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Downstream Users of Chemicals Co-ordination group

# How Can REACH/CLP Information Endorse Safe Use of Chemicals at Industrial Sites ?

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# EH&S Management at Industrial Sites



- Explosion protection documents
  - Based on parameters of mixtures (flash point); additional C/P information according **REACH annex II**
- Application for permit (under IED or other legislation), VOC solvent reduction scheme
  - Based on parameters for mixtures (NV/VOC content); specific emission limit values for **volatile CMRs**
- Effluent process water treatment and monitoring
  - Limit values also below SDS disclosure level/for undisclosed compounds (Cu, Ni, CrIII, Fe, Al, AOX, HHC)
  - **Risk assessment** under REACH, very complex for substances in mixtures, depending on release routes
- Storage of hazardous chemicals (standard and Seveso level)
  - Changes of mixture **classification under CLP** (flammability, acute toxicity, aquatic hazard)
- Waste management
  - Based on parameters for mixtures (organic content, calorific value for treatment vs. landfill)
  - Recyclers expect information also for undisclosed compounds (metals, halogen/S/P/N content)
  - Changes of mixture **classification under CLP** (hazardous due to flammability, toxicity, aquatic hazard)
- Occupational health protection
  - **Risk assessment** according to REACH based on DNEL values (much more data compared to OELs)
  - Substitution and/or appropriate control, especially when using **substances of very high concern**
  - Changes of mixture **classification under CLP** (much more mandatory safety data sheets)

# Changes of Classification under CLP 1/2

## Stricter classification based on REACH testing results (or political decision)

- Formaldehyde (in melamine and phenolic resins) Canc. cat. 1B
- Butanonoxime (anti-skin agent, blocking agent) Canc. cat. 1B
- Glycidylmethacrylate (in acrylic powders) Canc. Repr. cat. 1B, Muta. 2
- N-Methylpyrrolidon, N-Ethylpyrrolidon (WB coatings) Repr. cat. 1B
- Methylimidazol (phenolic hardener in powders) Repr. cat. 1B
- Dibutyltin compounds (catalysts) Repr. cat. 1B
- Styrene (in putties, gel-coats, impregnation resins) Repr. cat. 2

## New assessment of acute toxicity according to CLP criteria

- Diethylethanolamine, Dimethylethanolamine Acute tox. cat. 3
- Dimethylisopropanolamine Acute tox. cat. 3
- Triethylamine Acute tox. cat. 3
- Ethylenediamine, Xylylenediamine Acute tox. cat. 3
- Hexyloxyethanol Acute tox. cat. 3

# Changes of Classification under CLP 2/2

## Reduced thresholds for classification of mixtures

- Xi, R36/R38                      20 %            →            10 % (3 % without additivity concept)
- Xi R41                                10 %            →            3 % (1 % without additivity concept)
- C R34, R35                        10 %            →            5 % (1 % at pH  $\leq 2$  /  $\geq 11,5$ )
- Repr. tox cat. 3                    5 %             →            3 %
- Repr. tox cat. 1/2                0,5 %         →            0,3 %
- T, Xn                                 →            ATE logic

## Generation of SDSs with no substance content above declaration threshold

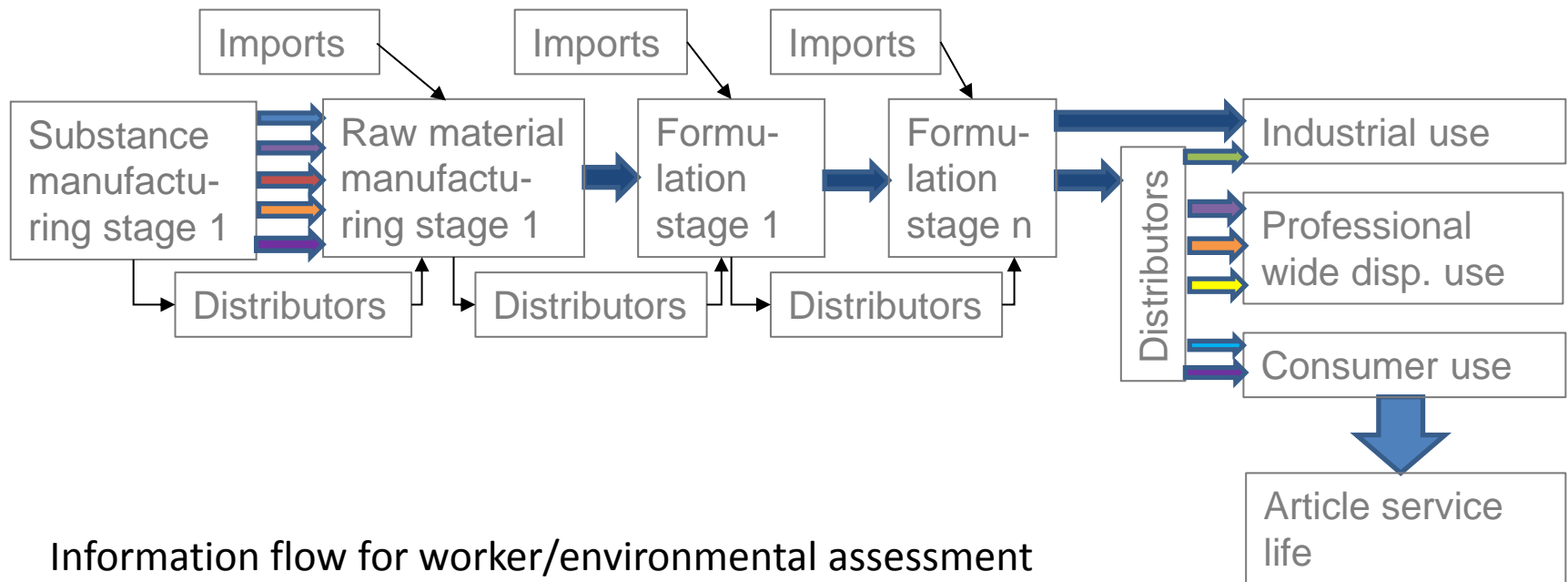
- EUH201 to EUH208 required as of 1/10 of declaration threshold

- **Multiplication of mandatory SDSs which require REACH extension**
- **Cross reference with storage and waste management requirements**

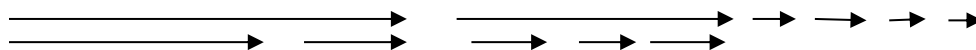
# Substance Life Cycle and Information Flow



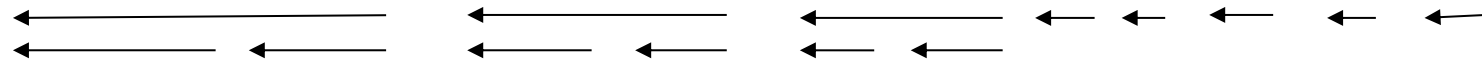
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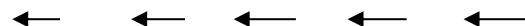
Information flow for worker/environmental assessment



Upstream information flow on use and general conditions of use



Upstream information flow on use volumes, specific conditions, releases



# eSDSs from Distributors and Formulators ?



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- Substance manufacturers market 80% of the chemicals to 20% of the market place
- Distributors market the remaining 20% to 80% of the market place
- For intermediates and mixtures, the distributors' role and the role of segment specific logistic centres is even more extended, up to 80 % for 95 % of the market
- By now, extended SDSs are widely available only for pure substances marketed by manufacturers/importers within the tonnage band of 2010/2013 registrations
- Very few extended SDSs for simple mixtures are available
- Formulators buying primarily mixture raw materials from distributors rarely receive any extended SDSs
- Even some competent authorities have discouraged formulators to provide extended SDSs for mixtures
- IT systems for SDS generation used by distributors and formulators do not yet support generation of extended SDSs

➤ **Industrial/professional end-users have mostly not yet been confronted with REACH related information on safe use**

# Product Stewardship vs. REACH 1/2

- REACH provides a legal frame for safe use information on chemicals
- Chemical industry developed Product Stewardship as part of Responsible Care
- Many formulators and end-users do have to fulfil additional specific legislation
- Some business associations decided to endorse voluntary SDSs for all products
- SDSs are often accompanied by technical data sheets with safe use information
- Plenty of safe use information available via technical rules (e.g. TRGS), technical guidelines from competent authorities, worker insurance (e.g. BG), and technical associations (e.g. VDI)
- Lot of safe use information generic rather than substance specific (e.g. spray mist, sanding dust, splashes, droplets)
- Long tradition of replacement of CMR and toxic substances when acknowledged, by law, but also by industry concepts like GADSL, green building specifications etc.
- Third party audits on Responsible Care, ISO 14001, EMAS (compliance, improvement)
- Compositional information provided along supply chain via IMDS, BOMcheck etc.

# Product Stewardship vs. REACH 2/2

- REACH enlarges and concludes (eco)toxicological information about substances
- REACH requires formal processes and documentation to ensure downstream user compliance, inside and beyond the chemical supply chain
- REACH helps to implement standardized exposure and risk assessment tools
- REACH authorization may help to overcome disadvantageous competitive situations with regard to SVHCs
- Formalized processes are expected to improve level of compliance and execution and to reduce number of deviations
- These processes have been implemented in companies which are purchasing raw materials from manufacturers/importers and which receive extended SDSs
- There may still be gaps with regard to information exchange under REACH between other actors inside and beyond the chemical supply chain

➤ There is not yet broad evidence about the practical impact of extended and updated REACH/CLP information for the safety performance at industrial sites



# Challenges for the Next Five Years

- Non-registration of low volume substances for economic reasons (not risk driven)
- Provision of appropriate safe use information for substances in mixtures and articles (see SUMI initiatives of formulators' associations)
- Full implementation of REACH at small and medium size formulator and at industrial/professional end-user level
- Product information to poison centres etc. adapted to the really necessary volume

## **After completion of the third registration phase 2018:**

- Availability of comprehensive (eco)toxicological information for all relevant substances
- Substance information would no longer need to be entered into national inventories inside EU
- (Eco)toxicological data might be taken out of safety data sheets for communication to downstream users

# Thank you



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