



**Royal
HaskoningDHV**
Enhancing Society Together

CHESAR

The tool for efficient CSR production
&
effective downstream user communication?!

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- ❖ Leo van der Biessen
- ❖ Industrial Hygienist
- ❖ Safe use of chemicals > 20 years
- ❖ REACH & CLP > 5 years
- ❖ Focus on human health & physical/chemical hazard



- ❖ REACH purpose & first results
- ❖ Chemical safety assessment and communication of risk information
- ❖ CHESAR – what can it do
- ❖ Structuring uses in CHESAR
- ❖ Making eSDS appendix in CHESAR

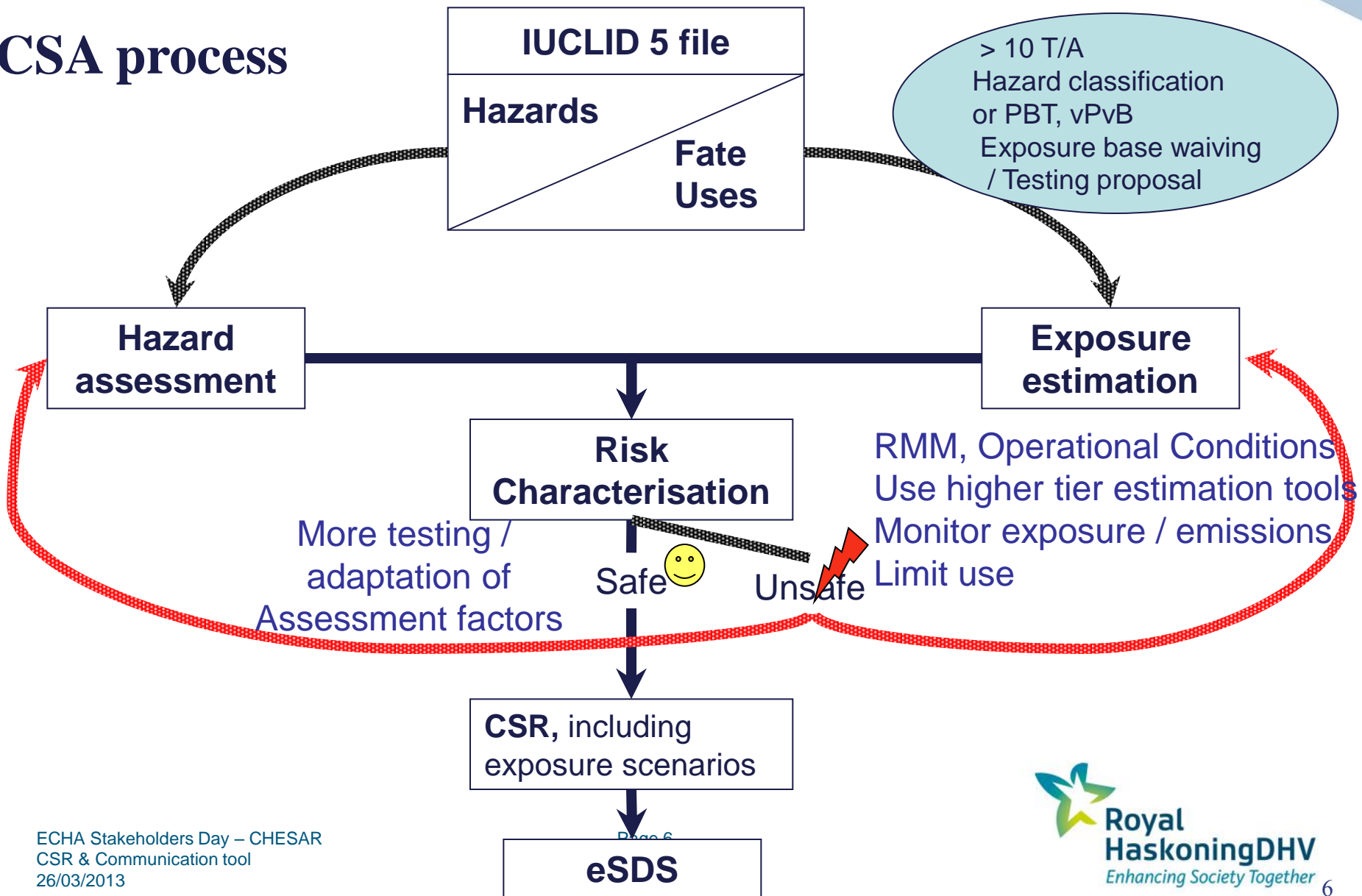
REACH 101 – core values of REACH

- ❖ Purpose of REACH →
Ensure Health & Safety of consumers & Workers
Protect the environment
- ❖ Producer & Importer responsible for the safe use of their substance throughout the supply chain → registration
- ❖ For very hazardous substance authorities have active role
→ Authorisation & Restriction
- ❖ Process of assessing safety is Chemical Safety Assessment

Purpose of the Chemical safety assessment

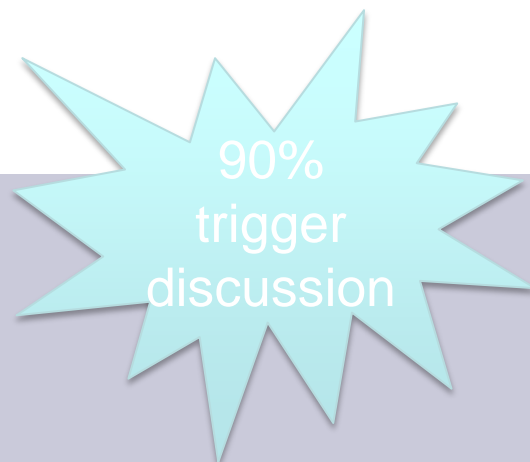
- ❖ Demonstrate safe use of a substance to ECHA
- ❖ Provide input for communication throughout the supply chain

CSA process



REACH results

- Determine hazard
- Demonstrate safe use of chemicals



Covered

- Provide information for users of chemicals on how to use the substance

Standard
Phrases
available

Software
almost
available

Struggle up till now

CHESAR tool
Available!!

Compliant
mixture eSDS
difficult

User and CSR information in eSDS

- ❖ Purpose eSDS: Communicating information on the safe use of substance from the chemical safety assessment
- ❖ DSU-er: Legal obligation to apply at least OC and RMM
→ meet risk characterization ratio
- ❖ eSDS content: all information needed to use substance safe & protect the environment within the supply chain
 - ❖ Communicating information on the safe use of substance from the chemical safety assessment
 - ❖ Providing information for the DSU to determine if his uses are covered by the ES
 - ❖ Information for formulators for their (extended) Safety Data Sheet

What information in should be available in the eSDS?

- ❖ All you need to know to use the substances safely
- ❖ In what sector of industry can it be used (SU)
- ❖ What activities are allowed (PROC)
- ❖ Conditions from an environmental perspective (ERC)
- ❖ Articles (AC) & product (PC)

- ❖ What volumes can be used
- ❖ Which concentrations
- ❖ Operational conditions & risk management measures needed
(OC: Process, concentration/volume, frequency, duration)
(RMM: all measures taken in order to reduce $RCR < 1$)
organizational, technical, ppe

Minimum obligations for an eSDS → Annex II REACH

- ❖ In all official languages of countries where substance is marketed
→ applies to sections 1-16 & appendix
- ❖ Content in line with information in chemical safety report & dossier
Chesar as tool of choice
- ❖ Sections 1-16 & appendix need to be in line with appendix
- ❖ Sufficient information for a DSU to determine if his uses are covered
- ❖ List all uses communicated to registrant
→ supported use or use advised against

The problem with extended safety data sheets

- ❖ Long
- ❖ Lack structure
- ❖ Users can not find their uses
- ❖ Operational conditions and RMM unclear
- ❖ Scaling information missing

Exposure Scenario

- ❖ Description of a covered use of a substance
 - ❖ Operational conditions (use descriptor system)
 - ❖ Risk management system (universal language under development)

- ❖ Communication tool

What is CHESAR

- ❖ **C**hemical **S**afety **A**ssessment and **R**eporting tool
- ❖ Developed by ECHA
 - ❖ Describe uses in exposure scenarios
 - ❖ Tier 1 exposure estimation
 - ❖ Production of chapters 9&10 of Chemical Safety Report
 - ❖ Export for IUCLID section 3.5 (3.7 in future)
 - ❖ eSDS appendix production

Why is CHESAR 2 the method of choice

Efficient, effective, compliant

- ❖ Use of data straight from IUCLID
- ❖ Flexibility in listing uses (copy/paste, placement)
- ❖ Extensive in- & export functionality
- ❖ Primary & contributing assessment in one use
 - legally obliged OC/RMM vs good practice
- ❖ Libraries → uniform approach
 - ECom
 - User defined definitions of higher tier input for activities
 - spERC information

ESCom System

- ❖ Standardized phrases to communicate operational conditions and RMM
- ❖ XML standard for communication between IT systems
- ❖ *Phrases can be imported into CHESAR as a library*
- ❖ *Added manually in Chesar to eSDS*

How does CHESAR work

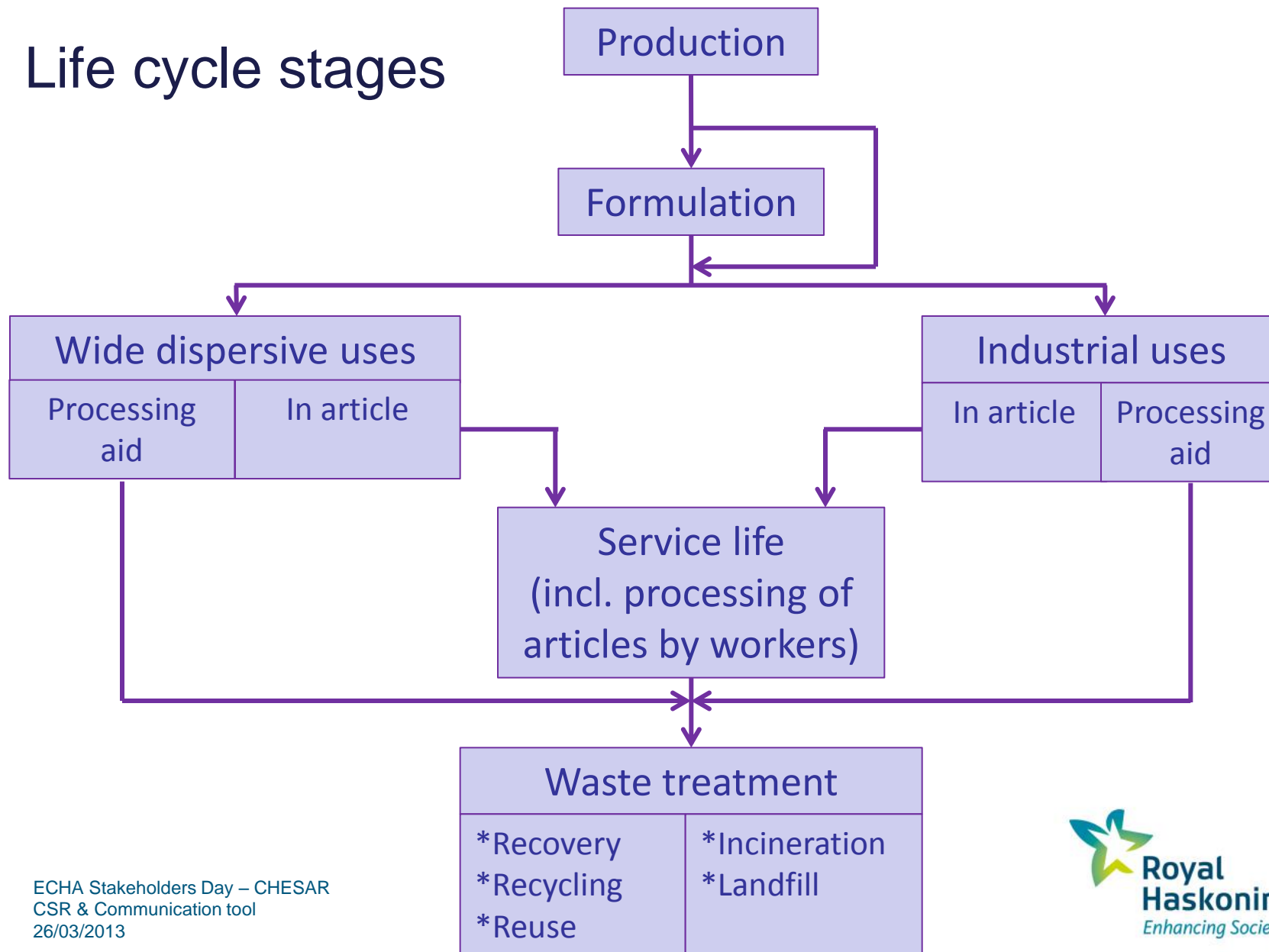
- ❖ Stand alone tool, all data on your computer
- ❖ 7 Boxes
 - ❖ Box 1 – Substance management (import from IUCLID)
 - ❖ Box 2 – Use management
 - ❖ Box 3 – Assessment management
 - ❖ Box 4 – CSR management
 - ❖ Box 5 – SDS ES management
 - ❖ Box 6 – Library management
 - ❖ Box 7 – User management

Box 2 – Use management

- ❖ Identified uses (life cycle tree)
 - Life cycle stages
 - Market sectors
 - Contributing scenarios
- ❖ Label and standard phrases
- ❖ Use descriptor system (PROCs, ERC)
- ❖ Life cycle management (import / export)



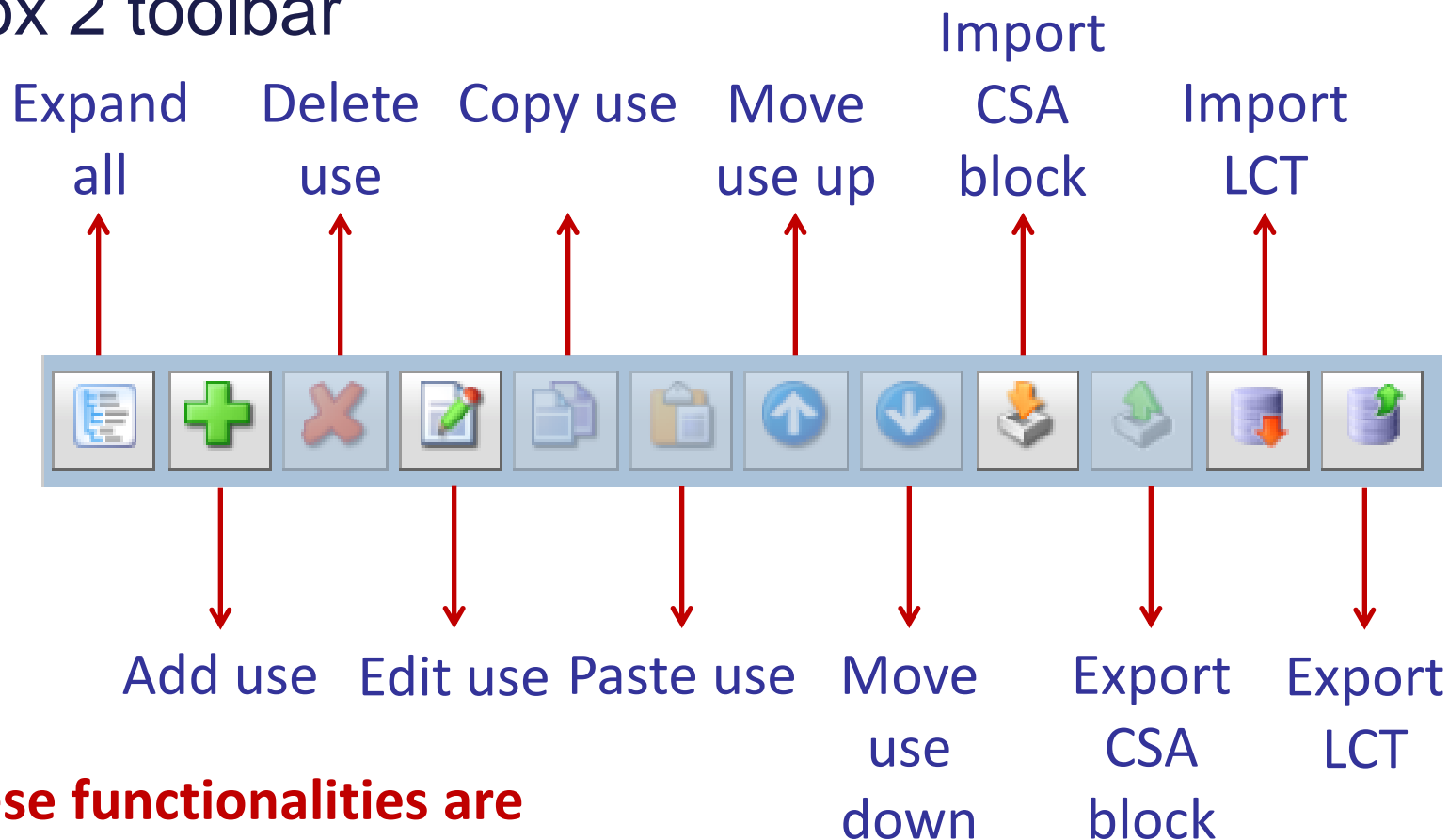
Life cycle stages



Life cycle tree elements in Chesar

- ❖ Manufacture
- ❖ Formulation
- ❖ Use of substances at industrial sites
- ❖ Use of substances by professional workers
- ❖ Consumer use of substance
- ❖ Article service life
 - Industrial site
 - Professional worker
 - Consumer

Box 2 toolbar



These functionalities are also available via right click in the LCT

Building LCT

- Starting with manufacture / import

The screenshot displays the CHESAR software interface. At the top, the user is logged in as 'rcleijsen'. The main window shows 'Selected Substance: Roos' and 'Selected CSA: CSA Roos'. A toolbar contains several icons, with a green plus sign icon circled in red. A dialog box titled 'Select use or contributing scenario type' is open, listing various options: 'Manufacture', 'Market Sector', 'Formulation', 'Use at industrial site', 'Use by professional worker', 'Consumer Use', 'Service life (worker at industrial site)', 'Service life (professional worker)', and 'Service life (consumers)'. The 'Manufacture' option is circled in red. Below this, a 'Create use of type Manufacture' dialog box is open. It contains the following fields: 'Label' (set to 'Manufacture', circled in red), 'Environment Release Category (ERC)' (set to 'ERC 1: Manufacture of substances', circled in red), 'Explanation for CSR contributing scenario' (empty), 'Tonnage manufactured (tonnes/year)' (set to '0', circled in red), and 'Internal remarks' (empty). At the bottom of this dialog, the 'OK' button is circled in red. The background shows a partially visible table with a '0' in one of its cells.

Building LCT

- Create worker contributing scenario

The screenshot displays the CHESAR software interface. At the top, the 'chesar' logo and a toolbar with icons for home, search, list, document, link, settings, and users are visible. Below the toolbar, the status bar shows 'Selected Substance: Roos' and 'Selected CSA: CSA Roos'. A tree view on the left shows the project structure: 'Manuf.Imp. (100.0 t) Manufacture / Import' > 'Manuf (100.0 t) ERC 1: Manufacture' > 'ERC 1: Manufacture'. The main area shows a 'Manufacture' process with an 'Environment' tab selected. A dialog box titled 'Create use of type Worker contributing scenario' is open. It has a 'Label' field containing 'Worker contributing scenario [edit]', a 'Process Category (PROC)' dropdown menu set to 'PROC 5: Mixing or blending in batch processes for formulation of preparations and articles', and an 'Explanation for CSR contributing scenario' text area. A smaller dialog box is also open, titled 'Select use or contributing scenario type', with 'Worker contributing scenario' selected. The 'OK' button in the main dialog is highlighted.

Building LCT

The screenshot displays the chesar software interface. At the top, the 'chesar' logo is on the left, and a toolbar contains icons for home, flask, process flow (highlighted with a yellow box), bar chart, document, paperclip, settings, and users. Below the toolbar, the status bar shows 'Selected Substance: Roos' and 'Selected CSA: CSA Roos'. A secondary toolbar contains icons for document, add, delete, edit, copy, paste, up, down, and other actions. The main area shows a tree view of processes:

- Manuf.Imp. (100.0 t) Manufacture / Import
 - Manuf (100.0 t) ERC 1: Manufacture
 - ERC 1: Manufacture
 - PROC 5: Worker contributing scenario [edit]

The 'PROC 5: Worker contributing scenario [edit]' item is circled in red. To the right, a panel titled 'Worker contributing scenario [edit]' contains three text input fields: 'Process Category (PROC)', 'Explanation for CSR contributing scenario', and 'Internal remarks'.

Simple Life Cycle Tree
 Manufacture, formulation,
 industrial, professional and
 consumer use stage

Environmental
 contributing
 scenario
 Worker
 contributing
 scenario
 Consumer
 contributing
 scenario

Selected Substance: **Roos** Selected CSA: **CSA Roos**

- Manuf.Imp. (100.0 t) Manufacture / Import
 - Manuf (100.0 t) ERC 1: Manufacture**
 - ERC 1: Manufacture
 - PROC 5: Worker contributing scenario [edit]
 - Formul. (50.0 t) ERC 2: Formulation
 - ERC 2: Formulation**
 - PROC 8a: Worker contributing scenario [edit]
 - Site (30.0 t) ERC 4: Use at industrial site
 - ERC 4: Use at industrial site
 - PROC 10: Worker contributing scenario [edit]**
 - Prof. (20.0 t) ERC 8a: Use by professional worker
 - ERC 8a: Use by professional worker
 - PROC 11: Worker contributing scenario [edit]
 - Consum. (50.0 t) ERC 8a: Consumer Use
 - ERC 8a: Consumer Use
 - PC 35: Consumer contributing scenario [edit]**

Life cycle stage

Other functionalities

- ❖ Copy
- ❖ Paste
- ❖ Move up
- ❖ Move down
- ❖ Import CSA block
- ❖ Export CSA block
- ❖ Import LCT
- ❖ Export LCT

The screenshot displays the CHESAR software interface. At the top, the 'chesar' logo is visible on the left, and a toolbar contains several icons. The icon for 'Copy' (two overlapping documents) is highlighted with a yellow box. Below the toolbar, the 'Selected Substance: Roos' and 'Selected CSA: CSA Roos' are indicated. A row of icons is circled in red, including Copy, Paste, Move Up, Move Down, Export CSA Block, and Import CSA Block. The main workspace shows a hierarchical tree of manufacturing and process blocks. A context menu is open over the 'Formul. (50.0 t)' block, listing actions: Add, Delete, Edit, Copy, Paste, Move-Up, Move-Down, Export CSA Block, and Import CSA Block.

Grouping of uses in exposure scenarios

- ❖ Type of main activity
Formulation, Industrial, Professional & Consumer uses
- ❖ Branch organization / Sector group
Stick to naming of uses & operational conditions selected
- ❖ Keep it short & simple
Only differentiate if it changes outcome of estimates
OR if it helps your DSU-er to comply

Box 2: Use management

- ❖ Input of all the uses communicated to you
- ❖ Allows for targeted information in eSDS
 - ❖ Branch / sector information [Cefic overview activities](#)
 - ❖ Types of client: Marketing & Sales

Box 3 – Assessment management

- ❖ Quantitative exposure assessment
- ❖ Default assessments: environment, human health (worker, consumer) and service life
- ❖ Integrated models
 - EUSES
 - ECETOC TRA worker
 - ECETOC TRA consumer
- ❖ External tools (e.g. Advanced REACH Tool, ConsExpo)



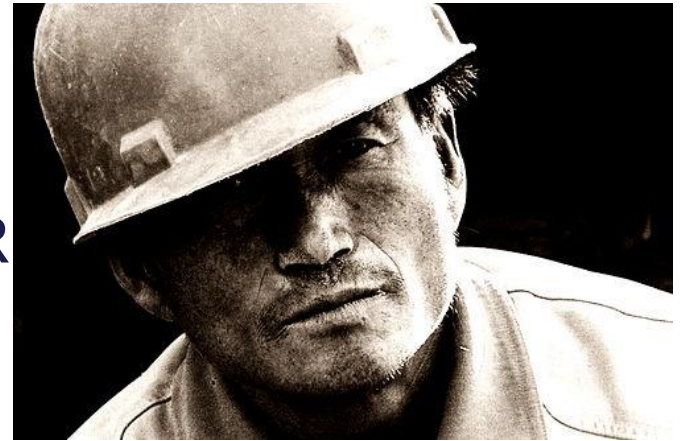
Environment assessment

- ❖ EUSES v2.1.2
- ❖ Based on environmental release category (ERC)
- ❖ Modifyable conditions of use
 - Amount used
 - Variables related to STP
 - Surface water flow rate
- ❖ Advanced assessment: SpERCs or measured data

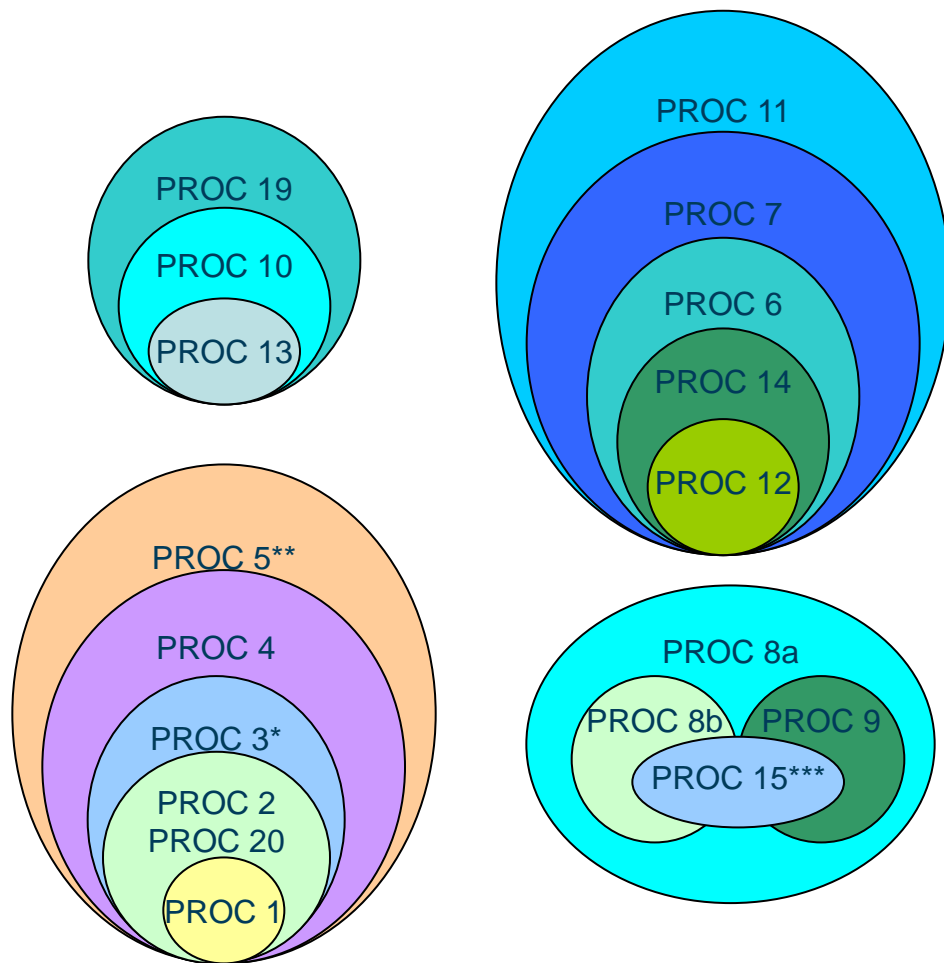


Worker assessment

- ❖ ECETOC TRA worker v3.0
- ❖ Based on process category (PR)
- ❖ Modifyable conditions of use
 - Concentration
 - Duration of activity, process temperature and place of use
 - Level of Occupational Health and Safety Management System
 - General ventilation and/or local exhaust ventilation
 - Dermal and/or respiratory protection
- ❖ Advanced assessment: other models or measured data



Hierarchy of exposure potential per PROC in ECETOC-TRA and CHESAR



- ❖ Chesar exposure estimation is higher in the larger bullets (so PROC 4 also covers PROCs 1, 2, 3 and 20)
- ❖ Only applies if operational conditions and risk management measures are identical
- * Not true for dermal exposure with LEV
- ** Not true for dermal exposure
- *** Not true for industrial use of solids with LEV

Consumer assessment

- ❖ ECETOC TRA consumer v3.0
- ❖ Based on product category (PC)
 - ❖ or article category (AC)
- ❖ Modifyable conditions of use
 - Spray use or not?
 - Weight fraction and amount used /application
 - Body parts potentially exposed and dermal transfer factor



- ❖ Advanced assessment: other models or measured data

Box 4 CSR management

→ what you report to ECHA

- ❖ Generation of (default) exposure scenarios
- ❖ Characterization of the risk
- ❖ Manual aggregation of combined uses risk
- ❖ Input of RMM from physical chemical hazards
- ❖ Automated generation of CSR
- ❖ Exposure assessment strategy, general information added manually
- ❖ Export of CSR

Box 5 – eSDS management, information down the supply chain

- Generation of annex for eSDS
- Selection of exposure scenarios & contributing scenario
- Editing of naming in line with downstream user info
- Trim information
- Standard phrases to be added manually
- Guidance for downstream user

ESCom System

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Scaling

- ❖ Method for downstream user to assess if his slightly different use is covered by an exposure scenario
 - variations of an exposure scenario
 - DSU documents results
- ❖ Scaled RCR < ES RCR (or maximum RCR allowed given total CSR)

Information needs for scaling

- ❖ Models used for exposure estimation
- ❖ Basic assumptions & effectiveness of RMM
- ❖ Description on how to scale
- ❖ Input data for higher tier assessment, validity band for measurement
- ❖

Box 6 – Library management

- ❖ Determinant types (environment, worker & consumer)
 - Quantitative
 - Qualitative
 - RMM with effectiveness
- ❖ SpERCs
 - Predefined by industry associations
- ❖ Standard phrases
 - ESCOM phrase list (.xml file)

Conclusion CHESAR benefits

- limits the amount of work
 - For similar assessments on multiple substances
 - Target DSU-er in eSDS using the same assessment
 - Grouping on uses based on potential for exposure
- Helps in communication
 - Table of content
 - Adaptation of names, explanations in eSDS
 - Free format text for section 4 of eSDS
 - Use of standard phrases that allow for automated transfer of information

- Thank you for your attention