ECHA
EUROPEAN CHEMICALS AGENCY

REACH 2018 webinars

Chemical safety assessment – what, when and how?

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Andreas Ahrens
European Chemicals Agency

Chemical safety assessment

- Purpose
- Who needs to do the assessment
- How to assess safety?
- Use and exposure communication up and down supply chain
- How to organise safety assessment?

Purpose

Chemical Safety Assessment (CSA) aims:

- to characterise intrinsic substance properties
  - Classification of hazards and no-effect levels
  - Properties determining distribution and fate
    e.g. vapour pressure, water solubility, degradability
- to determine conditions under which the substance can be used safely during its entire life cycle
- to communicate these conditions with safety data sheets (SDS) to all the commercial users of the substance (as such, in a mixture)

Documented in the chemical safety report (CSR):

- For own documentation (product safety)
- As part of the registration dossier

Who needs to do a "full" chemical safety assessment?

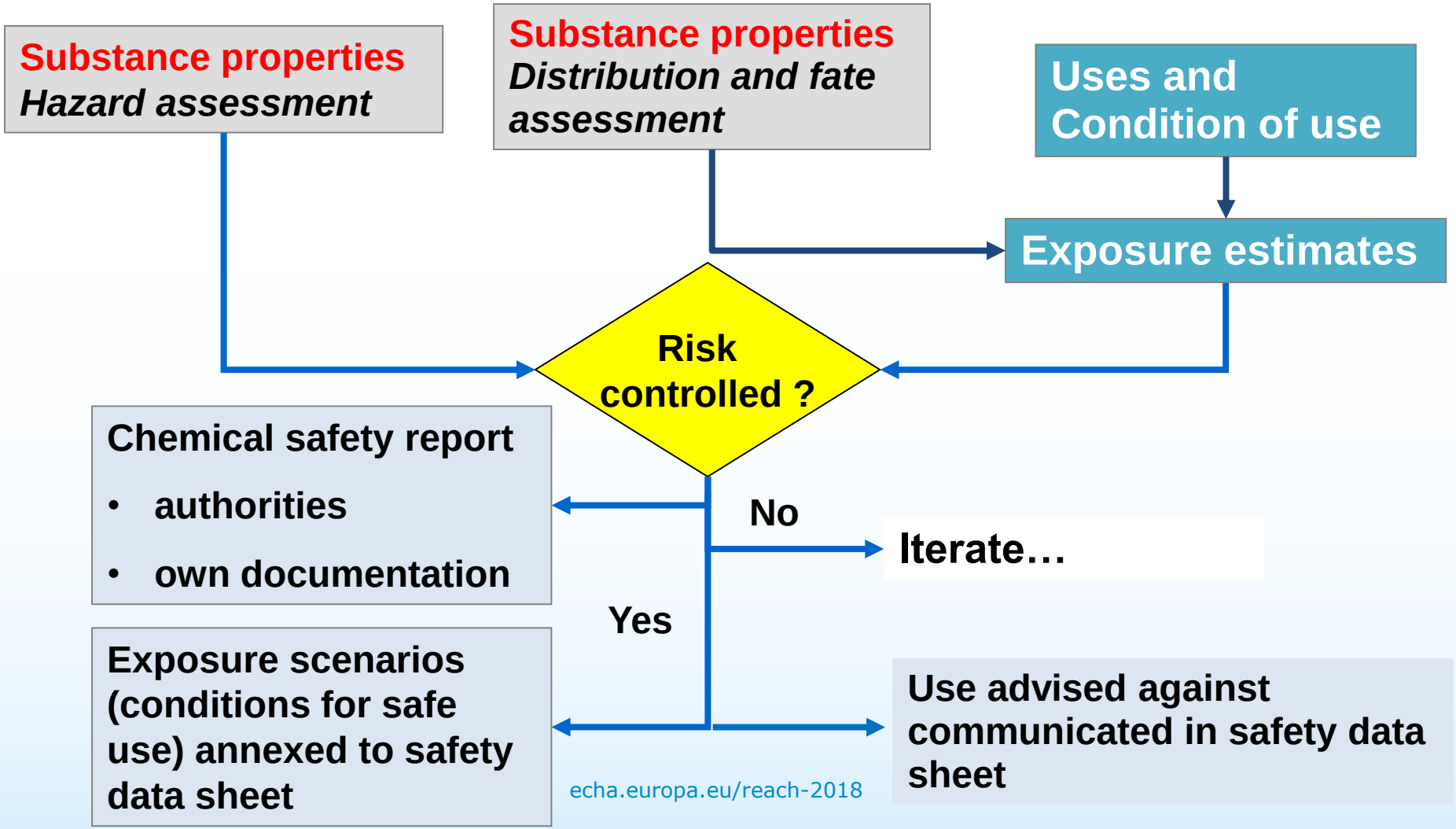
- Manufacturers and importers of substances of 10 or more tonnes per year (does not apply to intermediates under strictly controlled conditions)
- Where the substance meets the criteria to be classified hazardous or being a PBT/vPvB
- Duty on each registrant. Lead registrant may also perform chemical safety assessment on behalf of co-registrants (joint chemical safety report)
- Note: chemical safety report needs to cover **all** uses (for all life cycle stages) of the substance the registrant is aware of

- Imported mixtures: for substances present above the concentration levels defined in Article 14(2)

Typical assessment questions

- What types of protection measures are needed and suitable for working with the substance?
- How much of a substance can be used at an industrial site without the need for treating related waste water at site before discharge?
- How to ensure inherent safety of consumer products containing the substance?
  - Maximum concentration;
  - Amount per package or use event;
  - Particular packaging preventing contact while unpacking and discharging (e.g. packed blocks of dishwashing products);

How to assess chemical safety?



Chemical safety assessment: information on substance properties and conditions of use

Manufacturer

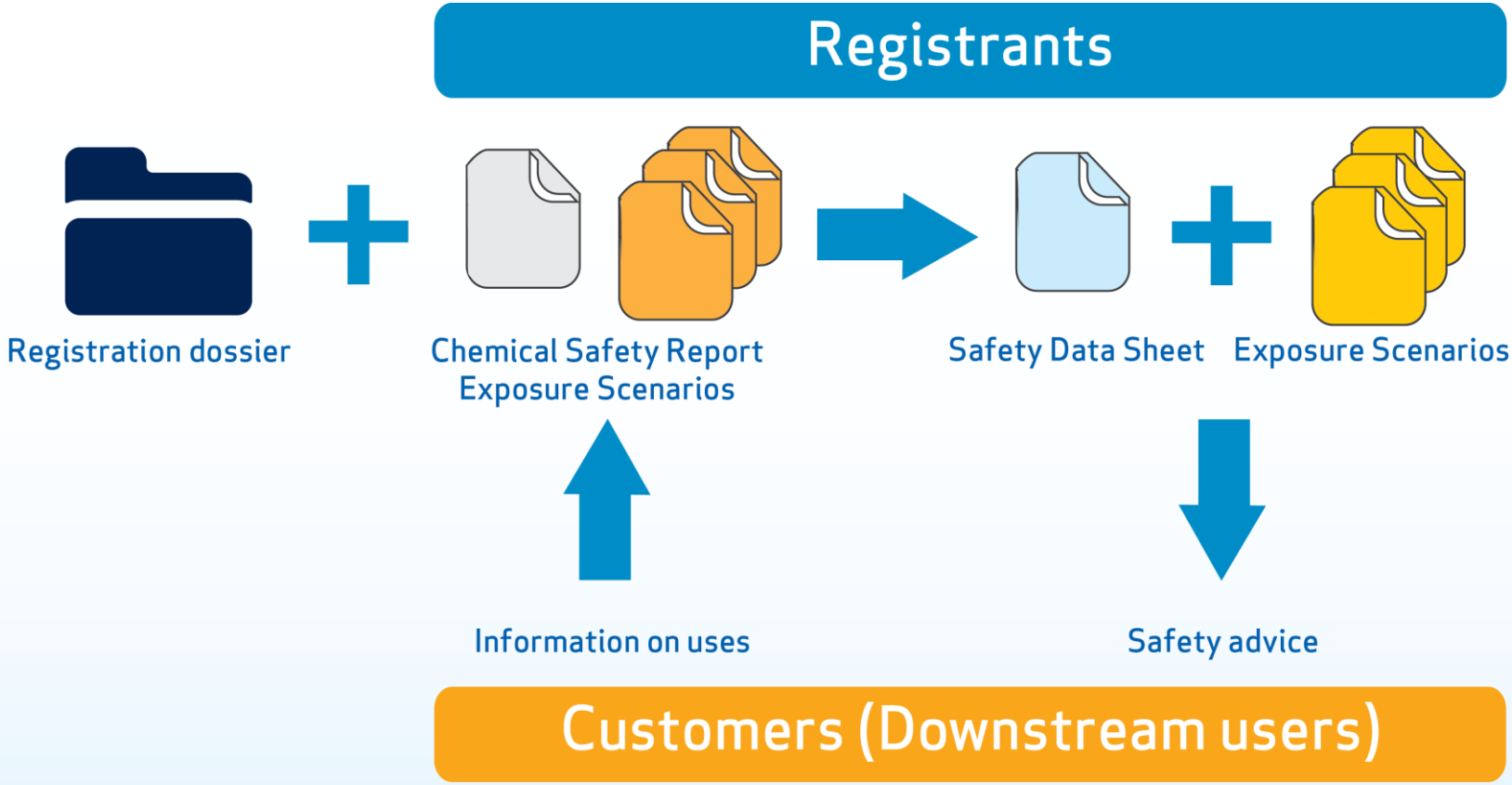
Knows the properties of the substance

Downstream user

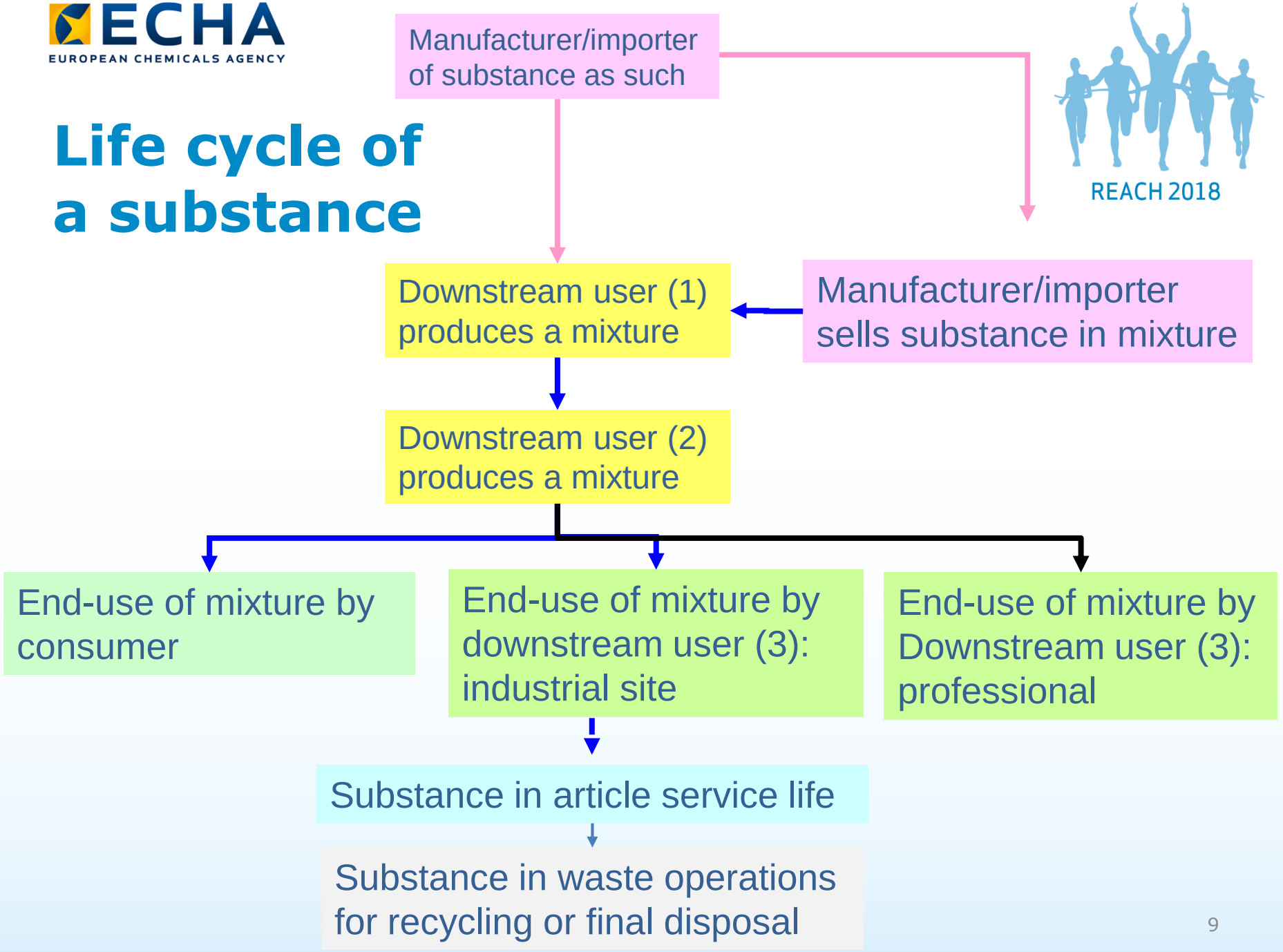
Knows how the substance is used

Communication in the supply chain is key

Communication in the supply chain



Life cycle of a substance



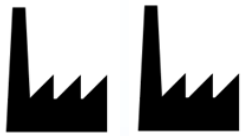
Communication in the supply chain

Registrants

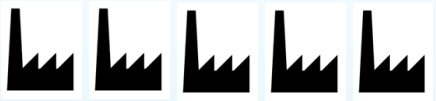
Uses
Existing conditions

- What are the existing uses (customer groups)?
- Under which conditions do they take place?

Exposure scenarios
= **Safe** conditions of use

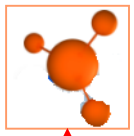


Downstream users
Formulators



Downstream users
End users

Tools



Registration Dossier → **Public**

ECHA and Member States

Registrants

ESCom XML and phrase catalogue

Exposure scenarios: describing the conditions for safe use for **individual downstream user**

Harmonised format
Advice for substances

Harmonised format
Advice for mixtures

Formulators

End users
Downstream users

Use maps developed by **downstream user associations**:

- What are the uses relevant in one sector?
- Under which conditions do they take place?

Reference to mixture types

How to organise the chemical safety assessment?

Registration dossier elements

Technical Dossier
International **U**niform **C**hemica**L** **I**nformation **D**atabase
Data structure following OECD harmonised templates

Chemical safety assessment reported in **chemical safety report** (CSR) (attached document in technical dossier section 13)

Report generator -> CSR

Hazard & PBT assessment & use description
Chapter 1, 2, 3-8 of CSR

Part A with declarations

Exposure assessment (if criteria met to be classified hazardous or PBT/vPvB)
Chapter (2), 9 and 10 of the chemical safety report

Technical dossier

Joint or individual chemical safety report

Our advice

Chemical safety report elements	Content	Submitter
Part A	Declaration • Risk management implemented • Risk management communicated	Lead and member registrants
Whole Part B (1-10)	Hazard assessment, exposure assessment	Lead as part of joint submission
Optional: Part B (1,2,9,10) Individual	Use description and exposure assessment for uses not covered in the joint CSR	Lead and/or member registrants

Experience so far

- Derivation of no-effect-level for the substance often not transparent or wrong (inappropriate risk management)
- Registrants included all potential uses into their registration; lack of use-specific volumes (real uses and their extent remain unclear)
- Advice on safe use is often too generic or too unrealistic to be helpful to users of chemicals

Experience so far

- Registrants copy/pasted exposure scenarios from chemical safety report into safety data sheets (very long safety data sheet)
- Multiple manual transfer of data from one document to another (inefficient and high likelihood of mistakes)
- Registrants have not planned chemical safety report updates (no contractual arrangements; chemical safety assessment not in database format). While lead's chemical safety report is updated, the members' remain unchanged

Risks for business

- Registration dossier is incompliant due to inconsistencies between IUCLID, chemical safety report and safety data sheet
- Customers complain about wrong or unhelpful safety data sheets
- Customers use wrong safety information
- Similar customers have to do the same assessments (efficiency lost)
- Maintenance and updating documents is burdensome/costly:
  - Registration dossier
  - All safety data sheets for products containing the substance
- Authorities pick the substance for further regulatory action for "wrong" reasons

Risks are collective - affect everyone in the supply chain (substance, mixture, article)

Practical Guide (1)

Practical Guide for SME Managers and REACH Coordinators, pages 123 to 130

https://echa.europa.eu/documents/10162/13655/pg_sme_managers_reach_coordinators_en.pdf/1253d9f9-d1f0-4ca8-9e7a-c81e337e3a7d

Tips

- Use information from sector use maps
- Search for in-house information
  - product development and technical department
  - marketing or sales department
- Do not compromise your obligation to provide downstream users with useful safety data sheets, including exposure scenarios they can use to ensure realistic safe working conditions

Practical Guide (2)

Tips

- Ensure that your chemical safety report is understandable for an outsider and does not contain elements that are not relevant or even wrong (e.g. uses that are not relevant in practice)
- Agree with your co-registrants whether you want to create a joint chemical safety report that fits all members in a SIEF
- If you opt for a joint chemical safety report, you may also develop the content of the safety data sheet with your co-registrants: all users will obtain the same information from their suppliers

Key messages

- Good chemical safety assessment is an asset for all companies using the substance in the supply chain
- It requires good knowledge on the substance as such and its uses
- It is the starting point for telling your customers how to use the substance safely
- Shared implementation efforts lead to increased safety at lower overall costs
- A chemical safety report is a living document that must be maintained over time

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