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

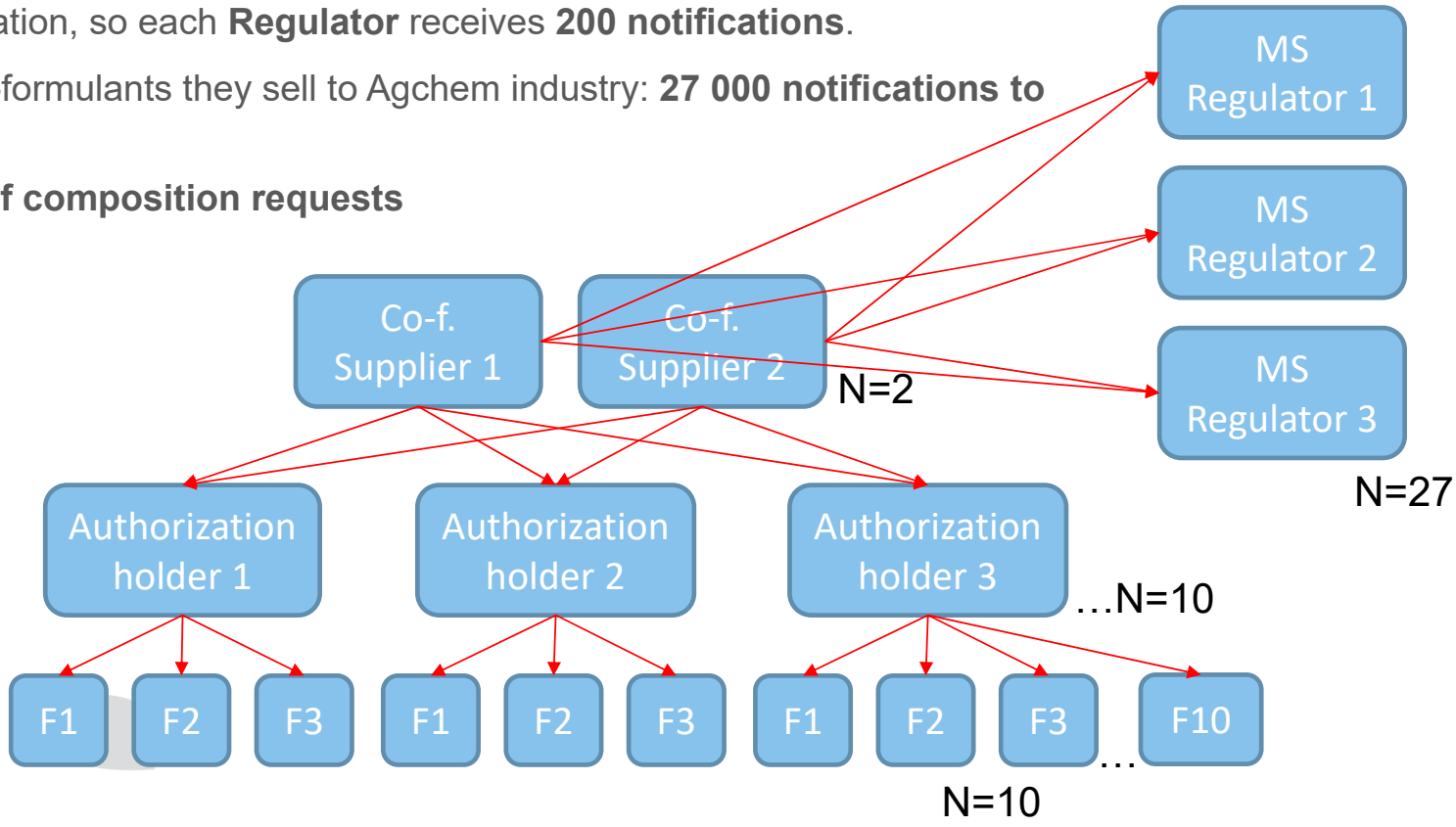
- **Annex III and requests for "full composition"**
  - In our view requests for full compositions are nearly always unnecessary for the implementation of Annex III: everything on the list is hazardous and should be found declared on the supplier SDS.
    - e.g. Benzene: it would be illegal for a co-formulant 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**

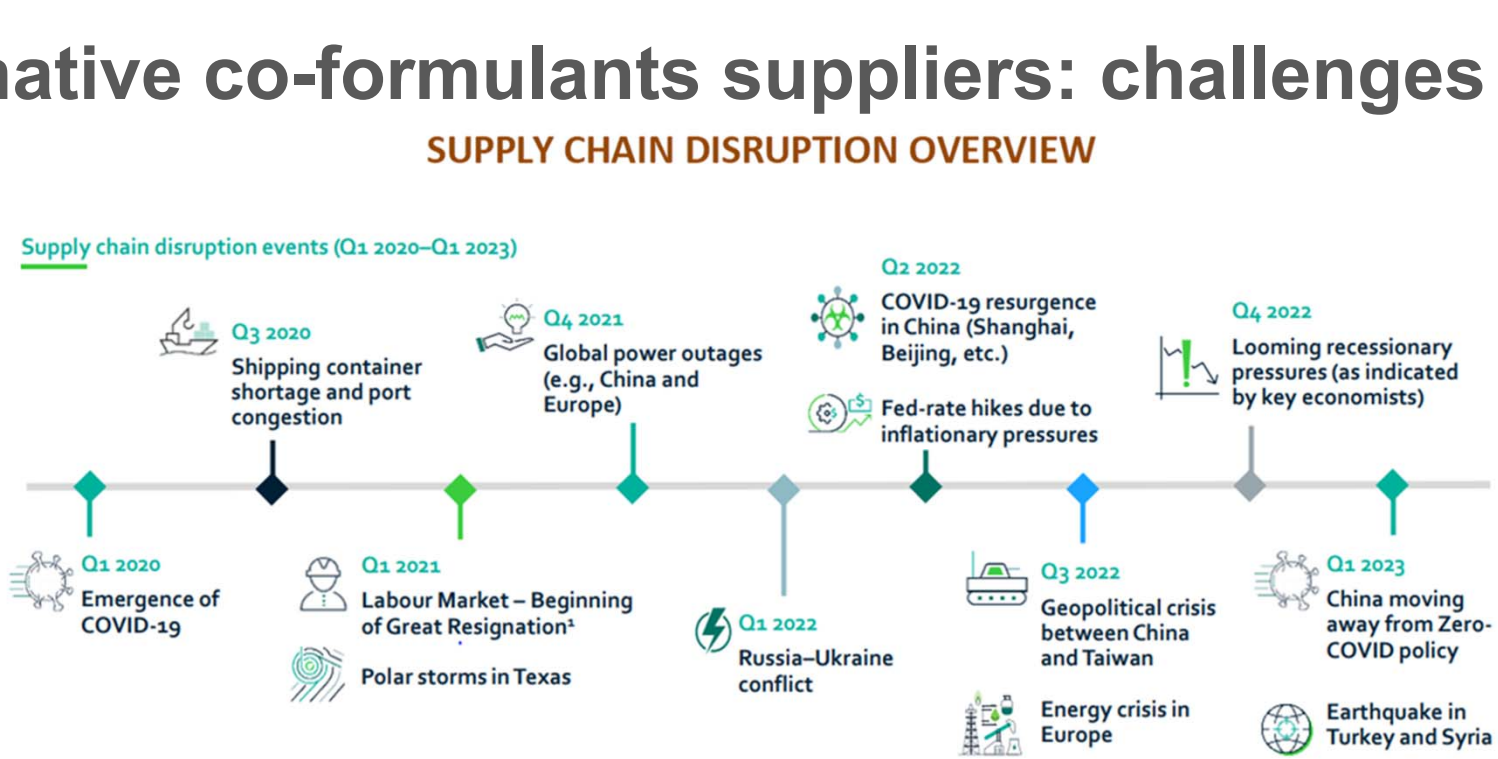
- Given that:
  - All hazardous substances are already listed on the SDS.
  - And the additional composition information is solely on **non-hazardous** substances, or those **below** the classification **threshold**.
- **In this context,** it is worth reflecting on **what is the value** brought by the 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



- 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.**

Source: The Smart Cube

Alternative co-formulants suppliers: challenges

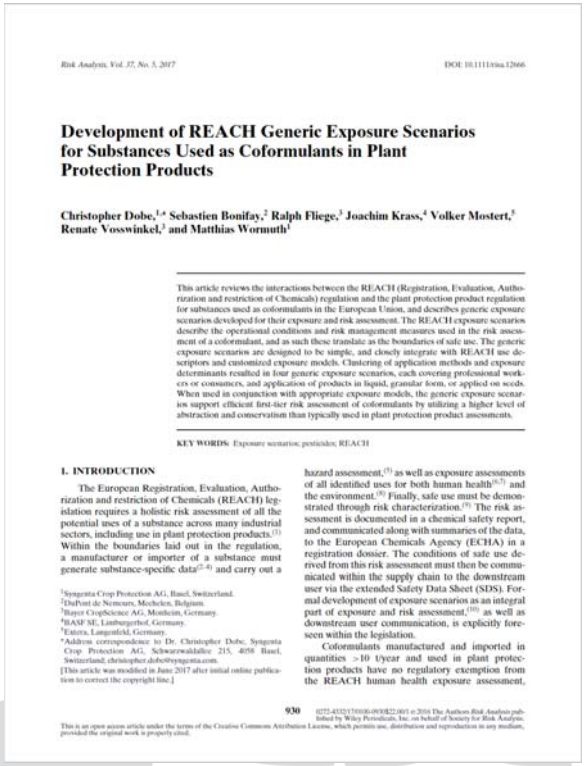
- **Different interpretations** of SANCO “non-significant change” guidance, and rejection of alternative co-formulants accepted in other Member States:
  - There appears to be a tendency towards assessing “identical” rather than looking for “equivalent” and accepting some variability, particularly aspects 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 <u>absolutely</u> 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 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 practise 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

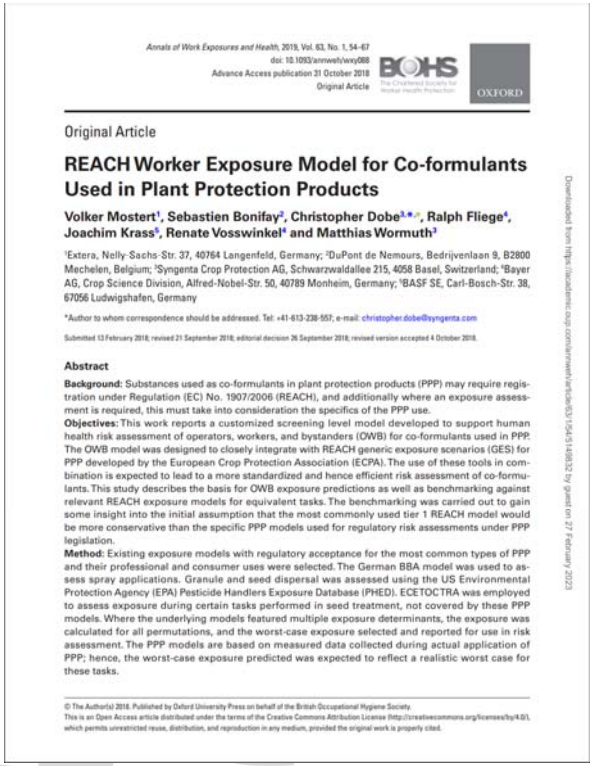
- REACH can provide a harmonized approach to co-formulant data generation, and includes screening risk assessments
- CropLife Europe publications on **REACH** co-formulant risk assessment to support **Suppliers**: REACH-IN project



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

Christopher Dobe,[1,*] Sebastien Bonifay,[2] Ralph Fliege,[3] Joachim Krass,[4] Volker Mostert,[5] Renate Vosswinkel,[3] and Matthias Wormuth[1]

Generic Exposure Scenarios

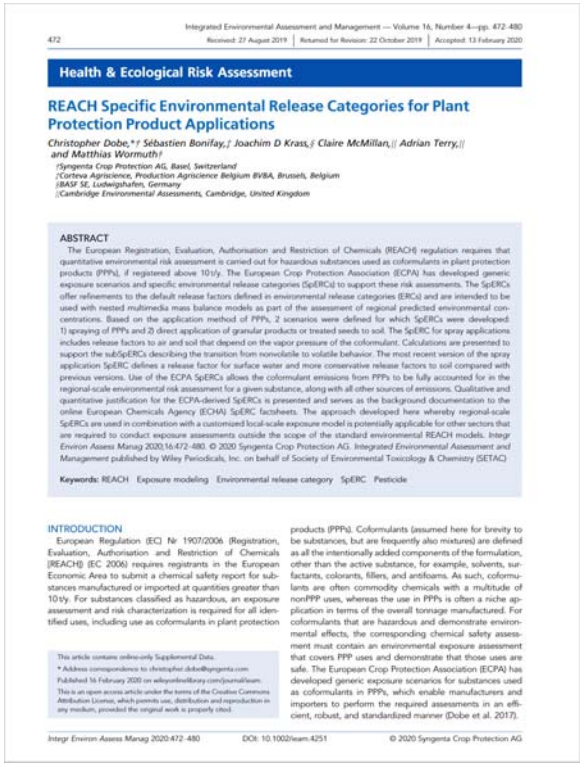


Original Article

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

Volker Mostert[1], Sebastien Bonifay[2], Christopher Dobe[3,*,#], Ralph Fliege[4], Joachim Krass[5], Renate Vosswinkel[4] and Matthias Wormuth[3]

OWB - worker exposure

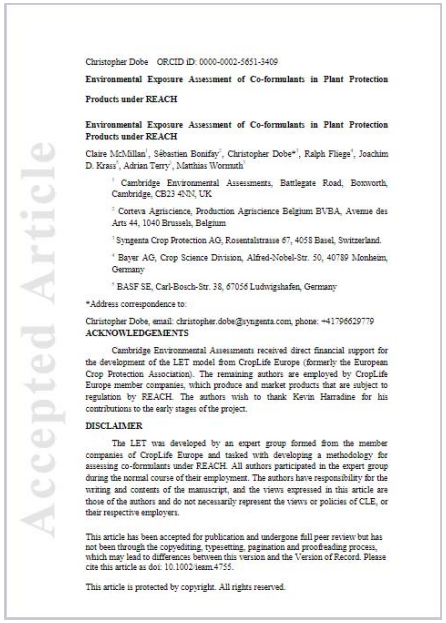


Health & Ecological Risk Assessment

REACH Specific Environmental Release Categories for Plant Protection Product Applications

Christopher Dobe,*† Sébastien Bonifay,‡ Joachim D Krass,§ Claire McMillan,|| Adrian Terry,|| and Matthias Wormuth†

SpERCs - Env exposure



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

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

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.