

Exposure Scenarios in the Chemicals Safety Report and ECHA's CSA-Tool *Chesar*

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Content

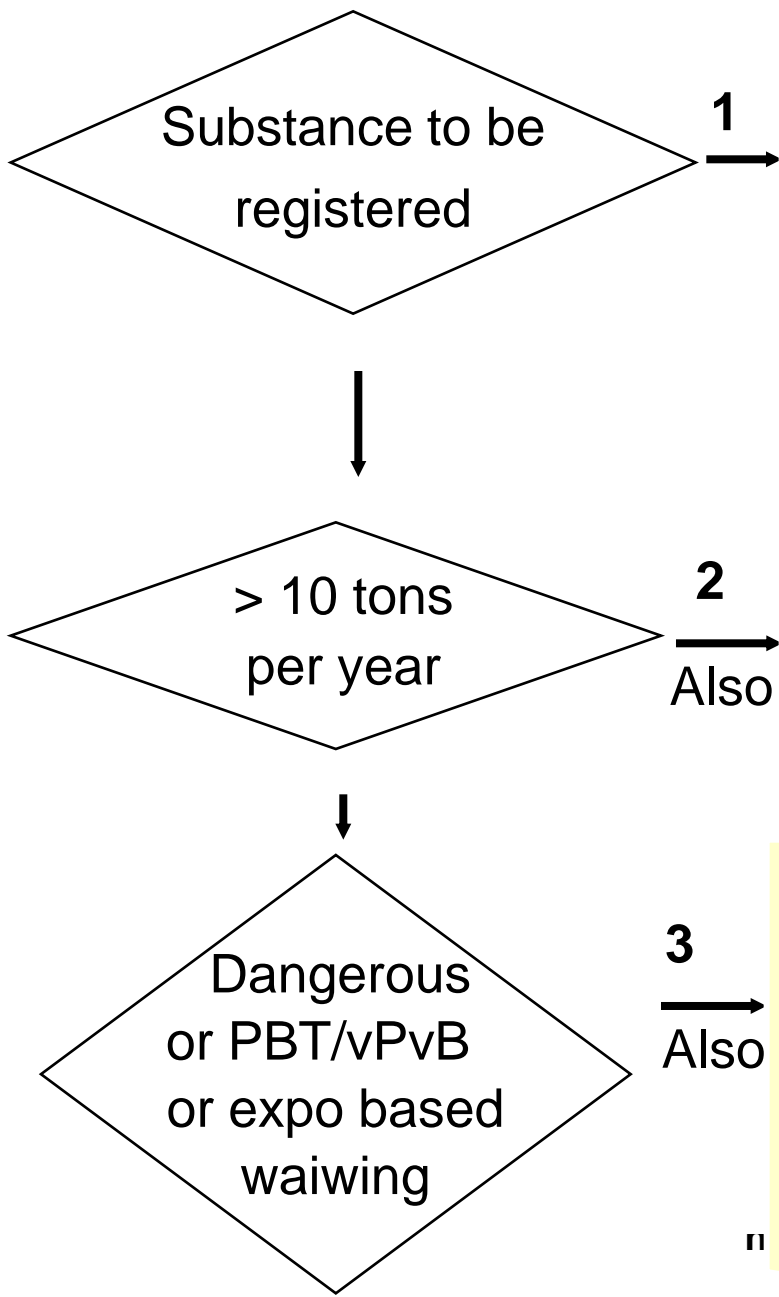
- Chemicals Safety Assessment Framework under REACH
- Content, format and information structure of the exposure scenario
- ECHA's CSA tool *Chesar* – overall concept
- Particular features of *Chesar*
- Conclusion

Aim of the CSA Process



- Identify the conditions ensuring control of risks arising from manufacture and use(s) of a substance.
- Prepare a set of corresponding information on operational conditions and risk management measures to be communicated to the users of the substance = Exposure Scenario (attached to eSDS)
- Document the assessment in a CSR for the companies' own records: Exposure scenarios (CSR), exposure estimates and risk characterisation
- Submit CSR to the authorities as part of the registration

Registration



- Information in Technical Dossier, i.a**
- Manufacture and use of the substance
 - Classification and labelling
 - Guidance on safe use of the substance
 - Study summaries – substance properties
 - Test proposals (if relevant)
 - Exposure

- 2**
- Chemical Safety Report**
- Hazard and PBT Assessment

- 3**
- Chemical Safety Report**
- Exposure Assessment
 - Exposure Scenarios
 - Exposure Estimation
 - Risk Characterisation
- CSA**

Information: available ⇔ required/needed

- substance intrinsic properties
- manufacture, use, tonnage, exposure, risk management

Hazard Assessment (HA)

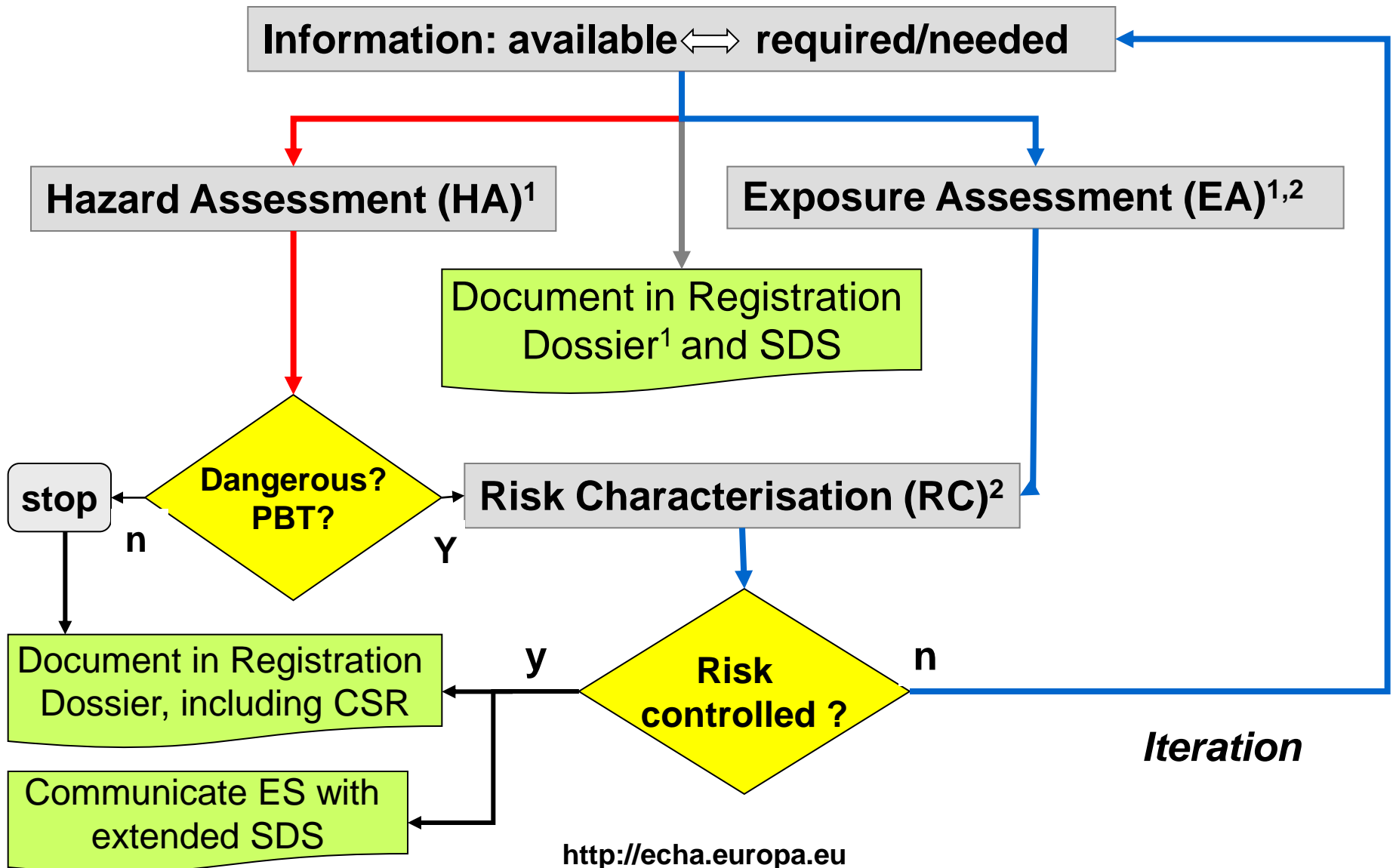
- Hazard identification
- Hazard Classification and PBT conclusion
- Dose/Concentration-Response Characterization

Exposure Assessment (EA)*

- Build Exposure Scenarios
- Estimate Exposure Level¹

¹ For PBT/vPvB: emission characterisation only

CSA Framework



Content of exposure scenarios

- Description of conditions suitable to ensure control of risks related to the uses of a substance during its entire life cycle. Environment, workers and consumers to be covered. One ES can cover one or more uses.
 - Operational conditions determining the exposure (e.g. temperature during processing)
 - Practical measures suitable/needed to prevent, reduce or limit risks (e.g. LEV or wearing gloves)
- Explanation how the exposure estimate for these conditions and measures has been derived
- Description of uses for which these conditions and measures are suitable (title and boundaries of the exposure scenarios).

- Overall format of an ES
 - Section 1: Title
 - Section 2.1: Conditions determining human exposure
 - Section 2.2: Conditions determining environmental exposure
 - Section 3 (eSDS): Exposure estimation and reference to its source
 - Section 4 (eSDS): Guidance to DU to evaluate whether he works inside the boundaries set by the ES
- 4 standard formats
 - Workers uses
 - Consumer uses
 - Article handling/processing by workers
 - Article handling by consumers

2.1 Control of workers exposure

Product characteristic

Amounts used

Frequency and duration of use/exposure

Human factors not influenced by risk management

Other given operational conditions affecting workers exposure

Technical measures at process level (source) to prevent release

Technical measures to control dispersion from source towards workers

Organisational measures to prevent /limit releases, dispersion and exposure

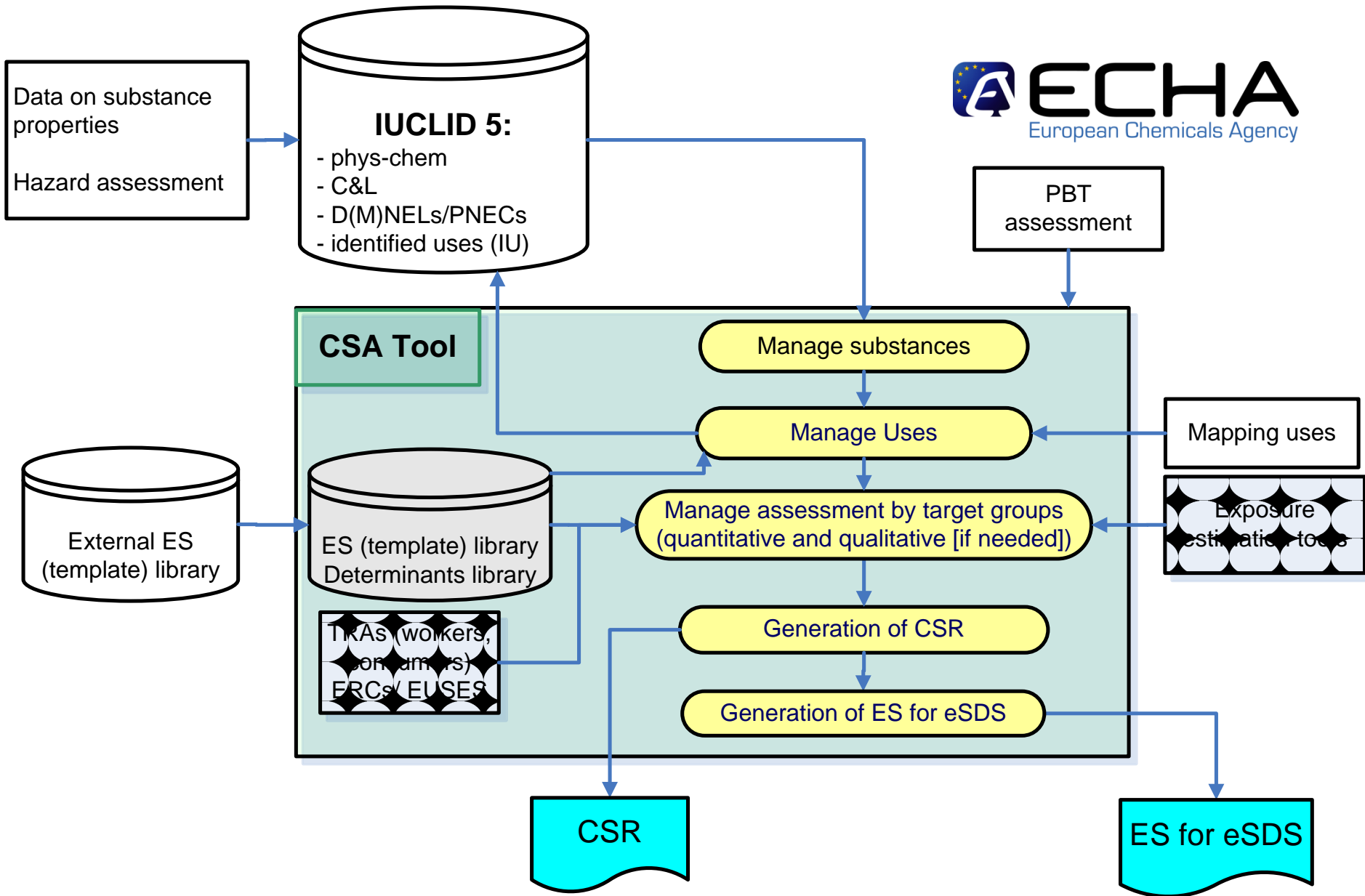
Measures related to personal protection, hygiene and health evaluation

Additional good practice advice beyond the REACH CSA

Concept of *Chesar*

General purpose of Chesar

- Basic goals
 - Support registrant's CSA process
 - CSR/ES authoring for a substance
- Supports
 - exposure scenario building based on internal Tier 1 exposure estimates
 - reporting exposure scenarios by other exposure assessment tools or based on measured data
 - starting from existing exposure scenarios (or parts of it) e.g available in libraries
 - some flexibility in structure of information sent to customers based on what is documented in the CSR



Flexibility and Learning

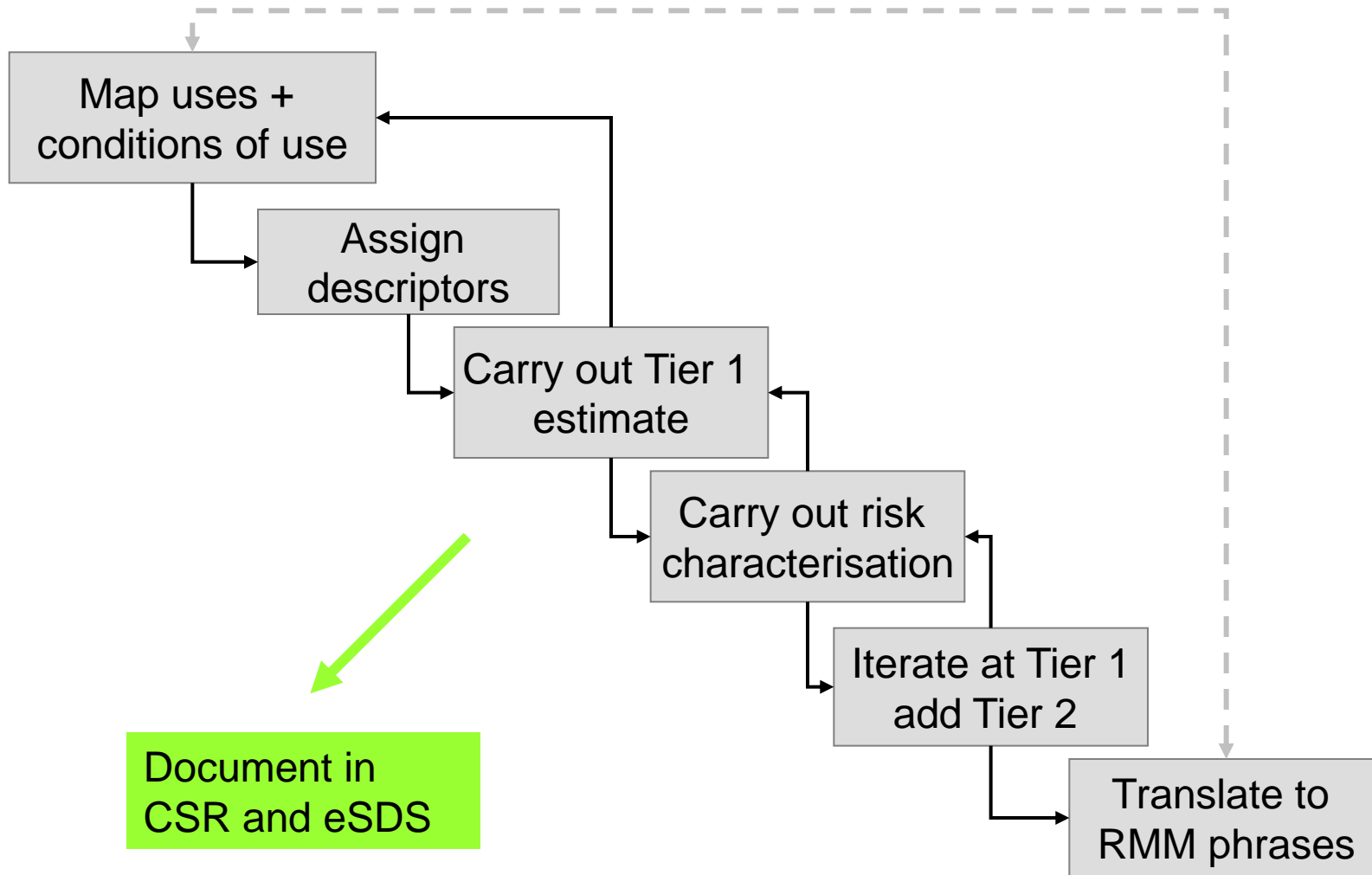
- The tool should be able
 - to support consistency of exposure scenario building within a company, a sector and across sectors
 - to incorporate more advanced models for exposure estimates
 - to support standardization in expressing risk management measures and operational conditions
 - to follow and support the further development of approaches to build exposure scenario over the next years

Particular features in *CHESAR*

Particular features

- Systematic description of uses as a starting point for the assessment
 - Assessment type driven by information from IUCLID (phys-chem and fate properties, DNEL/PNEC, CnL)
 - Quantitative, semi-quantitative, qualitative
 - Route and scope of effect
 - Flexible linking and de-linking of uses for “bulk assessment”
 - The tool supports combining different assessment methods for specifically addressing the relevant routes or scope of effects for workers and consumers
 - The user can define determinants beyond the plugged in exposure estimation tools.
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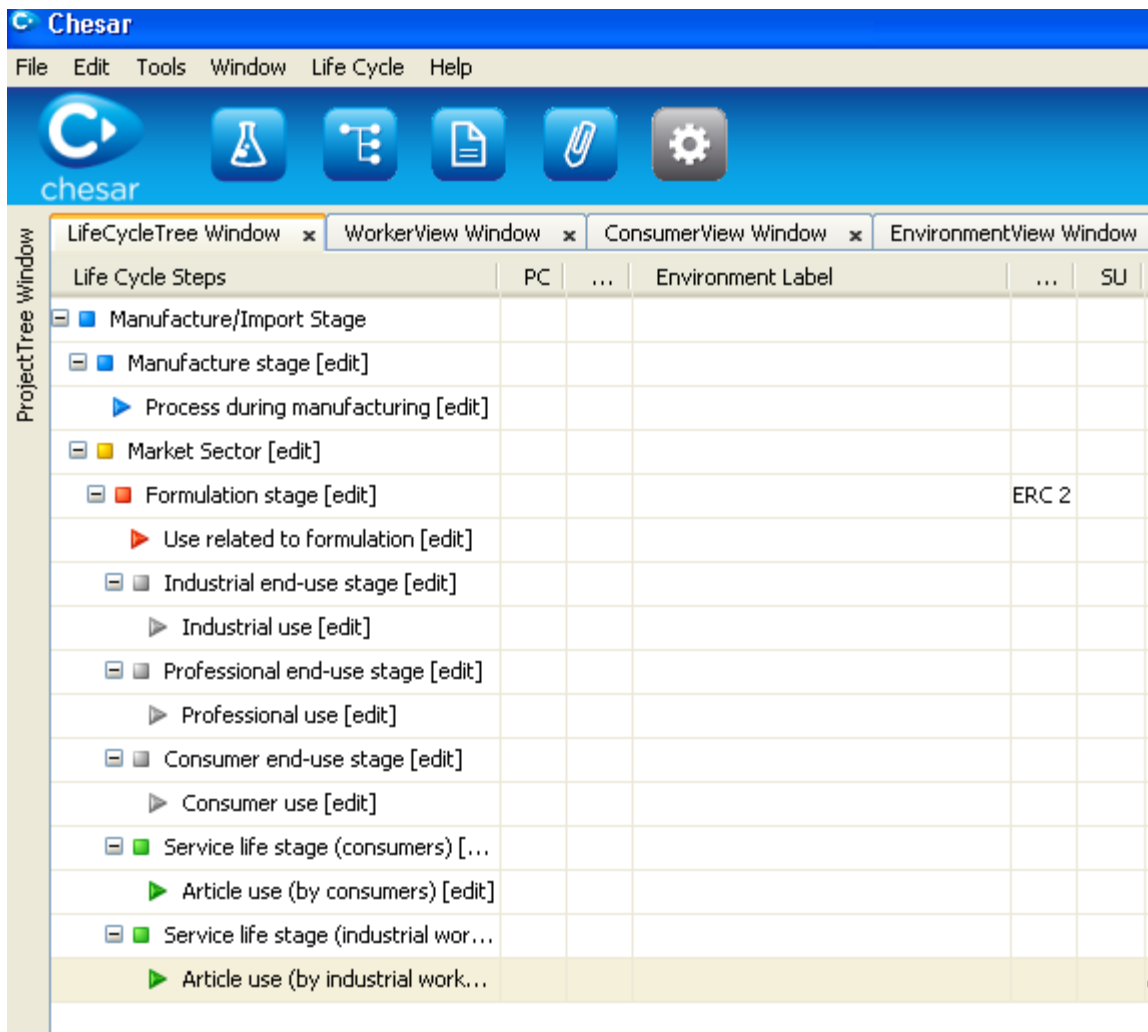
Default assessment process



Determinants for plugged in Tier 1

- (Volatility of substance)
- Generic type of process/activity (by process category)
- Industrial or non-industrial setting
- Duration of exposure per shift
- Concentration of substance in product
- Dustiness of product
- Indoor or outdoor conditions
- Availability of LEV
- Respiratory PPE
- Dermal PPE

Chesar use mapping structure



The screenshot shows the Chesar software interface. The title bar reads "Chesar". The menu bar includes "File", "Edit", "Tools", "Window", "Life Cycle", and "Help". The toolbar contains icons for a refresh button, a flask, a tree structure, a document, a paperclip, and a gear. The main window has several tabs: "LifeCycleTree Window", "WorkerView Window", "ConsumerView Window", and "EnvironmentView Window". The "LifeCycleTree Window" is active and displays a tree structure of life cycle stages. The tree is organized into a table with columns for "Life Cycle Steps", "PC", "Environment Label", and "SU".

Life Cycle Steps	PC	Environment Label	SU
[-] Manufacture/Import Stage			
[-] Manufacture stage [edit]			
▶ Process during manufacturing [edit]			
[-] Market Sector [edit]			
[-] Formulation stage [edit]			ERC 2
▶ Use related to formulation [edit]			
[-] Industrial end-use stage [edit]			
▶ Industrial use [edit]			
[-] Professional end-use stage [edit]			
▶ Professional use [edit]			
[-] Consumer end-use stage [edit]			
▶ Consumer use [edit]			
[-] Service life stage (consumers) [...]			
▶ Article use (by consumers) [edit]			
[-] Service life stage (industrial wor...)			
▶ Article use (by industrial work...)			

- Life cycle “stage” level
- ”use” level

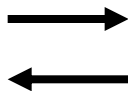
Selection of assessment type (HH)

Value in IUCLID	Choices available
no hazard identified for this route (data available)	<ul style="list-style-type: none">• no assessment needed
no or insufficient data available at present	<ul style="list-style-type: none">• Flag in the tool (and in the CSR) that data are needed, to perform the required assessment
DNEL	<ul style="list-style-type: none">• Plugged-in exposure estimation tool• External exposure estimation tools• Measured exposure estimates
DMEL	<ul style="list-style-type: none">• Semi quantitative assessment
No DNEL needed since no exposure expected	<ul style="list-style-type: none">• Qualitative assessment
No threshold effect: qualitative assessment needed	<ul style="list-style-type: none">• Qualitative assessment

Assessment with Chesar

Use description in
different tree view

- general
- worker
- environment
- consumer



Risk characterisation per route and
scope of effect and environmental
compartment

- worker
- consumer
- environment
- man via environment



Exposure assessment

- Determinants controlling exposure
- Release estimates
- Exposure estimates
- Justifications

State of play and conclusions

A challenging project

- Very tight time frame: ECHA aims at a solution to roll out version 0.5 of the tool (limited but useful in scope) end 2009/early 2010
- Difficult to construct a tool without experience available on “best practice” regarding building exposure scenarios;
- System architecture and data model need to be flexible to allow future developments

Project Implementation

- The CSA tool will be developed as a IUCLID plug-in
- Positive feedback from consultation group so far
 - Flexibility of the tool
 - In line with processes taking place in industry
- Programming has started in June
 - Use reporting module stable
 - Substance management (IUCLID interface) and assessment functionalities basically programmed
 - CSR building and eSDS attachment building not started yet
- Testing with stakeholders in September, October, November

Conclusions

- ECHA builds an IT tool to support registrants. The tool will need to be fed with information generated elsewhere:
 - Mapping of uses and conditions of use: The tool will only help to organise the information in a way that it facilitates the assessment.
 - Standardisation of RRM phrasing: The tool will not be equipped with a RMM phrase catalogue, however it can import phrase catalogues developed elsewhere.
 - Organising the communication within the supply chains is to be done now (if not already started).
- ECHA aims to facilitate plug-in of more advanced exposure estimation tools.

Thank You
for your attention

