



CropLife
EUROPE

Co-formulant challenges – an industry perspective

Regulatory Conference

7-8th March 2023

Co-formulant challenges

- ▶ Annex III issues
- ▶ Alternative co-formulant suppliers
- ▶ Co-formulant risk assessment

Common themes in this presentation: need for harmonized interpretation and implementation by Member State authorities; better collaboration between authorities and with industry.



Unacceptable co-formulants - implementation

Key challenges

- Overall “Annex III” implementation has run relatively smoothly in most Member States, with some exceptions.
 - Although has been some “last minute activity” with unrealistic timelines
- Biggest issues are **non-harmonized approaches** to: **Formaldehyde releasers**, Requests for co-formulant “**full compositions**”

Formaldehyde releasers

- **Only formaldehyde is listed on Annex III.** This means it cannot be used as a co-formulant, it cannot exceed 0.1% as an impurity in a PPP.
- Various unofficial lists have been circulated claiming that the formaldehyde listing on Annex III also means so called “formaldehyde releasers” are also banned. This is an issue because:
 - These **lists have errors** in them – this shows why it is so critical only officially evaluated and harmonized lists from REACH / CLP are used to set up Annex III.
 - There is **no legal mechanism** to “**read-across**” from Annex III to other substances – essential for legal certainty.
- There is no issue with “**unintentional** formaldehyde releasers” – simply comply with Annex III and ensure the concentration of any formaldehyde that may form as an **impurity** does not exceed 0.1%, e.g. stoichiometry (calculation), analytics, etc.

See backup slide for more details

Annex III - implementation

Annex III and requests for “full composition”

- In our view requests for full compositions are nearly always unnecessary for the implementation of Annex III: everything on the list is hazardous and should be found declared on the supplier SDS.
 - e.g. Benzene: it would be illegal for a co-formulant solvent supplier to have more than 0.1% benzene in their product and not declare it on the SDS.
- Note: not everything listed on an SDS is a co-formulant – meaning intentionally added by the Authorization holder to the formulation recipe:
 - Impurities are not co-formulants, these are only present unintentionally, and serve no function.
 - Impurities are typically recognisable on an SDS because the concentration is low, specified as a maximum e.g. <0.1%, and is usually hazardous. Extreme example: nobody is using benzene as a co-formulant!

Challenges for Authorization holders:

- Reliant on co-formulant suppliers to respond to Members State requests, and have no means to control or check compliance with imposed deadlines.
- Information deficit – if there is an issue we are “in the dark”

What are the other impacts of requesting co-formulant “full compositions”?

“Full composition” – includes identification of non-hazardous components.

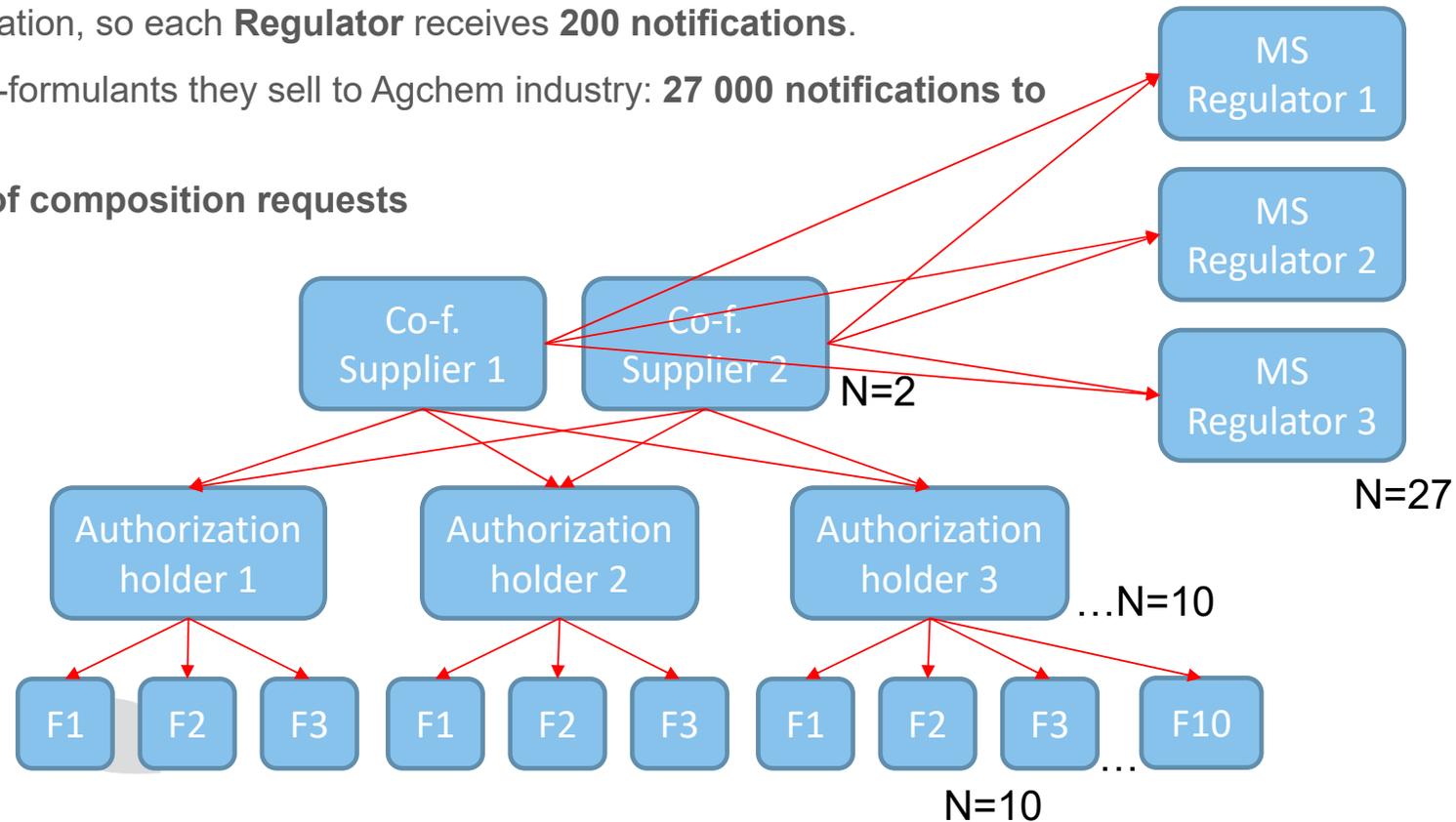
Compositions requests – there has to be a better way!

- Simple calculation: Each Co-formulant Supplier of a substance has 10 customers, each Authorization holder has 10 products. 27 Regulators.
- Each **Supplier** must make **2700 notifications** (10x10x27) to the Regulators. But each Authorization holder has 2 suppliers for risk mitigation, so each **Regulator** receives **200 notifications**.
- If each Supplier has 10 different co-formulants they sell to Agchem industry: **27 000 notifications to Regulators**.
- This is the “big picture” impact of composition requests

Given that:

- All hazardous substances are already listed on the SDS.
- And the additional composition information is solely on **non-hazardous** substances, or those **below** the classification **threshold**.

In this context, it is worth reflecting on **what is the value** brought by the collection of this additional information?



Compositions requests – possible improvements

- Rely as much as possible on supplier SDS information – the legal framework is already in place on what to declare, including enforcement options.
- Request additional information only if there is a specific concern.
- For **substances** the “sameness” identity is defined in the Joint Submission REACH registrations. Composition is only really a question for **mixtures** (i.e. often tradename products).
- Short term: Member States can make public a list of co-formulants for which **composition information** has already been obtained, and **no resubmission** is required e.g. approach of Germany, or US EPA. Ideal would be to share between Member States – legal issues?
- Longer term: consider a central confidential composition database?



Alternative co-formulants suppliers: challenges

SUPPLY CHAIN DISRUPTION OVERVIEW



- Alternative co-formulant suppliers are not “nice to have” – they are **essential for the security and robustness of European supply chains**.
- A **fast** alternative supplier notification response is essential. A recent CLE member survey found MS response times vary from 2 months to **2 years**.
- Harmonization and certainty of outcome between Member State assessments is **absolutely essential** for the EU common market.

Alternative co-formulants suppliers: challenges

- **Different interpretations** of SANCO “non-significant change” guidance, and rejection of alternative co-formulants accepted in other Member States:
 - There appears to be a tendency towards assessing “identical” rather than looking for “equivalent” and accepting some variability, particularly aspects which are not relevant to formulation classification or risk.
 - If an alternative is rejected because of a non-hazardous (confidential) component, the Authorization holders have no predictability.
- **Co-formulants which are mixtures:**
 - It is very unlikely to have mixtures with ≥ 3 components to be identical from different suppliers (this would imply IP infringement...).
 - A **rigid focus on “identical”** will result in **single supplier** situation and **fragile EU supply chains**.
- **Harmonization and certainty of outcome between Member State assessments is absolutely essential.**

Co-formulant data and risk

- CLE's view is that **REACH generates proportionate & appropriate hazard data** needed for substances (co-formulants), which are then available for use in other vertical legislation e.g. plant protection, cosmetics, etc.
 - **REACH offers an opportunity to manage co-formulants in a harmonized and efficient manner. The same substances are often used in other sectors e.g. cosmetics (OSOA).**
- Empirically, most registered co-formulants tend to be high-volume “commodity chemicals”, with the highest REACH data requirements – recently confirmed by an EFSA survey.
- REACH supplies **long-term / chronic (eco)toxicology hazard data** on the substances used as co-formulants. This can then be used to derive thresholds (DNEL, PNEC) for **REACH** risk assessments, which includes co-formulant use.
- **Regulation 284/2013** allows for testing on co-formulants: in the vast majority of cases this is unnecessary and should be seen as a **last resort**. Note: in practice any such testing would still be fully subject to REACH processes and approvals e.g. inquiry, testing proposals, data sharing, etc.

Co-formulant risk assessment - REACH

- REACH can provide a harmonized approach to co-formulant data generation, and includes screening risk assessments
- CropLife Europe publications on **REACH** co-formulant risk assessment to support **Suppliers**: **REACH-IN** project

Risk Analysis, Vol. 37, No. 5, 2017 DOI: 10.1111/risa.12066

Development of REACH Generic Exposure Scenarios for Substances Used as Coformulants in Plant Protection Products

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This article reviews the interactions between the REACH (Registration, Evaluation, Authorization and restriction of Chemicals) regulation and the plant protection product regulation for substances used as coformulants in the European Union, and describes generic exposure scenarios developed for their exposure and risk assessment. The REACH exposure scenarios describe the operational conditions and risk management measures used in the risk assessment of a coformulant, and as such these translate as the boundaries of safe use. The generic exposure scenarios are designed to be simple, and closely integrate with REACH file descriptors and customized exposure models. Clustering of application methods and exposure determinants resulted in four generic exposure scenarios, each covering professional workers or consumers, and application of products in liquid, granular form, or applied on seeds. When used in conjunction with appropriate exposure models, the generic exposure scenarios support efficient first-tier risk assessment of coformulants by utilizing a higher level of abstraction and conservatism than typically used in plant protection product assessments.

KEY WORDS: Exposure scenarios, pesticides, REACH

1. INTRODUCTION

The European Registration, Evaluation, Authorization and restriction of Chemicals (REACH) legislation requires a holistic risk assessment of all the potential uses of a substance across many industrial sectors, including use in plant protection products.⁽¹⁾ Within the boundaries laid out in the regulation, a manufacturer or importer of a substance must generate substance-specific data^(2–4) and carry out a

hazard assessment,⁽⁵⁾ as well as exposure assessments of all identified uses for both human health^(6,7) and the environment.⁽⁸⁾ Finally, safe use must be demonstrated through risk characterization.⁽⁹⁾ The risk assessment is documented in a chemical safety report, and communicated along with summaries of the data, to the European Chemical Agency (ECHA) in a registration dossier. The conditions of safe use derived from this risk assessment must then be communicated within the supply chain to the downstream user via the extended Safety Data Sheet (SDS). Formal development of exposure scenarios as an integral part of exposure and risk assessment,⁽¹⁰⁾ as well as downstream user communication, is explicitly foreseen within the legislation.

Coformulants manufactured and imported in quantities >10 t/year and used in plant protection products have no regulatory exemption from the REACH human health exposure assessment,

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Original Article

REACH Worker Exposure Model for Co-formulants Used in Plant Protection Products

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Abstract

Background: Substances used as co-formulants in plant protection products (PPP) may require registration under Regulation (EC) No. 1907/2006 (REACH), and additionally where an exposure assessment is required, this must take into consideration the specifics of the PPP use.

Objectives: This work reports a customized screening level model developed to support human health risk assessment of operators, workers, and bystanders (OWB) for co-formulants used in PPP. The OWB model was designed to closely integrate with REACH generic exposure scenarios (GES) for PPP developed by the European Crop Protection Association (ECPA). The use of these tools in combination is expected to lead to a more standardized and hence efficient risk assessment of co-formulants and their professional and consumer uses were selected. The German BEA model was used to assess spray applications. Granule and seed dispersal was assessed using the US Environmental Protection Agency (EPA) Pesticide Handlers Exposure Database (PHED). ECETOCTRA was employed to assess exposure during certain tasks performed in seed treatment, not covered by these PPP models. Where the underlying models featured multiple exposure determinants, the exposure was calculated for all permutations, and the worst-case exposure selected and reported for use in risk assessment. The PPP models are based on measured data collected during actual application of PPP; hence, the worst-case exposure predicted was expected to reflect a realistic worst case for these tasks.

Method: Existing exposure models with regulatory acceptance for the most common types of PPP and their professional and consumer uses were selected. The German BEA model was used to assess spray applications. Granule and seed dispersal was assessed using the US Environmental Protection Agency (EPA) Pesticide Handlers Exposure Database (PHED). ECETOCTRA was employed to assess exposure during certain tasks performed in seed treatment, not covered by these PPP models. Where the underlying models featured multiple exposure determinants, the exposure was calculated for all permutations, and the worst-case exposure selected and reported for use in risk assessment. The PPP models are based on measured data collected during actual application of PPP; hence, the worst-case exposure predicted was expected to reflect a realistic worst case for these tasks.

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Health & Ecological Risk Assessment

REACH Specific Environmental Release Categories for Plant Protection Product Applications

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ABSTRACT

The European Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) regulation requires that quantitative environmental risk assessment is carried out for hazardous substances used as coformulants in plant protection products (PPP). (if registered above 10 t/y, the European Crop Protection Association (ECPA) has developed generic exposure scenarios and specific environmental release categories (SpERCs) to support these risk assessments. The SpERCs offer refinements to the default release factors defined in environmental release categories (ERCs) and are intended to be used with nested multimedia mass balance models as part of the assessment of regional predicted environmental concentrations. Based on the application method of PPPs, 2 scenarios were defined for which SpERCs were developed: 1) spraying of PPPs and 2) direct application of granular products or treated seeds to soil. The SpERCs for spray applications include release factors to air and soil that depend on the vapor pressure of the coformulant. Calculations are presented to support the subSpERCs describing the transition from nonvolatile to volatile behavior. The most recent version of the spray application SpERC defines a release factor for surface water and more conservative release factors to soil compared with previous versions. Use of the ECPA SpERCs allows the coformulant emissions from PPPs to be fully accounted for in the regional scale environmental risk assessment for a given substance, along with all other sources of emissions. Qualitative and quantitative justification for the ECPA-derived SpERCs is presented and serves as the background documentation to the online European Chemicals Agency (ECHA) SpERCs factheets. The approach developed here whereby regional-scale SpERCs are used in combination with a customized local-scale exposure model is potentially applicable for other sectors that are required to conduct exposure assessments outside the scope of the standard environmental REACH models. *Integr Environ Assess Manag* 2020;16:472–480. © 2020 Syngenta Crop Protection AG. *Integrated Environmental Assessment and Management* published by Wiley Periodicals, Inc. on behalf of Society of Environmental Toxicology & Chemistry (SETAC)

Keywords: REACH, Exposure modeling, Environmental release category, SpERC, Pesticide

INTRODUCTION

European Regulation (EC) No. 1907/2006 (Registration, Evaluation, Authorization and Restriction of Chemicals [REACH]; EC 2006) requires registrants in the European Economic Area to submit a chemical safety report for substances manufactured or imported at quantities greater than 10 t/y. For substances classified as hazardous, an exposure assessment and risk characterization is required for all identified uses, including use as coformulants in plant protection

products (PPP). Coformulants (assumed here for brevity to be substances, but are frequently also mixtures) are defined as all the intentionally added components of the formulation, other than the active substance, for example, solvents, surfactants, colorants, fillers, and anti foams. As such, coformulants are often commodity chemicals with a multitude of nonPPP uses, whereas the use in PPPs is often a niche application in terms of the overall tonnage manufactured. For coformulants that are hazardous and demonstrate environmental effects, the corresponding chemical safety assessment must contain an environmental exposure assessment that covers PPP uses and demonstrate that those uses are safe. The European Crop Protection Association (ECPA) has developed generic exposure scenarios for substances used as coformulants in PPPs, which enable manufacturers and importers to perform the required assessments in an efficient, robust, and standardized manner (Dobe et al. 2017).

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Environmental Exposure Assessment of Co-formulants in Plant Protection Products under REACH

Environmental Exposure Assessment of Co-formulants in Plant Protection Products under REACH

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DISCLAIMER

The LET was developed by an expert group formed from the member companies of CropLife Europe and tasked with developing a methodology for assessing co-formulants under REACH. All authors participated in the expert group during the normal course of their employment. The authors have responsibility for the writing and contents of the manuscript, and the views expressed in this article are those of the authors and do not necessarily represent the views or policies of CLE, or their respective employers.

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Accepted Article

Generic Exposure Scenarios

OWB - worker exposure

SpERCs - Env exposure

LET - Env. exposure

Conclusions

- **We need a truly harmonized approach to co-formulant management to support the EU common market, for example:**
 - Formaldehyde releasers, Composition requests, Acceptance of alternative co-formulants
- **Utilize the information from the co-formulant supplier SDS as much as possible**
- **Use REACH processes as much as possible to assess hazard/risk of co-formulants (One-substance One-assessment)**

Many more stakeholders involved with co-formulants (suppliers, ECHA, etc): a more collaborative approach is needed for efficient co-formulant management



 **Backup slide**



Formaldehyde releasers

Formaldehyde releasers

- “**Intentional** formaldehyde releasers” – substances deliberately used to release formaldehyde, their function and efficacy come from formaldehyde. “**Unintentional** formaldehyde releasers” may degrade to form formaldehyde, but they do not derive their function or efficacy from this.
- **Only formaldehyde is listed on Annex III**: it cannot be used as a co-formulant, it cannot exceed 0.1% as an impurity in a PPP.
- Various unofficial lists have been circulated claiming that the formaldehyde listing on Annex III also means “formaldehyde releasers” are banned. This is an issue because:
 - These **lists have errors** in them – this shows why it is so critical only official harmonized lists from REACH / CLP are used.
 - There is **no legal mechanism** to “**read-across**” from Annex III to other substances – essential for legal certainty.
- Use of *intentional* formaldehyde releasers is **not** defended here – only that Annex III is applied precisely to ensure regulatory certainty, and to avoid mistakes and unjustified loss of products.

Way forward

- **No changes** needed for “**unintentional** formaldehyde releasers” – simply comply with Annex III and ensure formaldehyde impurity concentrations do not exceed 0.1%, e.g. stoichiometry (calculation), analytics, etc. This is already a CLP classification obligation.
- “**Intentional** formaldehyde releasers” – MS can submit a **CLH proposal to ECHA**, then add to Annex III. See **CLP, Annex VI, Note 8** for already existing examples e.g. CAS 5625-90-1 [Formaldehyde released from N,N'-methylenebismorpholine], CAS 70161-44-3, etc.