OVERVIEW OF CO-FORMULANTS IN PPP – NEW ASSESSMENT PARADIGM ? NEW CHALLENGES

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CropLife Europe Annual Conference
05 & 06 March 2024 Brussels

Plant protection product

co-formulants

active substance(s)

overview of co-formulants as part of the product(s) for representative use (EU approval of active substance)

classification & labelling

TRV

exposure (NDE)

hazard and risk mitigation measures

next step ? Risk assessment

LEGAL FRAMEWORK

COMMISSION REGULATION (EU) 2021/383 of 3 March 2021 listing co-formulants which are not accepted

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COMMISSION IMPLEMENTING REGULATION (EU) 2023/574 of 13 March 2023 setting out detailed rules for the identification of unacceptable co-formulants in plant protection products

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EFSA technical report (based on products submitted for representative uses in the dossiers for active substances since 2019)

ASSESSMENT OF CO-FORMULANTS IN PPP

Overview of co-formulants as part of the product(s) for representative use (EU approval of active substance)

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Overview of co-formulants as part of each product assessment (at Member State level in the PPPs authorisation process) (??)

ASSESSMENT OF CO-FORMULANTS IN PPP

New elements for the assessment of co-formulants in regards PPP

Short term toxicity (NOAELs)

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Genotoxicity

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Long-term Toxicity And Carcinogenesis (NOAELs)

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Reproductive toxicity: generational studies and developmental toxicity studies (NOAELs)

ASSESSMENT OF CO-FORMULANTS IN PPP

New elements for the assessment of co-formulants in regards PPP

Neurotoxicity

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Other toxicological studies: Endocrine disruptors (human health and environment) (!!)

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Persistent, bioaccumulative, and toxic (PBT) properties

POSSIBLE CHALLENGES

Incomplete data for the complete co-formulants identification (e.g., polymers, co-formulants without CAS number, UVCB) and breakdown products of co-formulants,

Classification: Difficulty in assessing co-formulants when no ECHA harmonised classification (CLH) is available on the ECHA website, or, when several divergent notified classifications are established by the applicant(s) in different Safety Data Sheet (SDS),

Available data e.g. from other regulatory frameworks are not fully exploited – not easy to retrieve them,

POSSIBLE CHALLENGES

- Reference values valid for active substance may not be applicable to the whole product as a mixture (mixture toxicity),

- Not all studies conducted for the active substance can also be conducted for co-formulants,

- Long term toxicity assessment / setting reference values for co-formulants is difficult to be addressed,

POSSIBLE CHALLENGES

- Co-formulants go beyond 1107/2009 but another legal framework (e.g REACH, EMEA, CIR) establishes different criteria,

- Accessibility and lack of data (in particular for the co-formulants that are produced in less quantities),

- Should risk assessments be performed for all or certain co-formulants of concern? (e.g., should we set reference values for all co-formulants?),

POSSIBLE CHALLENGES

Sometimes the applicant claim equivalence between different co-formulants, but such equivalence cannot be verified either because not even the applicant knows the composition of the co formulant (e.g. co formulants belongs to other companies),
or
because such composition is confidential.

In these cases, MS ask applicants to retrieve this information (e.g., by the co-formulants' manufacturers), which slows down the process.

POSSIBLE CHALLENGES

- Sometimes there is a different CAS in the MSDS, than the CAS available in the composition provided by the manufacturer of the co-formulant to MS,

- Applicants do not produce the co-formulants. Detailed information regarding composition only available upon request from authorities, directly from producer (co-formulant owner),

- Effective and robust analytical control for co formulants is needed,

POSSIBLE CHALLENGES

It is challenging to understand possible effects on terrestrial non target organisms.

REACH asks data on terrestrial to be assessed, but this is often missing in dossier for co-formulants.

Terrestrial toxicity is not well picked up by the Regulation, which is more focused on aquatic toxicity.

FINAL CONSIDERATIONS

- Create European Database with the identity of the co formulants and comparability between them,

- Prioritize the most common/used co-formulants to avoid duplication at MS level, (assessing the wealth of data will cause a big amount of work)

- Guidance document on the evaluation the co-formulants (including the comparability),

- Create better tools to identify co-formulants that are not considered of concern because used in other regulatory frameworks e.g. for cosmetics or as food additives,

FINAL CONSIDERATIONS

- Give guidance to navigate the different regulatory frameworks, data requirements, dossiers and databases,

- Database to be built to avoid requesting the same information to the suppliers and to share the information among MSs,

- Disregards the notified classifications from companies and to consider only the CLH classification if available ?

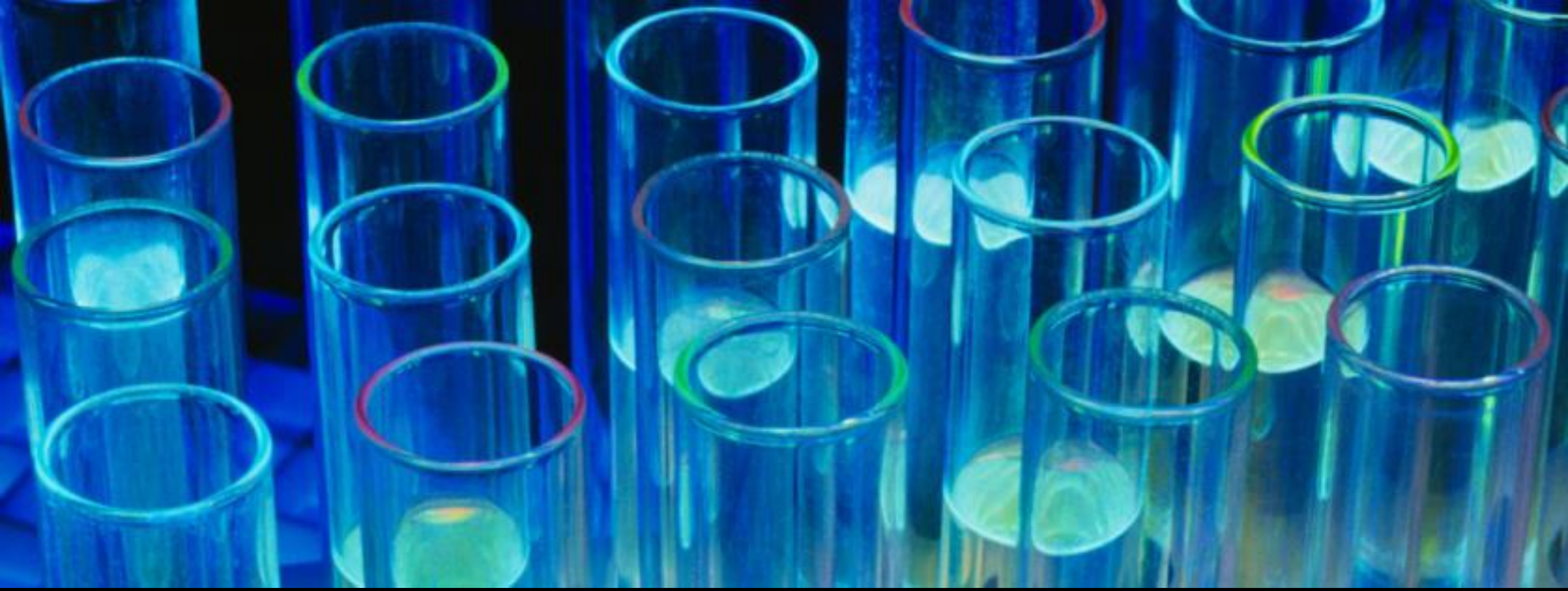
FINAL CONSIDERATIONS

- Commonly agreed approaches and harmonization of the evaluation of co formulants at EU level and at national level (Member States) ?,

- Stepwise assessment (tiered approach), starting with hazard assessment. Identify what else might be missing after the hazard assessment,

- Define criteria when we need a risk assessment – not to carry out a full risk assessment every time by default,

- Harmonize how we consider co-formulants to avoid parallel assessments with divergent outcomes at different authorities.



THANK YOU FOR YOUR ATTENTION

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