Chemicals Safety Assessment under REACH: How registrants can efficiently generate and communicate **information on *safe use*** of their substances

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Introduction

- For registration, the Chemical Safety Report is as important as the Technical Dossier.
- It is not simple, but doable.
- Take the right approach, communicate with your partners and use the right tool.
- Start in time – means now (if not already done).

Overview

- What is a Chemicals Safety Assessment, and who is required to perform it?
- Challenges and experience
- Approaches and tools for support: DNEL calculator, sector use-maps, communication via EScom, Chemicals Safety Assessment with Chesar

Chemical Safety Assessment under REACH

What is it?
Who is involved?

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Chemicals Safety Assessment

The Chemicals Safety Assessment (CSA) aims

- to characterise the intrinsic hazards of a substance
  - Classification
  - No-effect levels
  - Vapour pressure, water solubility, degradability, ….
- to determine the conditions under which the substance can be used safely during its entire life cycle
- to communicate these conditions with SDS to all the commercial users of the substance (as such, in mixture)

Chemicals Safety Report (CSR)

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

Who is required to do a full CSA

- Manufacturers and importers of substances of 10 or more tons per year (applies to non-intermediates)
- Where the substance meets the criteria to be classified hazardous or being a PBT (based on the required test data)
- Duty on each registrant, however co-registrant can delegate to lead-registrant (joint CSR)
- Note: CSR needs to cover **all** uses of the substance the single registrant is aware of

- For imported mixtures: For substances being present above the concentration levels defined in Article 14(2)

Market position of SME registrants

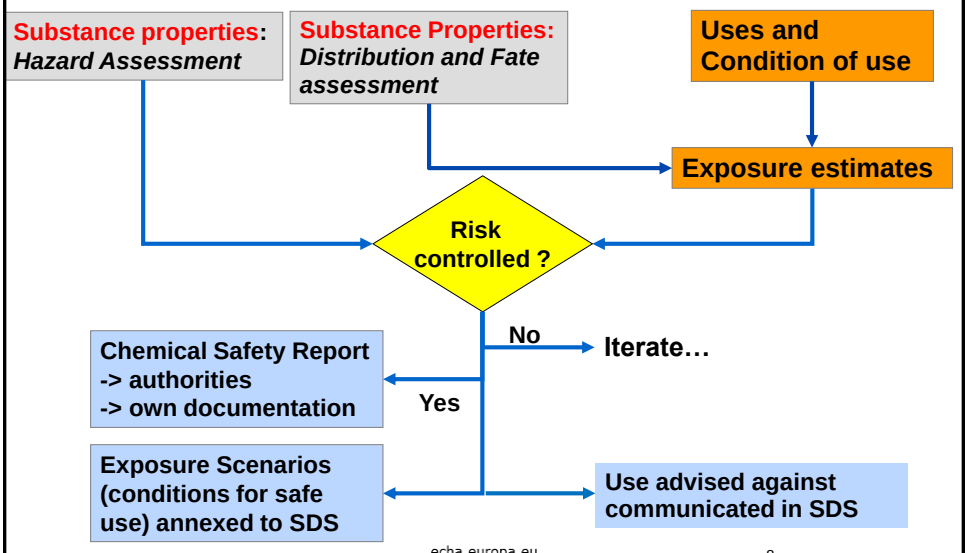
- Low volume registrant of a substance already registered; no particular special market; => join existing CSR
- Toll manufacturer of substance for another manufacturer; => knowledge of uses via your customer
- Manufacturer/importer of speciality for particular market; => knowledge on condition of use likely to be available in own company;
- Registrant of substance for one or more of the common DU markets => knowledge on conditions of use may be available from DU sector organisation

Challenges and solutions for the CSR may be different, depending on the position in the market.

Typical assessment questions

- Is the substance in general suitable to be widely used by untrained workers in small business and by consumers?
- Which types of exposure controls are needed at work places to handle the substance safely.
  - Activities at industrial work places
  - Activities at non-industrial workplaces
- How much of a substance can be used per day at an industrial site without onsite pre-treatment of wastewater?
- How to ensure the inherent safety of consumer products containing the substance:
  - Maximum concentration; amount of mixture per package/use; particular package design;
  - Maximum concentration; suitability for particular article types (e.g. toys, textiles, tyres,…..);

How to assess the safety of a chemical?



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

Manufacturer

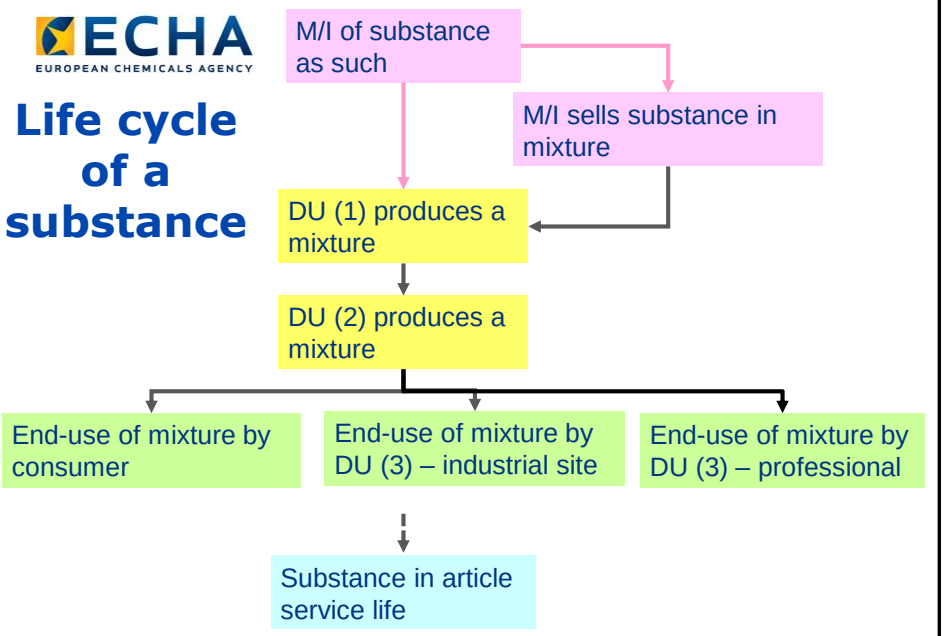
Knows the properties of the substance

Downstream user

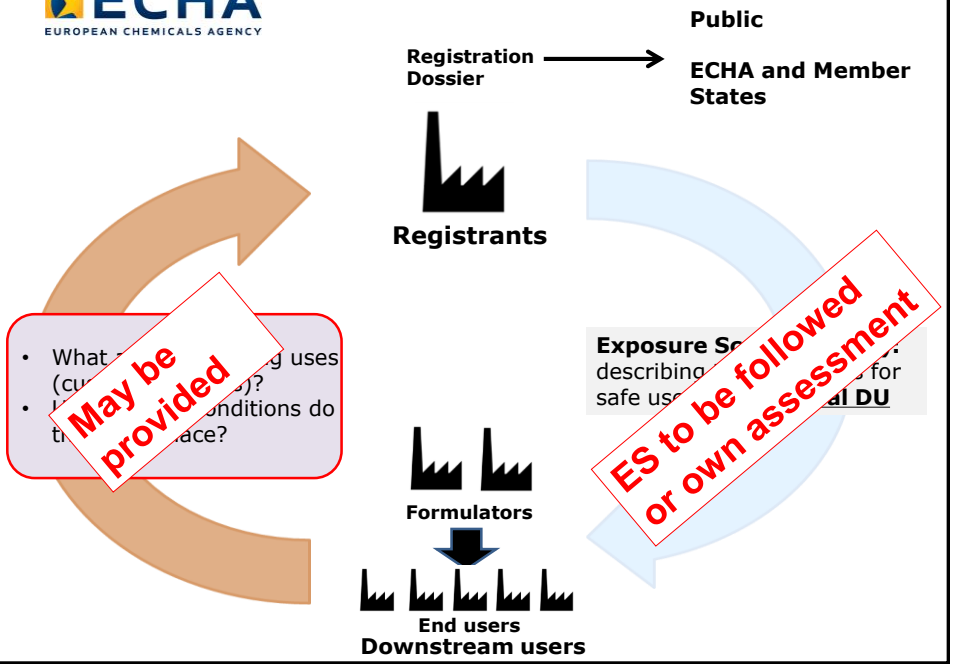
Knows how the substance is used

→ **Communication in the supply chain is key**

Life cycle of a substance



Information flow



Experience so far

- The derivation of the no-effect-level for the substance is in-transparent or wrong (=> inappropriate risk management)
- Registrants have 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
- Registrants have copied/pasted the exposure scenarios from the CSR into the safety data sheets (=> very long SDS)
- Multiple manual transfer of data from one document to another (=> inefficient and high likelihood of mistakes)
- Registrants have not planned CSR updates (=> no contractual arrangements; CSA not in database format)

Potential consequence for business

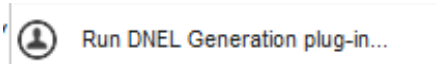
- Customers complain about wrong or unhelpful safety data sheets
- Authorities pick the substance for further regulatory action for the "wrong reasons"
- The registration dossier is incompliant due to inconsistencies between IUCLID, the CSR and the safety data sheet
- Maintenance and update of the registration dossier is burdensome/costly

Solutions available to reduce these business risks

Tool helping to derive the correct "No-Effect-Levels"

DNEL/PNEC calculator in IUCLID

- DNELs and PNECs are "no effect thresholds": used as basis for the CSA.
- IUCLID can now calculate DNELs and (soon) PNECs



- DNEL calculator helps you derive long term systemic DNELs for your substance and report it for your registration dossier
  - Available in IUCLID 6.1.2
  - Explanations available in Registration manual section 9.7.6.1
    https://echa.europa.eu/documents/10162/22308542/manual_regis_and_ppord_en.pdf
- PNEC calculator will be available in IUCLID 6.1.3 (to be released in April)

Tools to help communication in the supply chain

Tools to help

Registration Dossier → **Public**

ECHA and Member States

chesar

Registrants

ESCom XML and phrase catalogue

Exposure Scenarios: describing the conditions for safe use for **individual DU**

Harmonised formats
- Safe use information for substances
- Safe use information for mixtures

Use maps developed by **DU associations:**
- What are the uses relevant in one sector?
- Under which conditions do they take place?

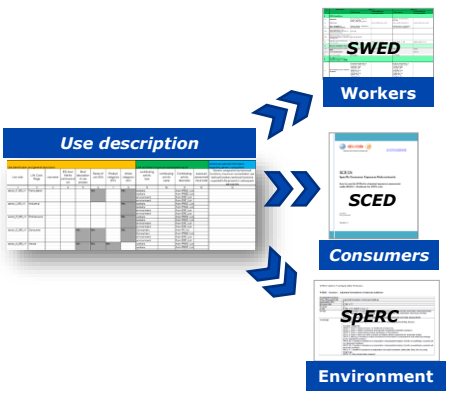
Formulators

End users
Downstream users

Use map elements

Empty templates:
https://echa.europa.eu/csr-es-roadmap/use-maps/templates-and-submission

Library of available information:
https://echa.europa.eu/csr-es-roadmap/use-maps/use-maps-library



Workers: Sector-specific Worker Exposure Description (SWED)

Consumers: Specific Consumer Exposure Determinant (SCED)

Environment: Specific Environmental Release Category (SPERC)

Working together on solutions

Key challenge: Identification of uses and conditions of use

- **CSR/ES Roadmap** is a joint action plan towards 2018
  http://echa.europa.eu/csr-es-roadmap
- Suite of tools for improving communication in supply chain
  https://echa.europa.eu/documents/10162/15669641/safe_use_chemicals_en.pdf/789d0235-5872-4527-baad-db681edefdb0
- Joint statement on use-maps
  https://echa.europa.eu/documents/10162/13563/Joint+statement+on+use+maps/d76045c3-a4ad-40db-a617-e8c429130071
- Exchange Network on Exposure Scenarios (ENES) meets twice a year to discuss and identify good practices
  http://echa.europa.eu/enes

Use map concept

Downstream user sector organisations

- map out the common uses among their membership and document in harmonised format
- describe the existing conditions of use in a way that they can be fed into the registrant's exposure assessment for workers consumers; environment;
- phrase the conditions so that downstream users will understand when they receive the information with the ES

Registrants

- select uses relevant for their substances and
- upload the information package into their assessment
- derive exposure estimate and risk characterisation
  - substance fits into existing conditions of use -> document and communicate in Exposure Scenario
  - Control of risk cannot be demonstrated -> refine assessment

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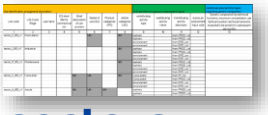


Request use maps from DU sectors

- Effective way to get representative information on uses
- Help downstream users to make sure their typical uses are covered in the registration dossier of a substance
- Provide structured comprehensible information allowing registrants to carry out a chemical safety assessments in an efficient way
- Help registrants to prepare more realistic chemical safety assessments for their REACH registrations
  - More helpful for customers
  - More helpful for authorities
- Increases consistency across assessments
- Avoid unnecessary (one-to-one) supply chain communication

Use maps can help to promote good practice and realistic advice on safe use of chemicals

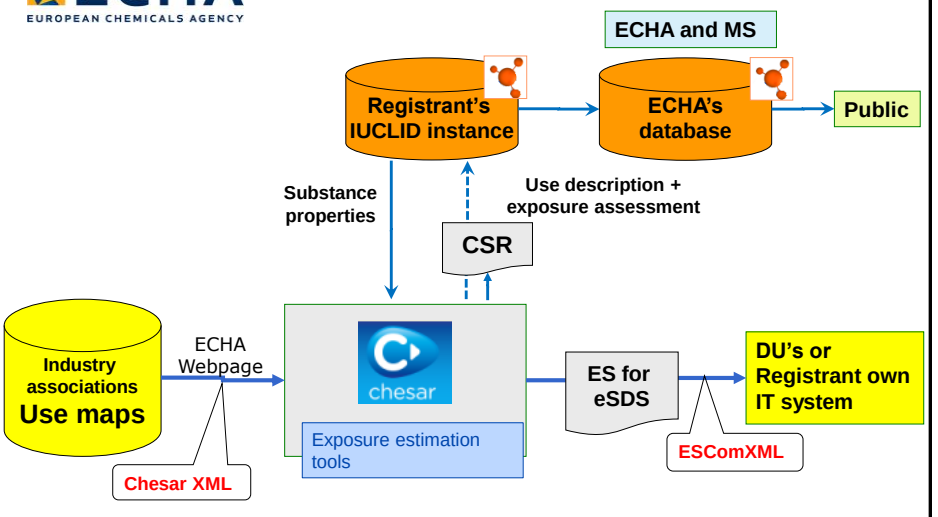
Chesar: Chemical Safety Assessment and Reporting Tool

Introduction

- Chesar is a web application developed by ECHA **to support registrants** in consistently
  - carrying out their chemical safety assessment
  - generating their Chemical Safety Report (CSR) as part of their registration
  - Exposure Scenario for communicating conditions for safe use (annex to extended Safety Data Sheet)
- It supports the generation of information useful for screening of substances **by the authorities**, via exporting data to IUCLID (registration)
- It is released as a standalone and distributed version
  - Chesar 1 was released in May 2010.
  - Chesar 3.1.1 released in December 2016

https://chesar.echa.europa.eu/home

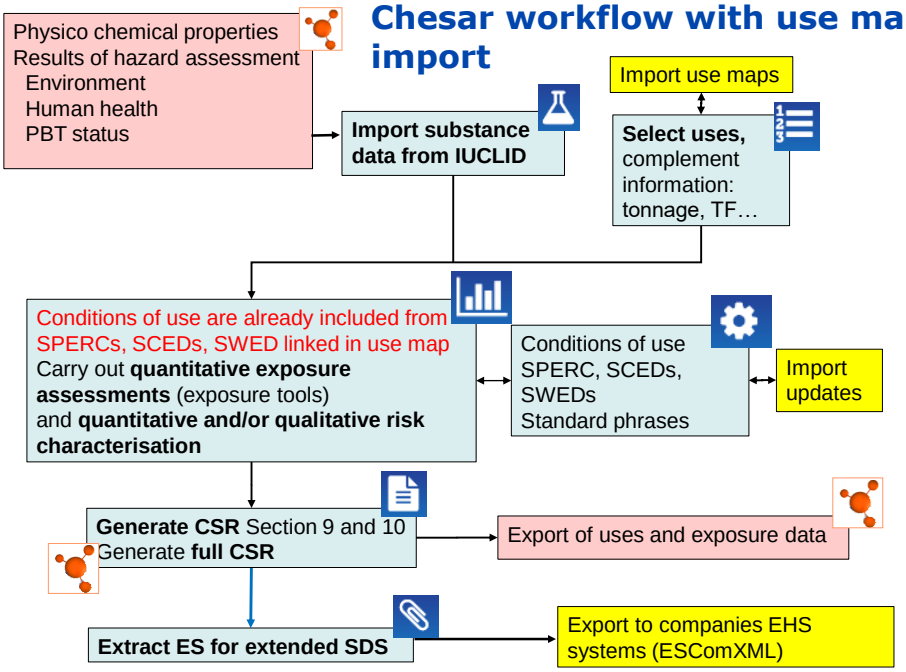
Information flows

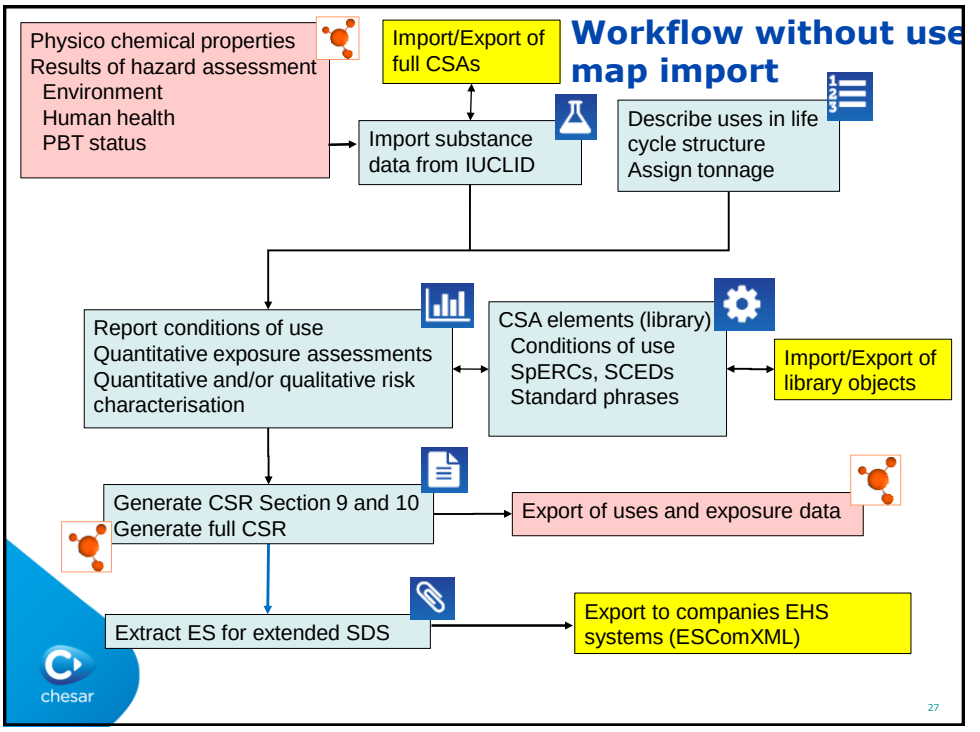


Organisation of Chesar: the Chesar "Boxes"

1. Substances
2. Uses
3. Exposure assessment
4. CSR
5. ES for extended SDS
6. Library
7. Users

Chesar workflow with use map import





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Concluding remarks (1)

- **Use, use conditions and exposure information obtained via CSA process useful for**
  - Supporting safe use within the supply chain by self sustained mechanism
  - The authorities to identify gaps and (de)prioritise substances for regulatory actions
- **Chesar provides opportunities for**
  - Consistency
    - Within the CSA: substance properties, uses reported in IUCLID and the chemical safety report
    - Information for the authorities (CSR) and for the supply chain (exposure scenario for communication)

Concluding remarks (2)

- **Chesar provides opportunities for**
  - Standardisation (efficiency gains for all actors)
    - Systematic workflow
    - Import/export/printed format of Use maps, Chemical safety report, Exposure scenarios for communication (Standard phrases: ESCom)
  - Efficiency in single assessment
    - Integrated exposure estimation tools
    - Re-use of information across substances
    - Automated generation of documents
    - Facilitated updates

Practical Guide (1)

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

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

Tips

- Utilize 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 (SDS), including ESs they can really use to ensure safe working conditions.

Practical Guide (2)

Tips

- Ensure that your CSR is understandable for an outside reader and does not contain elements that are not relevant or even wrong (e.g. uses that are not relevant in practice).
- You need to agree with your co-registrants whether you want to create one joint CSR that fits all members in a SIEF.
- If you opt for a joint CSR, you may also develop the content of the SDS with your co-registrants: all users will obtain the same information from their suppliers.
- Consider developing a structured system for your downstream users to provide feedback on the ESs you send them.

Thank you!

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