PESTICIDE PEER REVIEW UNIT

Network on Pesticides Steering Minutes of the 27th meeting

Held on 29 March 2021, TELE-conference

(Agreed on 21 April 2021) [1]

Participants

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

Country	Name
Austria	Klaus LEDER
Czech Republic	Lucie VANOVA
Denmark	Alf AAGAARD
Estonia	Eva LIND
Finland	Kaija KALLIO-MANNILA
Germany	Eva GOCLIK
Greece	Danae PITAROKILI
Hungary	Tamas GRIFF
Ireland	Aidan MOODY
Latvia	Liga BRENCE
Lithuania	Kristina VALIONIENE
The Netherlands	Carla HUIZING
Portugal	Bento CARVALHO
Slovakia	Marta GALUSOVA
Slovenia	Katja BIDOVEC
Spain	Jose Luis Alonso PRADOS
Sweden	Katarina LUNDBERG

- **Observers**

Agathi CHARISTOU

- **Hearing Expert**

Olavi PELKONEN (Chair of the In Vitro Comparative Metabolism Working Group)

1 Minutes should be published within 15 working days of the final day of the relevant meeting.

- **European Commission:**

Karin NIENSTEDT (DG SANTE)
Valerio SPINOSI (DG SANTE)

- **EFSA:**

Pesticide Peer Review Unit (Manuela TIRAMANI, Head of Unit)
Pesticide Residues Unit (Bénédicte VAGENENDE, Head of Unit a.i.)
Scientific Committee and Emerging Risks Unit (Jean-Lou Dorne)
Pesticide Peer Review Unit (Tunde Molnar)
Pesticide Peer Review Unit (Dimitra Kardassi)
Pesticide Peer Review Unit (Angelo Colagiorgi)
Pesticide Peer Review Unit (Mathilde Colas)
Pesticide Residues Unit (Giovanni Bernasconi)
Pesticide Peer Review Unit (Frederique Istace)
Pesticide Peer Review Unit (Arianna Chiusolo)
Pesticide Peer Review Unit (Maria Arena)
Evidence Management Unit (Jane Richardson)
Applications Desk Unit (Chiara Macchi)
Applications Desk Unit (Silvia Mazzega)

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from:

Anna MEHL (Norway)

Zsuzsanna KOENIG (DG SANTE)

2. Adoption of agenda

The agenda was adopted without changes.

3. Outcome of the consultation on Scientific criteria for grouping chemicals into assessment groups for human risk assessment of combined exposure to multiple chemicals

EFSA presented the draft Guidance on harmonised methodologies for human health, animal health and ecological risk assessment of combined exposure to multiple chemicals (hereinafter 'MIXTOX GD')[2] which provides harmonised methodologies to apply scientific criteria for grouping chemicals into assessment groups. It also provides prioritisation methods for human risk assessment (RA) of combined exposure to multiple chemicals. The scenarios for hazard assessment of chemicals can be data-based (e.g. (re)evaluation of a regulated chemical or contaminant) or poor data-based (e.g. emerging contaminant) using in silico models/bridging data, grouping or read across with similar component. The WoE approach is then followed.

A harmonized framework is proposed regarding the scientific criteria for grouping chemicals which are influencing each step of the risk assessment (from the problem formulation defining the mixture to be evaluated in the terms of reference, to the hazard and exposure assessment, until the risk characterization).

EFSA provided a brief background on the development of this Guidance document. On May 2019, EFSA requested the Scientific Committee (SC) to develop the scientific documents on criteria for grouping chemicals for human RA of mixture. Supporting publications and relevant considerations were included for drafting the document i.e. the key elements for setting cumulative assessment groups (CAGs) for human RA as requested by DG SANTE and consideration of Mode of Action (MoA), the relevance to CONTAM for grouping contaminants, the relevant to FEEDAP in mixture RA of essential oils/botanicals, to GD from FAF Panel for smoke flavourings and grouping and overall support to all panels dealing with chemical RA.

EFSA presented the Terms of reference:

- Scientific principles laid down in the relevant cross-cutting guidance
- Context of the risk assessment (priorities, urgent, pre- and post-market)
- Tiering and a range of fit for purpose scenarios considering available hazard and exposure information (including AOP, toxicokinetics and human biomonitoring)
- The need for prioritisation approaches: risk-based and exposure-driven
- Relevant EFSA areas and international activities
- Harmonisation, avoid duplication
- Publication for public consultation

The WG members included the chair (from CONTAM Panel), EFSA staff, SC member, experts from ANSES, RIVM, ISS and Magro Negri Institute.

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[2] EFSA Scientific Committee, More SJ, Bampidis V, Benford D, Bennekou SH, Bragard C, Halldorsson TI, Hernandez-Jerez AF, Koutsoumanis K, Naegeli H, Schlatter JR, Silano V, Nielsen SS, Schrenk D, Turck D, Younes M, Benfenati E, Castle L, Cedergreen N, Hardy A, Laskowski R, Leblanc JC, Kortenkamp A, Ragas A, Posthuma L, Svendsen C, Solecki R, Testai E, Dujardin B, Kass GEN, Manini P, Jeddi MZ , Dorne J-LCM and Hogstrand C, 2019. Guidance on harmonised methodologies for human health, animal health and ecological risk assessment of combined exposure to multiple chemicals. EFSA Journal 2019;17(3):5634, 77 pp. https://doi.org/10.2903/j.efsa.2019.5634

Following ECHA consultation, comments from ECHA on the Guidance document were considered and included as appropriate (ECHA references on in silico approaches and how to use them will be included in the Guidance).

After consultation with DG-SANTE, EFSA Panels, Scientific Committee and Units, it was agreed to deliver a Guidance document as a scientific output. This activity will be delivered to the SC plenary by April 2021 (endorsement for Public Consultation). EFSA will publish a draft Guidance document for public consultation in May/July 2021. The finalized document will be published after adoption by the Scientific Committee for the plenary in September 2021. Finally, in October 2021, a workshop in Brussels is planned on RA multiple chemicals including EFSA GD and future challenges (to be confirmed).
A pilot for the implementation in the area of pesticides is envisaged in 2021-2022.

Q&A:

- A more detailed explanation on the difference between exposure driven based and risk-based approach was given. EFSA specified that in case no data are available on the relevant compounds, the in silico approach or read across approach from other similar compounds can be used (e.g., pyrolyzing alkaloid, as naturally occurring). This will depend on the context.
- The EFSA Guidance will be published and adopted in September 2021 in the EFSA website. Consideration on how this will be implemented in the context of the peer review (application for approval of pesticide active substances) will be discussed with DG SANTE. It is reminded that the EFSA Guidance is mainly relevant for the residue discussions (i.e., MRL application, MRL review). For the time being, the Guidance document will mainly be used for post marketing assessment. It is also noted that the methodology recommended in the EFSA Guidance might also become relevant for the toxicological risk assessment of plant protection products (concerns for mixture).
- More information on next steps for cumulative risk assessment for pesticides can also be found in the recently published SANTE/EFSA action plan https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_mrl_cum-risk-ass_action-plan.pdf
- The MAF (a factor of 2) was defined in the MIXTOX 1 (2019).

Action point:

- EFSA to investigate with ECHA on which basis the MAF value was formulating in the context of REACH.

4. Outcome of the consultation on the Administrative guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances and on the MRL application procedure; state of the art on Transparency

EFSA presented the latest update on the **Transparency Regulation (TR)** implementation. In particular the revision of the Administrative guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances and on the maximum residue level (MRL) application procedure

https://www.efsa.europa.eu/en/supporting/pub/en-6464 (published 3rd March 2021) was presented alongside with the impact on RMS/EMS work.

The Practical Arrangements concerning aspects of the TR are published on EFSA website[3]. The Practical Arrangements are binding means to interpret and implement the legal framework provided by the TR. By specifying the details for the implementation of required processes, they commit to how the TR will be applied by EFSA.

- PAs-pre-submission-phase-and-public-consultations.pdf
- PAs-transparency-and-confidentiality.pdf
- PAs-confidentiality-Artt-7-and-16-of-regulation-1107-2009.pdf

It was also noted that in view of the TR implementation new Commission Implementing Regulations came into force and in particular **Commission Implementing Regulation (EU) 2021/428** of 10 March 2021 adopting **standard data formats** for the submission of applications for the approval or the amendment to the conditions of approval of active substances and **Commission Implementing Regulation (EU) 2020/1740** of 20 Nov 2020 on renewals. The need for revision of all EFSA's sectorial administrative Guidance Documents (GDs) including the administrative guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances[4] was revealed. Comments on a revised version of the guidance received during the PSN consultation in December 2020-January 2021 (altogether 136 comments from DE, BE, FR, AT, DK, NL, PL, SANTE) have been considered into the revised version of the Admin GD while ensuring alignment with EFSA's Practical Arrangements.

The main changes compared to the previous version of the GD were highlighted. An entirely new chapter (chapter 4) specifically addressing the provisions set out by the TR for MRL applications and for confirmatory data submitted within the scope of Reg (EC) No 396/2005 was added.

The revised administrative guidance[5] is applicable to all **applications** submitted to the competent authority of a Member State **as of 27 March 2021** and shall be used for the preparation of applications intended to be submitted from that date onwards and to all **assessment reports** concerning **applications submitted as of 27 March 2021**. For **applications** submitted **before 27 March 2021**, the **previous** version of the guidance applies (EFSA, 2019)[4]. The previous version of the guidance applies also to **assessment reports** concerning **applications submitted before** that date (regardless the submission date of those assessment reports).

The implication for RMS/EMS regarding the pre-submission advice (PSA) implementation were briefly presented. Potential applicants may request general pre-submission advice (GPSA) from EFSA at any time before submitting the corresponding envisaged application with respect to intended applications (applicable for all types of applications including basic substances). The GPSA is optional for the potential applicant. Within the framework of GPSA, EFSA provides advice on the rules applicable to, and the content required for, an application prior

[3] https://www.efsa.europa.eu/en/corporate-pubs/transparency-regulation-practical-arrangements

[4] https://www.efsa.europa.eu/en/supporting/pub/en-1612

[5] https://www.efsa.europa.eu/en/supporting/pub/en-6464

to its submission. The GPSA is given by EFSA in close collaboration with the intended or designated RMS, and where applicable, the Co-RMS. Following an administrative check, EFSA informs the intended/designated RMS (and co-RMS) whether the request for GPSA is accepted and whether a reply will be provided in writing or in the context of a meeting. Specific timelines have been included in the GD to facilitate the preparation of the advice in close collaboration with the RMS/EMS (co-RMS). All exchanges will take place in specific tool supporting the PSA in the EFSA website.

It was noted that GPSA is not precluding the possibility for the potential applicant to request pre-submission advice from the RMS outside of the framework of Artide 32a(1) of the TR. Requests for EFSA advice during the assessment phase originating from the RMS are still possible. EFSA is committed to provide support to the RMS at any time when assessing the application and before the peer review starts.

The new provision of the Notification of intended Studies (NoS) for renewals was presented. In accordance with Article 32c(1) of the TR, after the closure of the public consultation on the intended studies for renewal, EFSA reviews the comments received from third parties and provides renewal pre-submission advice (RPSA) to the potential applicant, taking into account those comments which are relevant for the risk assessment of the intended renewal. EFSA provides the potential applicant for renewal with its advice with the participation of the designated RMS and, where considered appropriate, the co-RMS. Specific timelines have been included in the GD to facilitate the preparation of the advice in close collaboration with RMS in the form of written advice or meeting. All the exchanges will take place in the tool supporting pre-submission activities available through EFSA's website.

The RMS/EMS is responsible for checking the compliance with obligations of notifications of studies during the admissibility check. EFSA will extract the relevant information from the database and share it with the RMS/EMS for checking the matching of studies submitted in the dossier with the studies previously notified and verifies the compliance with notification of studies obligations. The implications in case of non-compliances and the admissibility check are further explained in the Guidance. **Upon completion of the admissibility check RMS/EMS should notify EFSA** as soon as the **application is declared admissible**, providing the validation assistant report, confidentiality assessment report (NAS, amendment) and notification of studies report that can be **automatically generated by IUCLID** following the instructions provided in the IUCLID user manual.

After RMS/EMS notification the non-confidential version of the application dossier and where applicable, the summary of (G)PSA and the list of notified studies is made public by EFSA. The implications for RMS/EMS regarding the transparency and confidentiality were clarified. The assessment relating to dossiers/updated dossiers for NAS/amendment of approval conditions should be performed by the RMS, in consultation with EFSA following the provisions of the **PAs-confidentiality-Art-7-and-16-of-regulation-1107-2009.pdf** while for renewal dossiers/updated renewal dossiers/MRL dossiers, on DAR/RAR, updated DAR/RAR, peer review report and EFSA conclusions the requests for confidentiality are processed by EFSA.

All comments upon the closure of the consultation of third parties on the non-confidential version of the application dossier will be brought to the attention of the RMS/EMS. Upon the automated closure of the public consultation, EFSA extracts and publishes the received comments and EFSA will dispatch them to the RMS/EMS for consideration in the preparation of the DAR/RAR/ER. Relevant comments shall be considered by the RMS/EMS during the assessment phase and preparation of the assessment report. The DAR/RAR/ER should contain presentation of the results of the public consultation in an annex which clearly reports how comments have been taken into account by the RMS/EMS.

Main changes arisen by the Commission Implementing Regulation (EU) 2020/1740 were mentioned. Dossier submission via IUCLID (Art 7) is mandatory. New step has been added for the applicant to submit information at the end of the peer review (Art 13(4)) as part of a consultation step with applicant on draft EFSA Conclusion. This step is intended only on critical issues and/or critical data gaps identified late in the process and where applicant could not have known about at the time of submission of the application and did not have the possibility to address during the first 'clock stop procedure' because they emerged only after that period. EFSA plans to apply **standard criteria/conditions** that warrant eligibility, to ensure equal treatment and a **consistent implementation** of this step. Comments and new information shall be considered by EFSA in cooperation with the RMS and the co-RMS; EFSA shall finalise the conclusion within 75 days from the expiry of the two-week period.

Useful links:

New rules on transparency | web news

Practical Arrangements | web page

Stakeholder Training Programme | web page

Toolkit

Q&A:

- Answers to the Questions related to PAs received from the stakeholders are prepared by EFSA and will be published on the website (cf TR stakeholders page)
- All **Appendices (except Appendices A and B)** have been moved to IUCLID manual available via EFSA Knowledge Junction webpage
- The PSA is given by EFSA in close collaboration with the intended or designated RMS (co-RMS)/EMS, and cooperation in this context is expected as RMS/EMS are the first assessors of the dossier.
- It was clarified that if additional information are requested by EFSA for active substances and MRL applications for which the dossiers have been submitted before March 2021 the requested studies do not need to be submitted in IUCLID.
- The segregation of tasks applies only to EFSA when providing the pre-submission advice and not to RMS (giving pre-submission advice and performing the risk assessment).

- The public consultation aims to identify whether other relevant scientific data or studies are available. If such information is announced during the public consultation, the APPL will be requested to submit the missing studies in subsequent phase of peer review.
- Comments received in the public consultation on the non-confidential version of the application are considered by the RMS/EMS during the preparation of the DAR/RAR/ER.
- A dedicated session for MSCA on PSA and NoS will be organised in May 2021. EFSA will inform the PSN members when the date is confirmed and the registrations are open.

5. Pesticide Steering Network agreement on Terms of Reference for mandate renewal

Only one additional item was included in the Terms of reference for mandate renewal regarding the work on IUCLID for pesticides.

Terms of reference and action plan:

The main tasks of the network are to:

- plan, monitor, develop and improve the risk assessment (RA) and peer review (PR) process
- integrate the RA and MRL setting processes for coordinating and achieving efficiency in the implementation of the provisions of both regulatory frameworks.
- coordinate with the ECHA
- give advice on prioritisation and risk assessors needs in the development and the updating of RA GD documents
- ensure the cooperation and governance for IUCLID for pesticides

Action point:

- Comments for the adoption of the terms of reference are requested by 16 April 2021.

6. Outcome high Level Meeting between Competent authorities, European Commission and EFSA – follow up on collaboration activities with MSs

EFSA presented the outcome of discussion on collaboration activities with MSs that was presented in the 77th Advisory Forum meeting, 28-29 October 2020 and in the high level meeting between Competent authorities, European Commission and EFSA took place on 15th December. Partnerships are a main pillar of the draft EFSA Strategy 2022-2027 and there is significant increase in budget for outsourcing activities to MS in this context. A survey, open in 2020 to Art.36 organisations (responded by 18 MSCA on pesticides), indicated high interest in cooperation and highlighted the need for grant duration between 12 and 48 months to leave the possibility for hiring additional staff to support the work. It was noted that the duration and co-funding rate is less important if grant aligns with area of strategic

or current interest for the organization. The main drivers to work with EFSA were highlighted, in particular, the importance of aligning strategy and workplans, the interest of scientific developments and networking. Main blocking factors were indicated the lack of staff resources, the complexity in the application process and the low co-financing rate. It was stressed the need to optimise the training of experts across EU since training a new expert may last at least one year.

EFSA informed that a new Tasking grant will be launched beginning of April for seeking support by MSCA, in the areas of toxicology, residues/MRL, physical-chemical and analytical methods, fate, ecotoxicology, micro-organisms and human health, micro-organisms and environmental RA and scientific coordination. Tasking grant currently in place will end in November 2021 and the new framework is currently under preparation.

Potential tasks include the provision of support to preparing conclusions, reasoned opinions, guidance developments (see also topic 7 on PSN agenda), e.g. protocol development, feasibility checks, preparation of case studies, support in pre-submission activities, completeness checks of assessment reports, data collections and preparatory work for guidance development, cumulative prospective risk assessment, art. 4(7), negligible exposure, emergency authorisations, IUCLID further developments and other tasks.

EFSA noted the need of creation of training and learning platform for PPP. The rationale is that good training material has been developed by MSs and EFSA but currently not shared with all actors. Common training is also aimed to contribute to harmonization in performing RA across authorities. It was stressed the good experiences so far with online (recorded) trainings, webinars etc. The lack of qualified staff that could contribute to partnership with EFSA had been raised by MSs in the survey. Designing a common IT training platform facilitating sharing and using of training material developed by MSs and EFSA is one of the potential entrusting tasks, provided the initiative is supported by MSs.

MSs organisations are encouraged to apply for this Tasking grant call, bearing in mind that the framework partnership agreement is a long-term cooperation of up to 4 years and subsequently implemented through specific agreement that will set out the specific conditions for performing the respective assignment. When in EFSA a need of entrusting a task arises, a specific request will be sent to the beneficiary ranked first for a specific task where the specific tasks will be described.

Q&A:

- It was clarified that not all the potential tasks proposed in the Tasking grant might be used, when a need of a task arises in EFSA, a specific request will be sent to the beneficiary describing the specific tasks assigned. All potential areas are covered where an activity might be needed. But a specific agreement should follow where a task is entrusted to a competent authority where the precise scope of the specific asssignment is specified, as well as the expertise required to perform the task.
- The framework partnership agreement with MSs aims to facilitate the outsourcing activities avoiding having open call/selection procedure every time a need arises. The framework partnership agreement does not

guarantee that a specific agreement will take place but will be used in order to conclude a specific agreement for work to be carried out when needed.

Action points:

- EFSA to share an overview of the past tasking grants in view of preparation of a new Tasking grant (see excel file on past Specific Arrangements).
- EFSA to inform PSN when the new Tasking grant is launched on the EFSA website.
- MSs to inform EFSA by **16 April 2021** if the proposal for creating a shared training platform is supported.

–follow up on improvement areas in the peer review

EFSA provided an overview on improvement areas in the peer review. EFSA informed that an updated conclusion template was implemented recently following the data gap categorization exercise finalised following extensive commenting with MSs and SANTE. The new template makes a distinction between the major data gaps linked to critical areas of concerns and issues not finalized, and the minor data gaps not expected to lead to concerns, which are listed under a new section: 'List of other outstanding issues'. The new template has been used as from October 2020 and the first published conclusions are now available.

EFSA informed that following the customer feedback exercise a discussion has started with SANTE on the technical reports for basic substances, and it is clear that areas of improvement can be identified. A new general mandate for basic substances is due and it would be an opportunity to improve the overall process as well as better define tasks and roles.

A similar discussion applies to certain aspects of micro-organisms conclusions, which should also consider that the data requirements will be updated soon. EFSA will collaborate with SANTE and MSs to reconsider a new conclusion template, in particular reflecting differences with the chemical active substances.

Q&A:

- It was clarified that risk mitigation measures (RMMs) identified following consideration of MSs and/or applicant's proposal(s) during the peer review, if any, are presented in the conclusion. These measures applicable for human health and/or the environment for the representative uses and for the maximum residue level applications are presented. However it was noted that final decisions on the need of RMMs to ensure the safe use of the plant protection product containing the concerned active substance is up to the risk managers to decide during the decision-making phase.
- There is work on-going regarding the RMMs aiming to produce a guidance or list of acceptable RMMs. RMMs should be proposed by APPL and/or MSs in order to be considered in the peer review and in EFSA conclusions. This will also facilitate the decision-making process avoiding additional mandates to EFSA to refine the assessments including additional RMMs. Harmonisation of RMMs is also needed (see previous point on on-going work.

- It was clarified that in the new EFSA conclusion template the 'critical' data gaps are separated from other data gaps not leading to critical areas of concern or issues not finalised but considered necessary to comply with the data requirements, and which are relevant for some or all of the representative uses assessed at EU level. This will facilitate the MSs when using the EFSA conclusions in the evaluation of plant protection products at national level. Feedback from MSs is welcome when they have used the new template with data gap categorisation.

7. Guidance documents: preparation and updates. Medium and long term planning

EFSA informed that as follow up from the high level meeting between Competent authorities, European Commission and EFSA that took place on 15 December 2020, it was agreed that the PSN will develop a priority list of technical guidance requiring update and new guidance to be developed, whereas the PAI (Post Annex I group) will develop a priority list of procedural guidance. EFSA has drafted a list of topics that would benefit from further clarifications in revised guidance documents or topics that are identified as candidates for new developmental activities. The proposed projects were identified in discussions in peer review expert meetings, in discussions in PSN meetings and in internal discussions of EFSA staff. Additional proposals for being added to the list are welcome, as well as information on ongoing or planned projects at MS level. The order of the topics and the proposed priority should be further discussed with PSN members. PSN members will be invited to provide comments and indicate if there is an interest and support for these proposals.

Q&A:

- Based on a question it was clarified that the revision of the Commission Communications listing the test methods and guidance documents relevant to the implementation of the data requirements regulation is ongoing.

Action points:

- EFSA to share the list of guidances to be revised/developed or for which work is already ongoing after Easter.
- Comments will be requested by MSs with deadline **by 15 May 2021**. MS to indicate also prioritisation of the guidances' development/availability to support/lead specific subjects.

8. Update on the draft Guidance on Non-Dietary Exposure to Pesticides

EFSA presented an update on the Draft Guidance on Non-Dietary Exposure to Pesticides. The Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products issued

in 2014[6] includes several scenarios for outdoor uses, with an annexed calculator, as well as recommendations for further research. A mandate from SANTE in 2017 asked EFSA to update the EFSA Guidance and annexed calculator considering new available information. An **open call** for gathering new information/data was launched in 2018. The main outcome from the Open Call was that only few raw data (with original study reports) were obtained. Therefore, it was agreed with SANTE that the Guidance update will focus on the following ToRs: greenhouse scenarios inclusion, revision crop and human parameters and implementation of a user-friendly and transparent online calculator. The draft updated guidance documents including updated calculator is subject to public consultation from 15 March to 9 May 2021 before its finalization and approval by November 2021. The updated Guidance and calculator will be then published with the Technical Report on outcomes from the public consultation. EFSA presented the amendments in the updated Guidance and the improved functionalities of the new online calculator (available at https://shiny-efsa.openanalytics.eu/app/opex).

The draft updated Guidance is available at this link for comments by 9 May 2021.

Action point:

- MSs to submit comments on the Public Consultation of the draft updated Guidance on Non-Dietary Exposure to Pesticides by **9 May 2021** using the electronic template provided in the EFSA website **at this link.**

9. PSN open to stakeholders: a proposal to increase transparency

The implementation of open items during the plenary of the PPR Panel meetings was successful, as proved by the high level of public participation during these sessions. In addition, it is noteworthy that requests for attending the PSN meeting were made by the public to EFSA.

Given EFSA's continued engagement and interest in all external parties, it is proposed to apply the same concept to the PSN network as used for the open plenary. As a pilot, it will give stakeholders the possibility to follow the assigned work. As a starting point, EFSA proposes that questions from stakeholders will be sent before the meeting based on the agenda items. EFSA will screen the questions and engage with the PSN network to propose a common draft reply to be shared during the open session. The entire meeting (remote or physical), or parts of it, will be open to stakeholders and during the pilot phase, EFSA will not give the chance to engage in active interactions with stakeholders. The rules used for the open plenary meetings will be similar (e.g., code of conduct, confidentiality rules, etc.). The first pilot is expected to start for the 2022 PSN meeting and be tested for a couple of years.

[6] EFSA (European Food Safety Authority), 2014. Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products. EFSA Journal 2014;12(10):3874, 55 pp., doi:10.2903/j.efsa.2014.3874

Q&A:

- EFSA stressed that the questions will be limited to agenda items only.
- It was recalled that in previous years, industries were invited to participate in part of the PSN meeting.
- EFSA clarified that the registration to participate will be open to the general public. EFSA will review the list of registered individuals as observers. When drawing up the list of confirmed observers for the open PSN meeting, available places will be distributed on a first come, first served basis (in case of physical meetings). Attendance in person may be limited to one observer per organisation, group or party to allow attendance of the widest possible spectrum of groups, organisations and individuals, taking into account seating capacity (on average 15 observers per meeting for those attending in person). All those who registered but will not participate physically will have the possibility to attend via video-conference.
- MSs highlighted that overall, more meetings are needed to cover all the items to be discussed.
- MSs highlighted the need for timely submission of documents especially in case of PSN open to stakeholders.
- In the paper, a slight amendment was proposed in the introduction to avoid confusion: it was noted that the authorisation of PPP is not subject of PSN.

Action point:

- PSN participants to provide written comments and amendments on the draft proposal by the 16 April 2021.

10. The EFSA working group (WG) on ED

EFSA gave a presentation on the recently established EFSA WG on Endocrine Disruptors (ED), which was created in January 2021 and the first meeting took place in February 2021.

The scope of the EFSA ED WG is the following:

- Provision of specialized advice related to interpretation of results, upon request of the Pesticide Peer review Unit, in the form of a short internal EFSA report or minutes for consideration during the evaluation of the substance under assessment;
- Provide assistance to EFSA during the Pesticide Peer Review Experts' meetings organized with Member States aiming at discussing controversial issues identified during the peer review process;
- Feedback and recommendations on complex (specific/generic) scientific issues related to information and (tiered) testing needs for potential endocrine disruptors;
- May provide specialized advice to other EFSA Units, where relevant on ED specific issues.

It was highlighted that whilst the focus of the WG is to provide specific technical advice to the peer review in case of complex ED assessments or controversial issues encountered for pesticides, it is not intended to discuss each and every substance in the peer review. In addition, the WG may also provide

recommendations on matters of general nature, e.g. in case clarifications are needed in relation to the use of the ECHA/EFSA (2018) ED Guidance.

The WG members include the chair, Martin Wilks (from the PPR Panel), EFSA staff, experts from USEPA, Danish EPA, RIVM, universities and research institutes. In fact, the WG includes a wide range of expertise covering specialised scientific areas in both mammalian toxicology and ecotoxicology, including experts with regulatory experience. In addition, 3 ECHA experts are also involved in the WG activities as observers, indirectly linking also to the ECHA ED Expert Group activities, in order to ensure harmonization and consistency with the ED assessments under Biocides and REACH undertaken at ECHA. For the time being, specific expertise as regards population relevance is not available in the group.

Upon need, the RMS and Co-RMS may be invited as hearing experts to provide clarification on the data of the specific substance under assessment. Any preparatory work will be undertaken by EFSA.

It was clarified that MSs may also flag the need for the consultation of the WG during the peer review stage, however EFSA will take the final decision on the agenda of the WG meetings. For the time being there is no possibility for MSs to consult the WG during the preparation of the DAR/RAR, nevertheless this may be reconsidered in the future upon further experience is gained over time.

Similarly to the ECHA ED Expert group, the advice given by the EFSA ED WG is not binding. Detailed written advice is made available to the peer review experts as supporting documentation in the context of the pesticide peer review expert meetings and will be published as part of the background documents at the end of the peer review.

Short minutes of the WG meetings are also made publicly available on the EFSA website.

Action point:

- EFSA to include in the ED overview file shared with the MSs the ED clock stop applied to each of these substances.

11. Update on IUCLID including the Hypercare programme

EFSA provided an overview of the key steps that MSs need to perform once a dossier in the IUCLID format is received.

Use of IUCLID format for submitting PPP dossier has been specified in Commission Implementing Regulation (EU) 2021/428 and Commission Implementing Regulation (EU) 2020/1740, as well as in the "Administrative guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances and on the maximum residue level (MRL) application procedure".

Agency IUCLID has been presented, which is a secure instance of IUCLID hosted on ECHA cloud services and where all valid dossiers received via the Submission portal will be accessible and the dossiers will be available also for interacting with them. To ensure the highest standard of security, log in with the EFSA account

and use of VPN is required. Before accessing, it is necessary to sign a confidentiality assessment.

When a valid dossier is received, an e-mail message with a notification of the dossier will be received in the designated mailbox of the MSs and Commission (and other interested parties). The message includes the dossier unique identifier (UUID) that can be used for searching for the dossier.

Within the Agency IUCLID, the dossiers are available in the mixtures section of the dashboard, and by selecting "dossier" all the dossiers will be listed. The search function can be used to retrieve a specific dossier.

At this point is it possible to start the admissibility check, using the validation assistant (VA). VA will create a report including all the errors found in the substance or dossier. The checks performed by the VA apply not only to single documents but also check values across documents/datasets. In the future it will be possible to convert these settings in rules which can lead to the dossier submission failure, if this change is agreed with the MS and Commission. The report can be made available as an excel file, which can be useful for splitting it and sharing with different experts.

The Notification of studies (NoS) list can be generated using the Report Generator (RG) in different formats. Information on GLP and testing facility is also included. Using the information in the report RMS/EMS can check against the extraction from the NoS database that EFSA will provide to RMS/EMS.

Annotations can be created in an IUCLID document to indicate missing information and can be exported and sent to the applicant.

As the dossier is not editable, when a request for additional info is sent out, the compare tool can be used to check for differences when an updated version of the dossier is re-submitted by the applicant.

At this point it is possible or not to declare the dossier admissible, and the RMS/EMS must notify EFSA that the application is declared admissible via e-mail.

The information sent to EFSA can then be included in the central coordinating system (APPIAN) and display the status of the dossier on the EFSA dissemination portal (openEFSA). EFSA APDESK will filter the dossier and publish the dossier in Public IUCLID, a standalone instance of IUCLID which does not require an ECHA account for access. All material that will be flagged as confidential will be automatically removed before being published in the Public IUCLID instance. A public consultation on the dossier will be launched by EFSA via a dedicated tool. The comments received will then be provided in an excel file to RMS/EMS.

The report generator can also be used to obtain a list of all confidentiality claims and justifications.

Once confidentiality has been agreed, the next step is the evaluation by the RMS/EMS. Annotations can be used to record the conclusion of the evaluator, and the report generator can be used to obtain study summaries in RTF format (in April release GAP document, phys-chem and tox section will be available).

In case of any problem an e-mail should be addressed to EFSA servicedesk. Any improvement or suggestions can be reported in the IUCLID backlog.

EFSA also provided an overview on IUCLID Hypercare programme, a dedicated training programme developed to support first submitters and evaluators of active

substance renewal dossiers to be submitted in IUCLID format, with a legal deadline between July and August 2021. Hypercare core team is formed by 23 applicants, 11 RMSs, 10 observer MSs. The programme offers support in the use of the tool and focuses on IT technical knowledge of the IUCLID tool.

A number of 17 substances were selected out of 21 candidates. Among these, a new microbial active substance has also been included as there was no micro-organism (MO) renewal dossiers among the candidate substances and it considered of outmost importance to test the IUCLID tool also again a MO dossier to further develop the tool.

EFSA informed that the programme is structured in biweekly meetings on either IUCLID aspects (format topics like OHTs, residues etc) or IUCLID features (filtering, validation assistant etc). Participation to the meetings is granted to the core team and to the additional experts nominated by Applicants and Member States ahead of biweekly meetings based on the topic. A Microsoft Teams (MS) channel has been created through which material is shared ahead of each meeting in dedicated folders and a MS Teams chat is used for questions. All meetings are recorded and recordings are shared after the meeting with the participants.

The overview of the content planning for the biweekly meetings planned until the end of June was shared

Some examples of issues discussed have been provided (e.g. where to upload in IUCLID the confidential version of a study report, where to include info on the representatives GAPs or where to report in IUCLID information on the pre-submission ID and Notification of Study ID).

A large interest from applicants and MSs has been shown with an average of 120-150 experts attending each dedicated meeting and the MS Teams channel was used successfully to interact and engage. Hypercare has proven to be successful in driving the prioritisation of amendments for future IUCLID releases and in working in parallel to the IUCLID training material development.

EFSA kindly invited MSs not represented in Hypercare to get access to the dedicated team cannel, consult the material developed and listen to recorded sessions.

The e-mail address hypercare.iuclid@efsa.europa.eu can be used to contact EFSA on the Hypercare program.

Finally, EFSA provided an overview on IUCLID support material.

IUCLID manuals have been developed or are under development: the manual on MRL application has been published on 23 March 2021; the manual on microbial active substances (NAS and AIR) is under finalisation and will be published by early April; manuals on chemical active substances (NAS and AIR) and on basic substances are in the pipeline and will be published in May/June.

As the IUCLID training activities concerns, two session of "IUCLID for applicants" were held on 18 and 22 March 2021, with approx. 250 participants. The training "IUCLID for regulators" will be available by the end of April/mid-May, as training material is currently being finalised, and it will foresee two sessions and self-learning. A training with special focus on confidentiality will be organised both for applicants and for MSs authorities. In addition, training on Metapath covering Metabolism Study Summary composer (MSS composer), Data Evaluation Report

composer (DER composer) and data validation are also on-going or will come in next months.

EFSA presented a draft document ToR for creating a PSN subgroup dedicated to IUCLID, with technical expertise, with the scope of further improving the tool, taking advantage from the experience of the MSs as evaluators. EFSA invited MSs to submit any comment on the draft ToR in written form by 16 April, and in case there is an agreement, to nominate expert from national competent authority to follow this group.

Q&A:

- The Applicability of IUCLID for the submission of confirmatory information in the context of the peer review was investigated, and SANTE identified 3 different scenarios:
    - if the decision was taken and the confirmatory information was requested before 27 March 2021, and the studies were already started, the submission of the confirmatory information is outside the scope of IUCLID, as it falls under the previous regulation.
    - if the decision was taken and the confirmatory information was requested after 27 March 2021, the new regulatory framework applies, and the confirmatory information should be submitted through IUCLID. This does not apply to substances conditionally approved under Implementing Regulation (EU) No 844/2012.
    - if the confirmatory information was requested before 27 March but is committed and the studies start after 27 March, there is no legal framework to submit the information through IUCLID, but the applicant has to notify the study. Nonetheless, it is possible and advisable that the applicant submits the additional information through IUCLID.

  Note: It was clarified that in case the (renewal of) approval of an active substance is subject to the condition of the submission of further confirmatory information, studies necessary to meet that condition are likewise subject to the study notification obligations and to the obligation to use the IUCLID software for their submission if such studies are commissioned or carried out as of 27 March 2021 according to Administrative Guidance on dossier submission (under point 2.5 and 2.6). However, the obligation to use the IUCLID software for the submission of confirmatory information does not apply to substances conditionally approved under Implementing Regulation (EU) No 844/2012 regardless when the decision on the renewal was taken (e.g. before or after 27 March 2021) or substance approved under Regulation 1107/2009 if the decision on their conditional approval was taken before 27 March 2021.
- The identity of the RMS/EMS has been suggested to be included in the IUCLID dossier notification e-mail.

Action point:

- PSN participants to provide written comments on the draft ToR for the creation of a PSN subgroup dedicated to IUCLID (deadline: 16 April) and to

nominate experts from national competent authority to follow this group. MSs to submit feedback on expected MRL applications under IUCLID.

12. Outcome of the Commission workshop on SPG/ERA and general update from Commission

DG SANTE gave an update from a risk manager perspective including the outcome of the Commission workshop on specific protection goal (SPG)/environmental risk assessment (ERA).

It was noted that SANTE sometimes sends mandates to EFSA on issues critical for decision making which were not resolved. Horizontal actions to improve the decision making have been taken including general discussion at PAFF (standing point on agenda), bilateral discussions with EFSA (e.g. how to improve EFSA Conclusions, see point 6), on reduction of exposure to PPPs and risk mitigation and horizontal issue for micro-organisms. Discussion has been initiated on the basic substances and need of a wider scope for RA. Also the amendment to GFL and Implementing Regulation (EU) 2020/1740 and four legislative acts[7] on micro-organisms (aimed to be adopted in Q4 2021-Q1 2022) will contribute. SANTE highlighted in particular the scientific rationale behind the revisions, which focus on the biological properties of the micro-organisms and that the data requirements are organised in a tiered (step-wise) approach, higher tiers being triggered only when certain conditions apply, using a "weight of evidence approach" based on already existing knowledge (e.g. use of peer-review literature). It is expected that such an approach would reduce unnecessary burden for risk assessors.

SANTE also informed that, on the basis of a MS proposal, it is under discussion to mandate on horizontal issues for micro-organisms. SANTE informed on Better Training for Safer Food programme on Risk Assessment of Microorganisms used as Pesticides or Biocides, scheduled for 2021-2022 (+ 2 more years) aiming to increase specific expertise on risk assessment of microbial active substances and PPP. Risk assessors from MSs, Commission and Agencies' staff (EFSA, ECHA) are invited to the training. Information will be communicated in due time to MSs and Agencies.

SANTE presented the main outcomes of the workshop on Specific Protection Goals for the Environmental Risk Assessment of PPP (3 - 4 February 2020, Brussels). The objective of the workshop was to identify the ecosystem services that may be affected by the use of plant protection products (Step 1 of the European Food Safety Authority (EFSA) method[8,9]) based on several pesticide application scenarios. The workshop was also intended to deepen the understanding of the method proposed by EFSA, and it provided an opportunity to address questions, concerns, and recommendations from the participants.

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[7] Reg. 283/2013 active substances, part B, Reg. 284/2013 PPP, part B, Reg. 546/2011 uniform principle, part B, Annex II Reg. 1107/2009 (specific approval criteria for micro-organisms)

[8] EFSA Panel on Plant Protection Products and their Residues (PPR): Scientific Opinion on the development of specific protection goal options for environmental risk assessment of pesticides, in particular in relation to the revision of the Guidance Documents on Aquatic and Terrestrial Ecotoxicology (SANCO/3268/2001 and SANCO/10329/2002). EFSA Journal 2010;8(10): 1821. 55 pp.|

[9] EFSA Scientific Committee, 2016. Guidance to develop specific protection goals options for environmental risk assessment at EFSA, in relation to biodiversity and ecosystem services. EFSA Journal 2016; 14(6):4499. 50 pp

The workshop showed that by applying the EFSA method the list of the affected ecosystem services differs for various pesticide application scenarios. SANTE also informed about the follow up discussions with MS (PAFF), which include: defining SPG, development of working document on generic pesticide scenarios, working document on risk mitigation, update on the data requirements for micro-organisms and identify horizontal, general questions relevant for environmental risk assessment (including collection of future research topics). A Working Group of MSs has been set up which prepares materials to be discussed at the Standing Committee (EFSA is invited to the meetings). A dedicated website is planned.

13. PPR Opinion on Comparative In Vitro Metabolism Studies

The PPR Scientific Opinion on Comparative in vitro metabolism studies was introduced.

Despite the legal requirement in the Regulation (EU) 283/2013 (section 5, 5.1.1.), there are no validated test methods available for conducting comparative in vitro metabolism studies. Thus, it was needed to develop a PPR Scientific opinion to guide the applicant on performing these studies, helping assessors to evaluate the data and performing a risk assessment to human metabolites of concern, if required.

The terms of references were presented: first, it is requested to illustrate testing strategy that should be applied to investigate interspecies comparative in vitro metabolism, the minimum requirements that should be included in the testing protocol for the selected assays and interpretation of the study results in order to identify human metabolites not properly assessed by toxicological studies using laboratory animal species. Secondly, the relevance of the toxicological profile of human metabolites that were not properly assessed by toxicological studies using laboratory animal species, needs to be considered in the PPR opinion. It should be noted that the second point requires a stronger involvement of the PPR Panel.

The new title adopted for the document is the ***Scientific Opinion of the Scientific Panel on Plant Protection Products and their Residues (PPR Panel) on testing and interpretation of comparative in vitro metabolism studies***. The chair of the Working group, and the working group members have been appointed. It was noted that three additional PPR reviewers were assigned for this document. An overview of the content of the PPR Opinion was also provided.

The current recommendations outlined in the PPR Opinion are related to the experimental strategy and are as follows: use of primary hepatocytes as a test system, testing of 3 concentrations and 3 time points to maximise the chances of detecting unique/disproportionate metabolites and finally considerations of long-term in vitro incubation, if necessary, to cover the slow-metabolised chemicals. The general flowchart gives a general overview of the testing strategy recommended in the PPR opinion.

The PPR opinion also defined two types of human metabolites of concern to be considered: disproportionate metabolite and unique metabolite. Options for performing the toxicological assessment of unique and disproportionate human metabolites (in silico, in vitro and in vivo approaches) are described in the scientific document, from hazard to risk characterisation. Finally, a list of recommendations (e.g., human biomonitoring or PBPK modelling) was drafted in the last section of the PPR Opinion.

The timeline of the in vitro metabolism project was presented: at the next PPR Panel meeting on the 23rd/24th of June, the PPR Panel should be able to endorse the draft PPR Opinion for the public consultation. Working group members will then respond to and consider the comments submitted during the Public Consultation. The Scientific Opinion will be adopted in November 2021 by the PPR Panel, and the publication is expected in December 2021.

14. AoB

- **Request for more PSN meetings per year and improvement on the agenda**

PSN participants noted that one meeting per year is not sufficient for updating the MSs on developing topicsand itwas suggested to increase the number of meetings. It was commented that documents for the agenda should be distributed earlier in order to allow for a good preparation and a target-oriented discussion in the PSN meeting. With the involvement of stakeholders, it would be more constructive to distribute the documents at an earlier stage.
In addition, it was proposed to include a brief background/status of the art for each agenda item to support the MSs in preparing the meeting and make the discussion points more transparent.
EFSA invited MSs to also present topics of interest so information flows in all directions.

Action points:

- EFSA to consider these proposals for the next PSN meeting

- **Update of the database on processing factors: missing studies to be submitted by MSs**

A database on processing factors was developed in 2017. An update of the database is ongoing to include processing studies submitted after 2017. Some full study reports are still lacking for which MSs are requested to provide these to EFSA.

Action point:

- To build a more robust database, MSs are kindly requested to submit relevant studies for the update of this database.