PESTICIDES PEER REVIEW UNIT

Network on Pesticide Steering
Minutes of the 30th meeting

Held on 20 October 2022
TELE-conference

(Agreed on 10 November 2022)

Participants

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

Country	Name
Austria	Klaus LEDER
Denmark	Alf AAGARD
Estonia	Elise JOONAS
France	Suzanne PIERLOT
Germany	Martina ERDTMANN-VOURLIOTIS
Greece	Danae PITAROKILI
Greece	Agathi CHARISTOU
Ireland	Sadhbh O'DWYER
Lithuania	Kristina VALIONIENE
Netherlands	Carla HUIZING
Norway	Anna MEHL
Poland	Pawel STRUCINSKI
Portugal	Bento DE CARVALHO
Slovenia	Katja BIDOVEC
Spain	José Luis ALONSO PRADOS
Sweden	Katarina LUNDBERG

- **Hearing Experts**

Not applicable

- **European Commission:**

Karin NIENSTEDT (DG SANTE)

- **EFSA:**

Pesticides Residues & Plant Health Unit (Tobin ROBINSON Head of Unit) (Chair)

Pesticides Peer Review Unit (Manuela TIRAMANI Head of Unit)

Pesticides Residues & Plant Health Unit (Germán GINER SANTONJA)

Pesticides Residues & Plant Health Unit (Renata LEUSCHNER)

Pesticides Peer Review Unit (Marco BINAGLIA)

Pesticides Peer Review Unit (Mathilde COLAS)

Pesticides Peer Review Unit (Chloé DE LENTDECKER)

Pesticides Peer Review Unit (Tunde MOLNAR)

Pesticides Peer Review Unit (Dimitra KARDASSI)

- **Observer[1]:**

  See Annex I

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Italy (Pasquale Cavallaro)

2. Adoption of agenda and agreement of the minutes of the 29th meeting of the Network on Pesticide Steering held on 28 April 2022, Video/web/audio/conference.

The agenda was adopted with three points added under AOB.

The minutes were agreed by written procedure on 17 May 2022 and published on the EFSA website 20 May 2022.

4. Brief introduction of Network participants and Observers

The Chair indicated that around 130 observers had registered for the meeting, coming from all the major stakeholder groups (academia, industry, farmers, civil society etc).

5. Debrief on the observers/MSs feedback received from the 29th Pesticide Steering Network meeting on 28 April 2022

Positive feedback was received on the topics addressed during the 29th Pesticide Steering Network meeting. MSs expressed an interest to possibly receive the presentations for the different agenda items with some days ahead of the meeting.

[1] https://www.efsa.europa.eu/en/stakeholders/observers

5. Presentation of the EFSA Guidelines for observers

The meeting Chair presented the EFSA Guidelines for Observers, with specific attention to the code of conduct during the meeting.

For more details see slides presented during the meeting.

6. RA micro-organisms in light of the new data requirements

The European Commission (EC) presented the new data requirements for risk assessment of micro-organisms used as plant protection products (PPP).

New Commission Regulations on micro-organisms will be applicable as of 21 November 2022, and amend part B of the two Regulations on data requirements (Commission Regulation (EU) 2022/1439, amending Commission Regulation (EU) No 283/2013 for the active substances and Commission Regulation (EU) 2022/1440, amending Commission Regulation (EU) No 284/2013 for PPPs). From 21 November 2022 until 21 May 2023 applicants can voluntarily use the new data requirements specifying their choice in the dossier (which cannot be changed later on); the new data requirements are compulsory for dossiers submitted after 21 May 2023.

In addition, Commission Regulation (EU) 2022/1438 amending Annex II to Regulation (EC) No 1107/2009 as regards specific criteria for the approval of active substances that are micro-organisms and Commission Regulation (EU) 2022/1441 amending Regulation (EU) No 546/2011 as regards specific uniform principles for evaluation and authorisation of plant protection products containing micro-organisms will both be applicable to dossiers submitted as from 21 November 2022.

EC highlighted that the biological properties of the micro-organisms, to be used as PPPs, are at the core of the risk assessment and they play a key role in defining the type and extent of data needed for all the other sections (effects on human health, residues, environmental fate and behaviour, non-target organisms); these indeed are conditional to the specific biological properties of the micro-organism ('conditionality approach'). Tiered-based approach (mandatory vs conditional requirements) & Weight of Evidence (WoE) approach were highlighted as basic principles.

In addition, two EC Communications are in preparation listing the test methods and the guidance documents that can be used for the implementation of the new data requirements, alongside explanatory notes to provide clarifications to some data requirements.

For increasing the capacity of MS in the risk assessment of micro-organisms as pesticides, training courses in the framework of the Better Training for Safer Food (BTSF) programme have also been initiated.

At OECD level, many activities are ongoing (e.g. developing of test methods for microorganisms and producing consensus documents on specific micro-organism species). Horizontal review on specific micro-organism species could be also considered in the future at EU level.

In light of the implementation of the new data requirements, the templates for the EC review reports (Commission side), the draft assessment reports (MS side) and EFSA conclusions (EFSA side) are/have been revised.

For the time being, no MS volunteered to take the lead in revising the assessment report template. EC clarified that in the absence of a volunteer MS, the RMS with the first microorganism dossier falling under the provisions of the new data requirements regulations will need to revise the assessment report (NAS or renewal).

EC also informed of the upcoming call for 5-year grants offered by EC to MSs to reduce systematic delays in the PPPs and biocides risk assessments. The grant is an opportunity for MSs to also hire experts in the field of microbiology (if needed).

For more details see slides presented during the meeting.

7. Assessment of co-formulants: presentation of the EFSA technical report

EFSA presented the EFSA Technical Report on co-formulants published in August 2022 and possible ways to improve and harmonise the assessment on co-formulants.

The interest in pesticide formulations and co-formulants has been growing in recent years. In March 2021, the European Commission updated the list of co-formulants which are not accepted for inclusion in plant protection products. In this context, a data collection on co-formulants has been conducted in order to gain a better insight into the data available to EFSA on co-formulants and considerations for their assessment in the framework of Regulation (EC) 1107/2009.

The descriptive analysis gave a useful insight on the state of the art of the source of data available on co-formulants and considerations on their assessment. It was confirmed that REACH brings the most robust data package on co-formulants, as half of the listed co-formulants have been registered under REACH. The variable levels of data, the different ways of assessing co-formulants between EU Agencies and MSs and the possibility to change the initially notified formulation's composition are currently leading to misalignments in their assessment under the PPP framework. Roles and responsibilities of all involved parties need to be better defined.

Potential ways forward have been proposed by EFSA, including performing further analysis on aspects not fully considered in the Technical Report (e.g. the concentration levels of co-formulants in the PPP for representative uses, the outcome of the compliance check and testing proposals for those registered under REACH, exemption from registration for those not registered under REACH), the improvement of data sharing that could be integrated under the 'one substance one assessment (1S1A)' approach[2] and practical instructions to applicants, RMS,

[2] In the context of the Chemical Strategy for Sustainability (CSS) as part of the EU Green Deal, one of the objectives set by the European Commission is the simplification and consolidation of the legal frameworks, including the review on how to better use EU's agencies and scientific bodies to move towards a process of 'one substance on assessment' (OSOA). The OSOA concept foresees a central coordination mechanism of the activities

MSs and EFSA to perform the evaluation on co-formulants in a more harmonised way. The approach to be followed when a co-formulant is also approved as a pesticide active substance was introduced for discussion.

NL asked for clarification whether it would be possible to have co-formulants that are already approved as pesticide active substances, highlighting that this would seem contradictory to the definition of co-formulant as laid down in PPP Regulation Article 2(3)(c). More clarity is needed on possible derogations to this definition (e.g. co-formulant present in very low concentration or used with another function when considered an active substance). EC noted that further reflection on how to implement the definition is needed and outlined that the same discussion has been raised in the biocides area, where a guidance/agreement has been developed defining the conditions in which a substance would act as biocide active substance or as co-formulant depending on its concentration. The starting point is that if the concerned substance is an active substance, it has to be treated as such, unless the applicant demonstrates that the concentration used in PPP does not possess a pesticidal activity in the formulation, but only acts as a co-formulant. However, considering that co-formulants are neither active substances, nor safeners or synergists according to Article 2(3)(c) of Regulation (EC) 1107/2009, further discussion for PPP Regulation is needed and feedback on MSs' current approaches are welcome.

Actions:

EFSA will initiate a consultation with MSs in the PSN forum (via EU Survey) to collect experiences and views on how to improve and better harmonise the assessment of co-formulants used in PPPs.

7.a. Assessment of co-formulants for formulations for representative uses during active substance assessment

The European Commission welcomed the EFSA Technical Report on co-formulants and stressed that Annex III of Regulation (EC) No 1107/2009 listing the unacceptable co-formulants has been published in March 2021 (Commission Regulation (EU) 2021/383). The unacceptable co-formulants listed in this Annex III cannot be present in any formulation as of 24 March 2023, therefore the applicants need to replace them in the authorised PPPs and cannot declare them in formulations for representative uses.

Furthermore, EC informed that a Draft Implementing Act on co-formulants, shortly under public consultation, will set up a process to identify any further unacceptable co-formulants to be added to Annex III.

8. Risk assessment of second active substance contained in the product for representative uses

The present topic has already been discussed at the 22nd PSN in October 2017, and during SANTE/EFSA bilateral teleconference calls in July and September 2018.

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across different EU agencies, a better coordination and harmonised methodologies for risk assessment and the access to all available data in the same structured format for all EU authorities.

The inconsistent approach taken by applicants and RMSs in the risk assessment of formulated products containing a second active substance was highlighted, with the need to perform a combined assessment in case the formulation for representative use(s) contains more than one active substance, more consistently. In this respect, EFSA outlined the applicable provisions for the relevant peer review areas (i.e. mammalian toxicology, resides, e-fate and ecotoxicology), laid down in the Regulation (EU) 284/2013 as regards the risk assessment for the formulation and when specified, for a formulation containing a second active substance. In addition, the general principles/hypothesis applied in this respect (e.g. dose addition risk assessments) were presented.

EFSA indicated that an assessment concerning the second active substance should be done using agreed endpoints for the second active substance from past peer reviewed assessments. In the event that no combined assessment considering both active substances is presented in the DAR/RAR, a data requirement/open point may be set for performing a proper risk assessment of the formulation during the completion of the reporting table. This may then be reflected in the EFSA conclusions as:

i) a concern and/or data gap;

ii) an issue that could not be finalised if a risk assessment for the single active substance is performed but not for the combination.

iii) a high risk could be identified in cases where higher tier studies are submitted using the formulation (with 2 or more active substances) and if it could not be possible to determine which substance drives the toxicity. In such cases, it should be clearly explained that such outcome is based on data relevant for the two active substances.

EFSA underlined that, by legislation, it has to conclude whether a substance meets the approval criteria, and this requires at least a safe use for a plant protection product (PPP) to be demonstrated; should the PPP contain more than one active substance a combined assessment has to be performed. Therefore, a combined toxicity assessment should be included in the dossier and assessed in the DAR/RAR in a consistent manner.

In this regard, EFSA asked for volunteers to contribute to the development of structured and scientific instructions. Possible fora where to elaborate on this may be to create a working group(s) of the PSN, a general joint experts' meeting (covering all sections). A starting point may be the sharing of data from MSs.

EFSA reiterated that the idea is to build a more integrated and systematic approach on how to assess an active substance in combination with one or more additional components (e.g. combined assessment of 2 active substances in a formulation) and how to present the assessment.

AT expressed the need to first identify what would be 'scientifically sounded', meaning the scientific needs/approach to deal with the risk assessment of a formulation containing more than one active substance, and subsequently to see how best fitting in the existing legal framework if needed.

DK asked about the potential date for a workshop to be organised. EFSA replied that the idea was first to collect the feedback concerning the best forum according to the MSs to tackle this issue, and only after, the timeline could be discussed.

EL also welcomed the initiative of having a workshop or a general experts' meeting per section to tackle this issue.

Actions:

MSs to notify EFSA sending an email to pesticides.peerreview@efsa.europa.eu if they would like to be involved in this activity and/or indicate which format they would think more suitable in addressing this issue (e.g. working group of the PSN, general experts' meeting, workshop etc.) by **25 November 2022**.

9. State of play on Cumulative Risk Assessment

EFSA presented an update on Cumulative Risk Assessment (CRA). CRA started years ago in the context of the Regulation 396/2005 (the "MRL Regulation"), in which it is clearly laid down that cumulative and synergistic effects of pesticide residues should be taken into account. Many activities have been carried out to develop methodologies and since 2014 particular emphasis has been given to retrospective CRA activities.

In February 2021 an Action Plan agreed among EFSA and DG SANTE has been adopted to speed up the development of the methodology for CRA of pesticides and to facilitate its gradual implementation into regulatory risk assessment. Four main areas of work have been identified:

- prioritization of substances and organs/systems;
- retrospective CRA;
- prospective CRA;
- integration of non-dietary exposure.

DK asked if there is any CRA activity foreseen for environmental risk assessment. EFSA indicated that, in the short/medium-term, the CRA is foreseen only for the dietary exposure; environmental aspects will be taken into account in the long-term.

For more details see slides presented during the meeting.

10. A possible survey to explore piloting an 'Interactive pesticide residue exchange platform (IPREP)'

EFSA presented an opportunity to participate in a survey exploring the piloting of an "Interactive Pesticide Residues Exchange Platform (IPREP)".

In the context of the EFSA Strategy 2027, aiming to intensify collaboration, the Strategic Objective 2 states that "*Strengthened partnerships are crucial and will result in the identification of priority areas for knowledge sharing, knowledge development and capacity building*."

To intensify collaboration several key elements have been identified, among them the improvement activities for enhancing knowledge sharing and the collaboration between EFSA and MSs, the communication intensification and exchange of

information (including the outcomes of regular science meetings) and for building a knowledge information community including EFSA, MSs and EU risk assessors.

Under the umbrella of the PSN, the IPREP has the aim of intensifying collaboration between EFSA and MSs.

EFSA communicated that a survey with MSs will be launched in December 2022 addressing four key elements (i.e. Design, Tools, Identify perceived training needs for MSs and Efficiency gains). In this context MSs will have the chance to express their interest in the targets set in the survey as well as contribute proactively including suggestions, trainings and additional proposals.

The outcome of the survey will be presented in 2023 to the PSN.

For more details see slides presented during the meeting.

11. Substance Identity check in PPP/CLH process

EFSA presented the Substance Identity (SID) check in the PPP/CLH processes, which is an activity jointly undertaken by EFSA and ECHA aimed at:

- avoiding possible discrepancies in the naming between the same substances handled by the two agencies; and
- reducing requests for changes raised at a late stage of the peer review process when amendments on naming consistently in all background documents would be difficult to be undertaken.

The SID check includes the name used to identify the substance and the related identifiers (e.g. EC/CAS numbers).

The legal framework setting the alignment of the PPP peer review process and CLH proposal process is Commission Implementing Regulation (EU) No 2020/1740 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009, and repealing Commission Implementing Regulation (EU) No 844/2012.

EFSA explained that it is expected that in the near future, in the case of renewal of approval of active substances falling in the scope of Commission Implementing Regulation (EU) No 2020/1740, the issue of misalignment between the CLH and PPP process will not be an issue anymore as the joint launching of the public consultation will occur on a standard basis. Indeed, in accordance with Article 11(9) of the said regulation, RMS has the obligation to submit the CLH report to ECHA (to obtain an opinion on a harmonised classification of the active substance at least for the hazard classes defined in Article 11(9), or to confirm the existing classification (where applicable), or for re-classification of the active substance in accordance with the criteria of Regulation (EC) No 1272/2008) at the latest at the same time when submitting the RAR to EFSA.

EFSA highlighted the need for alignment at the intake phase among EFSA and ECHA. Indeed EFSA is bound by strict legislative timelines allocated for the circulation of the assessment reports for commenting after receipt of the initial DAR/RAR to the applicant and to the other Member States, i.e. within max 3 months, in accordance with the provisions laid down in Art 12(1) of Regulation (EU) No 2020/1740 for circulation of the RAR and max 30 days, in accordance with the provisions laid down in Art 12(1) of Regulation (EC) No 1107/2009 for circulation of the DAR. In view of the parallel consultation on CLH/RAR, EFSA and

ECHA are committed to ensure alignment in their processes, however it was stressed the uncertainty with respect to the timelines for revisions of RAR/CLH by RMS still in the intake phase. EFSA would appreciate MSs compliance with the timelines for revisions of DAR/RAR requested by EFSA in the course of completeness check (CC), this will facilitate a lot meeting the requirements of the legislation. Further improvement of timelines in CC/ACC is explored between ECHA and EFSA.

With respect to the SID check, the aim would be to align it during the completeness check (CC) of the RAR and accordance check (ACC) of the CLH report in the scope of joint PCs in EFSA/ECHA. This activity is aimed to improve the consistency of assessments common to both PPP and CLH also in view of One Substance One Assessment (OSOA).

ECHA SID team will perform a systematic SID check for all upcoming PPP substances, even in the case where no alignment is foreseen, at an early stage, before the start of the process. This is expected to provide benefits to facilitate the alignment and avoid possible divergencies at a later stage. The SID check will be undertaken on a standard basis, for all upcoming PPP substances, including those having an ISO common name. Priority will be given depending on when the substance is expected to enter the peer review process.

In this respect, ES indicated that the SID check should be performed before the RMS submits the dRAR/DAR otherwise this would trigger delay in the process should the name of the substance needed to be revised in accordance with the outcome of the SID check. EFSA explained that Document J (reporting the confidential core data containing the raw data on composition of the substance and manufacturing process) is extracted from the applicants' dossier for the upcoming substances (AIR and NAS) entering the peer review and it is uploaded on EFSA's DMS external folders, accessible also by MSs, therefore the relevant information is made available to the RMS as early as possible in the process, thus even before the finalisation of the DAR/RAR.

In addition, EC asked whether the SID check is meant to be applied also to basic substances as there might be a value of doing this as several times the chemical identity of the material to be used as basic substance is not fully clear/defined.

EFSA noted that currently the SID check is performed only for renewals or NASs that are expected to enter in the peer review process. In this respect, EFSA also indicated that the SID check for renewal/NAS is undertaken in the first instance by the ECHA SID teams and then it is verified by EFSA phys-chem team; however, for basic substances, no ECHA involvement is foreseen. The SID check may be part during the EFSA scientific check (or if SANTE may request EFSA advice concerning the naming during the validity check phase).

For more details see slides presented during the meeting.

12. Mandate "Azole-resistant Aspergillus": update

EFSA (as coordinator of the activity) presented an update in relation to the joint mandate addressed to EFSA, ECHA, EMA, ECDC, EEA and the JRC on preparing a Joint Scientific Report on the impact of the use of the azole fungicides, other than as human medicines, on the development of azole-resistant Aspergillus spp

The important role of MSs was highlighted in providing details about the use of azole fungicides, other than as human medicines, in the EU/EEA by giving information on: i) the types of use, ii) the current and trend in quantities used, and iii) as much detail as possible on geographical variation. In this regard MSs will be invited to reply to a survey that will be circulated by EFSA on the uses of azole fungicides as PPP.

The terms of reference of the mandate and the work done so far in relation to the development of the list of azole substances from 4 Regulatory regimes: PPP, biocidal products, industrial chemicals, veterinary products were shortly introduced. It was clarified that substances which are not anymore "authorised/approved" are also included on this list (as a pragmatic approach relevant substances are included if approval expired after 2010). A collection of data will follow on quantities, types of uses and as much as possible on geographical variation as from 2010 – 2022. EC asked whether the selected timeframe, 2010 - 2022, for developing the azole inventory is sufficiently broad for looking at resistance building. EFSA indicated that such timeframe was firstly put forward by NL and that the other MSs concurred with this proposal as being a good compromise. In this respect, it was also noted that MSs may not have (accurate) data/information on such uses from earlier than 2010.

Moreover, it was clarified that when compiling the inventory, substances were checked against different regulatory frameworks (e.g. biocides, veterinarian medicines).

For more details see slides presented during the meeting.

13. Basic substances: Post-Transparency Process

The new provisions, following entry into force of the EFSA Transparency Regulation, applicable to basic substances (Article 23 of Regulation (EC) No 1107/2009) have been outlined by EFSA. As part of the regulatory basis, EFSA reported about the general framework mandate on basic substances setting out the terms of reference and procedure for technical assistance and scientific evaluation of applications concerning basic substances by EFSA. The general framework mandate has been updated to reflect the new process in line with the provisions of the Transparency Regulation, the updated EC working document on basic substances (rev 10) as well as the EC expectations for more elaborated EFSA scientific views. Overall, all these elements were leading to the need for revision of the EFSA Technical Report template for basic substances. In this respect, the content of the EFSA Technical Report as defined in the general framework mandate will contain:

- the finalised reporting table;
- dedicated sections with an overview of the main findings for each area of the risk assessment;
- overall conclusion on the potential safe use(s) and a new Appendix with considerations on the criteria for eligibility of the substance to be approved as basic substance as specified in Article 23 of Regulation (EC) No 1107/2009;
- consideration of the significance of identified data gaps;

- where feasible, an assessment of the identified issues of potential concern on the basis of expert judgement and/or taking into account existing EU or other regulatory/governmental assessments.

Following an internal testing and several consultation rounds with the European Commission, the EFSA Technical Report template has been finalised in September/October 2022 and has subsequently been shared with the PSN. The revised template will be used for applications submitted as of 27 March 2021 onwards following the new transparency rules. Following the request of the European Commission, some elements of the revised template (individual dedicated sections for the main findings in each section and considerations on eligibility criteria) will be implemented also for new admissible applications in the pipeline falling still under the pre-transparency rules. Overall, it is expected that the revised EFSA Technical Report template will prove to be better fit for purpose and any potential refinements may be further considered once experience with the new process is gained over time.

The European Commission stressed the importance to MSs to make use of the commenting phase on the basic substance applications, in which, as a new element, MSs and public will be given the possibility to provide additional information and supporting material on possible further uses of the substance for plant protection purposes beyond the uses supported by the applicant and/or proposing extensions of the scope of the application to further crops, if any. This would assist in increasing the efficiency and speediness of the approval process under the framework of the basic substances.

For more details see slides presented during the meeting.

14. EFSA workshop on updated Guidance document on the application Benchmark dose in chemical risk assessment

EFSA announced that an EFSA workshop on Benchmark Dose Approach is being organised to take place in February 2023 (most likely in Brussels and online). The workshop is aimed at: i) disseminating the update of the guidance by highlighting the newly introduced concepts and methodological framework proposed; and ii) focussing on pesticide examples in order to get the community of experts in this area aware and engaged.

MSs inquired whether this workshop may also be a forum for discussions/exchanges amongst MSs about the BMD approach. EFSA informed meeting participants that the workshop will be open for registration to all stakeholders (including industry experts) and that during the workshop there might be room for open dialogue and engagement between participants. In addition, it was noted that more discussion on the use of BMD may be planned at pesticide experts' meetings (general meetings) if deemed necessary and that a number of BMD trainings will be rolled out in the near future.

For more details see slides presented during the meeting.

Actions:

MSs will be requested by EFSA to nominate experts to be invited to the workshop.

15. Replies to questions from Observers

See Annex II.

16. Any Other Business

1. Sharing the revised RAR/DAR with the applicant during the peer review

   EFSA highlighted different approaches among the MSs in sharing/not sharing the updated DAR/RAR with the applicant during the peer review process. While EFSA does not wish to interfere in the relationship between the RMS and applicant, it was nevertheless noted that each applicant should be treated the same way. It was agreed to deal with this aspect by next PSN meeting.

2. IUCLID issues

   EFSA reminded MSs that as of 27 March 2021 applicants are legally required to submit dossiers on active substances via IUCLID. Consequently, CADDY dossiers should no longer be asked by MSs to applicants.

   Issues and difficulties in working with IUCLID are fully recognised and acknowledged. Notwithstanding, MSs are strongly encouraged to share the difficulties encountered with IUCLID in the IUCLID PSN forum and make the best use of the services/support offered by EFSA.

3. Declaration of Admissibility of dossier

   The European Commission highlighted the frequent issue related to delays in submitting the admissibility declarations by MSs, causing subsequently delays in the entire process. Therefore, it is important to identify the reasons behind these delays and to solve them.

ANNEX I

List of registered observers

Last Name	First Name	Name of Employer	Affiliation
COSTA	Vera	Iceta- Faculty Pharmacy University Porto	University/public research institute
PATEL	Priya	Enviresearch Ltd.	Private sector
CUNHA	Sara	Researcher	University/public research institute
REČIĆ	Maja	Croatian National Institute of Public Health	National authority
PUKLJAK	Ivana	Croatian National Institute of Public Health	National authority
SKÁCEL	Petr	National Institute of Public Health, Prague, Czech Republic	University/public research institute
ZEDNÍK	Josef	NIPH Czech Republic	University/public research institute
GRIMALDI	Amélie	Staphyt Regulatory	Private sector
IZEVKOVA	Adriana	Agrofarm	Private sector
HALEY	Alasdair	Corteva Agrisciences	Private sector
MONTAGNAC	Julie	corteva	Private sector
GARCÍA	Manuel	Manuel García	Private sector
GOLREIHAN	Asefeh	KUI aLeuven	University/public research institute
LÓPEZ DOVAL	Sergio	Seipasa	Private sector
SCHMIDT	Britta	Eurofins Agroscience Regulatory	Other
REXER	Hans Ulrich	Eurofins Agroscience Services Regulatory Germany GmbH	Private sector
GÓRAK	Monika	Synthos AGRO Sp. z o.o.	Private sector
SCHWIENTEK	Sabine	ibacon GmbH	Private sector
PASCUAL	Judith	BIOREGULATORY SERVICES	Private sector
MORRISS	Alistair	Blue Frog Scientific	Private sector
NANA	Boahene	Norwegian Scientific Committee for Food and Environment (VKM)	University/public research institute
YOSHII	Maria	Ceradis Crop Protection BV	Private sector
DALAGIORGOU	Maria	UPL	Private sector
SCHILLER	Marta	Self-employed	Other
SOLDEVILA	Ferran	Sun Chemicals services	Private sector
ANSEDE	Emma	Nichino Europe	Private sector
HUSZCZA-PODGÓRSKA	Anna	Green&Property Consulting	Other
KANE	Matthew	LKC	Private sector
BUERLING	Kathrin	Kathrin Buerling	Other
WEYMAN	Justine	ERM	Other
MOODLEY	Catherine	ERM	Private sector
NAG	Jayanta	UPL Limited	Private sector
BERNTSSEN	Marc	Institute of Marine Research, Bergen, Norway	University/public research institute
COGALNICEANU	Elena	EAS Strategies	Private sector

LAMPERTI	Sara	sara lamperti	Private sector
CHEN	Xinrong	UPL	Private sector
REDMOND	Aisling	UPL Limited	Private sector
ASWALKAR	Dipti	UPL	Private sector
ANAGNOSTOPOULOS	Chris	BENAKI PHYTOPATHOLOGICAL INSTITUTE	National authority
GAVRIL	Georgiana-Luminița	National Institute of R&D for Biological Science	University/public research institute
MARTINEZ	Juan Antonio	Universidad Politecnica de Cartagena	University/public research institute
OGER	Laurent	CropLife Europe	Private sector
HUSSEIN	Said	NATIONAL INSTITUTE OF PUBLIC HEALTH _CZECH REPUBLIC	National authority
MARIN-BENITO	Jesús	IRNASA-CSIC	University/public research institute
NITIN	Kshirsagar	PLX	Private sector
STEFANOU	Constantine Richard	EU-FORA	Other
HAVOLLI	Valmire	K	University/public research institute
HASSAN	Ashraf	L T FOODS LTD	Other
TSIRIGOTAKIS	Ioannis	Ioannis Tsirigotakis	Private sector
SOUAI	Dorra	Laboratory of Mycology, Pathology and Biomarkers, Faculty of sciences Tunis-Tunisia	University/public research institute
POLAT	Seyfettin	Pistachio Research Institute	University/public research institute
DAGUÈS	Nicolas	BASF	Private sector
ALCÓN	Francisco	Francisco	University/public research institute
IVANOVA	Tsvetelina	Agricalture university	University/public research institute
SCARDUZIO	Aurora	student	Other
ABRAHAMYAN	Luisa	EFSA	EFSA staff
KOWALSKI	Natalie	knoell Germany GmbH	Private sector
CARA	Magdalena	Magdalena Cara	University/public research institute
KAYA	Zeynep Esin	Ministry of Agriculture and Forestry	National authority
TRAVNICKOVA	Zdenka	National Institute of Public Health, Prague - CZ	National authority
MIROSAVLJEV	Maja	The National Institute of Public Health	University/public research institute
CERNOCH	Marek	National Institute of Public Health (NIPH)	National authority
OLIVEIRA	Ana	Direção-Geral de Alimentação e Veterinária	National authority
WANG	Yan	FMC CORPORATE	Other
BENIKOVA	Katarina	Central Control and Testing Institute of Agriculture in Bratislava	National authority
GINER	Marta	DEVREG	Private sector
DE MONTE	Leonardo	Dr. Schär	Private sector

CONTRERAS	Josefina	Universidad Politécnica de Cartagena	University/public research institute
DOBE	Christopher	Syngenta Crop Protection AG	Private sector
LOPEZ DE ALDA	Miren	IDAEA-CSIC	University/public research institute
CORNELESE	Adi	Adi Cornelese	Other
HIDALGO	Carmen	UNIVERSITAT JAUME I	University/public research institute
PASOI	Georgiana	National Phytosanitary Authority	National authority
PANAYOTOV	Nikolay	Agricultural University - Plovdiv	University/public research institute
ŠUMBEROVÁ	Hana	National Institute of Public Health, CZ	National authority
HATZI	Vasia	Benaki Phytopathological Institute	National authority
BEMPELOU	Eleftheria	Eleftheria Bempelou	University/public research institute
ZABALA	Jose A.	Universidad Politécnica de Cartagena	University/public research institute
BROUFAS	George	DEMOCRITUS UNIVERSITY OF THRACE	University/public research institute
VRYZAS	Zisis	Democritus University of Thrace	University/public research institute
EGEA	Francisco J.	UNIVERSITY OF ALMERIA	University/public research institute
GEORGIEVA	Mariyana	Institute of plant physiology and genetics	University/public research institute
IVANOV	Atanas	Atanas Ivanov	University/public research institute
POPOV	Vladislav	Agricultural University of Plovdiv	University/public research institute
SEIFI	Brecht	SAS Institute	Private sector
SATCHANSKA	Galina	New Bulgarian University	University/public research institute
CANONNE	Joanne	UPL	Private sector
HIPPER	Clémence	UPL	Private sector
SEMAR	Martin	BASF SE	Other
KAISER	Anna-Lena	Lignopure	Private sector
NAVA	Luis	Fruco	Private sector
SOLMAZ	Asli	IComplai	Private sector
CHANDA	Renusha	Tiger Brands	Private sector
GRUSZECKA-KOSOWSKA	Agnieszka	AGH University of Science and Technology	University/public research institute
SEPEHR	Aref	Padova University	University/public research institute
MINGUEZ GONZALEZ	Raquel	Government of Castille and Leon	National authority
HENRIQUEZ	Joseph	Corteva Agriscience	Private sector
TOMUSANGE	Joseph	Corteva Agriscience UK Ltd	Private sector
KEMENY	Monika	BASF SE	Other
SCHALLAU	Kai	Bayer	Private sector
LAMPERTI	Sara	Sara Lamperti	Private sector
PARTRIDGE	Jason	BAT	Private sector

SGOURI	Vassilia	Bayer SAS, Cropscience deptm	Private sector
NHOATO	ANDREA	FMC	Private sector
PIKULIK	Krystyna	Gowan Crop Protection	Private sector
PRIOUX	stephane	FMC	Private sector
PÉREX	María	Ascenza Agro	Private sector
PEREIRA	Ana	Ana Pereira	Private sector
STINCHCOMBE	Stefan	BASF SE	Other
JAMES	Barnali	FMC	Private sector
DE MONASTERIO	Patricia	UPL	Private sector
LECONTE	Florence	Arysta LifeScience SAS UPL group	Private sector
DOUAIHER	Marie-Noelle	Janssen PMP	Private sector
FALCIGNO	Pasquale	BASF Schweiz AG	Private sector
BOOTH	Michelle	Syngenta	Private sector
WHEALS	Ian	Syngenta Crop Protection AG	Private sector
TERRY	Claire	Corteva	International organisation
CRIOLLO	Rosa	FMC	Private sector
GREBEL-KOEHLER	Dörthe	Bayer AG - Cropscience Division	Private sector
NECTOUX	Eric	FMC	Private sector
GRANT	Claire	RSA	Private sector
EAVES	Samantha	TSG Consulting Ltd	Private sector
WIDHALM	Siegrid	SAN Agrow	Private sector
DONAT	Christina	e-nema	Private sector
LAPORTE	Frank	Bayer AG	Private sector
FELKERS	Edgars	Bayer AG	Private sector
DE WAEN	Berenice	ISK Biosciences Europe NV	Private sector
TRICHET	Lucile	POULIQUEN	Private sector
GADE	Jagdish	Vadilal industried limited	Private sector
CALLOL	Carles	JRF Global	Private sector
BIBARS-REITER	René	Fine Agrochemicals Ltd	Private sector

ANNEX II
List of questions from observers and answers

Questions received upon registration as well as questions posed during the meeting were answered as follows:

NUMBER	QUESTION	ANSWER
Q. 1 (Adi Cornelese)	The topic is particularly relevant for microbial products, as all these products need co-formulants acting as carriers for the spores of the micros and several of these carriers are also active substances (e.g. quartz sand). If these substances would be no longer allowed to be used in the PPP, then this could create issues for microbial products. Applicants are usually recommended to demonstrate that a co-formulant, approved as active substance, is not part of the pesticidal activity of the products. If the co-formulant (e.g. the carrier) is an active substance it would need an assessment and maybe a complete separate dossier should be prepared as chemical active substance.	EC indicated that formulations can contain two active substances.
Q.2 (Berenice De Waen)	In case of an active substance renewal process with a second active substance involved, could it happen that the endpoints or general data made available for the second active are re-opened during the renewal of the first active substance?	EFSA indicated that it is up to the EC to decide whether or not to re-open the assessment on the second active substance. EFSA clarified that if during the peer review specific concerns are identified, these will be duly reflected in the relevant conclusion and these will be handled/followed up by risk managers accordingly, e.g. applying an Article 21 procedure. Nevertheless, the European Commission indicated that it is not their intentions to systematically review the second active substance if it is part of the representative use(s).

Q.3 (Lauren Oger)	The consultation on the Annex III proposal in the Have Your Say portal is not yet open. Is there a launch date?	The EC clarified that the public consultation on the Annex III proposal (i.e. list of unacceptable co-formulants) is not yet open, though in the upcoming days it will be. The consultation will last 4 weeks. Post meeting note Consultation opened on 21st October 2022 and closing on 18th November 2022: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13416-Plant-protection-products-pesticides-identification-of-unacceptable-co-formulants_en
Q.4 (Haley Alasdair)	Is there any consideration of how to treat safeners in the representative formulation for renewals/new active submissions in advance of the data requirements for safeners and their EU review?	The EC is currently working on data requirements for safeners and synergists, but no draft act is available for the time being.
Q.5 (Emma Ansede)	What is the procedure in the event the CLH report has not been prepared by the RMS? Should the RMS take retrospective action to complete this task?	EFSA clarified that, pursuant to Article 11(9) of Regulation (EU) No 2020/1740, the RMS must submit the CLH report to ECHA at the latest at the same time when submitting the RAR to EFSA. Therefore, in the absence of the CLH report, the submitted RAR would likely not pass the admissibility check by EFSA leading to request for re-submission.
Q.6 (Ferran Soldevila)	Why specific bio-pesticides are used in several countries around the world and not present in Europe; and why there isn't a specific regulation for biopesticides? Furthermore, why the bio-pesticides take 7 years to access the European market instead of 2 years required in other regions?	The EC replied that not all bio-pesticides need 7 years to access the EU market. The timeframe depends on the quality of the dossiers provided. Based on current experience, 3 years (in general) are needed from the receipt of the dossier until its approval. Furthermore, for what concerns the current legislative framework, it comprises of regulations setting out data requirements for chemicals

		(including also pheromones) and microorganisms. There is no intention for further specific legislation for bio-pesticides as they are covered by the legislation in place. EC referred to point 1.5 of the Annex of Reg.283/2013, which clearly states that some data requirements might not apply in particular cases if duly scientifically justified (e.g. because of the exposure or mode of action of the particular active substance). Therefore, the legislation in place is flexible enough to also address bio-pesticides and low risk active substances.
Q.7 (Adi Cornelese)	The DR are not suitable for UVCBs/complex mixtures. This is a major problem for a.s. like plant extracts. Update of the GD is much welcomed. The current one is the result of lots of discussion (I am one of the authors) and certainly not optimal.	The EC explained that there is a SANCO guidance document for botanicals (SANCO/11470/2012 – rev.8), which may be updated in the next future. EC referred to point 1.5 of the Annex of Reg.283/2013 (see Q6). In addition, applicants have the possibility to have pre-submission advice/meeting with the RMS and/or EFSA; and with the new Transparency Regulation provisions, also general and renewal pre-submission advice is given by EFSA. Applicants are warmly encouraged to exploit these services.
Q.8 (Laurent Oger)	An observer highlighted the high trend in submissions of bio-pesticide dossiers and he is asking how EFSA is organising itself in bringing relevant expertise.	EFSA replied that the composition of the EFSA Panel on Plant Protection Products and their Residues (PPR Panel) will soon be renewed and that each Panel renewal enables EFSA to review the scientific expertise needed in a given Panel. EFSA is also launching outsourcing activities (e.g. Tasking Grants, Scientific and Technical Support scheme) to ensure that it has access to most relevant scientific expertise.

		It was also noted that several BTSF training courses will be organised by the European Commission for capacity building purposes in MSs. Similarly, to the ED area, EFSA is considering the establishment of a WG on micro-organisms as pesticides aiming to give advice to MSs and to be eventually used as an advisory forum for the peer review. EFSA informed that in the second half of next year is planning to organise a peer review meeting dedicated to general issues on the assessment of micro-organisms as pesticides.
Q.9	An observer asked whether EFSA was aware about the work published by Croplife Europe experts' groups on the screening assessment of the co-formulants under REACH.	EFSA replied that it was not aware of that project and it is willing to receive any information/data on co-formulants from industries.