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

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March 26th 2013

- Leo van der Biessen
- Industrial Hyginist
- 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

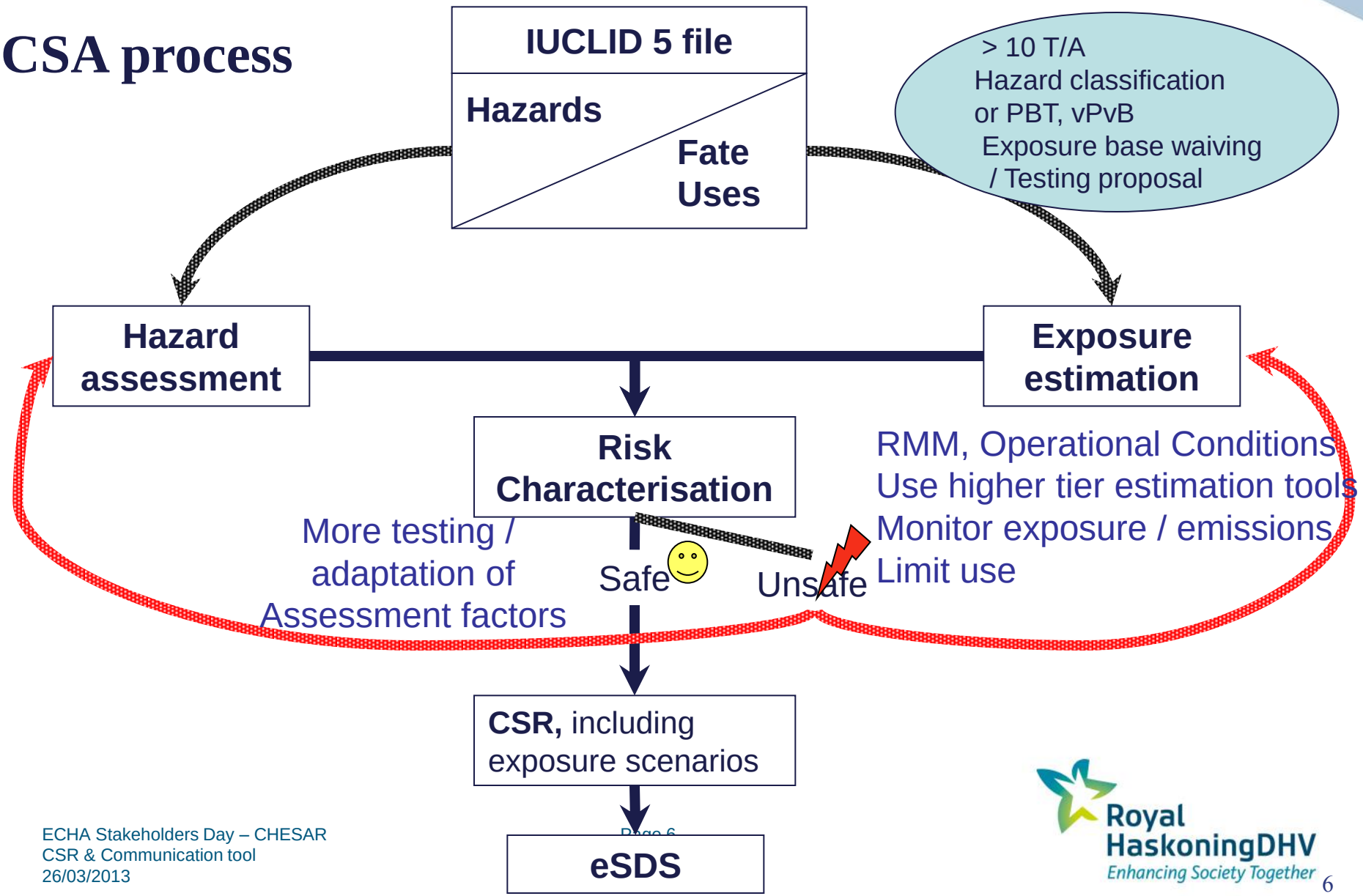
- Process of assessing safety is Chemical Safety Assessment

Purpose of the Chemical safety assessment

- Demonstrate safe use of a substance to ECHA

- Provide input for communication throughout the supply chain

CSA process


IUCLID 5 file
Hazards
Fate
Uses
> 10 T/A
Hazard classification
or PBT, vPvB
Exposure base waiving
/ Testing proposal
Hazard assessment
Exposure estimation
Risk Characterisation
RMM, Operational Conditions
Use higher tier estimation tools
Monitor exposure / emissions
Limit use
More testing /
adaptation of
Assessment factors
Safe
Unsafe
CSR, including exposure scenarios
eSDS

REACH results

- Determine hazard
- Demonstrate safe use of chemicals

90% trigger discussion

Covered

- Provide information for users of chem
  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
  - Provide the information in a clear and concise manner

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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

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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

- **Che**mical **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
  → ESCom
  → 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*

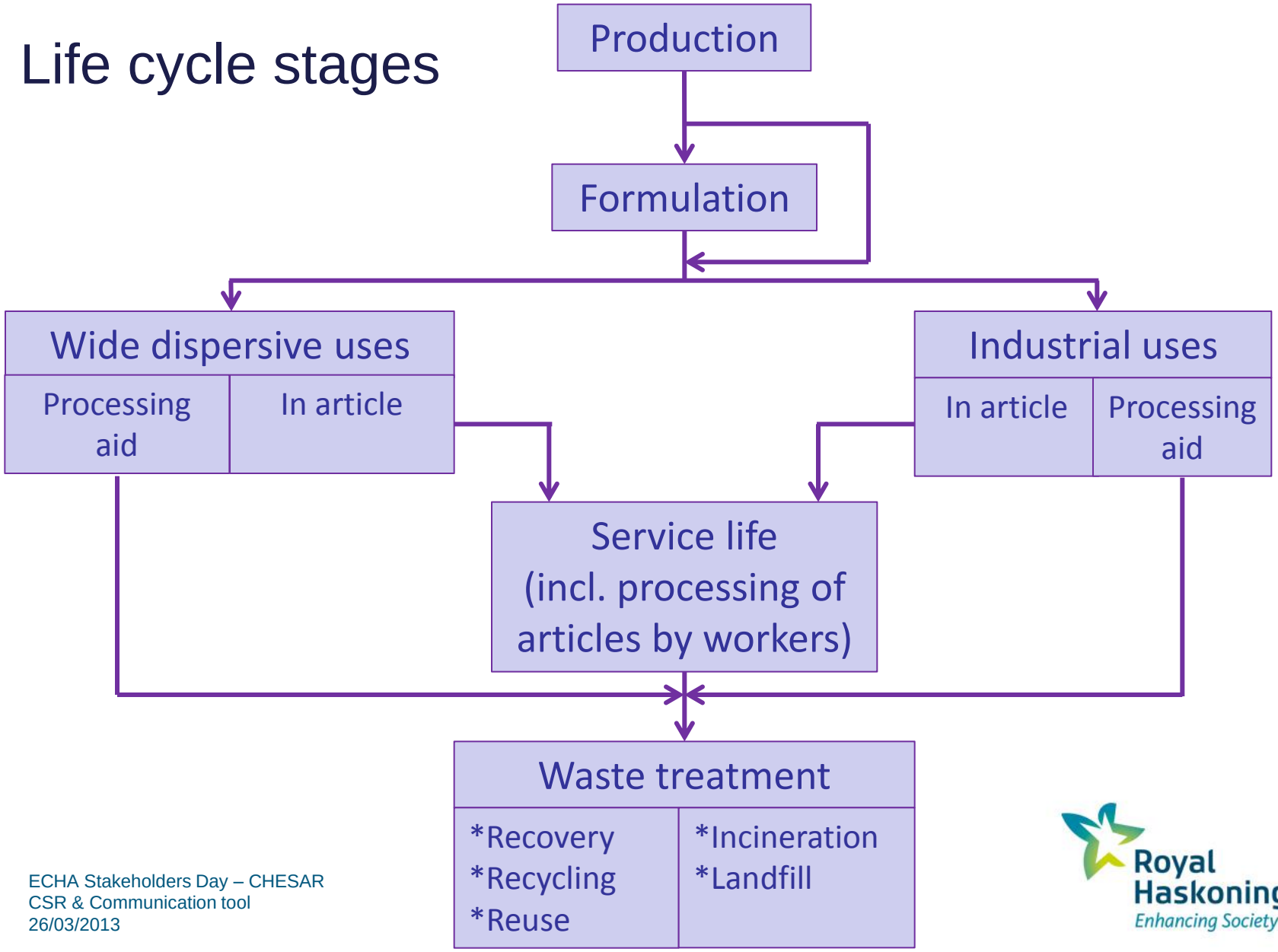
How does CHESAR work

- 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 / exp

Life cycle stages



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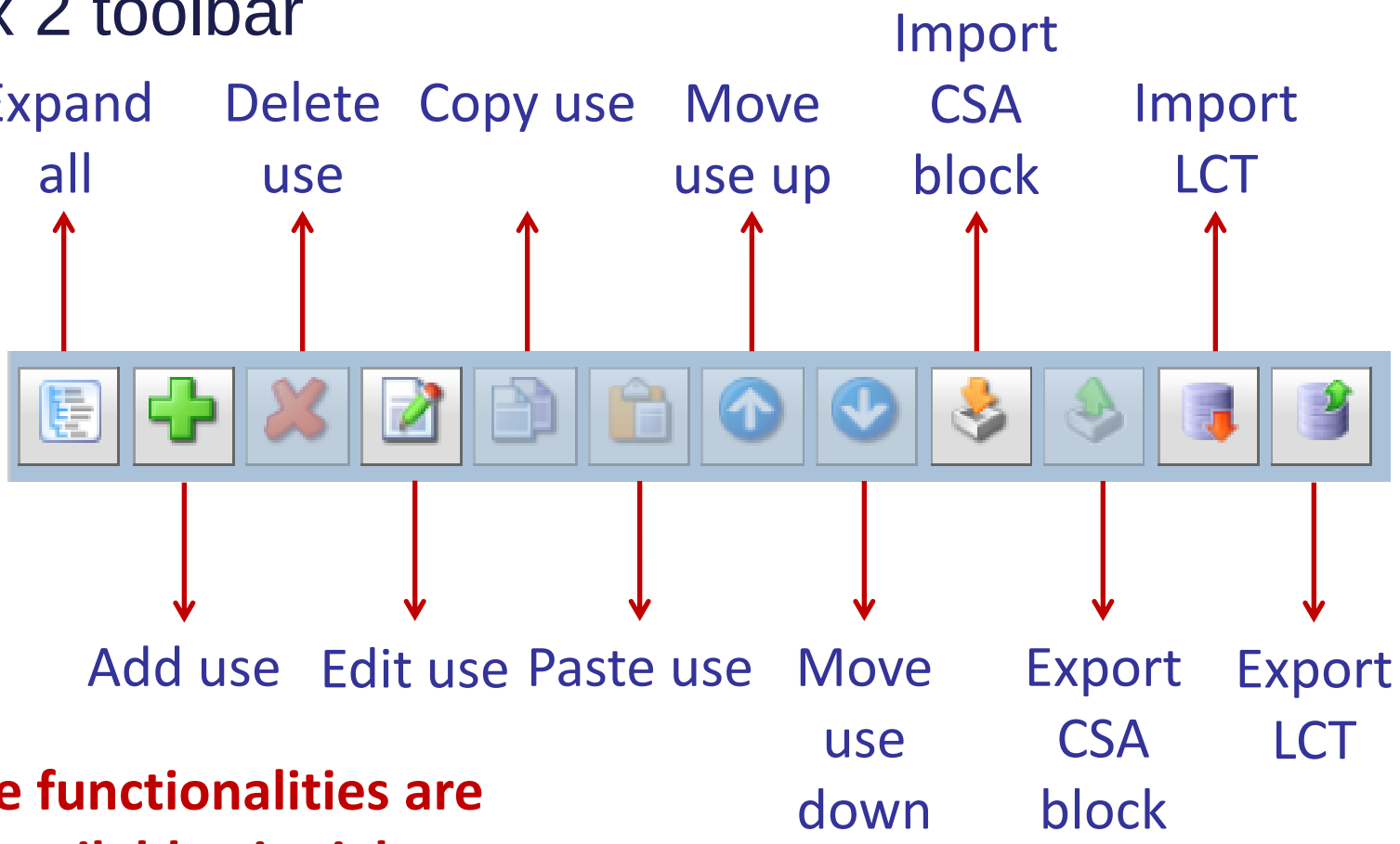
Life cycle tree elements in Chesar

- 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

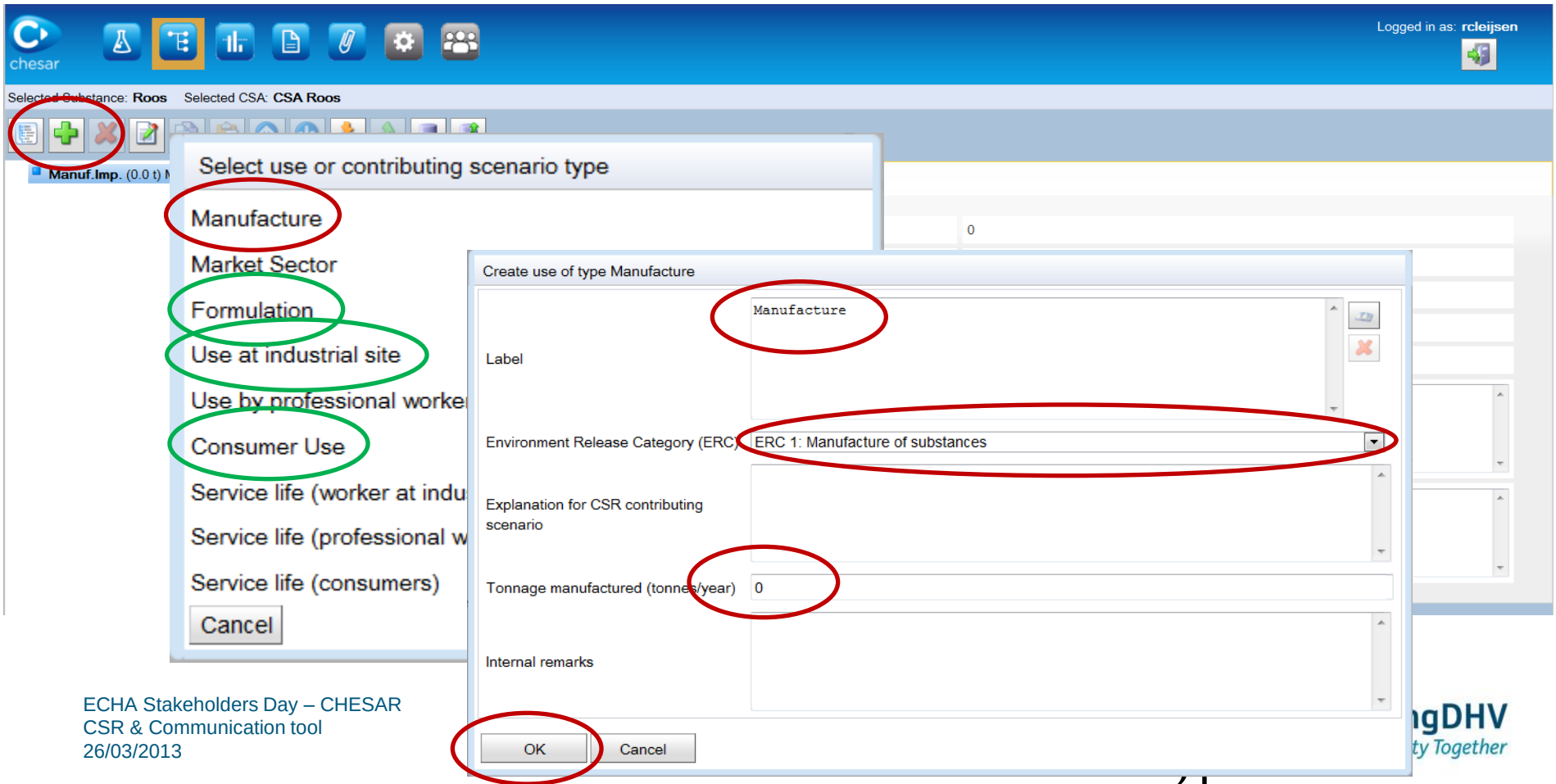
Box 2 toolbar



These functionalities are also available via right click in the LCT

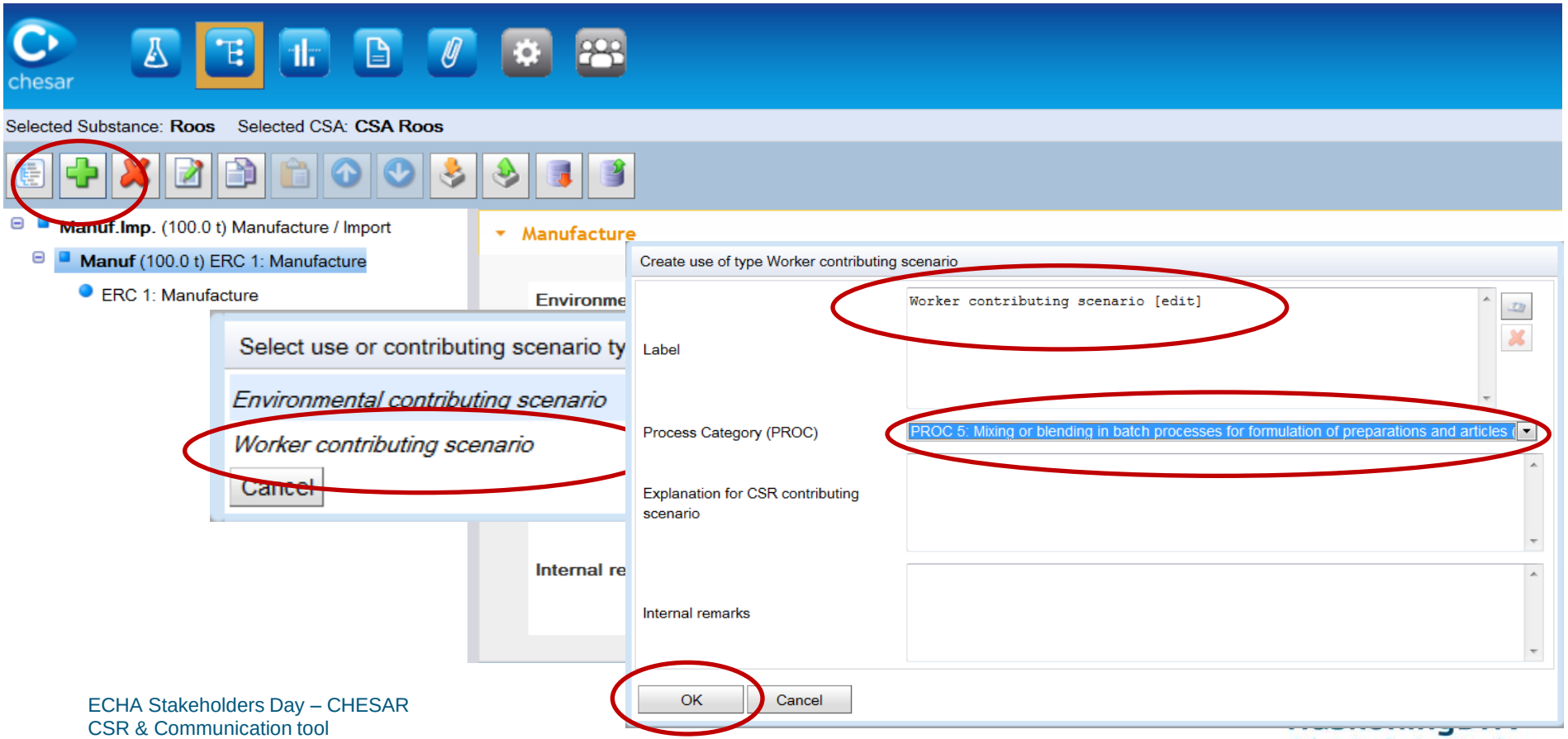
Building LCT

- Starting with manufacture / import

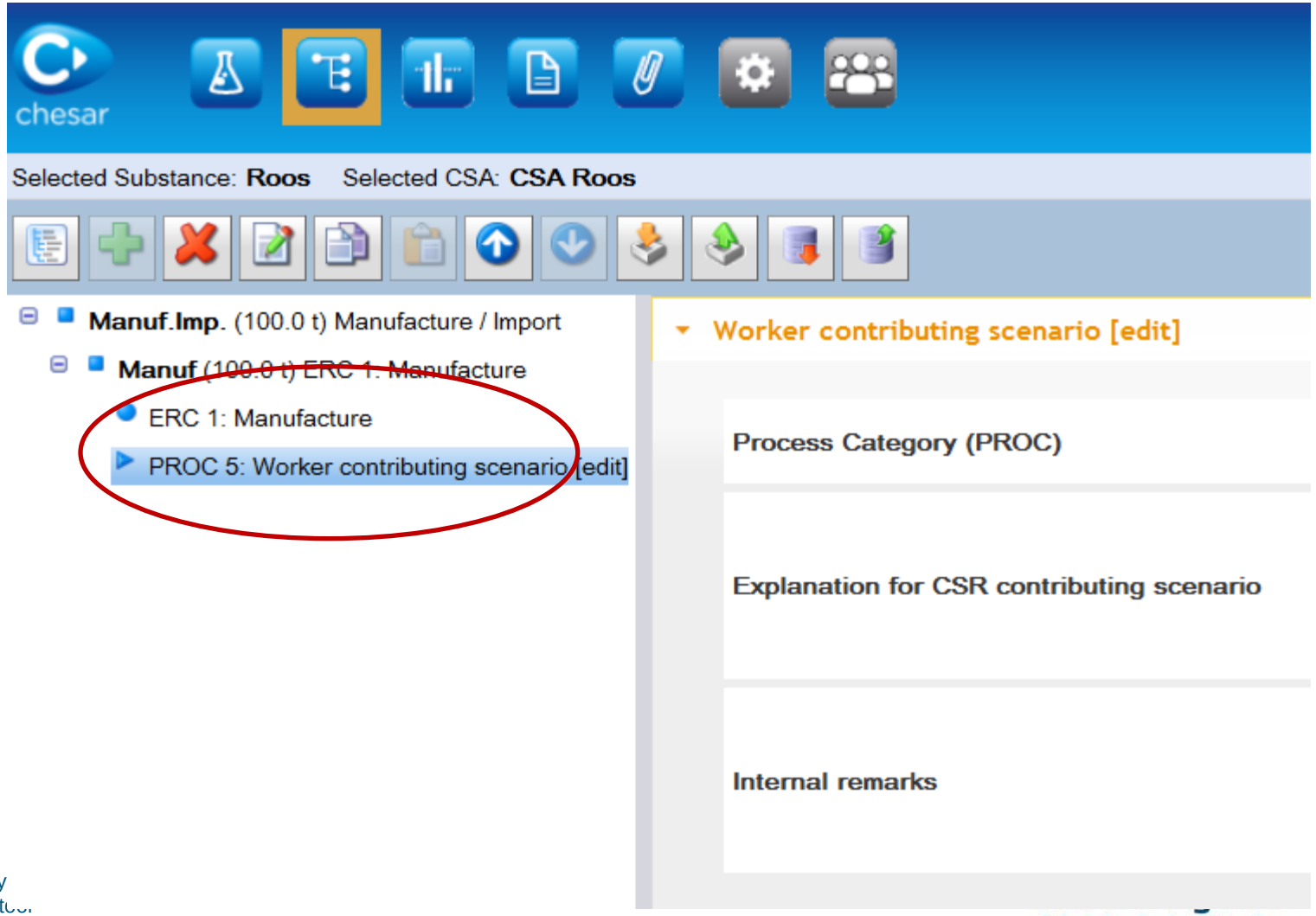


Building LCT

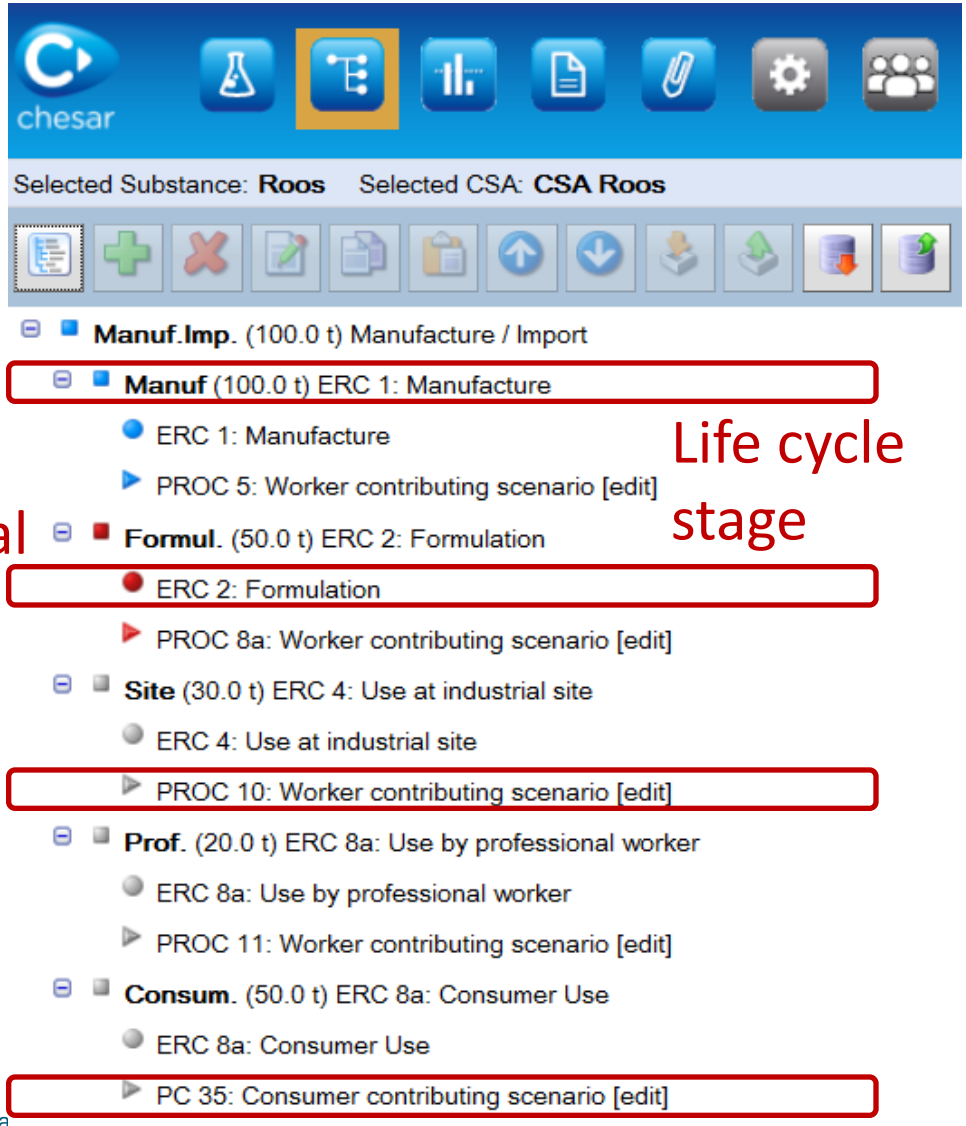
- Create worker contributing scenario



Building LCT



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



Life cycle stage

Environmental contributing scenario

Worker contributing scenario

Consumer contributing scenario

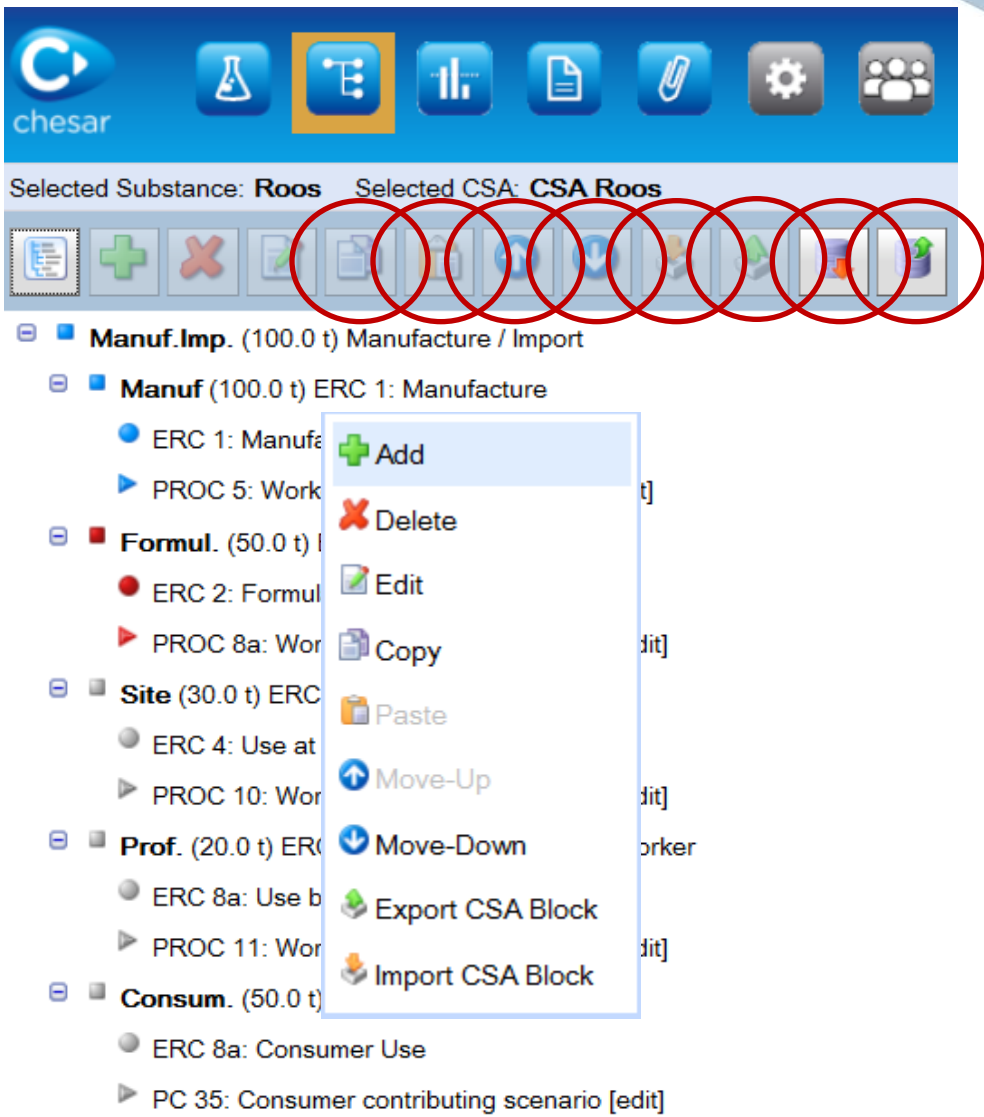
Other functionalities

- Copy
- Paste

- Move up
- Move down

- Import CSA block
- Export CSA block

- Import LCT
- Export LCT



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

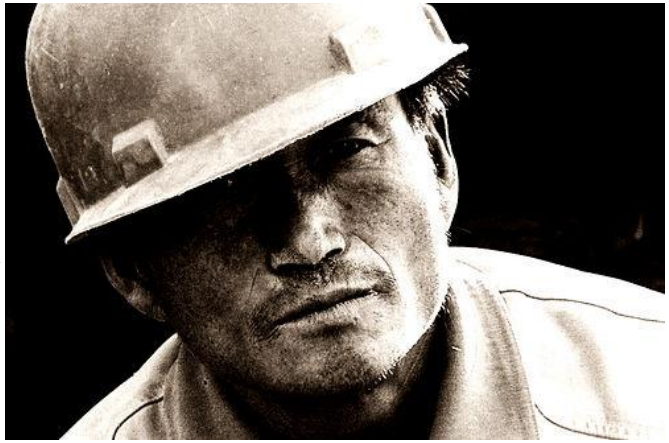
- External tools (e.g. Advanced REACH Tool, ConsExpo)

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

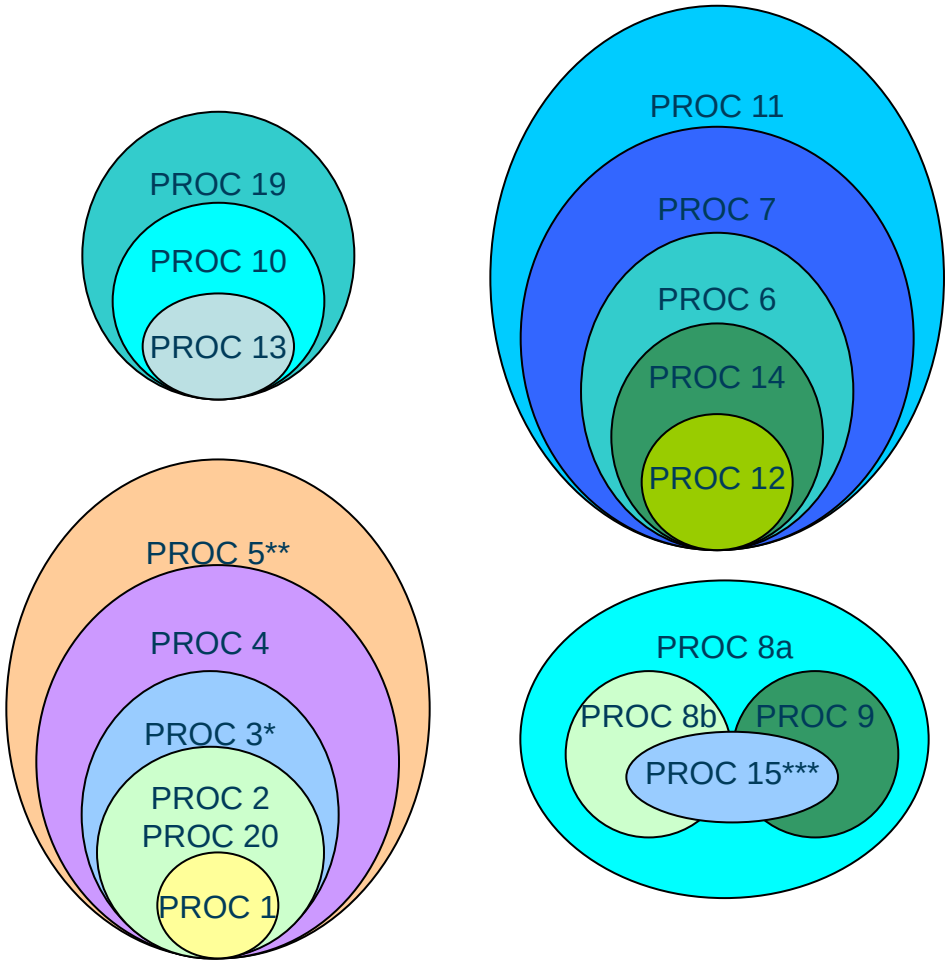
- Advanced assessment: SpERCs or measured data

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

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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 downstreamuser info
- Trim information
- Standard phrases to be added manually
- Guidance for downstreamuser

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*

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