PESTICIDE PEER REVIEW UNIT

# Scientific Panel on Plant Protection Products and their Residues

# Minutes of the 118th Plenary meeting

**Held on 7 December 2022 (web-conference)**

**(Agreed on 5th January, 2023)**

## Participants

- Panel Members:

  Paulien Adriaanse, Annette Aldrich, Philippe Berny, Tamara Coja, Sabine Duquesne, Antonio Hernandez-Jerez (chair), Marina Marinovich, Maurice Millet, Olavi Pelkonen, Silvia Pieper, Aaldrik Tiktak, Christopher Topping, Anneli Widenfalk, Martin Wilks, Gerrit Wolterink

- Hearing Experts:

  Not Applicable

- European Commission and/or Member States representatives:

  Not Applicable

- EFSA:

  PREV Unit: Fernando Alvarez, Maria Arena, Domenica Autieri, Marco Binaglia, Anna Castoldi, Arianna Chiusolo, Anna Cioca, Mark Egsmose, Gabriella Fait, Frédérique Istace, Dimitra Kardassi, Anna Lanzoni, Roberto Lava, Alberto Linguadoca, Christopher Lythgo, Iris Mangas, Laura Padovani, Martina Panzarea, Juan Parra Morte, Simone Rizzuto, Rachel Sharp, Manuela Tiramani, Laura Villamar

  PRES Unit: Andrea Mioc, Renata Leuschner

  COM Unit: Francesca Avanzini, Bernd Elzer

  MESE Unit: Laura Martino, Agnès Rortais

  ED Office: Yann Devos

- Observers:

  See Annex I

- Others:

  Not Applicable

## 1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Andreas Focks.

## 2. Adoption of agenda

The agenda was adopted without changes.

## 3. Declarations of Interest of Scientific Committee/Scientific Panel/ Members

In accordance with EFSA's Policy on Independence and the Decision of the Executive Director on Competing Interest Management, EFSA screened the Annual Declarations of Interest filled out by the Panel members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process.

## 4. Brief introduction of Panel Members and Observers

Panel members and EFSA Secretariat introduced themselves to the observers.

## 5. Presentation of the EFSA guidelines for Observers

EFSA presented the guidelines for observers for open plenary meetings.

## 6. Scientific outputs submitted for discussion and/or possible adoption, updates on ongoing activities, new projects

### 6.1 Development of Adverse Outcome Pathways relevant for the identification of substances having endocrine disruptors properties (EFSA-Q-2019-00492)

The Panel was informed on the comments received from reviewers (Gerrit, Olavi and Sabine) and other Panel members and how they were addressed. The Scientific Opinion was adopted unanimously.

### 6.2 Use and reporting historical control data (HCD) for regulatory studies (EFSA-Q-2021-00274)

The Panel was updated on the progress of the project and the planning for the next steps.

### 6.3 Request for a Statement on the design and conduct of groundwater monitoring studies supporting groundwater exposure assessments of pesticides (EFSA-Q-2021-00788)

The Panel was updated on the status of activities and planning for the finalisation of the output. Three Panel members (Silvia, Annette and Anneli) were nominated to act on behalf of the Panel as reviewers of the output before the foreseen adoption.

## 7. Other activities

### 7.1 Follow-up of the Roadmap for PERA (EU Partnership for next generation, systems-based environmental risk assessment)

As a follow-up of the outsourced activities (EFSA-Q-2022-00284)[1], The Panel was informed on a multiannual plan to advance the ERA that EFSA is currently working on. It considers regulatory needs (i.e., revision of existing Guidance Documents) in a wider context (e.g., to acknowledge the strategies of EU Green Deal).

### 7.2 On-going activities of the Scientific Committee

The chair updated the Panel on a number of activities of the Scientific Committee (SC), and in particular on:

- Revised Guidance on BMD approach;
- Re-evaluation of the existing HBGVs for copper and exposure assessment from all sources;
- Update of the Guidance on Particle – Technical Requirements (Annex on 'Degradation/dissolution rate under acidic conditions');
- EC mandate on Fluoride;
- Guidance on Read-across (RAx);
- Technical report to assess reliability and relevance of the Genotoxicity studies;
- Workshop on Biomarkers of effect.

[1] Building a European Partnership for next generation, systems-based Environmental Risk Assessment (PERA), https://efsa.onlinelibrary.wiley.com/doi/abs/10.2903/sp.efsa.2022.EN-7546

## 8. Q&A

Questions received upon registration as well as questions posed during the meeting were answered by the Panel and EFSA Secretariat (see Annex II).

## 9. AOB

None.

# ANNEX I

## List of observers

| Last Name | First Name | Name of Employer | Affiliation |
|---|---|---|---|
| Aksu | Pelin | Ministry of Agriculture and Forest | National Authority |
| Aktug | Uzeyir | Zirai Mücadele Merkez Araştırma Enstitüsü Müdürlüğü | University/public research |
| Alvarado | Karol | - | Other |
| Athanasiadis | Konstantinos | Hellenic Republic - Ministry of Rural Development and Food | National Authority |
| Aydar | Arzu | Plant protection central research institute | University/public research |
| Baša Česnik | Helena | Agricultural Institute of Slovenia | University/public research |
| Behr | Christina | RIFCON GmbH | Private sector |
| Bignami | Chiara | CSO Italy | Private sector |
| Boahene | Nana | Norwegian Scientific Committee for Food and Environment (VKM) | University/public research |
| Bothe | Kathrin | Bayer AG | Private sector |
| Bovicelli | Chiara | - | Private sector |
| Bukovec | Primož | Slovenian Institute of Hop Research and Brewing | National Authority |
| Burcak | Aydan | Mınistry of Agriculture and Foresty Plant Potection Research Institute | University/public research |
| Cermak | Matej | Ministry of health of the Czech Republic | National Authority |
| Chen | Xinrong | UPL | Private sector |
| Ciccotelli | Valentina | Istituto Zooprofilattico del Piemonte, Liguria e Valle D'Aosta | National Authority |
| Collarile | Magda | Team mastery S.r.l. | Other |
| Corvaro | Marco | Corteva Agriscience | Private sector |
| D'Amore | Teresa | Istituto Zooprofilattico Sperimentale di Puglia e Basilicata | National Authority |
| De Paoli | Gabriele | UPL | Private sector |
| Demiröz | Duygu | Republic Of Türkiye Ministry of Agriculture and Forestry Directorate Of Plant Protection Central Research Institute | University/public research |
| Dénes-Krutilla | Csilla | Pannon Analitika | Private sector |
| Dobiczek | Maria | Synthos Agro Sp. z o.o. | Private sector |
| Duman | Kamil | Plant Protection Central Research Institute | National Authority |
| Engelbrecht | Vera | PETA Science Consortium International e.V. | NGO |

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| Erdurmuş | Gamze | Republic Of Türkiye Ministry Of Agriculture And Forestry Directorate Of Plant Protection Central Research Institute | University/public research |
| Esposito | Mauro | Istituto Zooprofilattico Sperimentale del Mezzogiorno | Other |
| Fatur | Tanja | National Institute of Public Health | National Authority |
| Federici | Arianna | Student | Other |
| Goldmann | Till | Nestlé | Private sector |
| Gottesbueren | Bernhard | BASF SE | Private sector |
| Grandesso | Emanuela | Team Mastery | Private sector |
| Greco | Emanuele | Università Cattolica del Sacro Cuore | University/public research |
| Heni | Aymen | Veterinary services | National Authority |
| Hofmann | Thomas | BASF SE | Other |
| Kalaitzoglou | Joanna | Ministry of Rural Development and Food | National Authority |
| Karalis | Thanasis | Imerys Industrial Minerals S.A. | Private sector |
| Karazafeiris | Emmanouil | Ministry Of Rural Development and Food | National Authority |
| Kennel | Philippe | Bayer Cropscience | Private sector |
| Kralj | Edgar | Croatian Agency for agriculture and Food (HAPIH) | National Authority |
| Krzywonos | Małgorzata | Wrocław University of Economics and Business | University/public research |
| Lagadic | Laurent | Bayer AG Crop Science, R&D, Environmental Safety | Private sector |
| Listiani | Wendy Sri | Wageningen University and Research | University/public research institute |
| Lončarić | Paula | Croatian Agency for Agriculture and Food | National Authority |
| Lòpez | Sergio | Seipasa | Private sector |
| Madloo | Pari | Freelancer | Private sector |
| Martin-Opačić | Marijana | Croatian Agency for Agriculture and Food | National Authority |
| Melching-Kollmuss | Stephanie | BASF SE | Private sector |
| Menaballi | Luca | Team Mastery S.r.l | Private sector |
| Michaux | Jean | Université Paris Cité | University/public research institute |
| Müller | Dennis | Bayer AG | Other |
| Muresan | Daniela | National Institute of Public Health Romania | National Authority |
| Newcombe | Andy | Arcadis | Other |
| Nikl | Nataša | Croatian Agency for Agriculture and Food, Center for Plant Protection | National Authority |
| Padovani | Alexandre | FMC Coorporation | Private Sector |
| Paina | Andrea | ISPRA - The Italian Institute for Environmental Protection and Research | University/public research institute |
| Popov | Vladislav | Agricultural University of Plovdiv | University/public research institute |

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| Raicea | Camelia | National Institute of Public Health Romania | National Authority |
| Remešicová | Erika | Water Research Institute | University/public research institute |
| Ricciardi | Caterina | EuchemS | NGO |
| Rosato | Roberta | IZSAM | University/public research institute |
| Sagner | Anne | RIFCON GmbH | Private Sector |
| Santos Beade | Maria | Unicef | International organisation |
| Scarduzio | Aurora | Università degli Studi di Parma | University/public research institute |
| Scherer | Barbara | SCC GmbH | Private Sector |
| Schiller | Marta | Self-employed | Other |
| Schutte | Maaike | ADAMA Northern Europe BV | Private Sector |
| Sousa | Sofia | Toxicology Team Coordinator | Private Sector |
| Stanojevic | Dragana | ISI Food Protection | Private Sector |
| Šumberová | Hana | National Institute of Public Health CZ | National Authority |
| Sur | Robin | Bayer AG Crop Science Division | Private Sector |
| Tan | Nico | APIS applied insect science B.V. | Private Sector |
| Vaysse | Pierre-Maxence | Bayer | Private Sector |
| Wołoszynowska | Małgorzata | Main Inspectorate of Plant and Health Seed Inspection | National Authority |
| Yigit | Nuran | Ministry of Agriculture and Forestry | National Authority |
| Zarn | Jürg | Swiss Federal Food Safety and Veterinary Office FSVO | National Authority |
| Zednìk | Josef | NIPH Prague, Czech Republic | University/public research institute |

## ANNEX II

## List of questions from observers and answers

| No. | OBSERVER | QUESTION | ANSWER |
|---|---|---|---|
| **General questions** | | | |
| **1** | **Robin Sur**<br><br>Bayer AG Crop Science Division | Is there already any recommendation that EFSA can provide to notifiers that are planning to conduct regulatory monitoring studies according to Gimsing et al. (2019)? | The Statement of the Scientific Panel on Plant Protection Products and their Residues (PPR Panel) on the design and conduct of groundwater monitoring studies supporting groundwater exposure assessments of pesticides is under preparation taking into account the Terms or References provided by the European Commission for this mandate. Therefore, it is not possible at this moment to provide recommendations on the design and conduct of groundwater monitoring studies. Official guidance is available from the European Commission (2014)[1] on approaches for the use of groundwater monitoring data at Tier 4.<br><br>[1]European Commission, 2014. Assessing Potential for Movement of Active Substances and their Metabolites to Ground Water in the EU. Report of the FOCUS Ground Water Work Group, EC Document Reference Sanco/13144/2010 version 3, 613 pp. |
| **2** | **Thanasis Karalis**<br><br>IMERYS INDUSTRIAL MINERALS S.A. | Is there going to be any regulatory prediction -or even new framework- for adjuvants or co-formulants which present a proven secondary function, e.g. they act as | EFSA is working with Member States (MSs) to establish more consistency in the risk assessment of formulations for representative uses, with a focus on the role |

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| | | binders of pesticides residues in the soil or other chemical compounds residues? | of co-formulants. The example reported in the question is something that has not occurred so far according to the assessment prepared by MSs. The information will be shared with MSs as a point of attention, and the question could be addressed to SANTE for clarification. |
| **3** | **Teresa D'Amore**<br><br>Istituto Zooprofilattico Sperimentale di Puglia e Basilicata | Probably at the end of this year/start of the new one, new hazard classes were added in CLP (EDCs and PMT vPvM). At the same time SUD (Dir 128/2009) will be updated. What will be the impact on the PPPs market (e g. changes in cut-off criteria)? | EFSA and its Panel on PPPs are risk assessment bodies. Therefore, it is not in their remit to perform impact analysis on PPPs market when new or revised Regulations are implemented. It has to be noted, though, that since 2018, cut-off criteria related to endocrine disruptors have been included in point 3.6.5 (human health) and 3.8.2 (non-target organisms) of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605. |
| **Questions related to item 6.- Development of Adverse Outcome Pathways relevant for the identification of substances having endocrine disruptors properties (EFSA-Q-2019-00492)** | | | |
| **4** | **Laurent Lagadic**<br><br>Bayer AG Crop Science, R&D, Environmental Safety | Epigenetic modulation includes a variety of complex mechanisms. How does this fit with a single key-event? | Thank you for the comment, this part of the AOP network was developed by the awarded contractor (Viviani et al, in progress).<br><br>"Epigenetic regulation" was identified as a relevant KE following ER activation: activated ER can attract co-regulatory proteins like histone acetyltransferase or related enzymes involved in epigenetic DNA modulation, this supports the biological plausibility of the KER "ER activation" leading to "Epigenetic modulation". Evidence suggesting estradiol as a player in epigenetic mechanisms has been identified in breast cancer, but is less established in |

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| | | | uterine adenocarcinoma pathogenesis, and therefore a systematic search was conducted.<br><br>The KE (epigenetic modulation) developed in Viviani et al. does include different types of epigenetic events e.g., related to methylation (hypo/hypermethylation), acetylation/deacetylation, miRNA and lncRNA. |
| **5** | **Laurent Lagadic**<br><br>Bayer AG Crop Science, R&D, Environmental Safety | Were the Bradford-Hill criteria (e.g., biological plausibility, essentiality, strength of empirical evidence) applied to the proposed AOP/AOP Network? | All KERs included in the network were weighted in terms of biological plausibility and empirical support. KEs essentiality was also addressed as part of the KER. The<br>The criteria and recommendation on how to assess the KER (reported in the AOP handbook) were applied.<br>The methodology applied will be further explained by Laura Martino in the second part of the presentation. |
| **6** | **Melching-Kollmuss Stephanie**<br><br>BASF SE | Many thanks for the detailed explanation. You seem to have set up quite a formalized full review and assessment approach. Any next AOPs on the horizon, you are going to look into? Regarding implementing quantitative elements in an AOP, do you think, that the quantitative certainty assessment of the KERs (step 4) is sufficient? This is rather a formalized weight of evidence and probabilistic qualitative approach, than bringing in quantitative elements? | Developments on AOPs for ED are foreseen. A grant has just kicked off for developing AOP network(s) on ED for reproductive toxicity, offering the opportunity to develop on methodology too and to progress on regulatory acceptance.<br>Certainty quantification of KERs and associated methodology will evolve, capitalizing the experience from this opinion and other AOPs<br>Quantitative AOPs (i.e., quantitative understanding of the KERs) is indeed a different concept but methodology is evolving also in this direction (see e.g., Hassan et al., 2017). However, overall, it is |

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| | | | noted that both these elements are fundamental in the regulatory application of AOPs. |
| **7** | **Marco Corvaro**<br><br>Corteva Agriscience | Methodology question - re pillar 1 "protocol development" and pillar 4 "uncertainty" shown by Laura: could you please clarify if this methodology applies only to a generation of scientific assessment by EFSA such as SO/GD, or are these supposed to be used by RMS/EFSA or applicants for AOP assessment during Peer Review process? I believe the 2017-8 EFSA GDs on WoE, biological relevance and uncertainty analysis, are currently used and would be still relevant for this second purpose; I'd appreciate your confirmation. thank you. | At the moment the implementation of the protocol approach and the uncertainty analysis is mandatory for the so-called 'generic-assessments' (i.e. not related to applications) in EFSA. The principles behind those GD could be applied equally to the assessments related to applications. However, the application domain is strictly regulated and the implementation of any new methodology requires discussion and agreement with stakeholders (Member States (first assessor for pesticide applications), EC and applicants). |
| **Questions related to item 6.2 - Use and reporting historical control data (HCD) for regulatory studies (EFSA-Q-2021-00274)** | | | |
| **8** | **Laurent Lagadic**<br><br>Bayer AG Crop Science, R&D, Environmental Safety | It seems that the focus for HCD is currently more on mammalian toxicological studies (e.g., carcinogenicity studies). Are ecotoxicology studies included? | The Scientific Opinion aims to develop criteria for the acceptability of HCD and their integration in the index study. Therefore, they may be applicable to the ecotoxicological studies when relevant endpoints, covered by studies from the historical data set, have been investigated. |
| **9** | **Jürg Zarn**<br><br>Swiss Federal Food Safety and Veterinary Office (FSVO) | Thank you for the presentation. Typically HCD are used to avoid potentially false positive decisions. Will the Opinion also evaluate what role HCD should play to also avoid possibly false negative decisions to ensure balance in evaluations?<br>A second question: will the Opinion also discuss variability in HCD in the context of study design variability? | Indeed, HCD are currently primarily used to provide context to positive findings as one line of evidence. The opinion will make reference to methods for providing context also to potentially false negative findings. How exactly we can do that depends on what the evidence shows in the examples that we can find. |

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| | | | Variability in study conditions (biological, environmental, experimental variability) is covered by the first Terms of Reference (ToR) and will be therefore discussed in the Scientific Opinion. This aspect links with requirements the HCD have to meet in order to be integrated with concurrent control. |
| **Questions related to item 6.3 - Request for a Statement on the design and conduct of groundwater monitoring studies supporting groundwater exposure assessments of pesticides (EFSA-Q-2021-00788)** | | | |
| **10** | **Bernhard Gottesbueren**<br><br>BASF | Microbial population in GW are usually eliminated during water treatment e.g. for hygienic purposes). Is this a point of debate? | This issue has up till now not been discussed by the working group. It may be more relevant for other mandates related to drinking water treatment. An EFSA_ECHA activity (EFSA-Q-2020-00127) is ongoing on water treatment process and is expected to be finalized in June 2023. |
| **11** | **Robin Sur**<br><br>Bayer AG Crop Science Division | Modelled PECgw compared to monitoring (public or targeted data) is almost always greater, which shows already a good protectiveness of the current modelling approaches. | The conservativeness of the tiered approach in FOCUS groundwater is discussed in the working group. Higher tiers are intended to provide lower concentrations than in lower tiers in the assessment scheme although in practice this may not always be the case. |