Technical Workshop on risk assessment for the Plant Protection Product

Draft agenda

Venue: European Commission CDMA building, Rue du Champ de Mars 21, 1050 Ixelles, Belgium

Day 1 – 21 June 2023

Time	Title	Presenter
9:00 – 9:30	Registration	
9:30 – 9:45	Welcome	Ms. Manuela Tiramani, EFSA
9:45 – 10:05	EFSA introduction	Ms. Chloé De Lentdecker, EFSA Ms. Mathilde Colas, EFSA
10:05 – 10:25	SANTE presentation: state-of-art and summary of the workshop on 23 May 2023	Ms. Karin Nienstedt, DG SANTE
10:25 – 11:00	DE experience in assessing PPPs DK experience in assessing PPPs	Ms Claudia Grosskopf, Germany Ms Louise Lundberg, Denmark
Break		
11:20 – 12:00	ECHA experience: REACH CLP Biocide	 Mr. Sampo Karkola, ECHA Mr. Ari Karjalainen, ECHA Mr. Watze De Wolf, ECHA
12:00 – 12:20	Setting the scene and scope Issues at stake: general introduction to the breakout sessions	Ms. Chloé De Lentdecker, EFSA Ms. Mathilde Colas, EFSA
12:20 – 12:30	Logistic aspects	Ms. Chloé De Lentdecker, EFSA Ms. Mathilde Colas, EFSA
Lunch break		
13:45 – 15:45	Breakout groups	See Annex 1 – Detailed agenda See Annex 2 – Background information (non-exhaustive)
Break		

16:00 – 18:00	Breakout groups	See Annex 1 – Detailed agenda See Annex 2 – Background information (non-exhaustive)

Day 2 – 22 June 2023

9:00 – 11:25	Breakout groups	See Annex 1 – Detailed agenda See Annex 2 – Background information (non-exhaustive)
Break		
11:45 – 12:45	Outcome of the discussion from each breakout group	Ms. Chloé De Lentdecker, EFSA Ms. Mathilde Colas, EFSA
12:45 – 13:00	Conclusion	Ms. Manuela Tiramani, EFSA

Annex 1 – Detailed agenda

Topic 1: Transparency and identification, data, and hazard assessment

Chair: Ms. Rachel Sharp, EFSA
Co-chair: Ms Louise Lundberg, Denmark
Report writer: Ms. Mathilde Colas, EFSA

Item 1: Information about the identification, concentration, and function of the co-formulant in the PPP
1.1. What information is needed to fully identify the co-formulants (including mixture), their range of concentration and their function. 1.2. How to access the confidential data not owned by the applicant? Special considerations for when a co-formulant is a mixture.
Item 2: Hazard evaluation of PPP/co-formulants
2.1. What data should be available to assess the hazard effects; In which circumstances, would it be acceptable not to require data for substances presumed to be of no concern; How to identify which data are missing; In what circumstances should Member States request additional information to identify the hazards; And if data are needed, for which endpoint and what type of data/information. 2.2. On which basis could a justification for waiving considered valid and which approach or considerations to apply if no data is available. 2.3. Source and hierarchy of data required: which sources of data can be used for the hazard identification and which type of data should be considered. 2.4. How to share (if co-formulants list available at MS level) and harmonise information and evaluation of co-formulants (e.g., establishing an EU database). 2.5. Bridging assessment of PPPs, alternative co-formulants and equivalence assessment.
Item 3: Strategy to identify combined effects and level of data
3.1 How to identify potentially combined effects (e.g., additive, or synergistic effects)

Item 4: Specific co-formulants
4.1. Co-formulants that are approved/no more approved/not approved as pesticide a.s.
4.2. Co-formulants that are polymers in PPPs.
4.3. Co-formulants that are UVCBs.
4.4. Co-formulants that are PFAS.
4.5. Co-formulants that are formaldehyde releasers.

Topic 2: Exposure and risk assessment

Chair: Ms. Anja Friel, EFSA
Co-chair: Ms Claudia Grosskopf, Germany
Report writer: Ms. Chloé De Lentdecker, EFSA

Item 1: Mapping the current practices of the Member States
1.1. What are the current practices to assess PPPs.
1.1.1. In which cases is a purely hazard-based assessment accepted.
1.1.2. If not hazard-based assessment:
1.1.2.1. How the exposure assessment and risk assessment to single components and/or PPP are carried out? What are the data and methods used for the assessment of exposure to human and environment.
1.1.2.2. What are the assumptions used and on which basis.
1.2. Existing scientific information including monitoring data regarding exposure of humans and the environment.
Item 2: Establish the criteria for cases when risk assessments of co-formulants/PPPs is needed
2.1 What are the cases when risk assessment is not needed (e.g., no hazard, no concern, no exposure, existing RMM ensure safety of the PPP).
2.1.1 Proposals for initial criteria to build a list of co-formulants categorised as no concern. What are the next steps needed to further develop such a list.
2.2 Under which circumstances is the risk assessment of the co-formulant/PPP needed? e.g., co-formulants with certain properties, including long term toxicity.
Item 3: Specific exposure and risk assessment methodology and considerations for PPPs
Data on exposure
3.1 What data are needed to estimate the dietary exposure to co-formulants and/or PPP.
3.2 What data are needed to carry out the non-dietary risk assessment for co-formulants and/or the PPP.
3.3 What data are needed to estimate the fate and behaviour of the PPP and/or co-formulants in the different compartments? on co-formulants or on PPP.
3.4 What models or tools exist to calculate or estimate exposure? Which exposure scenarios to be considered.
Methods on risk assessment
3.5. Which methods to use for the risk assessment of the PPP/co-formulants.
3.6. In which cases can a combined assessment be performed.
3.7. Use of uncertainty factors (in some cases) to compensate for possible synergistic effects.

3.8. Co-formulants with particular properties (e.g., CMR, PBT).

3.9. Additional data for PPP for derivation / confirmation of reference values [in silico tools (read across, QSAR etc.); in vitro studies (e.g., comparative studies for active substance(s) and whole mixture); in vivo studies (which kind of studies)].

Item 4: Organisational issues and adaptation

4.1. Harmonised approach for the completeness check of the dossier.

4.2. Adaption of existing templates to harmonise assessment and improve transparency e.g., DAR/RAR/CLH report and/or draft registration report format.

4.3. Ways to ensure efficiency in the process.