

Chemicals Safety Assessment under REACH: how Chesar can help registrants

ECHA's stakeholders'day

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Overview

- Background on Chemicals Safety Assessment
- Tools to help communication in the supply chain
- ECHA's Chemicals Safety Assessment and Reporting tool (Chesar)

Chemical Safety Assessment under REACH

What is it?

Who is involved?



Chemicals Safety Assessment

The Chemical Safety Assessment (CSA) aims

- to characterise the intrinsic properties 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 Safety Data Sheet (SDS) to all the commercial users of the substance (as such, in mixture)

It is documented in the Chemical Safety Report (CSR)

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

Elements of the registration dossier

Technical Dossier



- International **U**niform **C**hemical **I**nformation **D**atabase
- Data structure following OECD harmonised templates

Chemical Safety Assessment* reported in **Chemical Safety Report (CSR)**
(attached document in technical dossier)



IUCLID Report generator for CSR



Technical dossier

Hazard & PBT assessment
Chapter 1- 8 of CSR



Chesar

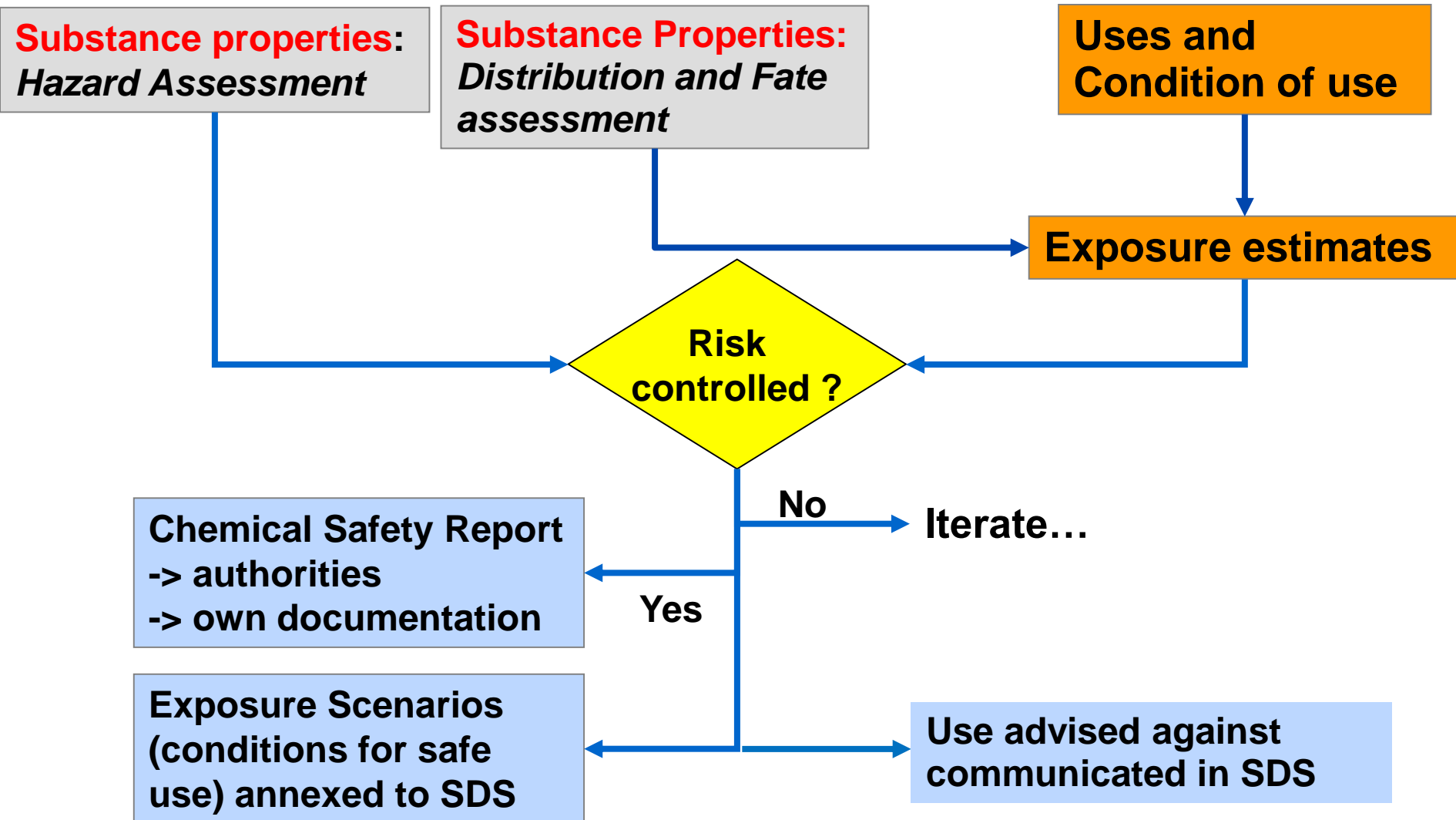
Exposure Assessment (if criteria met to be classified hazardous)
Chapter 9 and 10 of the CSR

* For substances manufactured/imported > 10 tonnes/year

Typical assessment questions

- 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?
- Is the substance in general suitable to be widely used by untrained workers in small business and by consumers?
- How to ensure the inherent safety of consumer products containing the substance: Maximum concentration; amount per package/use ?

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

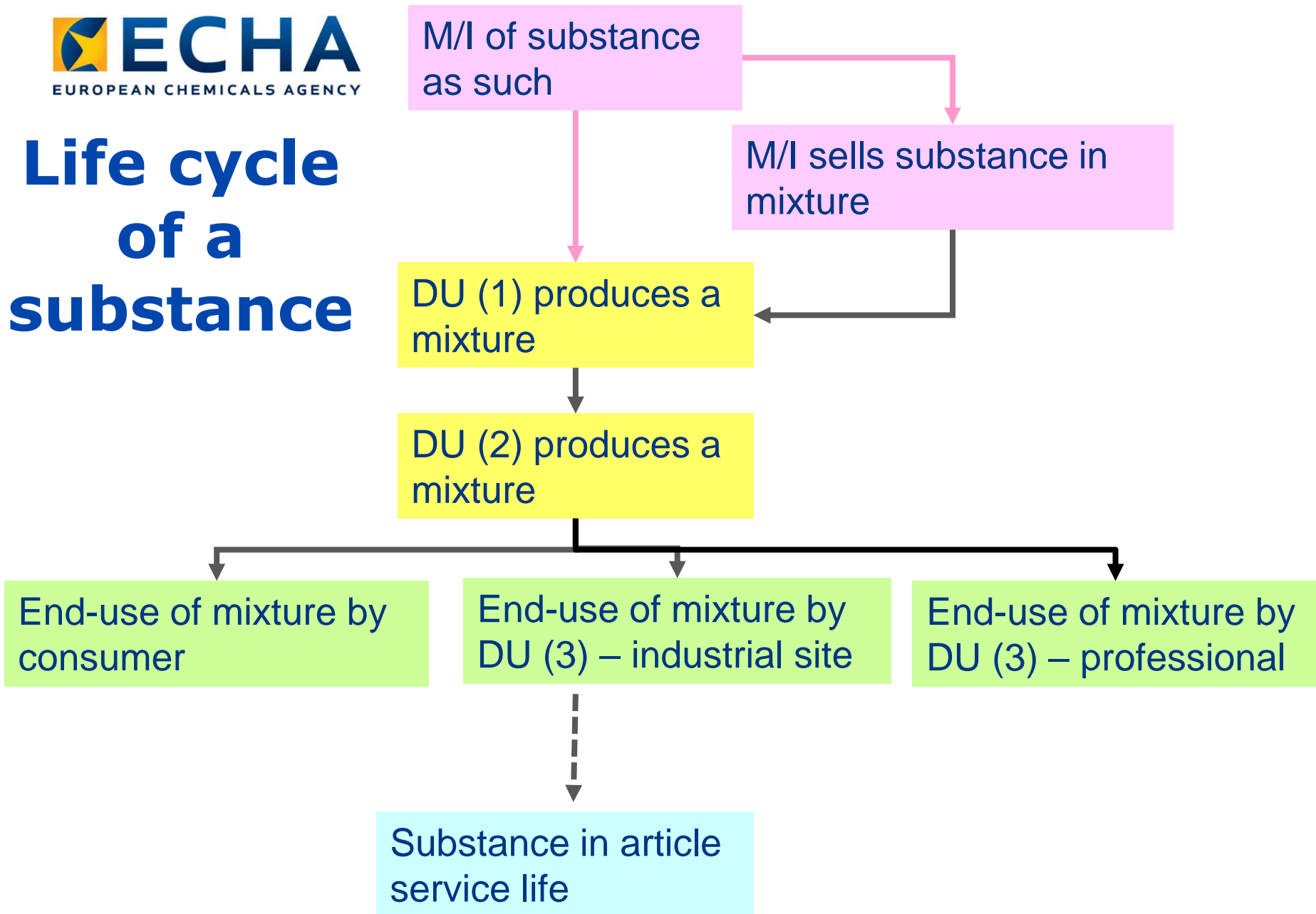
Downstream user



Knows how the substance is used

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

Life cycle of a substance



Information flow

Public

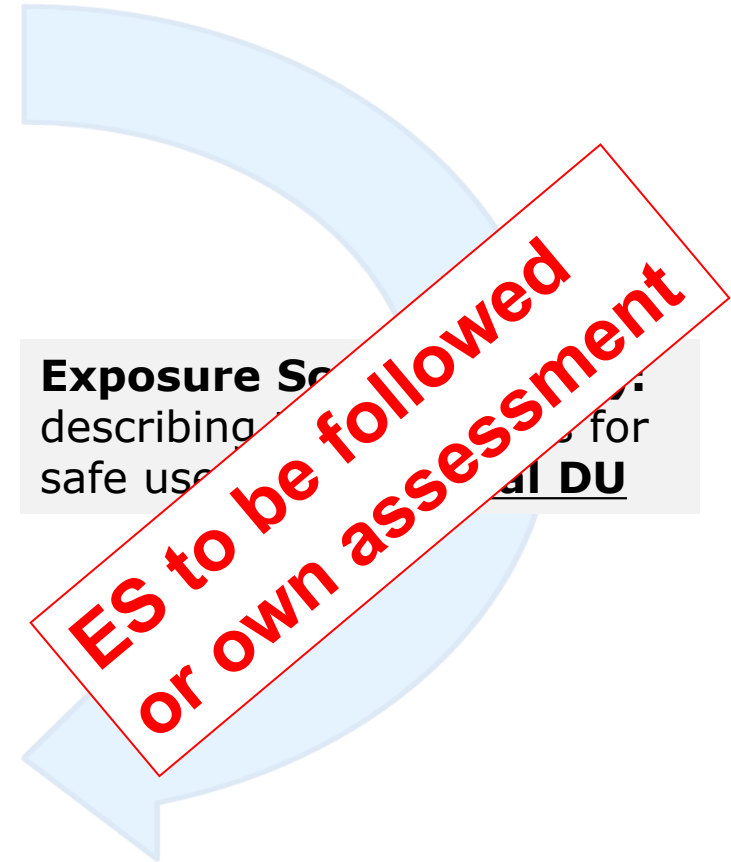
Registration Dossier



ECHA and Member States

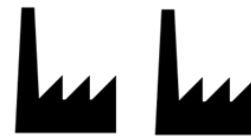


Registrants



Exposure Scenarios describing... for safe use... **DU**

ES to be followed or own assessment

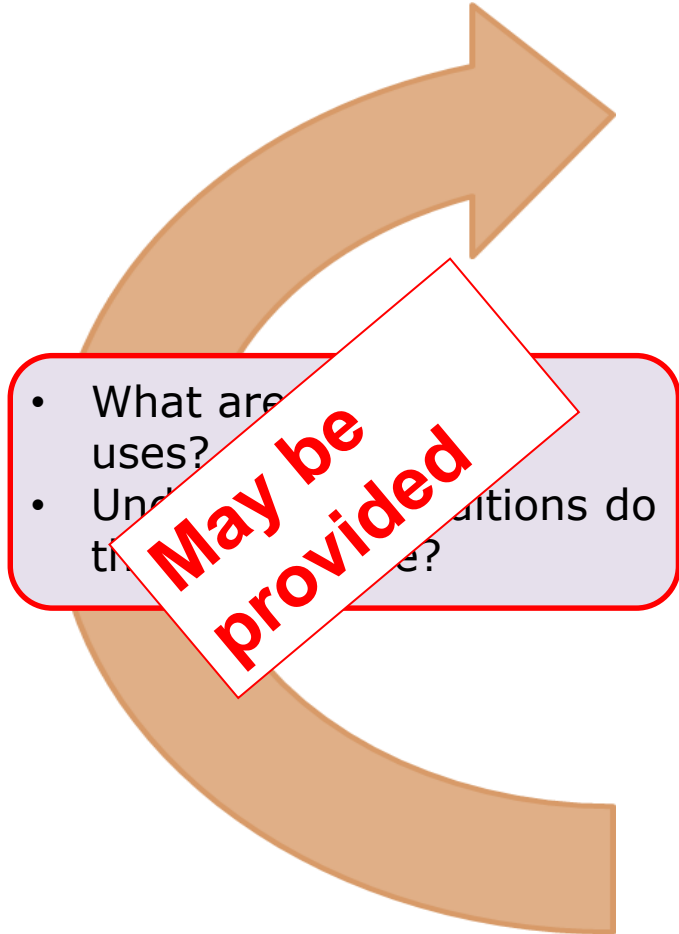


Formulators



End users

Downstream users



- What are the uses?
- Under what conditions do they use?

May be provided

Experience so far

- The derivation of the no-effect-level for the substance is intransparent 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

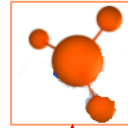
Tools to help communication in the supply chain



Tools to help

Public

ECHA and Member States



Registration Dossier



Registrants

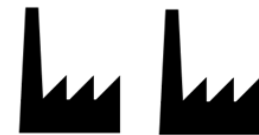
Exposure Scenarios:
describing the conditions for safe use for **individual DU**

ESCom XML and phrase catalogue

Harmonised format

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

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

Use maps can be found in <https://echa.europa.eu/csr-es-roadmap/use-maps/use-maps-library>

Chesar: Chemical Safety Assessment and Reporting Tool

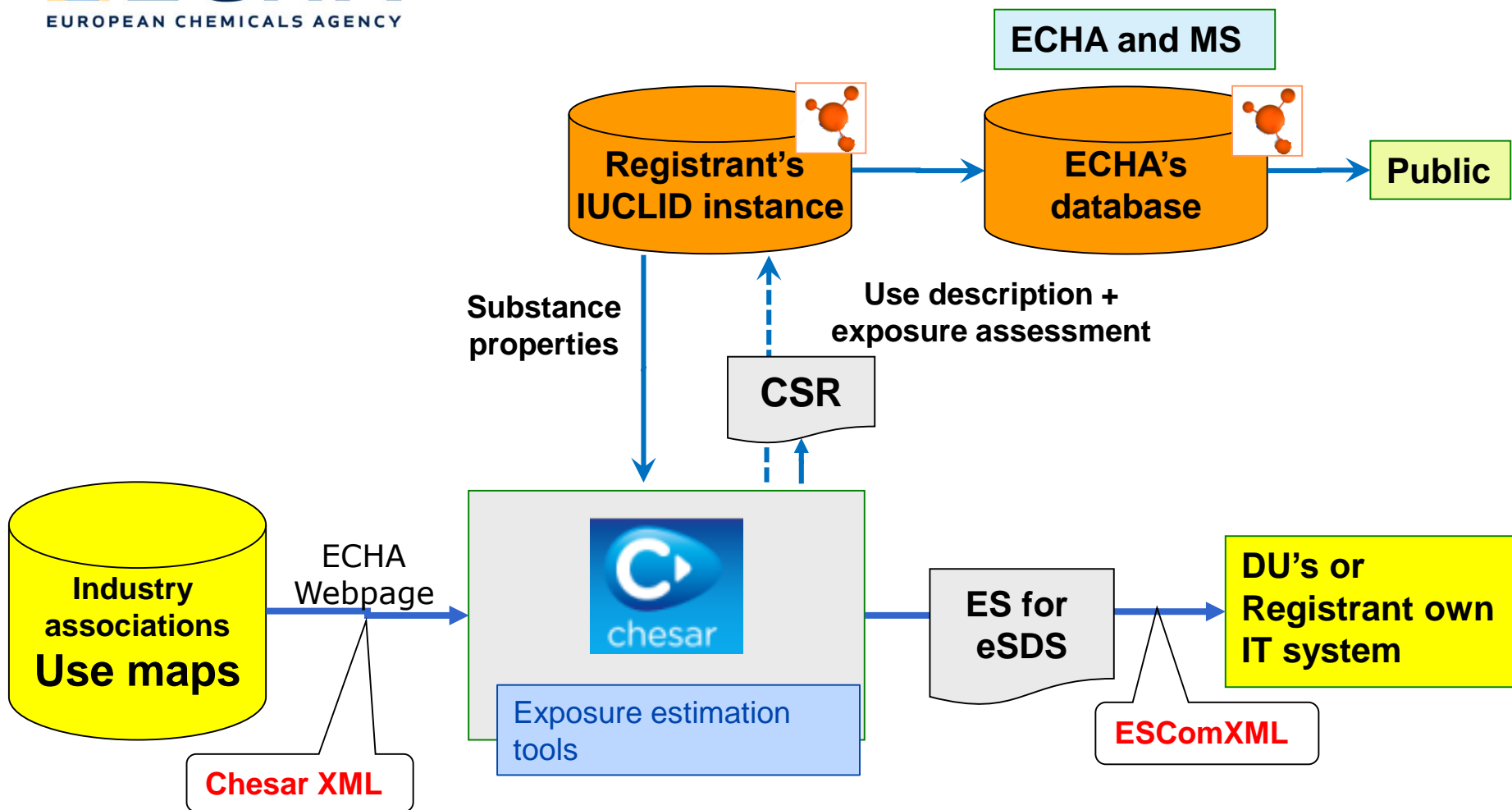


Introduction

- 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
 - generating the Exposure Scenario for communicating conditions for safe use (annex to extended Safety Data Sheet)
- It is released as a **Desktop** and **Server** version
- It is free-of-charge and easy to install

<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 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)
- 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

More information

- Chesar user manual
<https://chesar.echa.europa.eu/support/manuals-tutorials>
- Helptext within the application : the magic button 
- Webinars have been recorded
- Training: ECHA has been organising some trainings.
 - Next one in June

<https://chesar.echa.europa.eu/> will be updated at release time. **Subscribe** to be kept informed!



CHEmical Safety Assessment and Reporting tool

What is Chesar?

Chesar is an application developed by the European Chemicals Agency (ECHA) to help companies to carry out their chemical safety assessments (CSAs) and to prepare their chemical safety reports (CSRs) and exposure scenarios (ESs) for communication in the supply chain.

Chesar enables registrants to carry out their safety assessments in a structured, harmonised, transparent and efficient way. This includes the importing of substance-related data directly from IUCLID, describing the uses of the substance, carrying out exposure assessment including identifying conditions of safe use, related exposure estimates and demonstrating control of risks. Based on this, Chesar automatically generates the CSR and exposure scenarios for communication as a text document, and export information on use and exposure to IUCLID. Chesar also facilitates the re-use (or update) of assessment elements generated in a single Chesar instance or imported from external sources.

› [Chesar in a nutshell](#)

› [Video - Chesar: All you need for chemical safety assessment](#)



› [Download Chesar tool](#)



› [Subscribe](#)

External Links



› [REACH Regulation](#)



› [IUCLID](#)



› [Chemical Safety Report](#)



› [Practical examples of chemical safety report](#)

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Life Cycle: Use

Use name

Contributing Activity (CA) name
Environment + ERC

Contributing Activity (CA) name
by workers + PROC

Exposure Assessment per Use

Exposure Scenario (ES) name

Contributing scenario (CS):
Conditions of use from environmental perspective

Contributing scenarios (CS)
Conditions of use from worker perspective

Exposure to Environment
(all compartm.)

Release to Environment

Exposure of Man via Environment

Exposure of workers for each CS