Assessment of PPPs, including 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

- Recently, NGOs, EP and others have been highly critical 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”

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EU assessment of co-formulants in PPPs

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

   - 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)

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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
  - Admissibility and evaluation of the dossier for the active substance, including product(s) for representative use(s)
  - evaluation of applications for authorisation of the plant protection products
- Peer-review process (MS & EFSA)

Recent progress on co-formulants in PPPs:

- 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

Harmonisation and transparency have to improve

- Actions taken so far:

  -New website: The Assessment of Plant Protection Products (PPPs) (europa.eu)

  -1st Workshop (23 May 2023)

  set the scene with stakeholders

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

  -2nd Workshop (21-22 June 2023): technical workshop to discuss with risk assessors – today and tomorrow

- Follow up

  -3rd Workshop (ZAPID, December 2023): to discuss with Member States at zonal level

- We all need to cooperate and work together to ensure a smooth process

1st Workshop (23 May 2023)

- 128 participants attended the workshop (31 in presence and 97 online)
- Member States, Norway, stakeholder organisations, EFSA, ECHA, and DG SANTE
- Key challenges identified:
  - availability, quality and accessibility of data on co-formulants to MS to carry out the assessment of the PPPs;
  - need for a harmonised, transparent and resource-efficient risk assessment;
  - some additional specific topics
- The report will be available soon on the dedicated webpage

Thank you

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