

# Chemical Safety Assessment and Chesar

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## Key messages to registrants

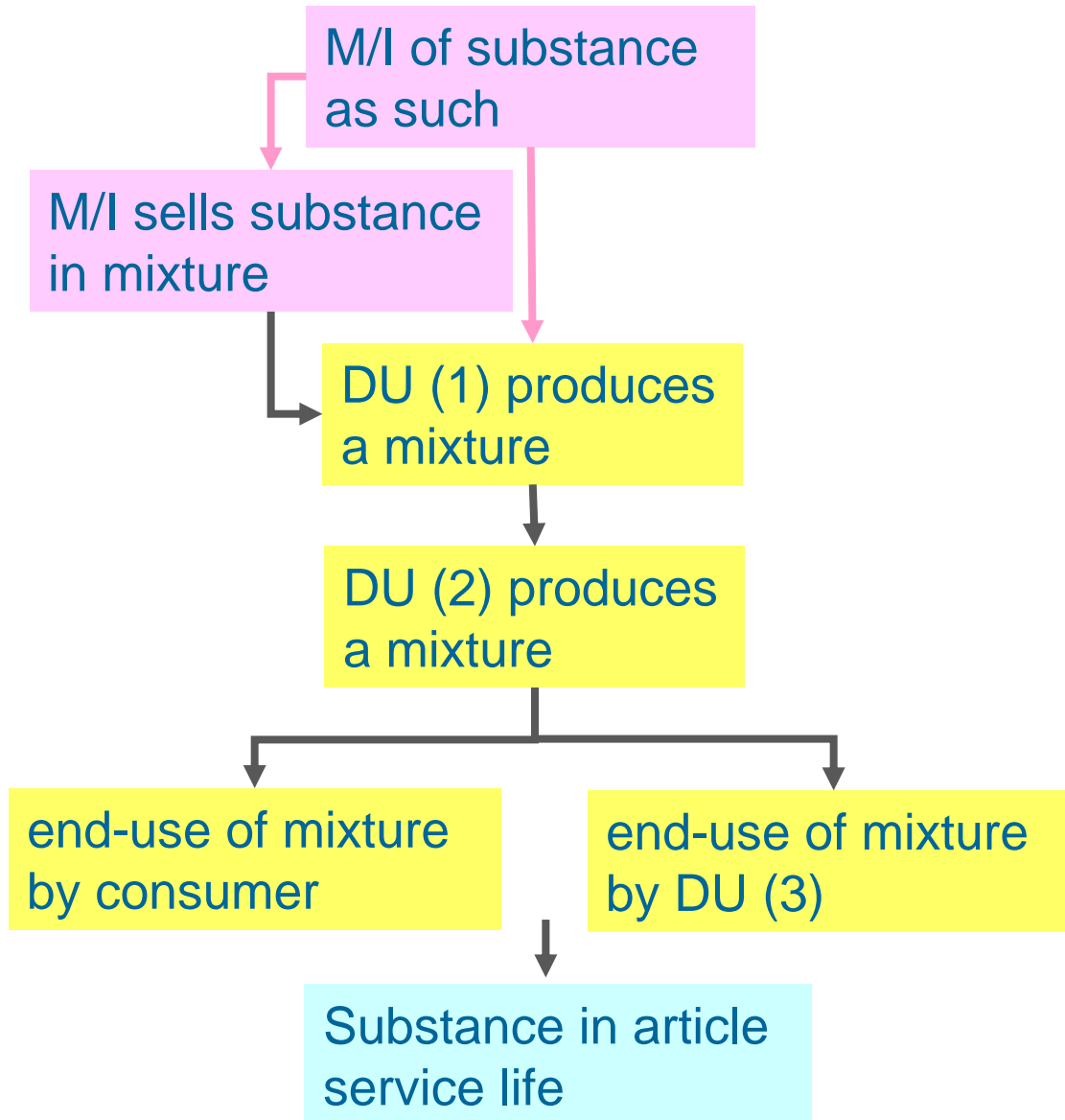
- Make sure that you fully understand the life cycle of your substance
- Be transparent in your CSR and justify deviations from standard methodology
- Cooperate with downstream users for realistic, harmonised and useful use descriptions and exposure scenarios
- Do not consider your registration dossier as a final product once submitted; be prepared to update your CSR
- As a member registrant – make sure that you understand the joint CSR; implement and communicate the respective condition of use

# Overview

- The purpose of the Chemical Safety Assessment
- Advice for registrants
- How Chesar can support registrants
- More support from ECHA

## CSA in a nutshell

- Determine the hazards based on the information required for registration of the substance
- Describe the conditions of safe use (operational conditions and risk management)
  - => set of **exposure scenarios** addressing all identified uses
- Estimate the expected exposure under these conditions
- Compare the expected exposure with the hazards
- Conclude whether control of risk is demonstrated; refine the assessment, if needed;
- *Annex I of REACH sets out the general provisions for the assessment*



## When is a CSA required?

- Required if the substance is manufactured or imported at 10 tonnes or more per year
- The CSA includes exposure assessment and risk characterisation for all the identified hazards
  - if one of the criteria is met to classify the substance as hazardous, or
  - if the substance is to be treated as PBT/vPvB, or
  - if information requirements are adapted based on exposure considerations according to Annex XI (3)
- Identified hazards = adverse effects observed based on guideline studies (or other adequate information)

## Advice to registrants (1)

- Make sure that you fully understand the life cycle of your substance
- Provide a transparent hazard and exposure assessment, justify deviations from standard methodology.
- Cooperate with DUs for realistic, harmonised and useful use descriptions and exposure scenarios.
  - Describe the uses in concrete terms. Clearly define which processes and activities are covered per exposure scenario. Use descriptors alone are not enough.
  - Communicate exposure scenarios to your customers that are practically useful for them.



## Advice to registrants (2)

- Make conditions of use for environmental assessment more explicit
- Coordinate among the registrants of a substance to ensure transparent CSRs
- Ensure that your CSR is consistent with the Technical Dossier
- Be aware that the CSRs will be used to inform regulatory processes by ECHA and Member States, e.g. prioritisation for substance evaluation; selection of substances for authorisation



## Advice to registrants (3)

- Do not consider your registration dossier as a final product once submitted
  - Ensure that structures and processes are in place to update the CSR after registration
  - Proactively update your dossiers when new information on hazards or uses becomes available
  - Do not await the outcome of potential compliance checks - improve the quality of the dossiers on your own initiative
  - Further compliance checks will be conducted and results will be communicated in a generic form
  - Be aware that in the long run (not before 2014) all CSRs will be checked for technical completeness

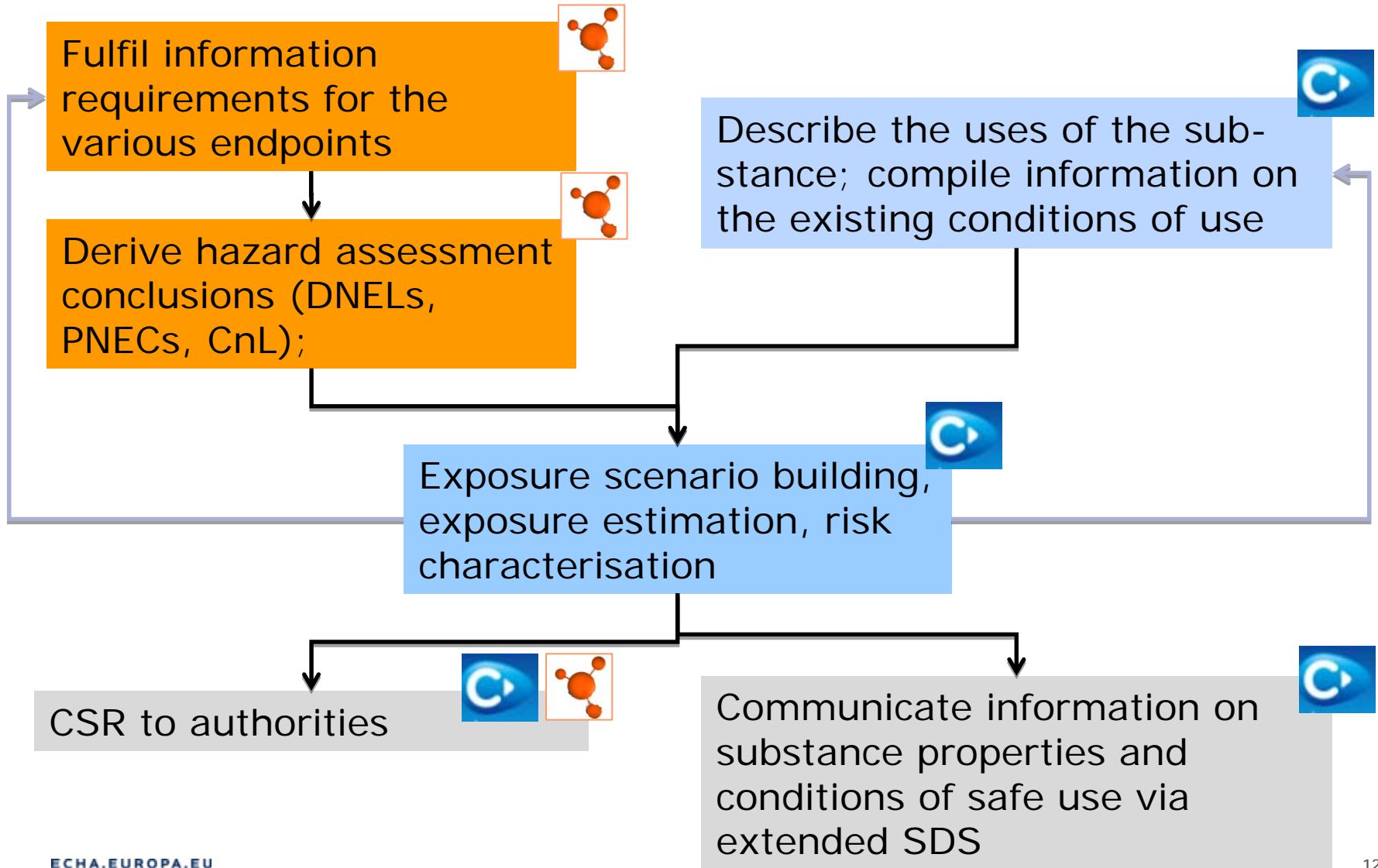
# How can Chesar support registrants?



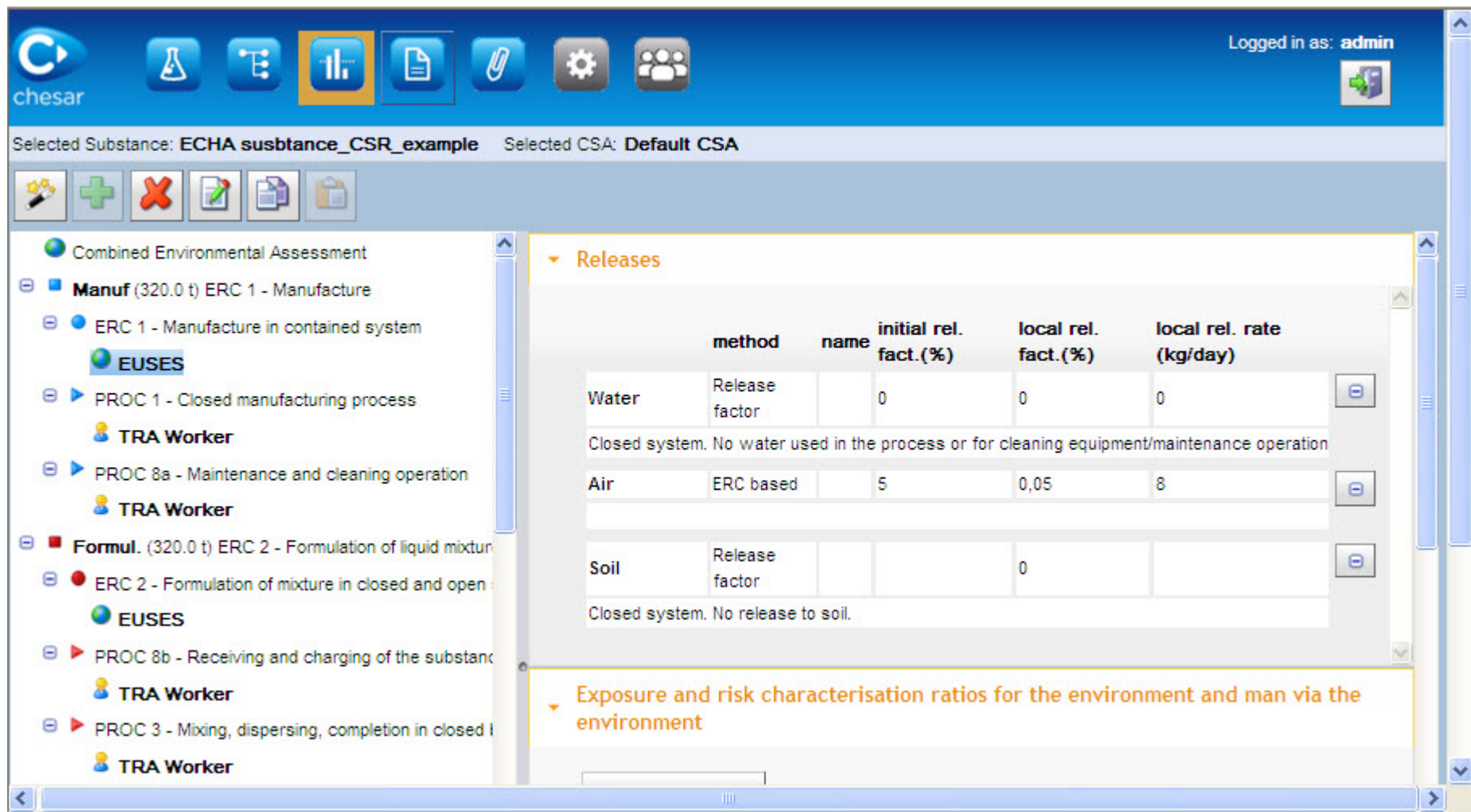
## What is Chesar?

- IT tool developed by ECHA, first release in May 2010:
- supports registrants to prepare, store (in a database) and update the Chemical Safety Assessment (CSA)
- facilitates the re-use of CSA building blocks generated in the single Chesar instance or imported from external sources (e.g. websites of industry organisations).
- enables automated generation of the Chemical Safety Report (CSR) and the exposure scenario (ES) for communication directly from the assessment.

# Assessment workflow



# Example: Release estimation in Chesar



Selected Substance: **ECHA substance\_CSR\_example** Selected CSA: **Default CSA**

Released in: **admin**

Combined Environmental Assessment

- Manuf (320.0 t) ERC 1 - Manufacture
  - ERC 1 - Manufacture in contained system
    - EUSES**
    - PROC 1 - Closed manufacturing process
      - TRA Worker
    - PROC 8a - Maintenance and cleaning operation
      - TRA Worker
  - Formul. (320.0 t) ERC 2 - Formulation of liquid mixture
    - ERC 2 - Formulation of mixture in closed and open system
      - EUSES**
      - PROC 8b - Receiving and charging of the substance
        - TRA Worker
      - PROC 3 - Mixing, dispersing, completion in closed system
        - TRA Worker

**Releases**

	method	name	initial rel. fact. (%)	local rel. fact. (%)	local rel. rate (kg/day)	
Water	Release factor		0	0	0	[-]
Closed system. No water used in the process or for cleaning equipment/maintenance operation						
Air	ERC based		5	0,05	8	[-]
Soil	Release factor			0		[-]
Closed system. No release to soil.						

**Exposure and risk characterisation ratios for the environment and man via the environment**

## Important key features of Chesar

- Supports consistency of the workflow from substance properties to risk characterisation
- Supports consistency between CSR and the information communicated to the downstream users
- Enables the re-use of CSA elements across substances
- Allows IT exchange between Chesar, IUCLID and companies' EHS systems (supports the EScomXML standard)

## Chesar 2 – release plan (1)

- **Chesar 2.0** -> end of June 2012. Includes the functionalities:
  - for carrying out chemical safety assessments (CSAs) based on a IUCLID 5.4 dataset
  - for generating chapter 9 and 10 of the chemical safety report (CSR).
- Update of **CSR generator** (IUCLID plug in)-> Q3 of 2012
  - export of information on uses from Chesar 2.0 to IUCLID 5.4
  - generation of the full CSR by combining information from IUCLID 5.4 and Chesar 2.0.

## Chesar 2 – release plan (2)

- **Chesar 2.1** -> early autumn 2012. Includes:
  - the exposure estimation tool for consumers developed by ECETOC (TRA consumer).
  - the standard phrases library (depending on the progress made in cooperation with CEFIC's EScom project)
- **Chesar 2.2** -> late 2012 or beginning of 2013. This will add:
  - the generation of exposure scenarios for communication.
- The application will remain stable: each release of this release plan will only add new functionalities.





## More support by ECHA

- ECHA is committed to maintaining and further developing IUCLID and Chesar to support efficient CSA and harmonised CSRs and ESs for communication
- ECHA, in cooperation with industry, has initiated the *Exchange Network on Exposure Scenarios* (ENES), aiming to share experience and solutions
- ECHA publishes illustrative examples of ESs and CSRs
- ECHA expects registrants to make their CSRs a source of good quality information
- ECHA welcomes the industry initiatives to create and maintain shared resources for efficient and harmonised CSA

**Thank you.**

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