Challenges around co-formulants

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European Commission

Increased scrutiny on co-formulants 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.

- A petition submitted by an NGO to the Parliament's PETI Committee, requested, among others:

  "*to amend Regulation (EC) No 284/2013 in order to require systematic long-term toxicity testing for PPPs or their co-formulants and 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*".

The rules

Article 4 of Regulation 1107/2009

General decision-making criteria – Annex II

2.1. Article 4 shall only be considered as complied with, where, on the basis of the dossier submitted, authorisation in at least one Member State is expected to be possible for **at least one plant protection product** containing that active substance for **at least one of the representative uses**.

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EU assessment of PPP

- Evaluation of co-formulants as part of the AS assessment at EU level (for the product(s) for representative use)
  - 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**
- Evaluation of co-formulants as part of each PPP assessment (MSs – PPP authorisation process)

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EU assessment of PPP – recent work

- list of unacceptable co-formulants (Annex III)
- process for identifying other co-formulants (implementing regulation)
- EFSA technical report (based on PPP products submitted for representative uses) https://www.efsa.europa.eu/en/supporting/pub/en-7547

→ a step forward but not fully addressing the issue

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Transparency on the assessment of co-formulants needs to be improved in the following areas:

- gathering all the information needed for evaluating all the components of a PPP;
- evaluating the hazard and the exposure of the components/whole product;
- providing additional data in case of lack of information;

When should this be applied:

- When applicants compile their dossiers
- When the RMS assesses the dossier of the representative product for representative uses
- During the peer-review process (EFSA)
- At Member States level during the authorisation of PPPs

Reminders to Member States:

- Document the requests of information (both for the product for representative use and for product at authorization stage)
- Discuss (at zonal level?) the possibility of agree on acceptable co-formulants

- Make an overview/database/update of national list of approved co-formulants (which are on the national market or have been withdrawn)
- Notify any unacceptable co-formulants according the requirements of the Implementing Regulation

Reminders to Applicants:

- Consider the importance of the products for representative use in the AS dossier
- Submit all the co-formulants available information with updated MSDS
- Make use of pre-submission meetings to discuss the products for representative use components
- Collect information along the supply chain (e.g. for mixture-in –mixture co-formulants), check the quality of the information
- Consider, also in terms of time, the possibility to receive request from Member States to complete the information submitted at authorization stage
- Consider the possibility of replacement of unacceptable co-formulants and plan the suitable test to be performed

Reminders to EFSA:

- Increase transparency as regards assessment of product(s) for representative use(s) in the EFSA Conclusions (EFSA and MSs during peer review);
- Request additional info on co-formulants if needed (EFSA and MSs during peer review);
- To complement the EFSA technical report on co-formulants (e.g. include additional info such as concentration ranges, classification-harmonised/not harmonised)

Commission is planning to:

- To prepare a series of workshops, in collaboration with EFSA and ECHA:
  - 1st WS (May 2023) – will set the scene with stakeholders and mapping the issues to be discussed and resolved (planned back-to-back of May PAFF)
  - 2nd WS (June 2023): a technical workshop to discuss with risk assessors (planned back-to-back of June PAI WG) to find possible solutions
  - 3rd WS (Nov 2023): to inform Member States at zonal assessment

- Work with EFSA to ensure more transparency in EFSA Conclusions as regards consideration of the co-formulants in the product(s) for representative use(s) in active substances approval/renewal.

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Specific groups of coformulants also raising attention by Stakeholders&Member States

- PFAS in co-formulant or in PPPs as contaminants;
- Co-formulants which are formaldehyde releasers;
- Polymers/monomers as co-formulants;
- Co-formulants which are mixture contained in a mixture;
- Co-formulants containing impurities

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