Network on Pesticide Steering
Minutes of the 28th meeting

Held on 13 October 2021, TELE-conference

(Agreed on 03 November 2021)[1]

Participants

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

Country	Name[2]
Austria	Klaus LEDER
Belgium	Philippe CASTELAIN
Denmark	Alf AAGAARD
Estonia	Uku ROONI
France	Suzanne PIERLOT
Germany	Eva GOCLIK
Greece	Danae PITAROKILI, Agathi CHARISTOU
Hungary	Tamás GRIFF
Ireland	Aidan MOODY
Italy	Pasquale CAVALLARO
Netherlands	Carla HUIZING
Portugal	Bento DE CARVALHO
Slovakia	Marta GALUSOVA
Slovenia	Katja BIDOVEC
Spain	José Luis ALONSO-PRADOS
Sweden	Katarina LUNDBERG

- **European Commission:**

Karin NIENSTEDT (DG SANTE)

Zsuzsanna KOENIG (DG SANTE): for agenda point 5.2

Domenico DESERIO (DG SANTE): for agenda point 10.3

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

2 Indicate first full name and then surname (John Smith) throughout the document

- **EFSA:**

Pesticide Peer Review Unit (Manuela TIRAMANI, Head of Unit)

Pesticide Residues Unit (Bénédicte VAGENENDE, Head of Unit a.i.)

Pesticide Peer Review Unit (Maria ARENA)

Pesticide Peer Review Unit (Dimitra KARDASSI)

Pesticide Peer Review Unit (Juan Manuel PARRA MORTE)

Pesticide Peer Review Unit (Andrea TERRON)

Pesticide MRL Unit (German GINER)

Pesticide MRL Unit (Alessia Pia SCARLATO)

Applications Desk Unit (Karine LHEUREUX, Head of Unit)

Applications Desk Unit (Remigio MARANO)

Evidence Management Unit (Stefano CAPPÈ)

Legal and Assurance Services Unit (Matthias HASLER)

Scientific Committee and Emerging Risks Unit (Reinhilde SCHOONJANS)

Scientific Committee and Emerging Risks Unit (Daniela MAURICI)

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Finland (new nomination is awaited replacing the current representative), Latvia and Lithuania.

2. Adoption of agenda

The agenda was adopted without changes.

3. Agreement of the minutes of the 27th meeting of the Network on Pesticide Steering held on 29 March 2021, web/audio/conference

The minutes were agreed by written procedure on 21 April 2021 and published on the EFSA website.

4. Assessment of endocrine disrupting properties: updates

EFSA provided an overview on the assessment for endocrine disrupting (ED) properties of pesticide active substances.

In total, EFSA has conducted 80 ED assessments in line with the ECHA/EFSA (2018) ED guidance: for human health, the number of active substances identified as meeting the ED criteria, not meeting the ED criteria, ED assessment waived and cases for which additional data were required is overall well distributed compared to non-target organisms where for most active substances the data package has been proved to be incomplete. Indeed, the human health data package appears well-substantiated while for non-target organisms the data provided to comply with the data requirements are rather considered supportive

to draw a conclusion on the ED properties of the substances. In total, nine active substances have been considered to meet the ED criteria. It was noted that the 4 substances identified as ED in non-target organisms have been also identified as ED in humans. According to the ECHA/EFSA guidance, in certain situations, where, due to the knowledge on the physico-chemical and (eco)toxicological properties of the substances, an ED assessment does not appear scientifically necessary or testing for this purpose not technically possible and thus it may be waived. For instance, Acetylcholinesterase (AChE) inhibitors may limit the exploration of other possible mode of action (MoA) analysis (e.g. pending on the dose at which AChE inhibition is observed). So far, the ED assessment for 20 substances was waived for human health and for 13 substances for non-target organisms. As an overall summary, the conclusions with the outcome of ED assessment for 24 substances have been published to date, with 3 substances considered meeting the ED criteria, 15 substances not meeting the ED criteria, and 6 substances for which a conclusion is available but additional data may be needed to draw a conclusion on ED (e.g. for new active substances where the clock stop provisions were not applicable). For the majority of the active substances additional data have been requested (up to 30 months). The 3-month clock stop has been applied to 7 substances due to ED criteria met.

A brief update on the activities of the recently established EFSA ED working group (WG) was also provided. The first meeting of the EFSA ED WG was organised in February 2021 with altogether 5 meetings taking place in 2021. Similarly, 5 meetings are also planned to be organised for 2022. The chair of the WG is Martin Wilks. Expertise for different modalities is shared between 4 experts supporting human health and 4 experts for non-target organisms. In addition, hearing experts from US EPA and the RMS/co-RMS of the pertinent substance, and observers from DG SANTE, JRC and ECHA are also part of the WG. The WG is intended to provide technical advice to the peer review on the interpretation of the data related to the ED assessment in particular in case of complex ED assessments or controversial issues encountered. The advice is shared with the peer review experts during the experts' meetings who will be responsible to conclude. The EFSA ED WG is working in close collaboration with ECHA to ensure consistency in the ED assessments. Similarly, EFSA is also involved in the activities of the ECHA ED Expert Group (EG) A dedicated workspace was created to share documents, including the EFSA database on ED assessments. ECHA can be also invited to participate in the Pesticides Peer Review Experts' meetings when interested. For instance, a joint EFSA/ECHA discussion was conducted related to the ED properties of a common metabolite to the biocidal active substance zineb and the pesticide active substance metiram. As a further example of cooperation, the Annex of the ECHA/EFSA ED Guidance document on the use in the testing strategy and interpretation of data conducted in accordance with OECD test Guideline 248 (Xenopus Eleutheroembryos Thyroid Assay (XETA)) has been updated by EFSA in close collaboration with ECHA and was published in April 2021.

Q&A:

- Based on questions raised on cases where waiving of the ED assessment is granted, it was clarified that a workshop is foreseen to be organised for defining potential criteria for waiving ED assessment/ED studies based on the experience gained over time. Indeed, no clear criteria are yet indicated in the ECHA/EFSA guidance.

- Based on a suggestion it was agreed that it would be more appropriate to indicate for these cases mentioned above that an assessment was conducted, leading to the conclusion that no further data are needed and that the substance does not meet the ED criteria.
- It was noted that a possible exchange of ED studies between the different regulatory areas would be of benefit for the alignment of the EFSA/ECHA ED assessment. The 'one-substance-one-assessment' (OSOA) concept, promoted by both EFSA and ECHA, is intended to ensure a harmonised and integrated assessment between the two agencies. For the time being, a first pilot case has been identified for the common biocides/pesticides renewal assessment of tebuconazole, with the same data package assumed and with DK as the RMS and competent authority (eCA) in both processes. In the future, the new IUCLID system as common format for submission of pesticide/biocide dossiers could further facilitate the close collaboration between the EU agencies. As part of the implementation of the Green Deal and Chemicals Strategy for Sustainability, there is a proposal to revise the CLP Regulation (Regulation 1272/2008 on the classification, labelling and packaging of substances and mixtures)[3] to include ED as a new hazard criterion in the regulation. In addition, it is aimed to expand the scope of the CLP Regulation to cover also other areas (e.g. food/feed additive, cosmetics, etc.). The revision of the CLP Regulation was announced by the Chemicals Strategy for Sustainability adopted on 14 October 2020 with the objective to improve in the EU the safe use of chemicals and to simplify existing CLP rules.
- As regards the timeline, DG SANTE informed that the implementation of the revision of any EU legislation, including also that on hazard classification, labelling and packaging of chemicals, usually is a a process requiring at least 3 years until adoption and/or entry into force: following an impact assessment and targeted consultation with stakeholders Commission will need to first agree on a legislative proposal followed by adoption via the co-decision procedure by the European Parliament and Council. Usually transitional measures are negotiated and reflected in such new legislative act.
- SE informed EFSA about a potential pilot case with the active substance deltamethrin. The biocide dossier is expected to be submitted in March 2022. At EFSA level, the peer review is ongoing, awaiting the assessment of additional information from the RMS (AT) following the clock stop. Considering the current status, the eCA (SE) could be involved in the upcoming peer review expert meeting discussions once the revised assessments will become available. The possible options for involvement of SE in the peer review of deltamethrin can be further discussed in a separate meeting with the competent authorities.

Action points:

- MS to share proposals for eventual pilot cases for testing parallel assessment for an upcoming substance common for biocides/pesticides they might have in their pipeline.

[3] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12975-Revision-of-EU-legislation-on-hazard-classification-labelling-and-packaging-of-chemicals/public-consultation_en

- EFSA to consider the need to include an additional column to group the substances by chemical classes in the EFSA ED assessment xls database. DE to share proposal on grouping by **31 October 2021**.
- SANTE and EFSA to reflect on how to address the publication of the Annex of the ECHA/EFSA ED Guidance on XETA at an upcoming SCoPAFF meeting.

5. Guidance documents

5.1 Guidance documents preparation and updates. Medium- and long-term planning

EFSA presented the proposed prioritisation of technical PPP guidance documents. At the high-level meeting between directors of Commission, EFSA and MSCAs held in December 2020, it was agreed to develop a list of technical guidance documents related to Plant Protection Products requiring updates and/or new guidance to be drafted. EFSA has been taking the lead on establishing such a technical guidance list, with the contribution of the PSN members in order to decide on priorities. The overall aim is to establish a single EU repository of guidance documents at EU level. An EU Survey was launched between April and May 2021 to collect comments on the prioritisation of new guidance to be developed and existing guidance to be reviewed. 220 comments were received from 9 MSs, DG SANTE and EFSA.

Based on the comments from the EU Survey, EFSA proposed a prioritised list of technical guidance documents covering both the PPP and MRL areas, and shared it with the PSN group, together with the outcome of the proposed prioritization. The criteria applied for ranking the documents as low, medium or high priority were briefly explained to the PSN members, based on the weighted feedback received during the commenting. Some changes on the prioritisation were discussed and agreed.

While EFSA was responsible to develop a list of technical guidance documents, the preparation of a list of procedural guidance documents was assigned to the responsibility of the PAI group. In addition, CTGB in cooperation with PAI, EFSA and Commission, is developing a document describing the procedural aspects for the management and update of the lists on a regular interval, as well as prioritisation.

In the next steps, the list can serve as a starting point for discussing cooperation activities with MSs and to consider work sharing. Based on their resources available, MSs can express their interest in supporting and/or taking the lead in the development and/or revision of guidance documents.

The prioritised list of technical guidance documents, as agreed at the PSN meeting, will be provided as input for the next high-level meeting between MSCA/EFSA/SANTE Directors that will take place on 5 November 2021: discussions will focus on possible partnership with the MSs (capacity, resources, budget, FTE). The priority list is not expected to be re-discussed or re-opened at the meeting of 5th of November 2021.

Q&A:

- Following a question, the difference between 'low priority' and 'no comment received' was clarified: the outcome is similar, in both situations there is no intention to revise the guidance for the time being. 'Low priority' status is allocated when at least one comment has been received.

  This point was discussed as some Member States did not comment on a priority of a guidance document if they agreed with the proposal by EFSA included in the draft for commenting. Therefore, on the comments received from the first EU survey, no comment did not necessarily mean no interest in a revision, but that the revision was not considered a priority at the moment by the Member States or that the Member States agreed with EFSA's proposal on prioritisation. A common understanding is proposed to be established in the procedural GD.

- PSN was given the opportunity to provide their last comments, if any, on the prioritised list of guidance documents. Indeed, it was acknowledged that certain compromise may need to be accepted and a pragmatic approach should be applied in order to be able to achieve a common prioritisation at EU level.
  - The majority of the MSs agreed on ranking the guidance on non-target arthropods as a high priority.
  - The NL proposed that instead of the guidance on non-target plants that should first await the availability of protection goals; development of a guidance on digital farming/precision techniques should be added to the list with high priority. In addition, several MSs supported to consider the guidance on negligible exposure assessment as a high priority.
  - It was proposed that the title of the guidance document on microorganisms should be amended and kept broad such as 'risk assessment for microorganisms', also in view of the upcoming changes due to the new data requirements.

- It was noted that the EFSA Guidance document on PECs in soil[4] is currently at the SCoPAFF level. EFSA will make a presentation at the SCoPAFF in October 2021. The document is expected to be endorsed in one of the next SCoPAFF meetings.

- Overall, EFSA's work on the list of guidance documents was appreciated by the PSN members, in particular the transparent way of undertaking the prioritisation exercise. For future updates of the list, it was suggested that more quality criteria (e.g. scope of revision of an existing Guidance document) could be included for a better prioritisation of the list, as reflected in the document under preparation which was mentioned above. In addition, it was proposed to be clearly emphasised in the list that any prioritisation proposal by EFSA should ideally be accompanied by one from the Member States, even if it is in line with EFSA's proposal since a lack of feedback may lead to bias.

[4] https://www.efsa.europa.eu/en/efsajournal/pub/4982

- It was proposed that a multiannual plan could eventually be created and financially supported by grants. This would allow for realistic resource planning for the coming years, with data collection/generation needed as preparatory work for the revision of the guidance documents.

Action point:

- PSN members to provide their input by **14 October 2021 (cob)** at the latest whether the 2 proposed guidance, i.e. 1) Draft Technical Guidance on Negligible exposure assessment and 2) development of a new guidance on new farming techniques/new pesticide application technologies) should be added as high priority to the PSN prioritisation list of GDs that will be submitted for the high-level meeting between MSCA/EFSA/SANTE Directors taking place on 5 November 2021.

5.2 Update of Communications on GD list

SANTE provided an update on the ongoing work of the revision of the Commission Communications on guidance documents in the framework of the implementation of Commission Regulation (EU) No 283/2013 and 284/2013.

The exercise started in 2016 with draft proposals followed by a consultation with stakeholders in 2018. The 600 comments received from this consultation are still being processed. SANTE acknowledged the support received from EFSA during this exercise. The work is still ongoing and in the next steps a consultation will be organised with stakeholders on the revised version of the Communications before endorsement by the SCoPAFF.

This activity is taking place to complement the process on establishment of a single repository of guidance documents at EU level.

Q&A:

- It was proposed to include additionally the date of applicability of the guidance documents in the EU repository. Due to lack of resources this is currently not planned. The applicability and implementation schedule of each guidance document is available in the introductory section of the respective document.

No action points.

6. Transparency regulation

6.1 Implementation of the Transparency Regulation: first experiences and feedback

EFSA (APDESK, PREV, DATA and Legal units) gave a joint presentation on the progress on the implementation of the Transparency Regulation and the experience gained following 6 months after its entry into force on 27 March 2021, including developments and opportunities to improve the processes.

- **Pre-submission activities**

Notification of studies (NoS)

For the notification of studies **for new applications**, following obtaining a pre-application ID, both applicants and laboratories/testing facilities are subject to study notification obligations according to Article 32(b) of the Transparency Regulation (TR). As a simplification mechanism, once a study notification is submitted by one of the entities subject to the obligation, the system foresees the possibility of co-notification by the other entity, to avoid duplications. Once the application is considered admissible, EFSA will publish the study notifications together with the non-confidential version of the dossier.

For the notification of studies **for renewal dossiers**, following obtaining the pre-application ID for renewal, the potential applicant should submit the list of intended studies together with the study design, in accordance with Article 32(c)1 of the TR. Following an administrative check performed by ADPESK within 10 working days, EFSA conducts a public consultation on the list of intended studies and subsequently, in close collaboration with RMS/co-RMS, EFSA proceeds with the renewal pre-submission advice. Applicants are also subject to study notification obligations according to Article 32(b) of the TR.

Overall, according to the new provisions, over 500 pre-application IDs and ca 2000 study notifications have been received by EFSA for new applications across all food sector areas. In case of renewals, around 100 pre-application IDs and ca 1000 intended studies have been entered into the system so far.

For the time being direct access by MSs to the EFSA Database of Study Notifications (NoS-DB) is not possible; due to confidentiality reasons it is restricted to a limited number of EFSA NoS managers who perform the extraction and make the list of studies available to RMS/EMS via the EFSA DMS, to allow verification of the notified studies and justifications during the admissibility check. So far 22 NoS extractions were carried out for renewals, 4 extractions for new active substances (NAS), and 11 in the context of MRL applications. EFSA is committed to provide support to all MSs in this new process: EFSA organised an Info session on NoS check on 22 June 2021 followed by a dedicated Hypercare session in September 2021. Ad hoc support is provided on specific substances. A Q&A document on the NoS check procedure has been compiled containing all questions received from MSs and will be soon shared with MSs, and in the next steps it is aimed to establish a database of justifications to ensure a common understanding on valid/non-valid justifications related to NoS obligations. EFSA is also working on optimisation of the timeline of the procedure to provide the NoS extraction to the RMS/EMS; currently this is a manual exercise performed within 10 working days, however from next year EFSA aims to reduce the timelines and provide the extraction as soon as possible following automatization of the process.

General pre-submission advice (GPSA):

In the area of pesticides, 7 requests were received so far for GPSA: 4 requests were rejected since they were considered out of scope (for instance requests for EFSA to attend a pre-submission meeting organised by the RMS is out of scope of GPSA). In case RMS asks the participation to EFSA to pre-submission meetings, this should be requested by the RMS as mentioned in the Pesticides Administrative

Guidance[5]. Two GPSA requests are ongoing, while 1 GPSA has been concluded in collaboration with the RMS/co-RMS. Once the application dossier is declared valid, the summary of the advice will be published in Connect EFSA.

Overall, EFSA stressed the importance and the need for a fruitful collaboration between EFSA, RMS/EMS/co-RMS in order to avoid duplication of efforts. So far, the advice was provided in written form, but a meeting might also be organised.

Renewal pre-submission advice (RPSA)

In the area of pesticides, in total 40 public consultations have been conducted by EFSA on the list of intended studies submitted for upcoming renewals; so far, no comments were received from 3rd parties. Out of the 40, the RPSA for 30 substances are closed (75%), while the rest is in progress or close to finalisation. Half of the advice have been drafted by the RMS, half by EFSA. There is a close collaboration with the RMS for the commenting phase to finalise the advice. The overall timeline for the RMS to draft the advice is 20 working days (5 days for confirming willingness + 15 days for drafting the advice). In addition, EFSA proactively sends the list of intended studies to RMS/co-RMS already upon launch of the public consultation to allow earlier availability, giving 3 additional weeks to anticipate the preparation of the draft written advice. For the time being, no meeting has been organised by EFSA.

It is acknowledged that the process is new and some MSs may face difficulties to embark in the process. EFSA is committed to provide support to the RMS by individual replies and would encourage RMSs, being the first assessors for their specific substances, to further engage in these activities once more experience is gained over time.

It was acknowledged that overall, limited information is provided by the applicants in the list of intended studies. In particular, the content of the application is not submitted as part of the list of intended studies and therefore essential information (e.g. on the scope of the renewal, representative uses, GAP) is not available, thus giving little possibilities to allow providing more elaborated advice. It was clarified that eventual other studies not included in the list cannot be commented by the RMS; indeed in accordance with the Practical Arrangements, the advice should be limited to the list of intended studies as submitted by the applicant, even though this may not fully represent the complete list of studies that will be submitted with the dossier. To improve applicants' input on the list of intended studies, it is currently under consideration whether some changes can be made to improve the interface of the tool (e.g. inclusion of an additional column to allow clarifying the purpose of the study in relation to the pertinent data requirement it aims to address). This will allow also applying filters and extract studies that are relevant for pertinent sections ensuring efficient coordination and avoiding a large number of irrelevant studies being shared with all specialised colleagues. In the meantime, applicants can be suggested to include such information in the 'Study Objective' field, as a workaround.

The structured excel template built up by EFSA including standard phrasings was found as a useful format for drafting the advice that facilitates establishing a harmonised approach to be applied across the substances in a uniform way. With

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

the improvement of the functionalities of the tool, it is aimed that the final advice to the applicant could also be provided in the same format.

Overall, it was acknowledged that the new systems may present some constraints and limitations, as also evidenced by the various feedback shared by the PSN, and therefore EFSA is constantly working on the improvement of the IT platform.

Confidentiality – Transparency Regulation

With the entry into force of the new transparency provisions, pesticide dossiers are subject to proactive disclosure except for information duly justified and accepted as confidential. As a general principle, transparency is the rule, and confidentiality is the exception. In the absence of confidentiality requests submitted with regard to information, documents or data supporting the application, EFSA will make proactively available to the public the entire dossier once the application is considered admissible. The confidentiality decision making process on the confidentiality claims submitted by the applicants starts after admissibility. If one or more confidentiality requests are rejected, a second version of the application dossier will be published after conclusion of the confidentiality decision-making process.

Based on the initial experience and lessons learnt with the first dossiers falling under the new rules, it was stressed that the proactive role of RMS/EMS during the admissibility phase is essential, in particular to verify the following elements:

- Information claimed confidential is identifiable
- Correct submission of attachments
- Personal data is claimed confidential and duly sanitised (in accordance with Article 63(2b)(d) of Regulation (EC) No 1107/2009 and EFSA's Practical Arrangements)
- Presence of item from closed positive list(s), i.e. from Article 63(2) of Regulation (EC) No 1107/2009 and, where Article 63(2)(a) of Regulation (EC) No 1107/2009 is invoked, from Article 39(2) of Regulation (EC) No 178/2002& availability of verifiable justification

In support of this exercise, Confidentiality and Attachments Reports can be generated in IUCLID.

As regards the next steps, an integrated confidentiality assessment workflow is under development for processing requests received via IUCLID. Changes will be made to certain filtering rules to ease submission and assessment of certain personal data. In addition, improvements are foreseen with a view for further adapting filtering and flagging features in IUCLID. MSs are invited to provide any feedback to EFSA on confidentiality-related features in IUCLID based on their first experiences gained.

- **Dossiers in IUCLID**

According to the new transparency provisions, 3 new active substance dossiers, 23 renewal dossiers and 15 MRL applications have been submitted in IUCLID so far. Support was provided via the dedicated Hypercare programme.

In the next step, a webinar[6] on the application procedure for active substances in pesticides and MRLs will be organised on 28 October 2021 to better respond to recurring questions received from stakeholders on the new provisions and tools introduced by the TR, and to consolidate understanding of the entire application process. It will aim to address dossier submission, confidentiality requirements, the creation of the public version of the dossier and the steps in the peer review.

A dedicated LinkedIn Group[7] for Applicants has also been established.

Overall, considering the **key role of Member States** playing in many of the new TR processes, close cooperation and feedback from the competent authorities are essential with a view to streamline and optimise the processes in the next phase, both on the tools and the processes. In addition, eventual training needs could also be identified.

Action points:

- PSN members (via the nominated PSN IUCLID members) to provide feedback on confidentiality-related features in IUCLID[8] via the dedicated Teams channel "02_IUCLID PSN All participants" by 19 October 2021, in particular:
    - PSN members screening applications are asked to perform a light check on the presence of key elements in confidentiality requests:
        - Personal data sanitised
        - For confidentiality requests submitted, background documents and
        - presence of justification
    - PSN members to share their suggestions in improving the confidentiality justification template currently available in IUCLID
    - PSN members to share feedback regarding current filtering and flagging scheme
- As regards the NoS check, PSN members are encouraged to include justifications from the applicants that were accepted or not in the 'database of justifications' to facilitate a common understanding.

6.2 MSs competent authority communication on GPSA/RPSA written advice and summary

Communication related to RPSA to both RMS and co-RMS has been channelled so far via email, whilst with gradual improvement of the functionalities, 'Connect EFSA' can be used as interface between EFSA and RMS/co-RMS: functionalities to

[6] https://www.efsa.europa.eu/en/events/webinar-application-procedure-active-substances-pesticides-and-maximum-residue-levels-mrls
[7] https://www.linkedin.com/groups/9083910/
[8] Detailed slides on confidentiality-related matters to be verified by the RMS/EMS at the admissibility/validity stage are made available via the Team channel

provide directly the draft advice and to share comments are now available in the tool. Likewise, when the RPSA is closed, the advice is sent to the applicant via Connect EFSA.

The aim is to move away from the email communication once the processes and tools become fully established.

According to the provisions applicable to intended renewal applications, EFSA, in accordance with Article 32a(1) and Article 32c(1) of the TR, should share the written RPSA and the summary of the RPSA/GPSA with the competent authorities of all Member States for information purposes. In the interest of efficiency, all closed GPSA/RPSA are made available for all MSs in 'Connect EFSA', and are visible in the sections 'closed PSA' and 'closed RPSA'. Upon closure of the advice, MS registered contact points will receive automatic notification by the system. For the time being, the system was designed to select only one contact point per MS. To improve MS access to 'Connect EFSA', accounts for 3 additional contacts have now been granted per each organisation. PSA contact points will be contacted in order to provide the names of colleagues for the activation of their accounts. Analysis is currently ongoing to improve clarify of the texts communicated via automatic notifications. It was suggested to automatically forward the notifications sent to the contact point to a functional mailbox, as a workaround.

7. IUCLID: brief update on first meeting of 1/10 IUCLID PSN group

EFSA gave a presentation on the first meeting of the dedicated PSN subgroup meeting on IUCLID held on 1 October 2021. The meeting minutes and presentations will be made available on the EFSA website. The IUCLID subgroup of the PSN has been created to continue the activity started with the EFSA Technical Group on IUCLID for PESTICIDES (Nov 2019 – June 2021), followed by the HYPERCARE programme to provide support for the first submitters (Nov 2020-Nov 2021). The PSN IUCLID subgroup contains a wide range of members[9] with representatives of 22 MSs, industry (CLE, ECCA, IBMA), Commission and ECHA.

The meeting provided a forum to share the first experiences with IUCLID submissions. Out of the 42 IUCLID dossiers received so far, 2 MRL dossiers were declared admissible and have been published, while for the rest the work is still ongoing. Based on the experience gained and the feedback collected from the group, EFSA prepared advice for applicants, in particular in view of the need for applying temporary workarounds for dossier submission until March 2022 and highlighting important elements that need attention when preparing the dossier (e.g. legal entity field, size of attachments, confidentiality claims). Applicants are also advised to consult the available manuals[10] and to get familiar with the filter rules[11] and to run the dissemination preview before submitting the dossiers.

Discussions took place also as regards practicalities on confidentiality related elements; in addition, EFSA provided updates on the developments on the following IUCLID features:

[9] ToR and membership published on EFSA website: https://www.efsa.europa.eu/en/science/scientific-committee-and-panels/ppr

[10] Active substance: https://doi.org/10.5281/zenodo.5091464
Micro-organisms: https://doi.org/10.5281/zenodo.4773527
MRL: https://doi.org/10.5281/zenodo.4630194

[11] https://doi.org/10.5281/zenodo.5118638

- The **Validation Assistant** is a tool available for all IUCLID users (applicants and evaluating authorities) to check completeness/accuracy of IUCLID dossiers, allowing users to perform checks on their dossiers according to the set rules[12]. With the next release of IUCLID, some rules will be updated as well as new validation rules will also be implemented (confidentiality, attachments, multiple products, dossier header);
- The **report generator** is a tool to extract data from IUCLID and present it in report (PDF, RTF) or machine-readable format (XML, CSV), to allow establishing a preview of the filtered dossier, and to generate reports needed during the admissibility phase (NoS report, validation report, confidentiality report). For the time being the following templates for report generator are available:
    - Documents M (active substance and product)
    - Documents D
    - NoS Extraction Request
    - Confidentiality Report for PPP
    - Literature references report
    - List of annotations
    - List of attachments

Following all these developments, a new version of IUCLID is intended to be released on 27 October 2021 (IUCLID 6.6).

The PSN members welcomed the feedback from the 1st IUCLID subgroup meeting. It was acknowledged that the quality of the reports generated in IUCLID (in particular on Doc M), although can be further improved, will be ultimately dependent on the quality of the dossier submitted by the applicant. A brief exchange of views took place also as regards practicalities concerning generation of the Evaluation Report for MRL applications. It was clarified that until a suitable report can be produced by the report generator and further improvements will be implemented, EMSs may continue to request in parallel a draft report from the applicants to serve as a starting point for the EMS assessment, in line with the current practice applied by some MSs. It was recalled that the RMS/EMS is the author of the assessment report; however, the RMS/EMS evaluation is based on the data and information provided by the applicants, therefore certain elements of the assessment report may be taken from the applicant's dossier for reasons of efficiency. Careful attention should be paid to provide a clear distinction in the report of the elements taken over from the applicant's assessment together with sound justification to avoid potential misperception by the public. The views and conclusions of the RMS/EMS should be clearly and transparently reported in order to differentiate the view of the applicant from that of their own.

Overall, the first PSN IUCLID subgroup meeting has proved to be a fruitful exercise. MSs are highly encouraged to continue to take part in the discussions on the IUCLID topics with a view to facilitate future improvements as well as prioritisation of tasks for IUCLID development.

- [12] **Filter rules** (publication): Zenodo. https://doi.org/10.5281/zenodo.5118638
- **Submission rules**: https://doi.org/10.5281/zenodo.5141357
- **Validation rules** (quality rules/warning) https://doi.org/10.5281/zenodo.5091464

Further to the PSN subgroup meeting on IUCLID, the NL in collaboration with DE is organising a workshop on IT strategy and the future of IT architecture for pesticides and biocides in the EU, taking place on 9 and 11 November 2021. The initiative is highly welcomed and relevant for both EFSA and MSs, also in view of further IUCLID developments including consideration on the strategic future of IUCLID for the management of chemical data in the medium/long term.

Action points:

- MSs are encouraged to provide written feedback on IUCLID related topics (e.g. input on confidentiality assessment, report generator, proposed changes to IUCLID) with a view to facilitate future improvements (feedback invited under the dedicated Teams space of IUCLID PSN subgroup to which nominated PSN IUCLID members have access)

- MS can still express interest in joining the IUCLID PSN subgroup by providing the contact details to pesticides.mrl@efsa.europa.eu
- PSN members can also apply to participate in the upcoming workshop on IT architecture for pesticides and biocides organised by NL/DE (9 and 11 November 2021, contact: OBSOProjectgroep@ctgb.nl)

8. EFSA Guidance on Aneugenicity

EFSA introduced to the PSN members the EFSA Guidance on Aneugenicity assessment, adopted by the EFSA Scientific Committee on 1 July 2021. In the Scientific opinion on genotoxicity testing strategies applicable to food and feed safety assessment (EFSA Scientific Committee, 2011), for tier 1 (*in vitro* testing), a combination of an Ames test (OECD TG 471) and a micronucleus test (OECD TG 487) is proposed. Depending on the results of the tests, further follow-up testing strategy is suggested for tier 2, in particular *in vivo* follow-up is requested in case of positive *in vitro* results. In 2019, the EFSA Scientific Committee was invited to develop guidance on the most appropriate *in vivo* follow-up for substances that are aneugenic *in vitro* and to provide recommendations on how should risk to human health be assessed for a substance exhibiting aneugenicity. The PSN members were reminded of the difference between clastogenic substances (structural chromosomal aberrations involving direct interaction with DNA) and aneugenic substances (numerical chromosomal aberrations with indirect interaction with DNA). A testing scheme for substances for which clastogenicity has been already ruled out is described in the EFSA Guidance document on Aneugenicity assessment.

Q&A:

- It was highlighted that ECHA was also consulted during the public consultation of the draft EFSA Guidance on aneugenicity assessment and no specific comments were received.

- It was clarified that the Threshold of Toxicological Concern (TTC) approach could be considered in very specific cases but not to be applied when "*toxicological data are available, or for regulated products requiring toxicological data*" as clearly stated in the EFSA Guidance on aneugenicity assessment.

Post-meeting note: it is noted that DE disagrees with the EFSA SC Recommendation (2011) on the genotoxicity *in vitro* test battery. As indicated by the European Commission, the recommendations on the genotoxicity *in vitro* test battery for groundwater metabolites will be further discussed in the context of future update of the European Commission Guidance on Groundwater metabolites.

No action points.

9. EFSA Guidance on the assessment of nano materials

The EFSA Scientific Committee Nano Guidance documents adopted on 30 June 2021 were presented: it includes the Guidance on nano risk assessment to be applied in the food and feed chain: human and animal health and the Guidance on particle technical requirements. During the drafting of the guidance documents alignments were ensured through consultations with JRC, ECHA, DG SANTE, hearing experts and MSs. There is a need to consider nanotoxicology due to the specific behaviour of nanoparticles compared to the classical toxicology of chemicals: such particle behaviour may lead to non-homogenous distribution, specific distribution of the particles in cells, high local concentrations of released components, size-dependent uptake in tissues. Furthermore, toxicodynamics for nanoparticles required the consideration of the chemical effects related to very high surface/volume ratio and the physical effects due to possible persistent nanomaterials. Specific test design should be applied *in vitro* and *in vivo* to study the effects of nanomaterials to cells and tissues.

The first guidance on risk assessment of nanomaterials outlines a full step-wise assessment addressing nano-specific properties. This approach is required for materials legally defined as engineered nanomaterial/nanoform, when the material has properties characteristic of the nanoscale or when the material contains a fraction of nanoparticles. For the latter conventional materials that may contain a fraction of small particles, the Guidance on technical requirements has to be applied first and provides practical appraisal routes to establish and characterise the fraction. Depending on the outcome, the guidance informs how the risk assessment has to be conducted in line with Guidance for risk assessment of nanomaterial or if the conventional risk assessment is sufficient.

The full assessment includes physico-chemical characterisation of nanomaterial, exposure assessment, hazard identification, hazard characterisation and risk characterisation of nanomaterial and an uncertainty analysis of the risk assessment provided. Specific considerations on pesticides active substances, co-formulants and plant protection products (PPP) are reported in the Appendix D2 of the Guidance. Nanopesticides are currently reported (in the literature) as having active substance in nanoparticle form, or having as co-formulant nanoparticles, or as PPP in the form of nanosized droplets in an emulsion, or nanoencapsulates with a natural or synthetic polymer shell. It is noted that there is no official definition for nanopesticides, but the guidance documents provide a scientific approach to risk assessment for consumers.

Q&A:

- Following a question, it was confirmed that ECHA and EFSA are committed to fully align with the recommendations of the guidance documents. JRC

was also actively collaborating with EFSA during the drafting of the guidance documents.

- A first example of the presence of silver nanoparticles was reported in the basic substance application on Hydrogen peroxide. The representative formulation is a soluble concentrate product containing the active substance Hydrogen peroxide and silver. The Outcome of the consultation with Member States and EFSA on the basic substance application for approval of hydrogen peroxide (silver-stabilised) is available on the EFSA website.[13]

Action points:

- MSs to share any feedback/indication on specific applications for pesticides with nanomaterials, if any received at MS level.
- EFSA/SANTE discussion needed on the implementation of EFSA Guidance documents on nano materials in the field of PPPs

Post-meeting note by DE:
Although not yet received by DE, nano silver application as a biocidal product was discussed last year at the ECHA ED EG working group. The ED assessment for silver by the applicant followed the ECHA/EFSA ED guidance document. The data used for the ED assessment included studies performed with silver salts, silver containing active substances (SCAS) and different types of silver nanoparticles (AgNPs), all releasing silver ions. The discussions on studies reliability, relevance or read across could be useful in case this nanoparticle is intended as active substance for plant protection products.

10. Any Other Business

10.1 Publication of Pesticides Peer Review meeting minutes

As a new initiative in view of the implementation of the Transparency Regulation and to increase EFSA's stakeholder engagement, the high level minutes of the Pesticides Peer Review Experts' consultations will be published within 15 working days after the last day of the meeting.

The communication regarding the publication of the peer review minutes was sent in September to all MSs, SANTE and EFSA's registered stakeholders. The high-level minutes of the pesticide peer-review experts' meetings are made available at the following link: https://www.efsa.europa.eu/en/science/scientific-committee-and-panels/ppr#pesticides-peer-review-experts-meetings
The minutes are published successively in chronological order in a single pdf document.

The full minutes with the detailed discussions will continue to be published at the end of the peer review, as part of the background documentation to the EFSA Conclusions.

No questions/action points.

[13] https://www.efsa.europa.eu/en/supporting/pub/en-6806

10.2 Revision of EU-RAR-template

The EU-RAR templates for preparation of assessment reports for active substances in plant protection products have been revised several times, with the latest version dated March 2019. Still, SE (KemI) has continued to use its own templates since SE found several shortcomings in the EU templates, in particular in Vol 1 and the List of Endpoints, hampering their use in practice (e.g. too many styles, inconsistent formatting, missing tables and headings, inconsistent use of abbreviations).

Indeed, some MSs shared similar views encountered during the use of the templates and DE has also started to address some shortcomings of the current template at national level.

For better efficiency and to avoid all individual RMSs working in parallel to revise the templates SE is proposing a common update of the EU-RAR templates to make them more user-friendly.

The issues identified and suggested to be addressed are all of administrative nature, therefore a formal note taking by the Standing Committee would not be needed.

It was noted that in the medium term, with further IUCLID developments, the report generator could solve the issue in providing the EU-RAR-template and the combined EU RAR-CLH report could be generated directly from IUCLID; therefore, the current EU templates are likely to become obsolete. Indeed, MSs expressed the need and would appreciate if the report generator could fit with the lay-out of the EU agreed templates and in case of the RAR templates will be revised, it would be useful to adapt the report generator accordingly to allow saving time and having benefits for the MSs from using this tool. In the meantime, DE will check whether it is possible to share their draft document to fix some shortcomings to facilitate work for the ongoing assessments. The template used in Germany consists of two different parts: the templates for the different chapters of the DAR/RAR and a file named report.dotm in which the formatting option is fixed.

Action point:

- DE is invited to share by 31/10 their draft/extract of the EU-RAR template following their work started at MS level to address eventual shortcomings of the current template (e.g. administrative nature / formatting issues etc) for distribution to PSN members and to avoid parallel work.

  Post-meeting note by DE: Generally, it is possible to provide the templates that are in line with the requirements according to "Combined Template to be used for Assessment Reports according to Regulation (EC) No 1107/2009 and Proposals for Harmonised Classification and Labelling according to Regulation (EC) No 1272/2008" (SANCO/12592/2012 –rev. 2, 22 March 2019). As far as the template "report.dotm" is concerned, for this purpose the certification of the template for external uses is expected to be finalised in the beginning of 2022. DE would suggest distributing the templates via the European Commission's website providing Guidelines on Active Substances and Plant Protection Products (https://ec.europa.eu/food/plants/pesticides/approval-active-

substances/guidelines-active-substances-and-plant-protection_en) as a similar template is also available there under "Format draft Registration Report – technical guidelines version 2018 – with report".

10.3 New data requirements Microorganisms (MO) / Feedback from RA on MO peer review: some examples

SANTE gave a presentation on the ongoing process on the amendment of the regulatory framework for microorganisms.

The work on amendment of data requirements and adaptation of the Uniform Principles for microorganisms started in 2018 and will impact 4 Regulations[14]. The draft Regulations are currently under InterService Consultation which will close soon and subsequently Commission will launch a consultation with stakeholders via the feedback mechanism. Voting at the Standing Committee is foreseen to take place at the latest by Q1 2022, followed by the formal adoption by the EP and Council via the co-decision procedure around Q2 of 2022. The entry into applicability of the new data requirements will be aligned with the annual IUCLID release envisaged for October 2022, allowing to adjust IUCLID accordingly. The two Commission Communications listing test methods and guidance documents relevant to the implementation of the Regulation (EU) No 283/2013, and the Regulation (EU) No 284/2013 as regards micro-organisms, will also be adapted.

New principles and scientific approaches are proposed for microorganisms in order to move away from following the current approach applicable for chemicals, taking into account evolution of science and technology and the experience gained with current applications. More focus is put on the weight of evidence (WoE) assessment based on a tiered based approach, with mandatory and conditional requirements to be applied on a 'need-to-know' basis. Indeed, the new data requirements are aimed to allow more flexibility in the assessments to be undertaken based on case-by-case considerations where applicants will be asked to provide only data that are needed. Accordingly, the new data requirements will rely on requiring less data from applicants but would still require a sound scientific basis for the assessment.

Biological properties of the microorganisms will be considered as a key element playing a central role in the assessment, supporting the WoE approach and determining the data that are really needed. Some examples and case studies were presented on the stepwise approach leading to requiring new data generation in the different sections, including the principles for identification of metabolites of concern.

Overall, although some uncertainties and concerns were highlighted by one expert of the PSN (in particular the possibility that some important data may be missed and as regards the lack of validated test methods), the PSN acknowledged the change in approach to be applied for the assessment of microorganisms that will require in the future more expert judgement, WoE and case-by-case considerations.

[14] Regulations 283/2013 and 284/2013 on data requirements; Annex II to Regulation 1107/2009 (approval criteria) and Regulation 546/2011 (Uniform Principles)

The on-going training sessions on microorganisms organised under the Better Training For Safer Food (BTSF) were considered as a good opportunity for risk assessors to expand and align knowledge on the risk assessment of microorganisms used as pesticides or biocides.

Action point:

- EFSA to include the topic of update on the microorganisms in the next PSN

10.4 Problem Formulation document / New data

In parallel to the developments on the new data requirements, Commission is working together with MSs on a Problem Formulation document as a follow up action from a previous workshop based on EFSA 2010[15] and EFSA 2016[16] on SPG (specific protection goals), which took place in February 2020. The document is at an advanced drafting stage and aims to describe different scenarios and specific *ad hoc* situations (e.g. particular mode of applications etc.). In the next step, a consultation on the document is foreseen to be organised towards end of the year 2021/early 2022. PSN will also be kept informed and is invited to liaise with their MS colleagues who participated in the workshop in February 2020, as the MS comments should be channeled via these participants.

Action point:

- SANTE to keep EFSA/MSs informed about the date of the event planned to be organised by the end of 2021/early 2022 with a view to consultation on the Problem Formulation document.

[15] https://www.efsa.europa.eu/en/efsajournal/pub/1821
[16] https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2016.4499