

UPDATE ON THE ACTIVITIES RELATED TO THE ASSESSMENT OF PPP/CO- FORMULANTS

31st PSN meeting - 24 October 2023
EFSA PREV coordination team

ACTIVITIES RELATED TO PPP/CO-FORMULANTS ASSESSMENT

1. New EC Mandate requesting EFSA to conduct further investigation on EFSA Technical Report (2022)
2. Update on the June 2023 Workshop on PPP risk assessment
3. Perspectives / future activities



1. NEW EC MANDATE REQUESTING EFSA TO CONDUCT FURTHER INVESTIGATION ON EFSA TECHNICAL REPORT (2022)

- Article 31 of Regulation (EC) No 178/2002
- Subject: Identification of unacceptable co-formulants which fulfil criteria according to the Commission Implementing Regulation (EU) No 574/2023.¹

EFSA to investigate whether the 182 co-formulants listed in the EFSA technical report (2022)² fulfil any of the criteria 1 to 9 listed in Commission Implementing Regulation (EU) No 574/2023, and whether they are not already listed in Annex III to Regulation (EC) No 1107/2009.

- Legal deadline: **31 March 2024**

¹ Commission Implementing Regulation (EU) No 574/2023² setting out detailed rules for the identification of unacceptable co-formulants in plant protection products in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council

² EFSA (European Food Safety Authority), 2022. Data collection on co-formulants used in representative plant protection product formulations in the context of the EFSA peer review process for approval/renewal of approval of active substances. EFSA supporting publication 2022:EN-7547. 97pp. doi:10.2903/sp.efsa.2022.EN-7547



2. UPDATE ON THE JUNE 2023 WORKSHOP ON PPP RISK ASSESSMENT

Technical workshop on risk assessment for PPPs

On 21-22 June 2022, in Brussels

Who attended?

- ✓ Circa 80 participants from 25 Member States
- ✓ DG SANTE
- ✓ ECHA
- ✓ EFSA

In practice, attendees divided in 2 groups:

- Topic 1: Transparency and identification, data, and hazard assessment
- Topic 2: Exposure and risk assessment



2. UPDATE ON THE JUNE 2023 WORKSHOP ON PPP RISK ASSESSMENT

Setting the scene

Scope

- Scientific aspects only (no legislative aspects, as outside the remit of EFSA)
- Not discussed:
Adjuvants, tank-mixture, synergists, safeners, cumulative assessment i.e., expo/risk assessment for multiple PPP



2. UPDATE ON THE JUNE 2023 WORKSHOP ON PPP RISK ASSESSMENT

Setting the scene

Objective of the workshop

- Harmonisation of the risk assessment of the PPP including co-formulants, in a harmonised way at MSs and EU level
- Collection and discussion on specific technical issues
- To share experience and ongoing activities at MSs and EU level
- Perspectives: e.g., possible cooperation among stakeholders, to draft instructions, find technical solutions, etc.



2. UPDATE ON THE JUNE 2023 WORKSHOP ON PPP RISK ASSESSMENT

Topic 1: Transparency and identification, data and hazard assessment

- Information needed to **fully identify** the co-formulants (including co-formulant mixtures), their range of **concentration** and their **function**,
- **Access to confidential data** not owned by the applicant. Special considerations for confidentiality when a co-formulant is a mixture,
- Definition of **relevant co-formulant and co-formulant of concern**,
- **Data** 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 MSs request additional information to identify the hazards; and if data are needed, for which endpoint and what type of data/information.
- On which basis could a **justification for waiving** considered valid and which approach or considerations to apply if no data is available.



2. UPDATE ON THE JUNE 2023 WORKSHOP ON PPP RISK ASSESSMENT

Topic 1: Transparency and identification, data and hazard assessment

- **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,
- **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),
- **Bridging assessment** of PPPs, **alternative** co-formulants and **equivalence** assessment,
- How to identify potentially **combined effects** (e.g., additive, or synergistic effects),
- Co-formulants that are approved/no more approved/not approved as **pesticide a.s, polymers in PPPs, UVCBs, PFAS, formaldehyde releasers.**⁸



2. UPDATE ON THE JUNE 2023 WORKSHOP ON PPP RISK ASSESSMENT

Topic 2 : Exposure and risk assessment

- Discussion on the **MSs current practices** to assess PPPs
- **Existing scientific information including monitoring data** regarding exposure of humans and the environment
- What are the **cases when risk assessment is not needed**:
- ✓ 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.
- Under which circumstances is the **risk assessment** of the co-formulant/PPP **needed**?
- What data are needed to estimate the **dietary, non-dietary exposure to co-formulants and/or PPP and the fate and behaviour** of the PPP and/or co-formulants in the different compartments



2. UPDATE ON THE JUNE 2023 WORKSHOP ON PPP RISK ASSESSMENT

Topic 2 : Exposure and risk assessment

- What **models or tools** exist to calculate or estimate exposure? Which **exposure scenarios** to be considered.
- Which **methods** to use **for the risk assessment** of the PPP/co-formulants.
- In which cases can a **combined assessment** be performed.
- Additional data for PPP for derivation / confirmation of **reference values**
- Harmonised approach for the **completeness check of the dossier**.



2. UPDATE ON THE JUNE 2023 WORKSHOP ON PPP RISK ASSESSMENT

Outcome of the discussion

Topic 1: <https://www.efsa.europa.eu/sites/default/files/2023-07/9.1-breakout-session-topic-1.pdf>

Topic 2: <https://www.efsa.europa.eu/sites/default/files/2023-07/9.2-breakout-session-topic-2.pdf>

- Background information
- Proposed solutions
- Proposed follow-up actions

Link to all presentations: <https://www.efsa.europa.eu/en/events/technical-workshop-risk-assessment-plant-protection-products>



3. PERSPECTIVES / FUTURE ACTIVITIES

Development of a common database on co-formulants

Medium-term project:

EU database on co-formulants

- One of the proposed actions at the May/June workshops
 - Consultation of Member States (e.g. PAI members, PAFF members) on the requirements of content and design needed for the database
 - MS support (e.g., BfR database)
- **Currently under development at EFSA level**

Long term project:

EU common data platform on chemicals

- **1S1A project (one substance one assessment)**
 - Online platform to facilitate sharing, access and re-use of information on chemicals from different EU Agencies/institutions
 - The EU-Common Data Platform on Chemicals will be hosted by ECHA
 - Building blocks: ECHA, EFSA, EMA, EEA, EC
- **Currently development – long term project¹² (several years)**



3. PERSPECTIVES / FUTURE ACTIVITIES

Drafting of guidance & Creation of a working group

Under discussion with SANTE (refer to the SANTE's presentation)



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