Assessment of PPPs and co-formulants

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Content:

- Increasing awareness about assessment of PPPs and co-formulants
- The regulatory requirements and actors
- Recent progress on co-formulants
- Needs and possible next steps

Increased scrutiny on coformulants and assessment of PPPs

- In the past months, NGOs, EP and others raised criticisms on the assessment of PPPs, claiming in particular that long-term effects are not considered.

- PETITION Committee (EP) looking at a Petition submitted by an NGO, requested, among others:

“ to amend Regulation (EC) No 284/2013… to include experimental studies on the long-term toxicity of pesticide products” and

“ to check in detail the registration dossier for each substance as soon as possible and to suspend marketing approvals for which toxicological data on co-formulants in representative formulations would have proved insufficient to decide on the absence of adverse effects”

EU assessment of co-formulants in PPPs

1. Evaluation of co-formulants **as part of the product(s) for representative use <u>(EU approval of AS)</u>**

   - The Blaise judgement (C-616/17) states that the assessment of a PPP must be undertaken as part of the EU assessment.

   - Therefore, all aspects of the product needs to be examined and safety demonstrated – **active substance and co-formulants**

2. Evaluation of co-formulants **as part of each product assessment** (at Member State level in the PPPs authorisation process)

Actors involved

- Applicants
  - when compiling dossiers for the active substance approval/renewal (including product(s) for representative use(s))
  - when compiling dossiers for PPPs authorisations
- RMS / MSs
  - when checking the admissibility and evaluating the dossier for the active substance, including product(s) for representative use(s)
  - when evaluating the applications for authorisation of the plant protection products
- Peer-review process (MS & EFSA)

Recent progress on co-formulants in PPPs (1):

- List of unacceptable co-formulants (Annex III): Regulation 383/2021
- Implementing regulation for identifying other unacceptable co-formulants: Regulation 574/2023
- EFSA technical report (based on products submitted for representative uses in the dossiers for active substances since 2019): https://www.efsa.europa.eu/en/supporting/pub/en-7547

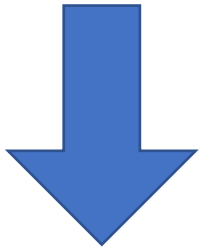
Recent progress on co-formulants in PPPs (2):

-1st Workshop (23 May 2023)

setting the scene with stakeholders and

mapping of issues for the next technical workshop preparing an action plan.

-2nd Workshop (21-22 June 2023): technical workshop discussing with risk assessors. EFSA Technical report available



3 objectives

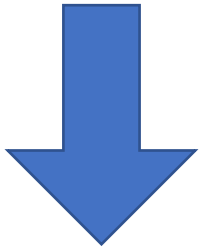
European Commission

3 main objectives:

1. To develop a guidance to harmonise the assessment of PPPs;
2. To establish an EU database of co-formulants (need for sharing data and assessments of co-formulants and products in view of ensuring efficient use of resources);
3. To improve a clear communication on the legal framework and on ongoing activities.

Actions so far:

- A new website: The Assessment of Plant Protection Products (PPPs) (europa.eu)
- Discussion with Member States on the objectives and next steps
  - SCoPAFF meeting (July 2023)
  - PAI meeting (13 September 2023)



- STRONG SUPPORT
- EFSA to coordinate the development of an EU database and a guidance

EU database of co-formulants

- The proposal is to start with a local database that would need to be integrated into the EU data platform under the ‘One substance – one assessment’ initiative;
- Based on the inputs from Member States, COM prepared a summary of the different requirements for the design and content that will be further discussed with Member States;
- EFSA takes the lead on the establishment of the data base.

Guidance to harmonise how PPPs are assessed

Input: outcome of the report of the June Technical Workshop (see the EFSA presentation)

What is needed?

1. To describe a harmonised process for the assessment of PPPs, including a process to narrow down the scope of the in-depth risk assessment to some particular situations (e.g. flow-chart)

2. Preparatory work (e.g. literature search, existing databases - see outcome of the report of the June Technical Workshop)

3. To be decided if there will be a new guidance or some existing guidance will be updated

How to work?

COM is in contact with PAI WG and EFSA to agree by the end of 2023 how the preparation of such a guidance would be done - close collaboration among MS (WG on phys-chem), ECHA, stakeholders would be needed (mandate to EFSA ?)

Possible topics to be addressed in the guidance:

Roles of the coformulants and their identification
Criteria for definition of “concerns” and “no concerns” for coformulants; impurities
Source and hierarchy of data required, confidentiality, possible waiving or bridging of data;
Alternative co-formulants, equivalence assessment
Hazard assessment of co-formulants : genotoxicity, classification, acute and long term toxicity (ecotoxicity and mammalian toxicity)
Exposure assessment, dietary and non dietary, fate and behaviour, models for estimation of exposure
Risk assessment methods, uncertainty factors, potentially combined effects
Special cases: mixtures, polymers, formaldehyde releasers, UVCB, PFAS,CMR, PBT, etc.
Active substances used as coformulants

Next steps- discussions on the data base and guidance

- Today: PSN (24 October 2023): to inform and discuss the objectives and next steps
- Working Group on phys-chem (22-23 November 2023)
- PAI meeting (29-30 November 2023)
- ZAPID workshop (4-7 December 2023)
- SCoPAFF meeting (11-12 December 2023)

Thank you

European Commission