SCIENTIFIC PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES

123rd Panel Plenary meeting – OPEN to observers

07 - 08 November 2023
14:00-17:30 / 09:00-13:00
MINUTES - Agreed on 17 November 2023

Location: EFSA, Parma and Teleconference (for Observers)

Attendees:

- Panel Members:
Pauline Adriaanse, Annette Aldrich, Philippe Berny, Tamara Coja, Sabine Duquesne, Andreas Focks, Antonio Hernandez-Jerez (chair), Marina Marinovich, Maurice Millet, Olavi Pelkonen, Silvia Pieper, Aaldrik Tiktak, Anneli Widenfalk, Martin Wilks, Gerrit Wolterink
- Hearing Experts[1]:
Not Applicable
- European Commission and/or Member States representatives:
Not Applicable
- EFSA:

  PREV Unit: Sofia Batista Leite, Marco Binaglia, Anna Federica Castoldi, Arianna Chiusolo, Katia Chukwubike, Mathilde Colas, Federica Crivellente, Frederique Istace, Dimitra Kardassi, Anna Lanzoni, Matteo Lazzari, Renata Leuschner, Jochem Louisse, Iris Mangas, Tunde Katalin Molnar, Martina Panzarea, Juan Parra Morte, Monica Nepal, Andrea Terron, Manuela Tiramani, Giorgia Vianello

  PLANTS Unit: Fernando Alvarez, Maria Arena, Domenica Auteri, Gabriella Fait, Roberto Lava, Christopher Lythgo, Vincenzo Padricello, Laura Maria Villamar Bouza, Elena Zioga

  MESE Unit: Laura Martino

  FIP Unit: Gloria Lopez Galvez

  HUCAP Unit: Kehinde Olajide
- Observers:

See Annex I

1. Welcome and apologies for absence

The Chair welcomed the participants and the observers.
Apologies were received from Christopher Topping.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Panel members

[1] As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf

In accordance with EFSA's Policy on Independence[2] and the Decision of the Executive Director on Competing Interest Management3, EFSA screened the Annual Declarations of Interest filled out by the Working Group 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, and no interests were declared orally by the members at the beginning of this meeting.

4. Panel members introduction

Panel members and EFSA staff introduced themselves to the observers.

5. Presentation of Guidelines for observers

EFSA presented the guidelines for observers for open plenary meetings.

6. Scientific output(s) submitted for discussion/adoption

6.1 Draft Opinion on 'Use and reporting historical control data (HCD) for regulatory studies' (EFSA-Q-2021-00274)

The Panel was updated on the progress made by the Working Group during 2 meetings in October. Draft Opinion and Annexes, still under development, were introduced to the Panel together with planning for finalisation. Marina, Sabine and Gerrit were nominated to act as reviewers on behalf of the Panel. Based on the feedback received, the Working Group will finalise the draft before endorsement for public consultation (launch foreseen in March 2024).

7. Other scientific topics for information/discussion

7.1 Update from the ED WG and EFSA ED database

The Panel was updated on the activities of the EFSA Endocrine Disruptors (ED) Working Group and on the EFSA database collecting available data and conclusion for the assessed substances since the implementation of the ECHA/EFSA ED Guidance and Regulation 2018/605.

7.2 PPR Panel 2024-2029: workplan

The Panel was informed on the outcomes of the EFSA internal workshops recently held to collect possible future developmental activities aiming at shaping a workplan for the upcoming mandate of the PPR Panel.

7.3 Waiving of dog studies for pesticides risk assessment

Background information for a developmental activity on the waiving of dog studies in the risk assessment of pesticides was presented for discussion. The Panel agreed to self-task the activity.

[2] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf
[3] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

7.4 PBK modelling for quantitative interpretation DNT-IVB

Background information for a developmental activity on the use of PBK modelling for quantitative intepretation of Developmental Neurotoxicity (DNT) In Vitro Testing Battery (IVB) data. The Panel agreed to self-task the activity.

7.5 Cumulative Risk Assessment: update on ongoing activities

The Panel was updated on the status of the activities for the cumulative risk assessment (CRA) of pesticide residues.

7.6 One Substance One Assessment

The Panel was updated on the EFSA activities for the implementation of the "One Substance One Assessment (1S1A)" concept proposed in the European Commission Chemicals Strategy for Sustainability.

8. and 9. Q&A Session

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

10. AOB

None.

11. Next meeting

The next meeting will be held on 21 February 2024, via teleconference.

Annex I List of Observers

Observer	Organization
Alberti Ilaria	CREA CI
Bakro Fatema	BfR
Balzan Silvia	University of Ferrara
Belenguer Veronica	Kerona Scientific
Bellucci Valter	ISPRA
Bono Gioacchino	National Research Council
Bourne Richard	TSG Consulting
Bragard Claude	UCLouvain
Bura Laszlo	NEVEX Institute Ltd.
Cantatore Andrea	Regione Lombardia
Carpentieri Ilaria	IZSLT
Cassar Mark	Malta Competition and Consumer Affairs Authority (MCCAA), Technical Regulations Division (TRD)
Cipolla Ramona	Francia Latticini spa
Comes Ana	Conselleria de Sanitat de Valencia, España
Debecker Sara	ARCHE Consulting
Demortain David	INRAE
Dénes-Krutilla Csilla	Pannon Analitika
Dobiczek Maria	Synthos Agro Sp. z o.o.
Drozdzynski Dariusz	Institute of Plant Protection - NRI
Eghbalinejad Mahla	Masaryk University
Federico Lorenzo	Università degli Studi Milano-Bicocca
Federowicz Agnieszka	Main Plant Health and Seed Inspection Service (SPHSiS)
Giner Marta	Devreg Consulta
Hegedüs György	National Food Chain Safety Office
Hidalgo GádorIndra	Laboratorio Arbitral Agroalimentario. Ministerio de Agricultura, Pesca y Alimentación
Jin Qiwen	Syngenta
Krivohlavek Adela	Teaching Institute of Public Health
La Rocca Cinzia	Istituto Superiore di Sanità

Leedale Joe	Syngenta
Mantovani Alberto	Italian National Food Safety Committee
MIHAYLOVA Dasha	University of Food Technologies
Milano Azzurra	ASST Fatebenefratelli - Sacco
Mineo Desiree	Syngenta
Othim Stephen	Ditarm consulting ltd
Padovani Alexandre	FMC Corporation
Paina Andrea	ISPRA - Institute for Environmental Protection
Palmiotto Marinella	ICPS (international Centre of pesticides and health risk prevention)
Pereira Andre	Ascenza
Pérez María	Albaugh
Picciolo Massimiliano	ENEA
Pignoni Elisa	PHD
Rachtan-Janicka Joanna	Warsaw University of Life Sciences
Reijnhoudt Hieke	Fresh Produce Centre
Renahan Tess	PETA Science Consortium International e.V.
Rylkov Igor	FGBU VNIIKR
Salmazo Natalia	Albaugh Europe
Sbernini Alice	IZSLT
Silli Valerio	ISPRA
Stier Agnes	National Food Chain Safety Office (Hungary)
Šumberová Hana	National Institute of Public Health CZ
Thouvenin Isabelle	HumExpo SAS
Webb Morag	COLEAD
Zarn Jürg	Federal Food Safety and Veterinary Office FSVO
Zidda Cosimo	Istituto Zooprofilattico Sperimentale della Sardegna
Τηοµloudi Eirini	SustChem Technical Consulting SA

ANNEX II

List of questions from observers and answers

No.	OBSERVER	QUESTION	ANSWER
General questions			
1	**Nafosat Kurbonova** Plant Protection and Quarantine Scientific Research Institute	Beneficial nematodes are effective biocontrol agents against agricultural crop pests, and as a result we can reduce the amount and risk of using many pesticides. In this regard, is it possible to get scientific and financial support in Central Asian countries, especially in Uzbekistan, to carry out the experience of mass breeding useful nematodes in standard biolaboratories and using them in the open field? For example, through grants and online courses, I think we can further reduce the risk of pesticides by deepening IPM and biocontrol.	The question is considered out of scope as not related to the agenda. EFSA is funding grants and procurements in relation to projects supporting EFSA in carrying out its operations. We invite you to check the dedicated pages to be updated on activities of potential interest: https://www.efsa.europa.eu/en/calls/procurement https://www.efsa.europa.eu/en/calls/art36grants
2	**Davide Rizzo** Food technologist	To date, what is the most dangerous chemical to our health potentially found in food? What could be the alternatives and how is Europe moving forward?	The question is considered out of scope since the PPR Panel is only dealing with the risk assessment of pesticides. In the area of pesticides, following the publication of the Chemical Strategy for Sustainability and the European Green Deal, a number of initiatives are proposed to try to reduce the use of pesticides and reach the goals of zero pollution. One of this is the publication of European Commission publishes toolbox of Integrated Pest Management practices, i.e., use of natural methods whenever possible and chemical pesticides as last resort. For questions on other food domains or of general nature we invite you to contact EFSA through https://www.efsa.europa.eu/en/applications/askaquestion
Questions related to item 7.1- Update from the ED WG and EFSA ED database			

3	**Alberto Mantovani** Istituto Superiore di Sanità	Thyroid: why adults? Should juveniles be more sensitive?	Thyroid endpoints in the form of thyroid histopathology, thyroid weight and thyroid hormones and TSH are included in several TG studies. There is a quite strong correlation between thyroid weight and thyroid histopathology and the young adult male rat is known to be the most sensitive population because of the baseline status of thyroid gland activation and the low reserve of circulating T4 mainly due to the very low level of circulating TBG; making the young adult rat as very sensitive model for substances perturbing the HPT axis. However, this is not the population of concern as the AO of concern is mainly (if not only) the developing brain. The dams, fetus and neonatal rat is therefore representing the correct population for the assessment of TDC. This is also representing the most adequate population from the physiological condition because the neonatal rat has a much higher level of TBG when compared to the young adult rat and closer to the human condition. For this reason, the CTA study should be considered the in vivo gold standard for thyroid assessment.
4	**Jin Qiwen** Syngenta	Does EFSA consider using the modeling method to address the positive result in the ED in vitro mechanistic studies instead of going straight to animal testing?	EFSA is considering qIVIVE, PPBK modeling and reverse dosimetry as valuable methods to be applied in RA. For the regulatory definition of the ED properties of an a.s. the inclusion of the hazard identification is a mandatory step and the current criteria, and the ED GD are not giving a definition of what should be considered an in vitro hazard. Therefore, although the question is overall relevant for EFSA, is not applicable for the assessment of the ED properties following the current regulation.
5	**Alberto Mantovani** Istituto Superiore di Sanità	Hormone measurements (insulin, leptin..) can suggest the concern for metabolic syndrome if used as standard parameters in in vivo assays?	This is theoretically true. The current problem is that an animal model replicating the "metabolic syndrome" is very hard to reproduce. Even with the known antipsychotic drugs, which are recognized to induce the metabolic syndrome in treated patients, the syndrome is hardly reproducible in an in vivo animal model. Therefore, the scientific readiness of using these endpoints to predict an ED AO consequent to xenobiotics exposure needs more work.
6	**Tess Renahan** PETA Science Consortium International e.V.	Is the ED WG in discussions with the US EPA regarding their recent EDSP updates and are they discussing ways to share data and ensure the minimization of duplicated in vivo tests?	Although, a formal procedure for data sharing is not in place, EFSA is constantly working in collaboration with US EPA for the assessment of endocrine disruptors. US EPA representatives are member of the EFSA ED WG. It has also to be noted that applicants have the legal obligation to submit all available data available with a substance dossier and this, therefore, also refer to data performed to comply with regulatory requirement of non-EU legal frameworks. Nevertheless, EFSA constantly checks the US EPA website for substance specific data in this context.
Questions related to item 7.2 - PPR Panel 2024-2029: workplan			

7	**Tess Renahan** PETA Science Consortium International e.V.	What is the process for developing and updating EFSA guidance documents, especially to reflect new non-animal methods? How is the panel involved in the Commission's NAMs roadmap (concerning the decision to transition to a non-animal regulatory system)?	In 2022 EFSA published the" Development of a Roadmap for Action on New Approach Methodologies in Risk Assessment", see link below: https://www.efsa.europa.eu/en/supporting/pub/en-7341 The road map is based on multiple aspects for the inclusion of NAMs in the risk assessment and several case studies are included as Proof of Concept studies (POCs) for the use of NAMs in different areas of the EFSA remit, including PPPs. The implementation of NAMs is part of the EFSA strategy 2027 and is therefore a common item in the EFSA agenda. The PPR Panel is not directly involved in designing the EC road map for phasing-out animals' studies but EFSA is; the PPR is however involved in supporting EFSA in activities where the inclusion of NAMs or the implementation of the 3Rs in general are applicable in the frame of the current pesticide legislative framework. The exclusion of the dog as a second species in the assessment of agrochemical, the implementation of DNT-IVB and the "Environmental neurotoxicants" project are all EFSA activities/projects in which the PPR Panel is and will be engaged.
8	**Alberto Mantovani** Istituto Superiore di Sanità	Besides ERA, would also residue definition be updated considering climate changes? Residues are widely influenced by climate-dependent factors.	Indeed the climate change is posing new challenges in many areas, residue definition being one of them. The discussion on residue definition is ongoing at OECD level based on the current knowledge. It is not excluded that the impact of the climate change might be considered in the future, however currently not in the programme. EFSA will be constantly following the scientific updates to implement them if and when possible.
Questions related to item 7.5 - Cumulative Risk Assessment: update on ongoing activities			
9	**Alberto Mantovani** Istituto Superiore di Sanità	How to exploit mechanistic data from NAMs in cumulative risk assessment?	According to the Guidance of the EFSA Scientific Committee (EFSA, 2021), the golden standard for grouping chemicals into assessment groups is considered to be the common mode of action (MoA) and/or the Adverse Outcome Pathways (AOPs). In the absence of fully defined and validated AOPs the cumulative assessment groups (CAGs) are currently proposed on the basis of adverse outcomes retrieved only from in vivo studies available in toxicological dossiers. Substances showing the effects of interest are included into CAGs and characterised by the assignment of a NOAEL and LOAEL that will be used later on for the risk characterisation. All other data possibly available (e.g. in vitro, in silico, mechanistic, etc.) can be taken into consideration for the lines of evidence for assessing the CAG-membership probabilities. Considering that new approach methodologies can be integrated as part of a weight-of-evidence approach for hazard or risk assessment using the adverse outcome pathway framework, EFSA is currently recommending in the reports (e.g. kidney report) to further develop AOPs by

			focusing on the adverse outcomes that are available in the pesticide dataset.