Downstream Users of Chemicals Co-ordination group

FEA conference

22nd Sept 2022

Who is DUCC ?

- 11 EU associations
- **>9.000 companies** across the respective sectors in Europe, **the vast majority being SMEs**
- Turnover = more than 215 billion euros
- Common voice on **REACH** & **CLP**
- **20 years - A respected partner with authorities, COM, ECHA for Downstream Users**

Chemicals Strategy for Sustainability

- Published in 2020

- Aims to simplify and strengthen the regulatory framework on chemicals to further increase the level of protection of human health and environment while boosting the competitiveness of the EU chemicals industry

- Reopening of key pieces of EU legislation, including the REACH Regulation and the Classification and Labelling (CLP) Regulation

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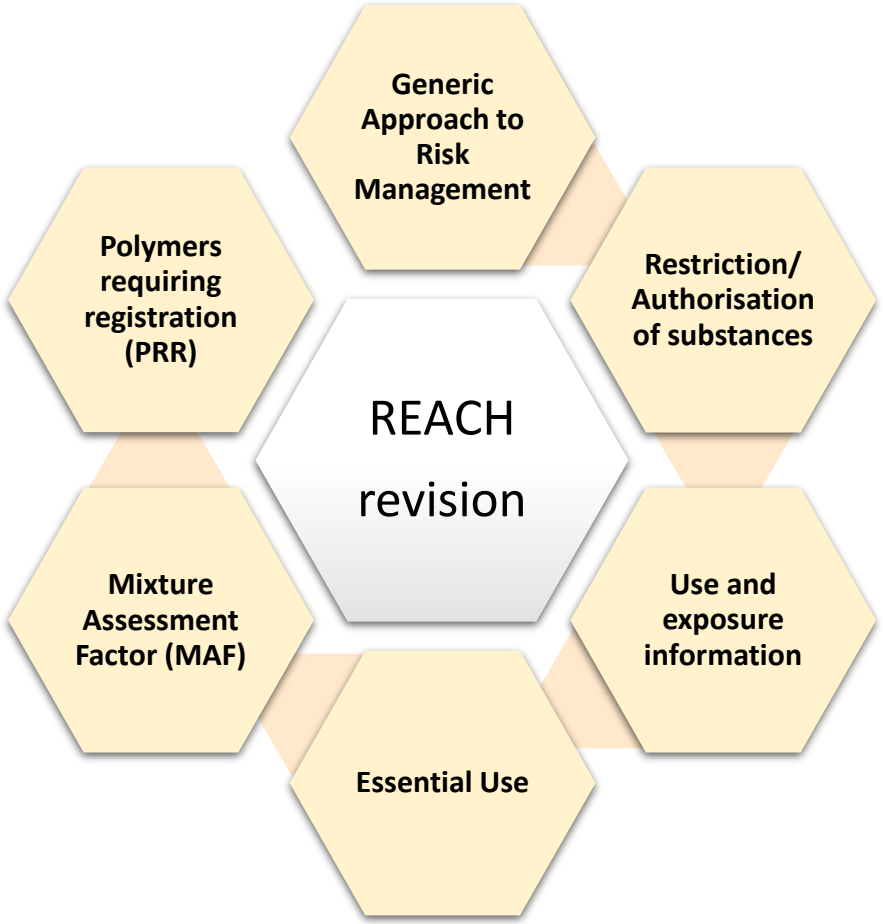
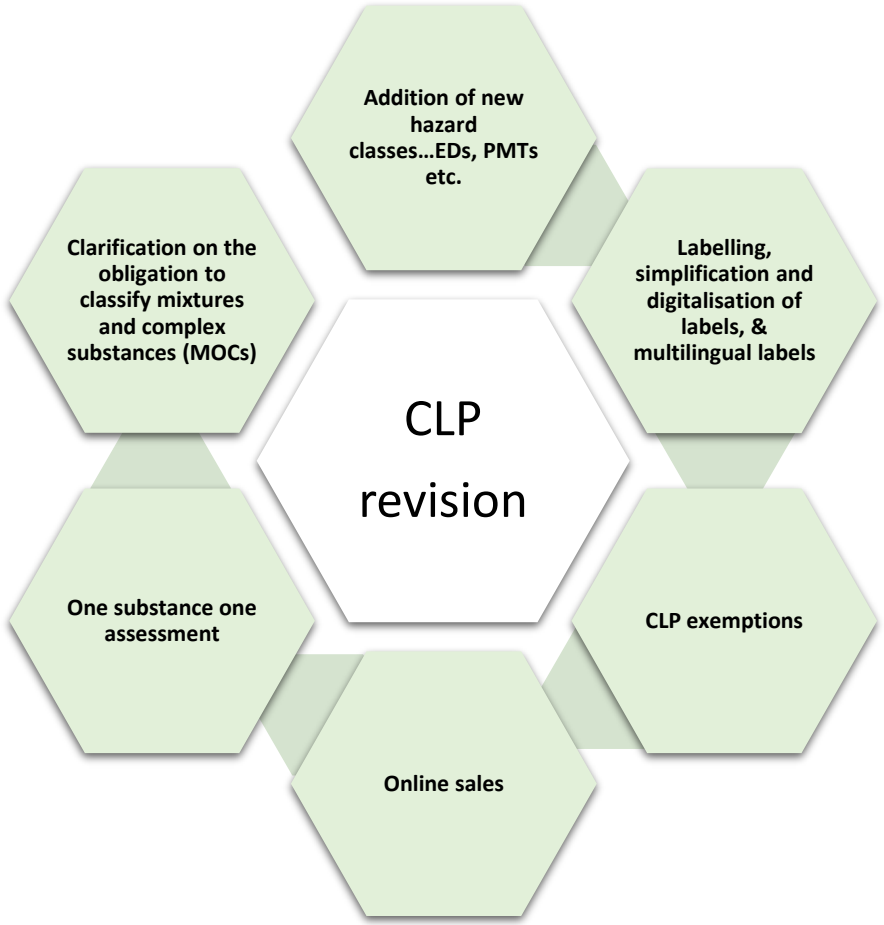
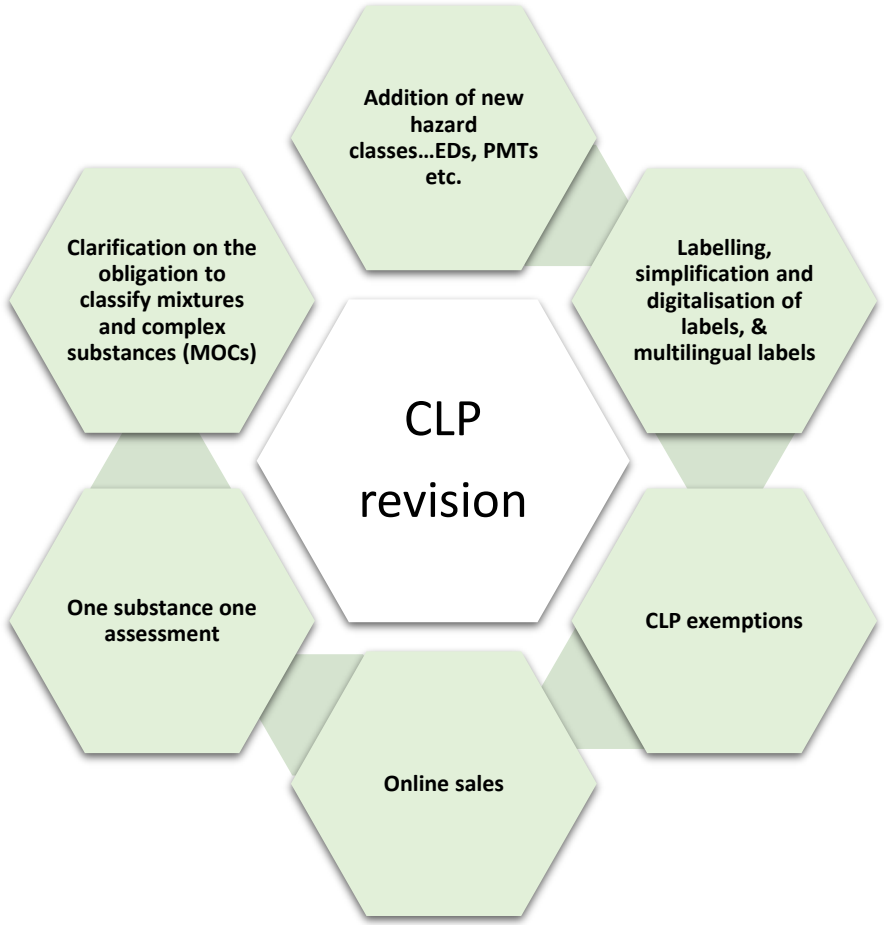
Chemicals Strategy for Sustainability





CLP revision

- May 2021- June 2021 - **Roadmap**
- August 2021 – November 2021 – **Public consultation to stakeholders**
- December 2021 – **Targeted consultation to stakeholders**
- **DUCC** participated in the **expert group of REACH & CLP (CARACAL)** and **expert group on Endocrine disruptors (CASG ED)**

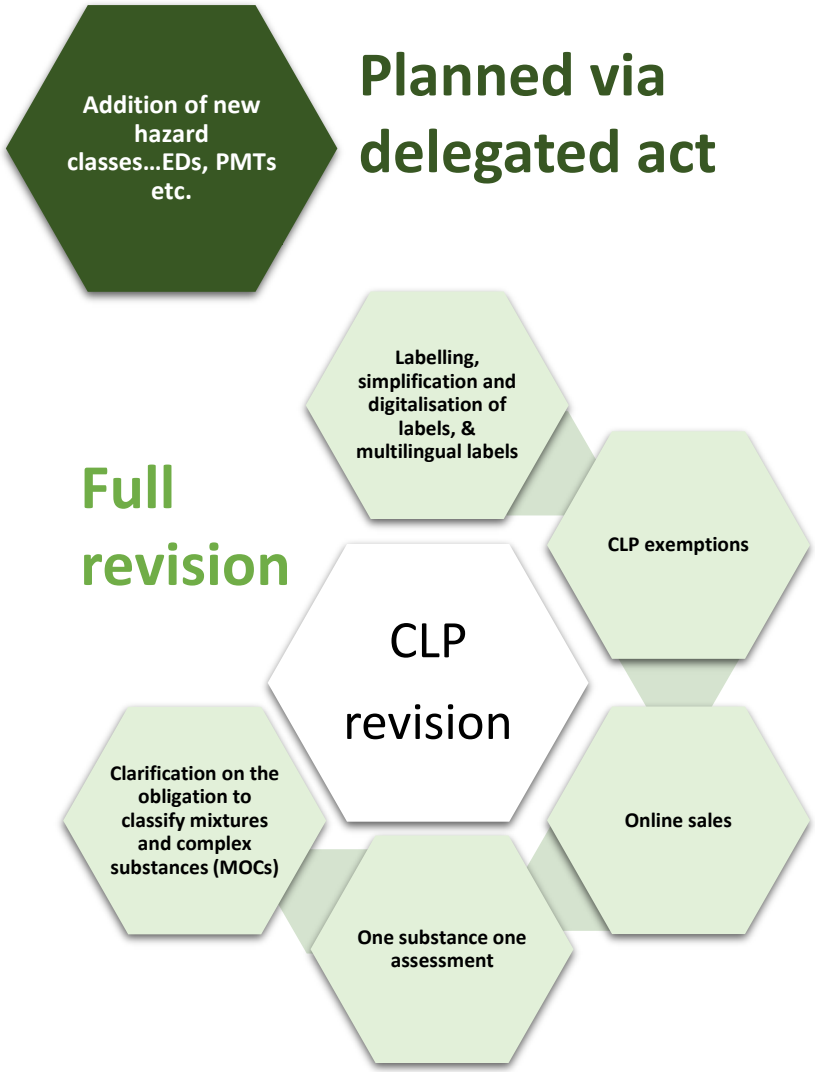


CLP Revision

- **Autumn/ September 2022** - Ad hoc CARACAL meeting for discussion on the delegated act for CLP hazard classes

- **Autumn 2022** – Commission's proposal to revise CLP will be presented to the College of Commissioners after the summer break

- **26 October (*?*)** - Adoption by College of Commissioners prior to submission to EP and Council.



CLP Revision - DUCC

CLP revision

CLP will have wide ranging impacts on downstream users. DUCC strongly urges the European Commission to include evaluation of sectorial implications in CLP impact assessment.

Addition of new hazard classes…EDs, PMTs etc.

The foreseen CLP criteria should be the criteria in place for plant protection products or for biocide products, which are based on the WHO definition and criteria.
Allow the use of additional data to classify substances as “mobile” under CLP

Labelling, simplification and digitalisation of labels, & multilingual labels

DUCC supports for labelling requirements to be end-user relevant. In this, data supporting that consumers prefer simpler labels, and the value of the use of icons, should be considered. DUCC supports the work of Commission on simplification of the label and digitalisation. For professional Users/ I&I it is key to also note that these users also receive information through other means (e.g. multilayer fold out labels).

CLP Revision - DUCC

CLP exemptions

Adding labelling requirements to small packaging will result in additional labelling requirements for Downstream Users/ producers of certain mixtures.

Online sales

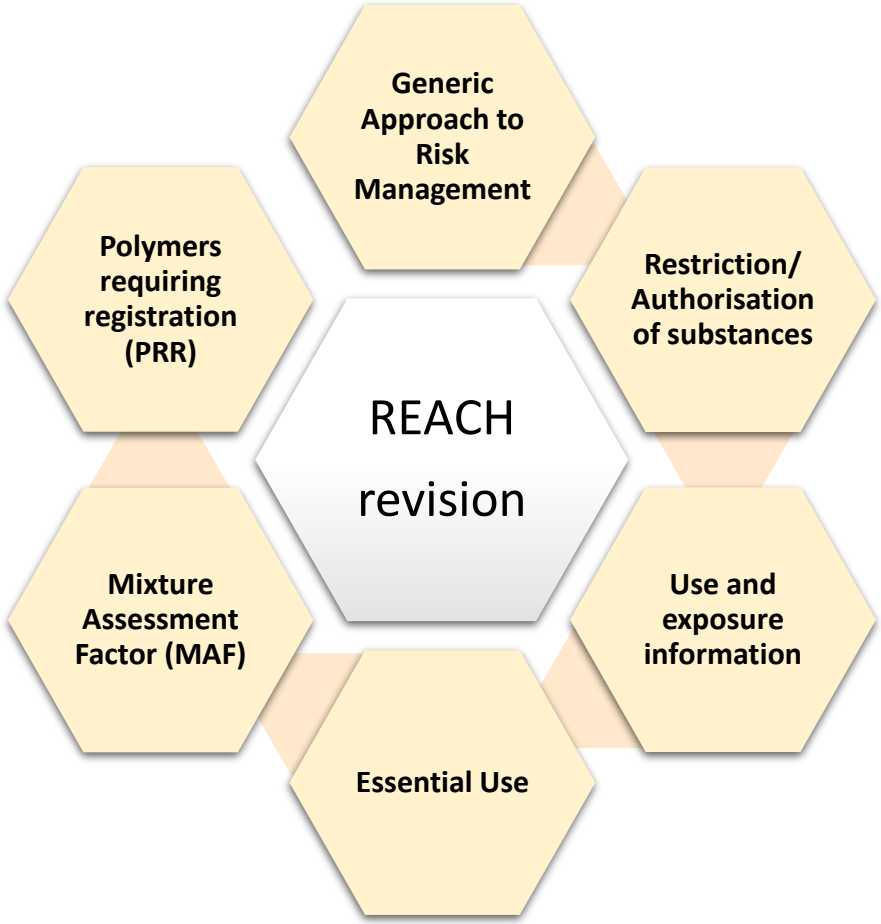
Clear information on products needs to be available for all items sold via online platforms. The requirements to list product ingredients as well as hazard and precautionary information needs to be same for online stores as it is in physical stores. However, DUCC refers to the Digital Product act and question if CLP is the adequate framework for this discussion.

DUCC factsheet on online sales

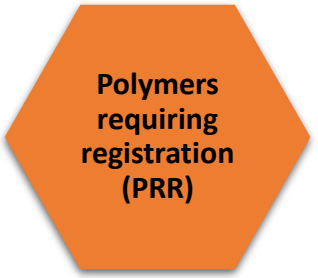
One substance one assessment

DUCC agrees that good access to data by regulatory agencies is important. It is crucial that this is made possible respecting **data protection (data access rights)** and **confidential business information** (e.g. confidential technological processes, persons names).
The weight of evidence criteria must be clear and reliable.
Data collected should be limited to relevant chemical substances only (data access to chemicals that are placed on the market only).
Data generated by companies for R&D purposes should remain confidential, this is vital to encourage innovation.

REACH Revision



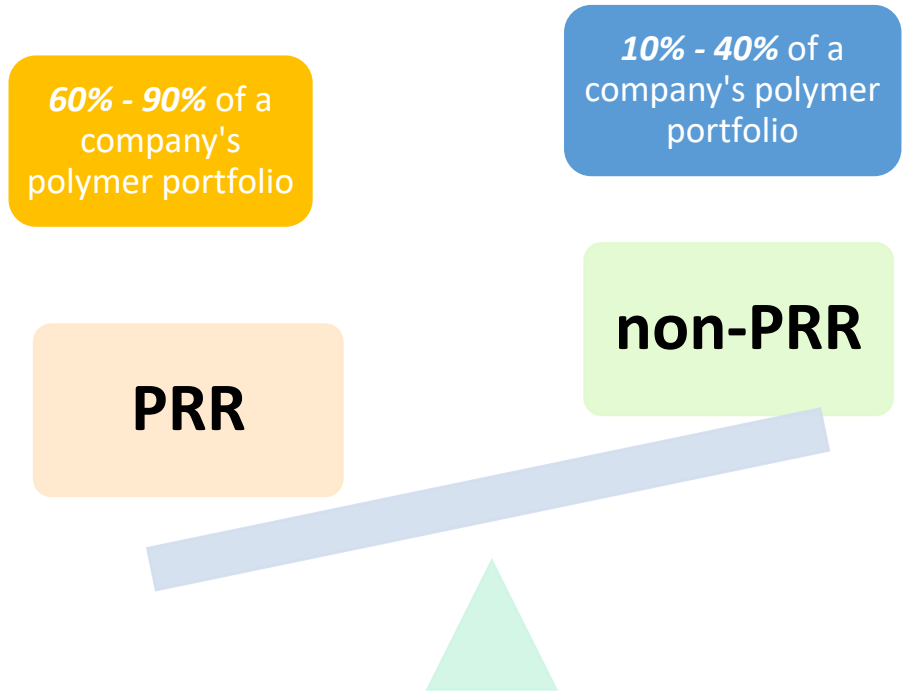
Polymers requiring registration (PRR)



- The Commission to make a proposal to extend the duty of registration under REACH to certain polymers of concern.
- A CARACAL-subgroup on polymers was formed in 2020
- 8 meetings between Sept 2020 and May 2022 to discuss: identification of PRR (Polymers requiring registration), Notification, Grouping and Registration of polymers
- On several aspects no unanimous view.
- Summer 2022 – Commission has identified different options and been working on an impact assessment

PRR - DUCC

- The split of Polymers Requiring Registration (PRR) and those not Requiring Registration (non-PRR) is estimated to be:



Polymeric precursors exempt from registration if handled under Strictly Controlled Conditions

OR

Polymeric precursors exempt from registration if handled under Adequately Controlled Conditions (as currently handled)

Up to 85% of polymeric precursors would be subject to the exemption.

Stricter requirements do not ensure greater safety.

Polyesters built from a list of ECHA-approved monomers are exempt from registration

Polyesters are known to break down in aqueous media into their building blocks (monomers). These monomers are known and of negligible hazard. Thus, they are considered to be safe for human health and environment (as found by EPA in 1995). Similar registration exemptions have been granted in the USA, Canada and Australia

Up to 60% of a company's portfolio would be subject to this exception.

Polymers > 1000 Da with low oligomer content (< 2% of MW <500 Da, < 5% of MW <1000 Da) are PRR

OR

Polymers > 1000 Da with high oligomer content (< 10% of MW <500 Da, < 25% of MW <1000 Da) are PRR

The number of registrations of option 1 would increase between 25% - 50%, depending on the company, compared to option 2. DUCC clearly favours option 2

Notification - Detailed information for PRR and non-PRR, deadline 3 years Entry into Force

OR

Notification with fewer information requirements for PRR & non-PRR. Plus pre-registration with more information only for PRR, 1 year after Entry into Force for notification, 5 years for pre-reg for PRR

Make the notification timelines proportionate to the notification requirements.

PRR - Plans

Registration Process

1. PRR-assessment
   - on basis of PRR-flowchart
2. Notification of all polymers
   - information submitted to an inventory at ECHA
3. Registration of PRRs
   - preferably in groups

European Commission

Next steps

- Impact Assessment of options by **Summer 2022**
- Finalisation of Commission proposal by **Q1 2023**
- Co-decision process on Commission proposal – **3 years?**
- Final step: COM Regulation amending REACH for polymers – **2026?**
- Entry into force- **2027?**
- Notification- **2028?** (information to be submitted)
- Registration- **203? => stepwise**

European Commission

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REACH Revision – GRA/Essential Use/Restrictions

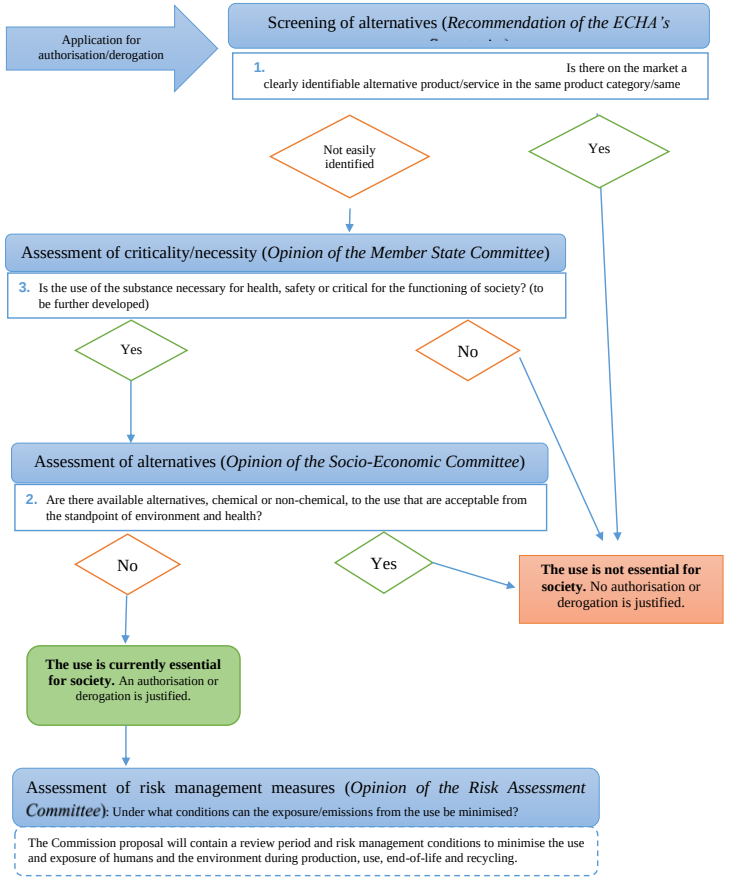
Major change in chemical management (risk-based vs. hazard- based)

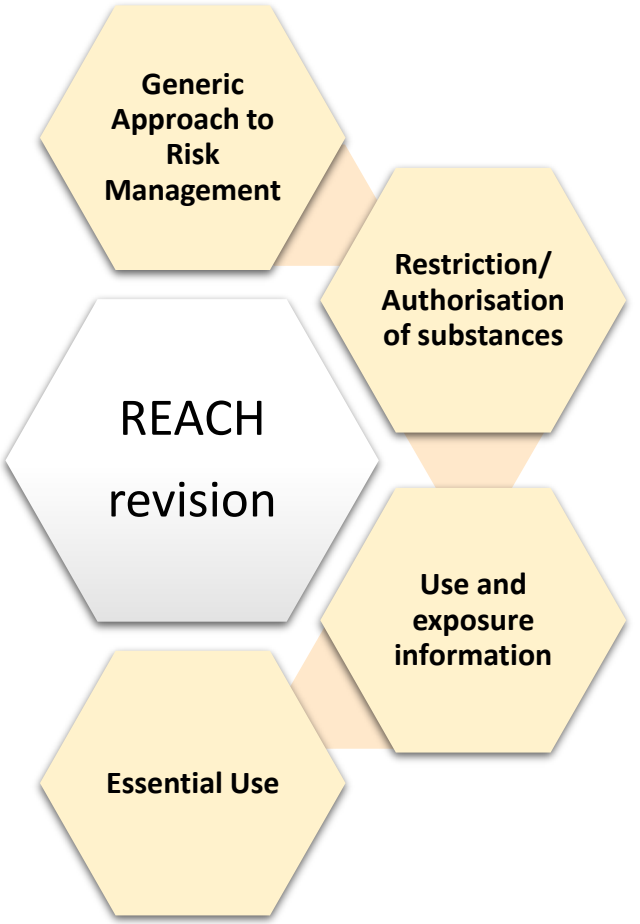
"Generic Risk Approach" - automatic trigger that withdraws certain substances from the EU market at a specific threshold, whether there are identified substitutes or not.

- Expansion to certain professional users

Increased obligations for DU on use and exposure information

Reform of the restriction and authorization approach





GRA/Essential Use/Restrictions - DUCC

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Alternatives

Elimination of an entire product category should be considered enough of an impact for a robust assessment of alternatives.

- Industry should have the possibility to demonstrate lack of alternatives.
- Must make sure the alternative also does not contain substances that are subject to GRA and does not have other adverse impacts.
- If a suitable alternative is found, then downstream users/formulators will innovate to use different chemistries
- However, if no alternatives are available then time must be given for innovation

Disproprotionate impacts

If a substance is impacted by the GRA, and the assessment of alternatives shows no suitable alternatives with a ban leading to disproportional impact on a use that is clearly demonstrated as safe, then exceptional derogation should be an option. A disproportionate impact can include socioeconomic considerations including job losses deriving from the restriction and elimination of product categories or industry (sub-)sectors.

Definitions

When assessing if the use of a substance is necessary for health, safety or society:

- "Mental health/ self-esteem" should be considered as part of the definition of 'health'.
- Accident prevention should be considered part of safety
- The definition of 'Essential Use' should also consider the EU Green Deal /Sustainability benefits of a substance compared to potential alternatives

Professional users

DUCC wants to engage in improving training for professional users, for the sectors and uses where it is applicable

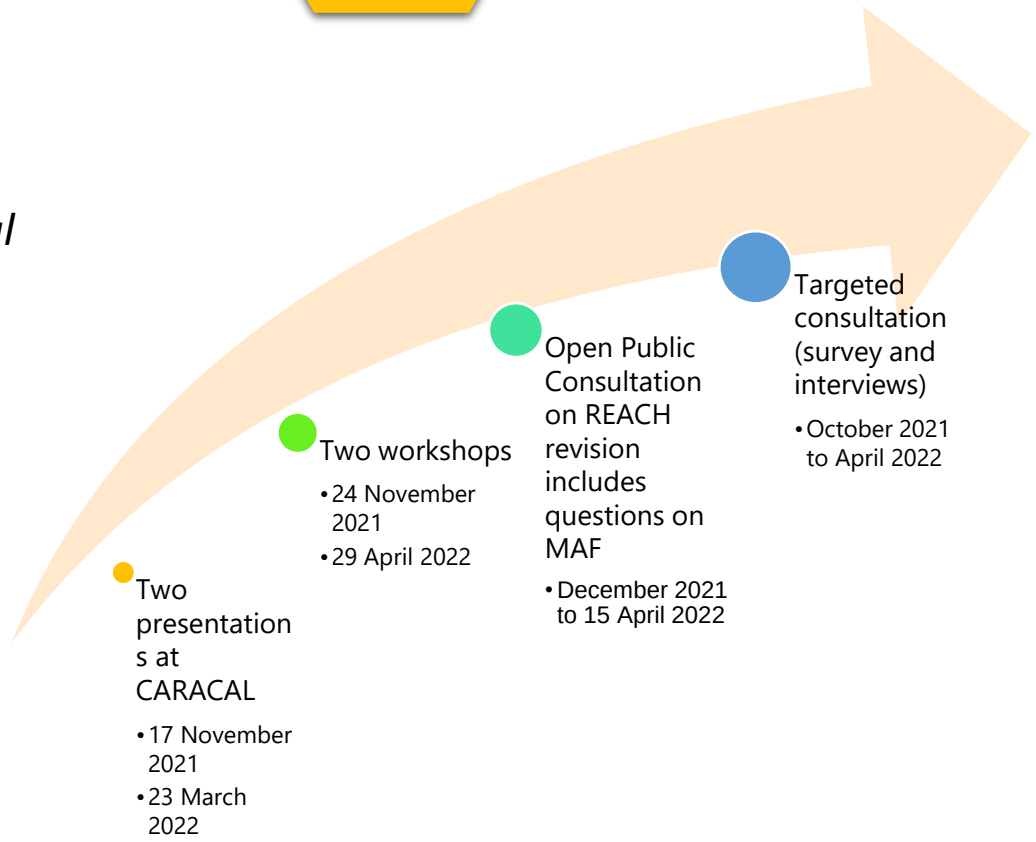
Mixture Assessment Factor

Mixture Assessment Factor (MAF)

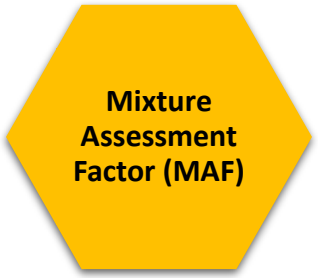
"A pragmatic approach to manage the current situation where there is a lack of toxicity and exposure data on unintentional mixtures, and therefore limited ability to account for unintentional mixtures in chemical risk (and safety) assessment of single substances"

"A MAF is a factor which could be applied in single substance chemical safety assessment, for example, in calculating the PNEC/DNEL3 or the RCR (risk characterisation ratio), in order to generate a risk estimate which accounts for unintended mixture effects."

(Ref: Wood Report 24th November MAF Workshop)



MAF - DUCC



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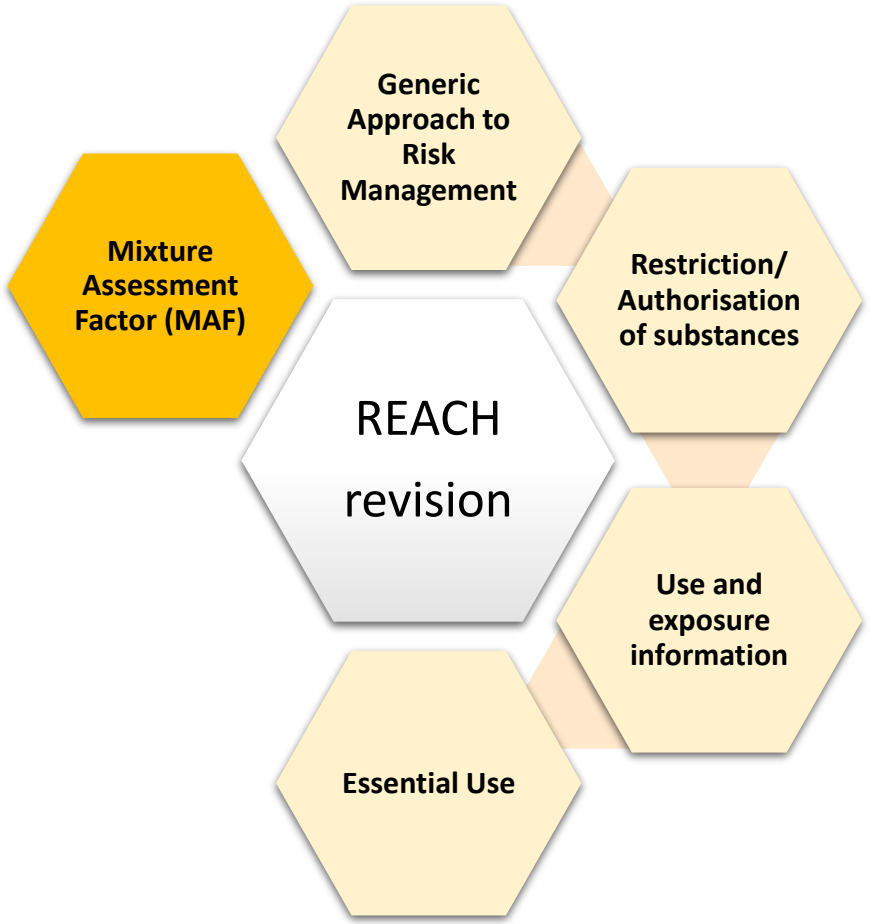
- A blanket MAF will have substantial impacts on downstream users. These impacts cannot always be mitigated.
- On the 18th February DUCC organised a workshop on the MAF with the consultant Wood. Various examples were brought forward to demonstrate that a blanket MAF will result in a great number of impacts on valuable, sustainable substance uses, animal testing and other key issues.
- **A more targeted approach** however, that focusses on what matters, will allow the objective of addressing unintended mixtures while still permitting for the resources of industry to be targeted and well directed towards reaching the objectives of the Green Deal.
- **The MAF should be applied to substances that, based on their characteristics, can end up in an unintended mixture and, if so, contribute to the mixture toxicity.** Unintentional co-exposure has spatial and temporal dimensions. Because the likelihood of possible unintentional co-exposure to chemicals for Human Health and to the Environment is highest for **substances that can bioaccumulate**, and substances that are **persistent**, respectively, the focus of MAF should be on PBTs that are used in **high tonnages** and **wide dispersive uses**.

REACH Revision

- Consultations finalised July 2022
  - Public consultation April 2022
  - SME panel in May
  - CARACAL meetings
- Summer 2022 - Commission worked on the impact assessment for amendment to REACH to identify the preferred options
- Submission to Commission Regulatory Scrutiny Board by the end of summer 2022, for a meeting in the autumn
- Commission adoption of proposal expected in Q1 2023



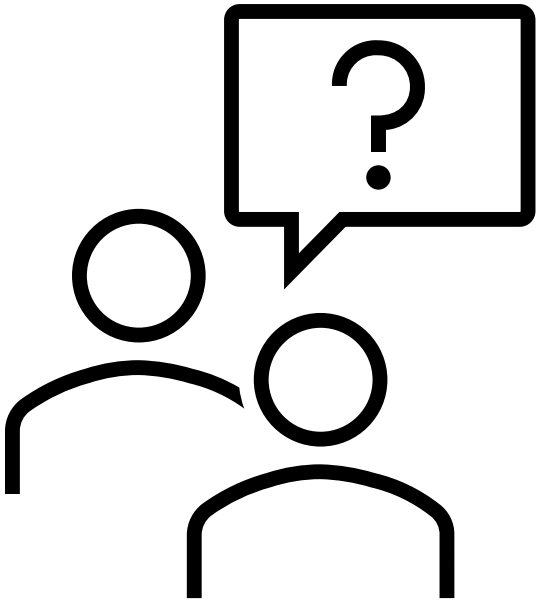
Call to Action

1. GET INVOLVED IN THE CHANGES THAT ARE COMING → FEA AND DUCC

2. SUPPORT ARGUMENTS BY SHARING REAL LIFE EXAMPLES SHOWING THE IMPACT OF THE POLICY CHANGES – CONSIDER IMPACTS ON SUSTAINABILITY, SOCIETY AND ECONOMIC

3. PREPARE YOUR PORTFOLIO

Questions ?



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