and **section 9 (concerns)**

During the commenting MSs expressed the need for careful and precise wording of data gaps. EFSA will commit to pay particular attention when formulating the data gaps to add sufficient level of details in order to increase the transparency and to allow a clear understanding of the 'weight' of each data gap.

- New appendices:
 - a. A new **Appendix B** has been introduced to increase transparency as regards the wording used in section 4 of the conclusion, in relation to persistency (DT) and adsorption (Koc) categories, consequent to the request from a MS (NL) for transparency on the wording used in conclusions; while making also clear that this wording is not related to Annex II persistence classes.
 - b. A new **Appendix C** has also been introduced for the specific request from SANTE to include considerations of the Annex II cut off criteria (Carcinogenic, Mutagenic, reproductive toxic (CMR), ED, Persistent, Bioaccumulative and Toxic (PBT)/ Very Persistent and Very Bioaccumulative (vPvB), Persistent Organic Pollutants (POP)) for better clarity and transparency reasons, and to be in line with the BPC (Biocidal Products Committee) opinions.
- Updated tables in **Section 7** (Overview of the assessment of compounds listed in residue definitions triggering assessment of effects data for the environmental compartments):
 - a. Tables 1-2: to simplify the tables, the columns on persistence and mobility were removed, while the relevant information is transparently available in the new Appendix B.
 - b. Table 2: Groundwater: the table has been changed to transparently reflect the steps of the assessment according to the European Commission (2003) guidance on the relevance of groundwater metabolites.
- Table 5: **Overview of concerns** as a result of the discussions with SANTE, and as presented at the last PSN:

The title of the table has been amended to clarify that the table reflects the issues not finalised, the critical areas of concerns as well as the risks identified that may be applicable for some but not for all uses or risk assessment scenarios.

The table also aims to better reflect the outcome of the risk assessments for specific use scenarios, whenever applicable, to allow a clear conclusion on different use cases or scenarios, in particular in case the representative uses include very different use types (e.g. seed treatment and spray applications).

Furthermore, it was agreed to avoid including 'X'-es without any indication in the table. For this purpose, as necessary, explanatory footnotes are added in the Table 5 to include additional details or explanations to facilitate the identification of

potential safe uses by risk managers (e.g. in case safe use could be identified for permanent glasshouse uses, indicating the subset of non-target organisms (NTOs) with high risk, differentiation of risk to bees if cops are allowed to flower, etc).

In addition, EFSA also discontinued the practice of greying out the table since this might convey contradictory message in case a safe use or scenario might still be identified at the decision-making phase.

EFSA clarified that these changes have already been implemented following agreement with SANTE. It is expected that with all these refinements and increased completeness, the table can become more self-explanatory and overall more useful for risk managers.

2) Joint mammalian toxicology/ecotoxicology ED section:

In order to improve the readability of EFSA Conclusions, a new stand-alone section (**section 6**) has been introduced to present the overall conclusions on the ED assessment for both humans and non-target organisms in one joint section. The aim is to avoid repetition of texts (mainly occurred in the ecotoxicology section), while having a single place for the ED outcome would also facilitate risk communication on the outcome of the assessment. In this way there is no need to search for the overall outcome within 2 different sections, in particular in case of different conclusion reached in the mammalian toxicology and ecotoxicology sections.

It is expected that the outcome will also become more clear and visible for both risk managers and the general public.

The joint section is also in line with the instructions provided in the DAR/RAR template.

The pros/cons were also discussed with SANTE and presented in the December 2019 PAFF meeting. Since no objections were raised, the joint section has been implemented for all Conclusions issued afterwards.

Overall, with all the above changes, the new Conclusion template is expected to improve the clarity and transparency of the peer review as well as the understandability of the EFSA Conclusions, making it more fit for purpose for risk managers for the decision-making and at MS level.

Since no major changes seem to have been raised during the commenting on the structure of data gaps compared to the proposal presented in the last PSN, it was proposed by EFSA to start implementing the new template for all Conclusions (except for active substances currently in the final stages), in case there are no major objections.

Some MSs (DE and EL) indicated that their previous comments on the data gap categorisation in the EFSA Conclusion did not seem to have been considered. In addition, SANTE requested to share with them the last updated Conclusion template and the MS commenting table with the EFSA responses for a final check.

Along the discussions, it was also suggested to explore the possibility to include in the template the reference specification for renewals. It was clarified that a proposal is already included in the EFSA Conclusion, however, a final decision on the

reference specification is taken by risk managers at the decision-making phase. The agreed reference specification will subsequently be included in the Commission review report and therefore, apart from EFSA's recommendations, it is not feasible to include it in the EFSA Conclusion beforehand.

- **efficiency of planning of the experts' meetings, challenges in organisation of the PREV expert meetings in 2020**

In order to increase the efficiency of planning of the experts' meetings, EFSA has established a plan for the Pesticide Peer Review experts' meetings in 2020.

The overview of the planned Pesticide Peer Review meetings 2020 dates is published on EFSA's website¹⁴. It is noted that changes in the meeting dates/additional meetings might be needed depending on the work programme whereas the exact meeting/teleconference dates and times will be decided based on the final list of active substances to be discussed.

Nevertheless, a provisional list of active substances to be discussed in Experts' meetings and Teleconferences (TCs) has been communicated to MSs.

In addition, for better and proactive preparation of the experts, the Reporting table is now made available in the meeting folders and communicated with the Call for nominations to the Contact Points. The Reporting table is expected to serve as a source for more details on the type of the issues that will be discussed in the experts meetings.

As challenges impeding the proper planning of the expert meetings, EFSA highlighted in particular the delayed submission of the revised documents, leading to potential bottlenecks or workpeaks upon submission of all delayed revised assessments. In addition, heavily revised DAR/RAR received before the meeting cannot allow a proper preparation of the EFSA staff and of MSs. Therefore, further reflections are needed on the procedure to apply if substantial changes have been introduced in the updated documents, including consideration of the necessity of a Public Consultation, on a case by case basis.

Action points:

- DE and EL to explore if their previous comments on the data gap categorisation in the EFSA Conclusion have been now addressed with the proposed amendments. If not, DE and EL to provide their comments on the updated template to pesticides.peerreview@efsa.europa.eu by **27 March 2020**.
- EFSA to share the last updated template and MS commenting table with EFSA responses with the Commission.
- Efficiency of planning of the experts' meetings:
 - EFSA to reflect on better communicating to MSs/RMSs the status of the peer review of active substances and on planned PREV meeting dates.

¹⁴ <http://www.efsa.europa.eu/en/pesticidespeerreview/peerreviewexpertsm meetings>

- RMSs to inform EFSA **proactively** on possible delays in submission of revised assessments in order to ensure proper planning of the substance to be discussed in the experts' meetings.

7. Endocrine disrupting properties

Commission Regulation (EU) No 2018/605¹⁵ introduced new scientific criteria. The Criteria entered into force and are applicable from 10 November 2018.

It is relevant to applications for approval/renewal of active substances, including pending applications. For applications submitted before 10 Nov 2018 (i.e date of submission of application and not the date of submission of supplementary dossier) the provisions of Regulation 2018/1659¹⁶ apply, including the possibility for a second clock stop for renewals.

For applications submitted after 10 Nov 2018: the initial dossier should already contain the ED assessment in line with ECHA/EFSA GD¹⁷. No second clock stop will be applicable.

Based on ED assessment updated in line with ECHA/EFSA GD, different scenarios are possible for pending renewal applications:

- ED Criteria not met (the substance is not an ED): No clock stop, Conclusion on approval criteria can be finalised.
- ED Criteria met (the substance is an ED): Applicant is given 3 months to submit any additional information to address the approval criteria and/or an application for 4(7)/negligible exposure derogation. Conclusion is finalized after the additional information is assessed.
- Not enough information to conclude on ED properties: EFSA, in consultation with MSs, proposes a testing strategy for additional information to conclude on the ED assessment (duration of clock stop from 3 up to 30 months). Maximum time of clock stop defined in Regulation 2018/1659 is limited to 30 months: this has strong implications on the study/ies to be included in the strategy. EFSA therefore suggests a strategy but leaves it to applicant to decide on final strategy.

For better clarity on the procedures, detailed flowcharts are published on the EFSA website¹⁸.

¹⁵ Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties. OJ L 101, 20.4.2018, p. 33–36

¹⁶ Commission Implementing Regulation (EU) 2018/1659 of 7 November 2018 amending Implementing Regulation (EU) No 844/2012 in view of the scientific criteria for the determination of endocrine disrupting properties introduced by Regulation (EU) 2018/605. OJ L 278, 8.11.2018, p. 3–6.

¹⁷ ECHA (European Chemicals Agency) and EFSA (European Food Safety Authority) with the technical support of the Joint Research Centre (JRC), Andersson N, Arena M, Auteri D, Barmaz S, Grignard E, Kienzler A, Lepper P, Lostia AM, Munn S, Parra Morte JM, Pellizzato F, Tarazona J, Terron A and Van der Linden S, 2018. Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009. EFSA Journal 2018;16(6):5311, 135 pp. <https://doi.org/10.2903/j.efsa.2018.5311>. ECHA-18-G-01-EN.

¹⁸ **procedure for renewals:**

(<https://www.efsa.europa.eu/sites/default/files/applications/Renewalapprovalprocedure.pdf>),

procedure for new active substances:

<https://www.efsa.europa.eu/sites/default/files/applications/NewActSubstancesProcedure.pdf>

procedure for specific cases (conclusion under finalization but not yet adopted by EFSA, or adopted by EFSA but no voting on draft Regulation took place at the Standing Committee on Plants, Animals, Food and Feed (SCoPAFF) by the date of application of the new ED criteria introduced by

The current **status on ED assessments** is the following:

- ED assessments in standard peer review: ca 40 substances based on EFSA/ECHA GD discussed in peer review expert meetings in 2019 - 2020 following the initial evaluation by the RMS

ED assessments prepared by EFSA: 15 a.s.

- i. for Conclusions under finalisation when new criteria entered into force: 6 substances
- ii. for Conclusions adopted but no voting at PAFF took place when the new criteria entered into force, ad-hoc mandates were sent to EFSA for re-assessment of the ED potential: 9 substances

The majority of the substances are currently under clock stops. So far EFSA finalized the Conclusions for 10 and there are currently 4 conclusions under drafting stage.

Cooperation between EFSA and ECHA is strongly needed to ensure alignment in the scientific assessments. The overall scientific outcome related to ED should be aligned in both EFSA and ECHA to ensure smooth decision-making. Discussions started between EFSA-ECHA to establish a practical approach for the alignment of the pesticide and biocide processes, in particular that the same ED criteria and the joint EFSA/ECHA GD are applicable for both biocides and pesticides. A kick off teleconference took place on 6 March 2020.

Current cases for alignment of EFSA-ECHA processes on ED assessment are tebuconazole and carbon dioxide.

MSs welcomed the collaboration between EFSA and ECHA including the information exchange on the ED assessments for both biocidal product and plant protection products. DE also raised the concept of "one substance - one assessment", however, considering the legal uncertainties due to the 2 different legal frameworks, there are doubts whether a 'mutual recognition' would be legally acceptable.

To ensure consistency and harmonization across all substances, EFSA developed an **excel database** to keep track of all the assessments done so far (one for toxicology, one for ecotoxicology). As a next step, EFSA plans to create a consolidated database to include both the toxicological and the ecotoxicological assessments in a single file as well as to ensure alignment between ECHA and EFSA. Once the database is finalized, it will be shared with MSs. The aim is to create a database that meets all the needs.

There were suggestions from DE to include more information on the active substance to enable an unambiguous identification of the substance (e.g. Chemical Abstracts Service (CAS) number) as well to add reference to the chemical class of the substance with the aim of grouping chemicals based on structural similarities to facilitate decisions on the endocrine disrupting properties assessment for similar moieties in future assessments. Additionally, it is proposed to report any new general decision taken regarding endocrine disrupting properties assessments and the corresponding meeting for future reference.

Regulation EU 2018/605):

<https://www.efsa.europa.eu/sites/default/files/applications/Renewalprocedurespecific.pdf> (renewal)
<https://www.efsa.europa.eu/sites/default/files/applications/Newactsubprocedurespecific.pdf> (NAS)

Furthermore, DE suggested to develop criteria for information on waiving endocrine disrupting properties, e.g. for substances with no toxic effects as well as for substances with already known severe hazard profiles.

Extensive discussion took place as regards the **requests for additional information** in case the data set is incomplete. It was clarified that EFSA strictly follows the testing strategy of the ECHA/EFSA GD. Case by case decision might also be taken depending on the studies already available in the dossier.

EFSA also highlighted that during the long-term clock stop period, the applicants can change their testing strategy depending on the outcome of the commissioned studies. In all such cases, they should inform EFSA in writing and according to the provisions of the legislation, the time period for submission of the additional information should be justified according to the type of information submitted. It was also clarified that applicants cannot use the ED clock stop period to fill any other data gap identified in other areas than ED or submit data not related to the ED assessment since currently there is no legal basis to do so.

MSs welcomed all initiatives that would facilitate harmonization of the ED assessments across substances and at both EU and MS level. MSs are encouraged to contact EFSA and ask for advice in case of uncertainties or questions on the assessment of the ED properties when applying the ECHA/EFSA ED GD, and to communicate to EFSA any examples in case they encounter any inconsistencies in the additional data requests.

To facilitate harmonization and to share experience, DG SANTE is considering to organize an additional training for MSs on the application of the EFSA/ECHA Guidance to identify endocrine disruptors.

Action points:

- Member States to communicate any inconsistencies on the additional information requested to the Applicant to conclude on ED assessment. Email to pesticides.peerreview@efsa.europa.eu by **31 March 2020**.
- Member States are encouraged to contact EFSA and ask for advice in case of uncertainties or questions on the assessment of ED properties. Email to be sent to pesticides.peerreview@efsa.europa.eu
- DG SANTE to reflect additional training for MSs on the application of the EFSA/ECHA Guidance to identify endocrine disruptors (to be organised as BTSF training)

8. Forthcoming Practical Arrangements harmonising the confidentiality assessments of Member States and EFSA under Regulation EC No 1107/2009 –state of play and next steps

There has to be a harmonised decision making, managed by Rapporteur Member States, on confidentiality requests by applicants concerning applications for approval of a new active substance.

The legal basis for the harmonised decision making is Article 7(3) of Regulation (EC) No 1107/2009¹⁹: "The Authority, following consultations with the Member States, shall lay down practical arrangements to ensure the consistency of those assessments."

A questionnaire has been sent to the National Authorities to gain insight in how they handle confidentiality requests from applicants. 13 National Authorities replied of which 9 are taking decisions on confidentiality requests from applicants.

Outcome of the questionnaire:

- Notification of the decision of the confidentiality to the applicant: EFSA form or email is used
- Screening criteria: No screening criteria or criteria based on Article 63 of Regulation 1107/2009.
- Review in case of rejection of the confidentiality claim: in most cases there is no internal review procedure
- Right of the applicant to be heard: in most cases this is not granted
- Timelines: the confidentiality requests are assessed in different stages of the process. The duration of the decision making varies from 0.65 day to 4 weeks.
- Working language: varies
- Person/organisation in charge of the sanitization process: applicant, National Authority or another organisation
- Fee for processing the confidentiality claim: varies
- None of the National Authorities faced a complaint or case in the last 5 years

The practical arrangements harmonising the confidentiality assessments will include the responsibilities, the selections criteria and other arrangements:

Assessment of confidentiality requests

- Responsibility of Rapporteur Member State for explicit decision
- Substantive screening criteria as per the Practical Arrangements implementing Article 39d(5) of the General Food Law (GFL)
- EFSA's consultation mandatory and not binding
- EFSA's advice focused on compliance of draft RMS decision with these Practical Arrangements

Minimum standards

- Written and explicit decision
- Case by case decision
- Non-disclosure of items claimed confidential pending finalisation of confidentiality decision
- Reasoned decision

¹⁹ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1-50.

- Right to be heard: The notifier has the right to be heard. The decision about the confidentiality claim has to be provided to the notifier before proceeding
- Notification of the decision
- Confirmatory application optional
- Judicial review available
- Review of initial decision in case of safety concerns: For example in case of impurities where it can depend on the point of time in the process whether it might be confidential information or not

Next steps:

- MAR-MAY 2020: EC and MS consultation
- MAY-JUN 2020: EFSA SANTE Stakeholder consultation
- AUG 2020: Freezing of substance - Final document
- OCT 2020: Stakeholder event
- NOV/DEC 2020: Formal signature

Member State consultation is foreseen by law and will be at PAFF level.

9. Feedback from the discussions at the PAFF meetings in view of decision making on the basis of the outcome of the EFSA peer review

9.1. PRIMo 3.1 Implementation

EFSA presented the new approach taken at the PAFF residues held in November 2019 regarding the Pesticide Residue Intake Model (PRIMo) 3.1 implementation. It was decided to use PRIMo 3.1 for all outputs finalised by EFSA from 01/01/2020 onwards to respond to requests from MSs who refused to vote on maximum residue levels (MRL) proposals when done with an old version of PRIMo. Therefore, the same approach should be followed for the assessment performed in the peer review process to ensure consistency.

The agreed approach on the implementation of PRIMo 3.1 is that for all MRL processes, PRIMo 3.1 should apply. In the framework of the peer review in relation to the representative uses, both PRIMo 3.1 and PRIMo 2 should be applied. For the additional uses proposed in the peer review via an MRL application form such as other minor EU uses, PRIMo 3.1 should be applied.

Practically, PRIMo 2 and 3.1 should be applied for the DAR/RAR currently under preparation by RMS, for the substances in peer review process i.e. conclusions under drafting, active substance under the 3-month clock-stop and those ones under long-term clock-stop for ED assessment. PRIMo 3.1 should be used for the MRL application assessed under the peer review process.

9.2. Key drivers in the decision making for active substances

Commission explained the needs for a good decision making that arrives at the end of a long regulatory process. The decision making builds on work of others under challenging conditions and it was mentioned that issues are surfacing at decision making which should have been resolved before.

Commission reminded the legal deadline of 6 months to propose drafts of review reports and legal act to the PAFF committee.

In the context of decisions made at active substance level, the critical factors identified so far are related to metabolites, genotoxicity, cut-off or unclear CLP classification, ED assessment and birds and mammals assessment (treated seeds). Decisions can be approved or not approved (renewed/not renewed) but also renewed or approved with restrictions in case the good agricultural practice (GAP) allows for it, or with restrictions via risk mitigation set at EU level. For some cases, a mandate is sent to EFSA if the issue is critical for decision making and not resolved. Mandates are also sent to EFSA in case of significant changes during peer review leading to unresolved issues (not all GAPs are explored, not all risk mitigation possibilities are explored, not all data are considered), or in case available evidence is not taken into account because considered not reliable during the peer review. The Commission recalled that guidance documents are not legally binding and thus, ad-hoc assessments may be needed.

Horizontal actions identified to improve decision making are legislative acts (amendment 844/CLP, amendment to GFL and its implementation), more general discussions at PAFF committee level, bilateral discussions with EFSA for the improvement of EFSA conclusions, discussion of reduction of exposure to PPPs (workshop held on 17/01/2020), and discussions at PSN level.

It is concluded that incomplete risk assessment leads to increased difficulties in decision making.

Some ideas to improve the decision making process were presented. The ideal EFSA conclusion would be a conclusion without any data gaps or unresolved issues after the peer review (e.g. clear CLP classification or use of weight of evidence/ expert knowledge). A risk assessment on all representative uses presented in the dossier and not only for the worst case should be provided; a better definition of GAP tables could be proposed. The potential risk mitigation and the weight of evidence/expert judgment should be also considered. Finally, the importance of pre-submission meetings was stressed.

Commission wondered if the use of a checklist would decrease the number of difficult cases of decision making.

In conclusion, Commission reminded the MSs that the risk assessment is not "stand alone" exercise but should fit for the purpose of the decision making and no issues should remain open at the end of the process. The evaluation should further consider also the assessment of alternative scenarios if available, the use of the weight of evidence and expert knowledge when needed, the assessment of the risk mitigation options and the good documentation of the peer review.

Action points:

- EFSA and DG SANTE to discuss bilaterally a possible use of a checklist during the final steps of the peer review.
- EFSA to send an email to MSs to inform on the new approach regarding the implementation of PRIMo 3.1 and impact on the on-going substances in terms of recalculation needed of dietary exposure and consumer risk assessment.

9.3. Any Other Business

- Glyphosate renewal – update on the state of play

The state of play on glyphosate renewal was presented. The current approval of glyphosate expires in December 2022 and the renewal process has started. The applicant is consisting of the Glyphosate Renewal Group (GRG). The RMS consists of a consortium of 4 MSs (France, Sweden, Netherlands, Hungary), called AGG - Assessment Group of Glyphosate. EFSA has acted as observer in the pre-submission meetings.

On 15 December 2019 the application for the renewal of the active substance glyphosate was submitted by GRG.

In February 2020 the EFSA APDESK Unit published the sanitised application.

By 15 June 2020 the full application dossier should be submitted by the GRG and by 15 June 2021 the Renewal Application Report (RAR) should be issued; subsequently EFSA will start the peer review process.

The EFSA conclusion should be delivered in 2022 (within 5 months + clock stop).

- Ecological modelling

This agenda item was brought up by NL. National risk assessment authorities are receiving a large and growing number of plant protection product registration dossiers that include ecological modelling. NL noted that there is a strong interest of Member States for guidance to evaluate these models.

There is an EFSA scientific opinion on good modelling practice, which seems to be not concrete enough to allow conclusions about specific modelling studies.

There has been an EFSA working group (WG) on Toxicokinetic-Toxicodynamic (TKTD) models which provided some guidance in the format of a scientific opinion for individual-level models. This is however applicable for only a part of the ecological models.

The Society of Environmental Toxicology and Chemistry (SETAC) has established a working group (WG) to develop further guidance on ecological modelling: SETAC MAD (Model Acceptability, version control and scenario Development) WG.

The SETAC MAD WG exists of experts from Member States, Academia, Industry and Contract Research. The main aim of the MAD WG is to create a communication forum that allows exchange of information and critical discussions on evaluation of effect models for regulatory risk assessment of pesticides.

The remit includes discussing processes, institutional aspects, organization of workshops and meetings, and criteria for and aspects of acceptability (e.g. scientific fit for purpose, regulatory & ecological scenarios, software). Documentation of discussions and processes and transparent provision of such documentation is an explicit aim of the MAD WG. Decisions on the acceptability of specific models are explicitly not within the scope of this WG. Apart from models, the WG will support activities towards the development and/or evaluation of ecological and landscape scenarios as well as the preparation of version control for effect modelling software (including liaising with other groups, e.g. the FOCUS version control group).

It is the intention of the WG that once criteria have been developed, it will be peer reviewed with involvement of EFSA and be submitted to PAFF for endorsement.

DE proposed instead that Commission should be asked to mandate EFSA to develop a GD on this issue under consideration of the SETAC paper so that it is clearer to the public that the GD is not an industry paper.

Member States are invited to join the SETAC MAD WG by contacting the Dutch authorities for this request.

The initiative is welcomed by DG SANTE.

For EFSA this is an important topic to be considered for the workplan of 2021.

Action points:

- Based on the outcome of the SETAC group and once an output is available, SANTE to consider mandating EFSA to organise the peer review/ a public consultation of the guidance on ecological modelling (proposed by NL, several MSs supported). This will be considered based on the prioritisation between all the guidance documents to be tackled.