EFSA REPOSITORY ON CO-FORMULANTS

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BACKGROUND

Follow-up action from the June 2023 Workshop on PPP risk assessment:

- Harmonisation of the PPP risk assessment, including co-formulants, at MSs and EU level
- Proposal to develop a common database on co-formulants

EFSA continued the work started with the EFSA technical report (2022):

- Expanding the scope of the analysis from March 2022 onwards.
- Including (eco)toxicological information on the components declared in the PPP.

→ Development of the **EFSA repository on co-formulants present in PPPs declared in the framework of EFSA peer review processes**

BACKGROUND

EFSA repository on co-formulants

OBJECTIVES:

1) To gain a better insight into the data on co-formulants available to EFSA
2) To facilitate the assessment of co-formulants/PPP safety
3) To avoid duplication of work at national and EU level

Support from external experts:

- ISA experts
- Tasking grant with Benaki Pharmaceutical Institute (BPI)

GENERAL CONSIDERATIONS

- **Living document**, tab ‘search by product’ regularly updated by EFSA.
- The **date of the latest data update** (when the data have been collected and reported in the repository) is provided in the last columns of each row in each sheet.
- In this first version, toxicological and ecotoxicological data have been collected for the **182 co-formulants** identified in the EFSA technical report on data collection on co-formulants
- For **ongoing peer review processes**, information on co-formulants may be subject to change based on updated versions of the DAR/RAR.
- Each co-formulant is uniquely identified by its **ECHA ID number**. If not identified, 'n.a.' (not applicable) is indicated.
- The repository is divided into **four cross-linked main tabs**: search by product, search by co-formulant, mammalian toxicity and ecotoxicology hazard data.

ACCESS TO THE EFSA REPOSITORY

- Access to the **EFSA repository** and related **instructions describing the content**
- **Two versions** of the EFSA repository on co-formulants:
  - Confidential version on DMS (with 'read only' rights) :
    - ✓ **Member States Competent Authorities** involved in the PPP authorisation and EFSA peer review procedures
    - ✓ **ECHA** colleagues
  - Non confidential version on the EFSA website:
    - ✓ **Public**

Publication and sharing date: end of June 2025

STRUCTURE OF THE EFSA REPOSITORY

SEARCH BY PRODUCT

- The information was extracted from pesticide active substance **assessment reports (DAR/RAR)** (if information not available or unclear, the **safety data sheet**) for which a peer review output has been issued since January 2019.
- The tab labeled 'search by product' should be treated as confidential.
- This tab provides:
  - Information on which PPPs contain the co-formulant
  - Substance identification data
  - Content of the co-formulants in the PPP
  - References to DAR/RAR, EFSA conclusions and link to the peer review experts' meeting report for the mammalian toxicity and ecotoxicology sections.

STRUCTURE OF THE EFSA REPOSITORY

SEARCH BY CO-FORMULANT

- Substance identification, legal status under different frameworks, whether criteria 1 to 9 of Regulation 574/2023 are met.

Mammalian toxicity properties
Ecotoxicity and environmental fate and behaviour properties

- Available (eco) toxicological data, sorted by endpoint, as retrieved from the consulted sources, with references and key results, dose descriptors, and conclusions from data sources or providers
- These data have not been peer reviewed by EFSA, except for EFSA outputs.
- Overview of available data on each endpoint and any potential concerns.[7]

STRUCTURE OF THE EFSA REPOSITORY

Data source

Substance identification, toxicological and ecotoxicological data (tabs 2, 3 and 4) have been collected from non-exhaustive publicly available sources:

- ECHA website: as chemical under REACH, biocide, if classified under CLP
- EFSA website: as MRL, feed additive, food additive, contaminant, novel food
- EC website: as cosmetic ingredient
- US EPA website: as component present in PPP
- JMPR-FAO website.

NEXT STEPS

- Possibility to add other data sources (e.g., from EMA as veterinary drugs, excipients, etc.)
- Maintenance to be planned
- Communication:
  - PAFF
  - Communications to stakeholders
  - Info session

Microsoft Teams

Video for the PSN - repository

2025-04-30 13:17 UTC

Recorded by
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Thank you for your attention!

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