ACTIVITIES RELATED TO PPP AND CO-FORMULANTS ASSESSMENT

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EUROPEAN FOOD SAFETY AUTHORITY

CONTEXT

- Increasing interest as regards RA formulation
- In particular for co-formulants:
  - February 2021: letter from MEPs
  - March 2021: Regulation (EU) 2021/383 – list of unacceptable co-formulants
  - Decision of the Court of Justice of the European Union of October 1st, 2019*

*Case C-616/17. Judgment of the Court (Grand Chamber) of 1 October 2019. Criminal proceedings against Mathieu Blaise and Others. Available at: https://curia.europa.eu/juris/liste.jsf?num=C-616/17)

FROM THE LEGISLATION

- EFSA has to conclude against the approval criteria, and this requires **safe use(s)** for a product to be demonstrated.

-> Data should be sufficient to assess the safety of the formulation and if needed, following the component-based approach, data on co-formulants should be provided and an assessment performed.

- Definition from Article 2(3)c of Regulation (EC) 1107/2009

Co-formulants: ‘substances or preparations which are used or intended to be used in a plant protection product or adjuvant, but are neither active substances nor safeners or synergists.’

FROM THE LEGISLATION

- Regulation (EU) No 284/2013 – setting out the data requirements for PPP

SECTION 1
IDENTITY OF THE PLANT PROTECTION PRODUCT

1.4.1. Composition of the PPP
- Content of co-formulants

1.4.3. Information on safeners, synergists and co-formulants:
- Chemical name, structure, EC and CAS number, composition of mixtures
- Safety data sheet (SDS)
- Function
- Description of the formulation process

SECTION 5
ANALYTICAL METHODS

5.1.1. Methods for the analysis of the plant protection product:
- Methods for the determination of relevant co-formulants

SECTION 7
TOXICOLOGICAL STUDIES

7.4. Available toxicological data relating to co-formulants / non-active substances:
- Registration number of the REACH dossier
- Study summaries included in the REACH dossier
- Safety data sheet

It is possible to request the same type of data for co-formulants as required for the a.s. according to point 1.11 of the introduction to the Annex to that Regulation.

ACTIVITIES RELATED TO PPP/CO-FORMULANTS ASSESSMENT

- March 2021: **List of unacceptable co-formulants** (Annex III): Regulation (EU) 383/2021
- March 2022: **DG SANTE EU survey** on long-term toxicity of the formulation
- August 2022: EFSA technical report (TR)→ **Data collection on co-formulants** used in representative plant protection products in the context of the EFSA peer review process for (renewal of) approval of active substances
- November 2022: **EFSA EU survey** on co-formulants
- March 2023: **Implementing regulation for identifying other unacceptable co-formulants**: Regulation (EU) 574/2023

ACTIVITIES RELATED TO PPP/CO-FORMULANTS ASSESSMENT

- May 2023: **first workshop led by DG SANTE** on the assessment of plant production products and co-formulants → scene setting and identification of possible ways forward
- June 2023: **second technical workshop led by EFSA** on risk assessment for the plant protection product
- Second half of 2023: MSs discussions at PAFF, PAI, PSN and ZAPID workshop
- September 2023: **EC Mandate** requesting EFSA to conduct further investigation on EFSA TR: deadline 31/03/2024

European Commission webpage on PPP activities: https://food.ec.europa.eu/plants/pesticides/authorisation-plant-protection-products/assessment-plant-protection-products-ppps_en#ongoing-activities-on-improving-the-assessment-of-plant-protection-products-ppps

EFSA TECHNICAL REPORT

Terms of reference

- **Overview of the data and considerations for the assessment on co-formulants:**
  - **identification** of the co-formulants declared in the PPP for representative uses
  - collection of **the main comments/aspects** examined during the PR process
  - **EU regulatory frameworks** other than pesticides applicable to co-formulants

- **Data collection on co-formulants** contained in all PPP for representative use(s)

-> Dossiers for which an EFSA output was finalised between January 2019 and March 2022

- **Methodology:**
  - Collection of information from Volume 4 of the DAR/RAR and SDS
  - Relevant data sources from other EU legal frameworks for the assessment of co-formulants

OVERVIEW OF THE RESULTS

- Key figures:
  - 58 active substances
  - 82 formulations for representative uses
  - 182 co-formulants declared (from 0 to 13 co-formulants per PPP)

- 96 out of 182 co-formulants have been registered under REACH (circa 53%) and most of them (circa 80%) are registered for the highest category of tonnage per year (> 1000 t/y)
- For 41 out of 86 co-formulants that do not have a REACH dossier, are regulated by at least another European legislation e.g. biocides, cosmetics, feed/food additive… or food stuff.
- For the 45 co-formulants remaining e.g., exempted under REACH, not exempted and (not) registered under REACH, or not possible to identify the component.

JUNE 2023 WORKSHOP ON PPP RISK ASSESSMENT

Who attended?

- Circa 80 participants from 25 MSs,
- 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

JUNE 2023 WORKSHOP ON PPP RISK ASSESSMENT

Scope

- Scientific aspects only (no legislative aspects, as outside the remit of EFSA)

Objective of the workshop

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

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

FOLLOW-UP ACTIONS

Activities led by DG SANTE currently under discussion also with the MSs:

- Establishment of a common database on co-formulants
- Drafting of a guidance on the assessment of PPP including co-formulants.

CURRENT ACTIVITIES

Activities led by EFSA:

➔ continuing the work started with the EFSA technical report (EFSA, 2022)

- Expanding the scope of the analysis to the previous 5 years (prior 2019)
- Including (eco)toxicological information on the components declared in the PPP.

ENVISAGED OUTCOME

- A data repository will be created and made public by the first half of 2025
- Serve as the basis for further developments, including the preparation of a guidance, currently under discussion with DG SANTE and MSs.

FEEDBACK – HOW IS THE TOPIC EVOLVING?

- Good collaboration with MSs and with the applicants
- Assessment already performed in a more consistent way
- Topic more commented/discussed at every level by all the actors.

Thank you for your attention

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