PESTICIDE PEER REVIEW UNIT

SCIENTIFIC PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES

MINUTES OF THE 105TH PLENARY MEETING

Held on 10 (closed session)- 11 (open session) June, 2020 (webconference)

(Agreed on 26 June, 2020)

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, Gerrit Wolterink.

- Hearing Experts:

  Not Applicable

- European Commission and/or Member States representatives:

  Not Applicable

- EFSA:

  Maria Arena, Domenica Auteri, Arianna Chiusolo, Mark Egsmose, Alfonso Lostia, Christopher Lythgo, Iris Mangas, Laura Padovani, Andrea Terron, Manuela Tiramani.

- Observers:
  See Annex I

CLOSED SESSION (10 June)

1. Welcome and apologies for absence

The Chair of the Panel, Antonio Hernández-Jerez, welcomed the participants.

2. Adoption of the agenda

The agenda was adopted without changes.

3. Declarations of Interest of Scientific Panel Members

Declarations of Interest of Scientific Panel Members In accordance with EFSA's Policy on Independence[1] and the Decision of the Executive Director on Competing Interest Management[2], 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, and no interests were declared orally by the members at the beginning of this meeting.

4. Report on written procedures since 104th Plenary meeting

None.

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

5.1. Framework for conducting environmental exposure and risk assessment for transition metals when used as active substances in PPPs (EFSA-Q-2019-00374)

The Panel was updated on the status of activities of the WG for the development of the Statement and the next steps. Main comments received from reviewers (Sabine Duquesne, Aaldrik Tiktak and Gerrit Wolterink) were presented for discussion. The need for an additional *ad hoc* Plenary for presenting the draft statement for possible endorsement before public consultation was agreed by the PPR Panel.

5.2. Scientific advice on the translocation potential by Pseudomonas chlororaphis MA342 in plants after seed treatment of cereals and peas and, if applicable, for a revision of the assessment of the risk to humans (EFSA-Q-2020-00116)

The Panel was updated on the status of activities of the WG for the development of a Statement on the microbial active substance Pseudomonas chlororaphis strain MA 342. The Panel was also informed about the finalised assessment for the aneugenicity potential of the metabolite 2,3-deepoxy-2,3-didehydro-rhizoxin (DDR) produced by the microorganism. The Panel was also informed about the ongoing assessment for the potential for translocation/degradation of the

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

microorganism/DDR metabolite. Maurice Millet and Gerrit Wolterink were identified as peer reviewers of the draft output and accepted the assignment.

6. AOB

The Panel was informed about the outcome from the experts mutual assessment and that individual dialogues among PPR Panel experts and the Scientific Coordinators will be organised during the Summer period.

OPEN SESSION (11 June)

7. Welcome

The Chair of the Panel, Antonio Hernández-Jerez, welcomed the participants.

8. Brief introduction of Panel Members and Observers

Panel members and EFSA introduced themselves to the observers.

9. Presentation of the EFSA guidelines for Observers

EFSA presented the guidelines for observers for open plenary meetings.

5. Scientific outputs submitted for discussion and/or possible adoption, updates on ongoing activities, new projects [cont.]

5.3. Scientific Opinion of the PPR Panel for developing Integrated Approaches to Testing and assessment (IATA) case studies on developmental neurotoxicity (DNT) risk assessment (EFSA-Q-2019-00100).

The Panel was updated on the status of the Scientific Opinion, on the case studies, the methodology for evidence assessment, including uncertainty analysis. An update on the planning for the project was also provided.

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

The Panel was updated on the status of activities for the development of the Scientific Opinion, including the problem formulation, chemical selection, possible synergisms with other projects and the next steps.

5.5 Framework for conducting environmental exposure and risk assessment for transition metals when used as active substances in PPPs (EFSA-Q-2019-00374)

The progress of the activity for the development of the Statement and the next steps were presented.

10. 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).

11. AOB

The Panel was informed about the publication of the call for expressions of interest to establish a list of individuals with scientific expertise to assist EFSA in carrying out the preparatory work in the areas of generic risk assessments and the assessment of applications for the authorisation of regulated products.

ANNEX I

List of observers

Last Name	First Name	Employer	Affiliation
Huang	Chasel	REACH24H	Private sector
Zhang	Wanjun	China Agriculture University	University/public research institute
VACCA	GIANLUCA	VACCA GIANLUCA	Press/media
Kumric	Goran	EFSA - ENCO	EFSA staff
Merlo	Rosemeire	SIPCAM NICHINO BRASIL S.A.	Private sector
Boahene	Nana	Norwegian Scientific Committee for Food and Environment (VKM)	University/public research institute
Guido	Renata	Andrade Sun Farms	Private sector
Rossi	Luca	Regional Regulatory Manager	Other
Mizzotti	Chiara	Università degli Studi di Milano	University/public research institute
Wright-Williams	Sian	Staphyt	Private sector
MONTIS	Valeria	MIUR	Other
HALE	Michael	Staphyt Ltd.	Private sector
Collison	Elizabeth	Staphyt Ltd	Private sector
Dvorzakova	Miluse	Mirapol	Private sector
Vida	Patrizia	Manica	Private sector
Viviani	Barbara	University of Milan	University/public research institute
Pereira	Dora	Dora Pereira Consultoria	Private sector
CALUTU	Daniela Mirela	Sanitary Veterinary and Food Safety Division DOLJ County	Other
MANCHEVA	Neli	Ministry of Agriculture, Food and Forestry	National authority
MOCALI	Stefano	CREA	University/public research institute
nencioni	maria	CREA-PB	University/public research institute
STRANO	Maria Concetta	CREA	University/public research institute
VIZZARRI	VERONICA	Ministry of Agricultural and Forestry Policies- CREA Research Centre for Olive, Citrus and Tree Fruit	University/public research institute
Valerio	Battaglia	CREA - Research Centre for Cereal and Industrial Crops	University/public research institute
Malusa	Eligio	Research Institute of Horticulture	University/public research institute
Collina	Marina	University of Bologna, Italy	University/public research institute
D'Arcangelo	Mauro	CREA	University/public research institute

DEL VALLE DE SOUSA GAVAIA	NICOLA	ECUADORIAN BANANA CLUSTER	Private sector
Weidenauer	Matthias	European Union Copper Task Force (EUCuTF) c/o Battelle UK Ltd.	Private sector
PIEROBON	ENRICA	Università Cattolica del Sacro Cuore - PIACENZA - IT	University/public research institute
ALBERTI	ILARIA	CREA	EFSA Panel/WG/Network
Pereira	Marina	Humane Society International	NGO
Nishimura	Takayuki	ISK Biosciences Europe N.V.	Private sector
DE MONASTERIO	PATRICIA	HELM AG	Private sector
VANHOOF	Bart	UPL Europe Ltd	Private sector
LAGADIC	Laurent	Bayer AG, Crop Science Division	Private sector
Lazzari	Silvia	TEAM mastery S.r.l.	Private sector
KRUEGER	Katharina	HELM AG	Private sector
Bretesche	Loic	UPL	Private sector
Corvaro	Marco	Corteva Agriscience	Private sector
Medrzycki	Piotr	CREA	University/public research institute
Nicoletti	Rosario	Council for Agricultural Research and Economics	University/public research institute
TIGRANYAN	Margarit	Rockberry	Other

Annex II

List of questions from observers and answers

Question maker	Question	Answer
General question		
Ecuadorian Banana Cluster	Any short-middle term revision expected that may affect PPP used on bananas?	EFSA is responsible of the risk assessment of active substances used in plant protection products (PPP). Decision on approval of active substances are taken by the European Commission (DG SANTE) together with risk managers of Member States. Authorization of PPPs is done at Member State level.
Questions related to item 5.3.- Scientific Opinion of the PPR Panel for developing Integrated Approaches to Testing and assessment (IATA) case studies on developmental neurotoxicity (DNT) risk assessment		
BAYER	Please can you explain how the exposure concentration in zebrafish compares to the exposure dose in human? please can you explain how the exposure concentration in zebrafish compares to the exposure dose in human?	Thank you. Indeed AO zebrafish and human data will be used in the AOP for hazard characterization in an integrated way. At this point, considering the intrinsic difficulties of extrapolating exposure data obtained in the zebra fish, it is unlikely that these data will be used in the process of risk assessment (which is however not in EFSA mandate). They will be however used to assess dose concordance in the context of the AOP informed IATA that includes the assessment of the uncertainties associated with the model (e.g. stability in water, internal concentration). This item is of particular attention in the OECD DNT expert group where a subgroup including a number of labs and organizations, is working to provide a standard protocol and proposals to address these specific questions
CORTEVA Agriscience	Thanks for ppt. In terms of evidence of Adverse human Outcome, how will the identified the "sensitive" Neurotox concentration from in vitro battery, relate to target cells exposure in humans tissues (either Central or	In the context of this project, in vitro concentrations and exposure data, are relevant for contextualizing the dose concordance and the response-response concordance in the AOP. Pending on available data (e.g. available models validated by animal PK data including plasma concentration and brain concentration), different models could be applied and associated

Question maker	Question	Answer
	peripheral Nerveous system?). This is essential to understand if the KE actually occurr in an in vivo human situation. Today, prediction of human concentrations at target tissue is still a challenge even for Pharma sector.	uncertainties described. For DLM the situation is quite comfortable because PK data are available in the experimental target species and the extrapolation of the in vitro nominal concentration will have to consider uncertainties associated with lack of data on intracellular concentration and partitioning of the chemicals with plastic lipid and protein. We are also experiencing this challenge along additional projects with less data and we are providing a list of minimum set of data to conduct the PB/PK analysis as a first step and allow to understand which additional data would be likely needed to reduce uncertainties
Milan University	How are you addressing the role of glia population (both microglia and astrocytes) in the project (collecting data from in vivo studies and in the in vitro approach)? Glia strongly contributes to brain development (including differentiation, migration, synaptogenesis and neuronal network maturation) by interacting with neurons or through the release of soluble factors. In addition, it may metabolize some substances in situ	The DNT in vivo studies are very poorly powered in their design to assess glia specific toxicants. Even at detailed histopathological level it would be highly complex to specifically identify glia related effects. However, indeed the glia is having a fundamental role in many KEs and for this reasons glia is included in multiple test systems of human relevance used in the battery and specifically assessed in two endpoints, glia proliferation and migration. What is remaining uncertain is the ability to capture processes that associated with myelination, which also a process in vivo that can continue after weaning in rat. This would remain an uncertainty
Questions related to item 5.4.- Development of Adverse Outcome Pathways relevant for the identification of substances having endocrine disruptors properties		
China Agriculture University	Would you think that AOP will play a great part in chemicals risk evaluation?	The AOP conceptual framework have become an organizing framework to facilitate the development and integration of alternative test methods for assessing hazard of chemical to human health and the environment. AOPs can support the development of integrated testing strategies and their application in risk assessment. Therefore, the data generated by alternative methods, when combined with existing animal, and human observational data, are used and assessed by means of a fixed data interpretation procedure, and, as such, it has its own regulatory value. Indeed, mechanistic approaches provide

Question maker	Question	Answer
		advantages for risk assessors because they describe the causal pathways from sources of exposure to adverse outcome and therefore can facilitate a science-based evaluation of the current knowledge, data gaps, and uncertainties in risk assessment results. With the increasing use of alternative methodologies, the demand of a mechanistic shift in chemical risk assessment, the political and societal pressure of reducing animal uses and the attention now-days given to exposure to chemical mixtures, EFSA is considering the implementation and use of AOP as a strategic step in the current and future chemical risk assessment.
BAYER	How many chemicals are you going to select?	There is no a definitive number of prototype chemicals needed to develop and AOP. The main aim is to select chemicals with high evidence they induce the adverse outcome of interest. Therefore also few chemicals, as 2-3, might be sufficient. Also practical considerations should be taken into account: more chemicals can "facilitate" the development process but since systematic literature review will be applied for each chemical, having several chemicals to be evaluated will imply careful resources' planning.
Questions related to item 5.5.- Framework for conducting environmental exposure and risk assessment for transition metals when used as active substances in PPPs		
European Union Copper Task Force (EUCuTF) c/o Battelle UK Ltd	The framework is expected to provide general guidance for environmental exposure and risk assessment, which is likely to require new methodology not covered by current guidance. How will subsequently new models be identified and validated (and by whom)?	The PPR statement is not a guidance document. However, the PPR statement will include advice and recommendations for model developers, applicants and evaluators to follow the PPR opinion on good modelling practice (2014) when modelling tools are used for assessment of transition metals to be used as plant protection products.
European Union Copper Task Force (EUCuTF) c/o Battelle UK Ltd	Will EFSA be able to complete the framework within the deadline, given the current situation? Anticipating changes to reg. 844/2012, the next renewal dossier for Cu	The PPR Panel is working according to the deadline for the anticipated adoption of the PPR statement by the Panel by February 2021. EFSA cannot comment on the regulatory timelines for EU submissions as this is under the responsibility of

Question maker	Question	Answer
	will be due end of 2022, leaving just 22 months between the issuing of the framework and dossier submission. Should the expiry date for Cu be extended to allow sufficient time to implement the recommendations?	the European Commission.
European Union Copper Task Force (EUCuTF) c/o Battelle UK Ltd	Will a stakeholder hearing be organized during the public commenting period?	For the time being the organisation of a stakeholder hearing is not foreseen. The public consultation will allow stakeholders to provide comments and give feedback on the draft output.
Manica Spa	Concerning Transition Metals (Copper), has effective bio-availability in the soil being considered and, most important, how?	The draft statement contains a framework for transition metals and includes approaches on how bioavailability in soil can be considered taking soil properties and soil residues of the compound in agricultural soils into account.
European Union Copper Task Force (EUCuTF) c/o Battelle UK Ltd	Will essentiality of TMs be taken into account in the uncertainty evaluation (i.E. assessment factors)?	Essentiality is discussed in the assessment of uncertainties in the environmental risk assessment of metals in the statement, but it is not proposed to generally increase the AF.
Università Cattolica del Sacro Cuore - PIACENZA - Italy	BLM is still considered for the purpose?	The suitability and applicability of BLM is discussed in the statement. Especially, it is reviewed which exposure routes and which conditions (E.g. equilibrium) are addressed by BLM.
Regional Regulatory Manager	Will also national guidelines developed in the past for metals taken into account (i.e. Italian ENVIRONMENTAL RISK ASSESSMENT OF ACTIVE SUBSTANCE COPPER COMPOUNDS)?	Reference to other guidelines or framework is included in the statement if applicable, but the main focus lies on the ECHA guidance and ECHA specific endpoint guidance.
Regional Regulatory Manager	Is IDMM model for PECsw calculation be considered as possible alternative toll to FOCUS?	The IDMM is reviewed in the statement and the steps needed to be performed are outlined. It is concluded that processes and scenarios should be included in the current framework. All model development should follow the GMP by EFSA (2014).