Advantages of using CHESAR

In the chemical safety assessment

& effective communication

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Program

- Importance of realistic risk assessment and readable eSDS

- Why do we use Chesar

- Benefits of using Chesar for the registrants and downstream users

- Key features in Chesar

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- Chemicals management support for over 3 decades

- Fathered systems on efficient SDS communication

- Guidance of substance identity

- Full REACH and CLP portfolio

- (Eco)toxicologists and Industrial hygienist

- Specialty in "difficult substances"
    - PBT, CMR
    - Multi-constituent substances, UVCB's

REACH Purpose

- Ensure that hazardous substances are used safely

- Minimize use of SVHC's

- Stimulate R&D

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Safe use of substances

- Information on hazard

- Realistic assessment of risk

- Effective communication of hazard and risk
  - Clear
  - Concise
  - Reflecting good practices
  - Harmonized

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Functionality of CHESAR

- Evaluation of the risk of uses

- Ensure integrity of data

- In- and export of life cycle trees, sets of operational conditions and RMMs, determinants, standard phrases

- Import of results from higher tier exposure estimation tools

- Generation of section 9&10 of CSR in readable format

- Generation of eSDS appendix using ESCOM phrases

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Why do we use CHESAR

- Quality

- Increases efficiency and uniformity

- Realistic appraisal

- Allows for rapid evaluation adapted hazard data

- Readable CSR & eSDS

- Works fast

- Stable

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Why do we use CHESAR

Improvements in version 3

- Increases efficiency by implementation of assessment entity

- Increases flexibility

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Benefits of use of CHESAR to registrants

- Compliant to REACH
  Data in dossier, CSR, eSDS stem from the same origin

- Use same lifecycle tree and OC and RMM for different substances → less data to communicate

- High quality, readable documentation
  - Use of ESCOM standard phrases
    - Automated translation of eSDS appendix → compliance
    - Automated transfer allows formulators to select and forward information
  - Use of branch specific naming
  - Trimming of unnecessary information

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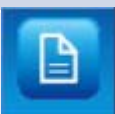
How does CHESAR work

❖ Stand alone tool, all data on your computer

❖ Highly structures

❖ 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

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Key features of Chesar

- Import/export of life cycle tree and CSA

- Within CSA (Box 3),
    - copy paste of OC and RMM
      → Increased uniformity
    - Import of spERCs and SCEDs
    - Import from Stoffenmanager

- CSR (Box 4)
    - Inclusion of phys/chem risk assessment, strategies

- eSDS (Box 5)
    - Tailoring of information, Standard phrases

- Box 6
    - Determinants

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7 Boxes of Chesar

Symbol	Chesar Box	Description
	Box 1	Substance management
	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

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Box 1 Substance management

Box 1 Substance management

- Substance management
  - Import, export, select substance
  - When making export from IUCLID
    → information in chapter summaries
    → select correct format

Selected substance
- CSA management
  → import/export
  → multiple CSA's
- Scope of assessment → in/exclude man through environment
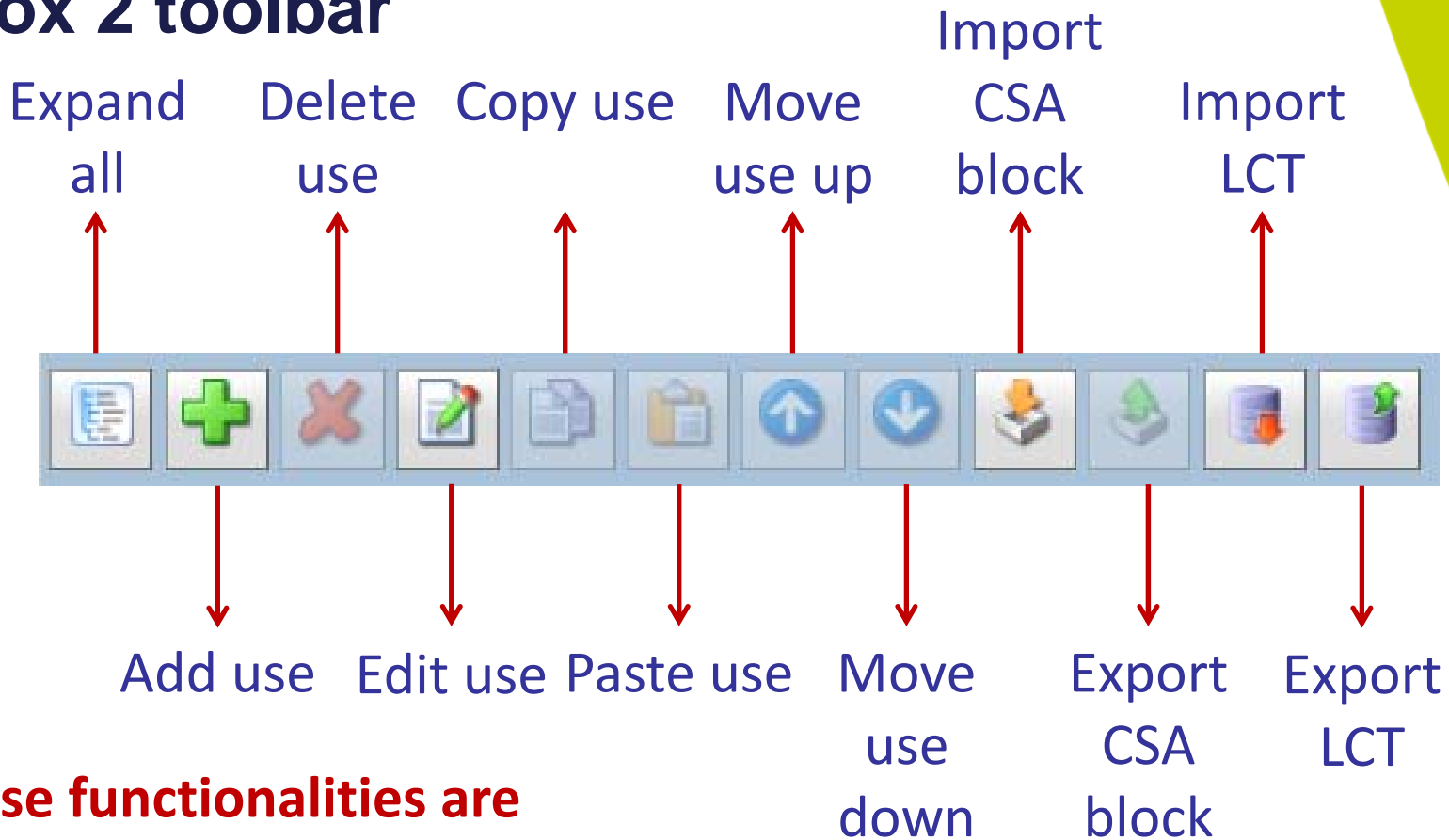
Version 3
- Assessment entity → multiple limit values for same route

Box 2 – Use management

❖ Identified uses (life cycle tree)
  ■ Life cycle stages
  ■ Market sectors
  ■ Contributing scenarios

❖ Label and standard phrases

❖ Use descriptor system (PROCs, ERCs)

❖ Life cycle management (import / export)

Box 2 toolbar

Expand
all

Delete
use

Copy use

Move
use up

Import
CSA
block

Import
LCT

Add use   Edit use   Paste use   Move
use
down

Export
CSA
block

Export
LCT

These functionalities are also available via right click in the LCT

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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

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20

Other functionalities

❖ Copy
❖ Paste

❖ Move up
❖ Move down

❖ Import CSA block
❖ Export CSA block

❖ Import LCT
❖ Export LCT

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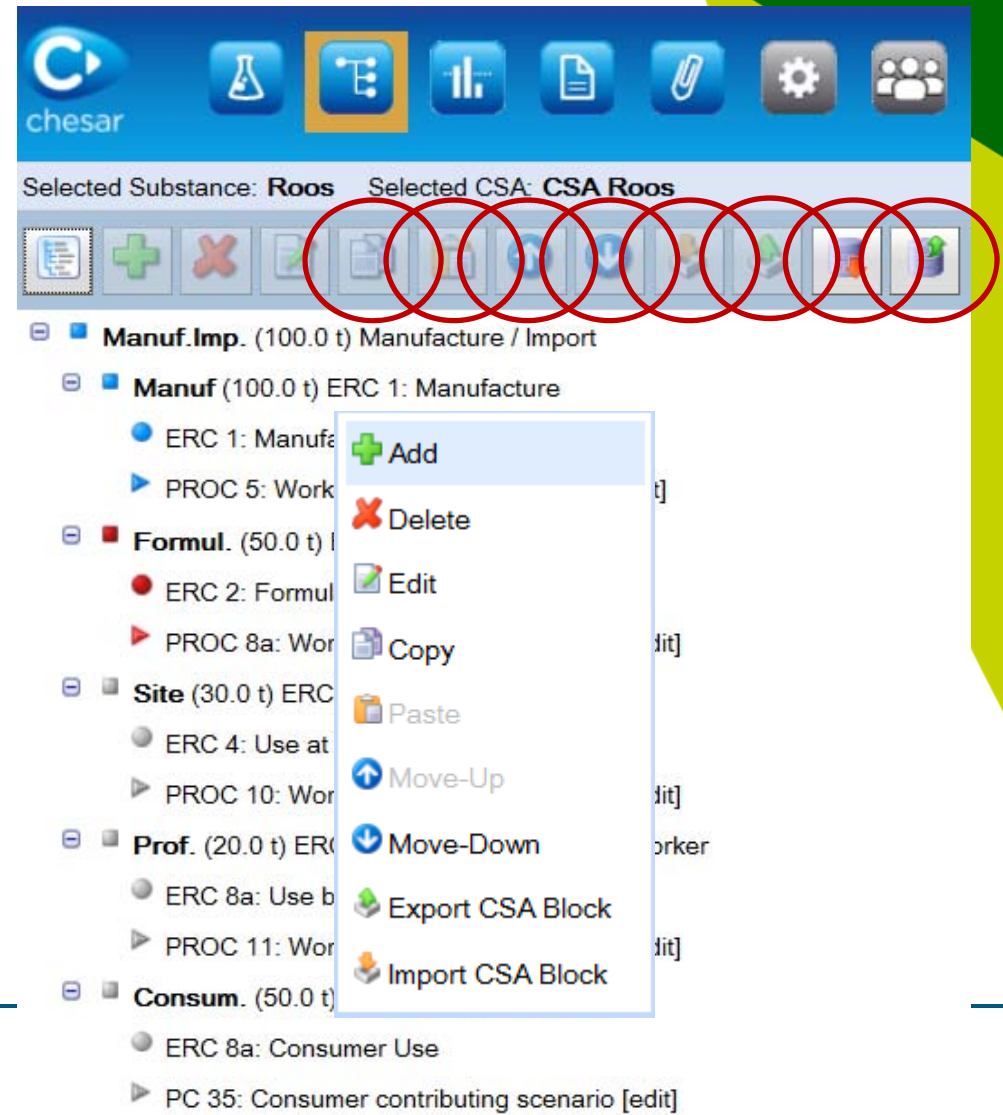
Grouping of uses in exposure scenarios

❖ 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

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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, StoffenmanagerConsExpo)

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Worker assessment

❖ ECETOC TRA worker v3.0

❖ Based on process category (PRO

❖ 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

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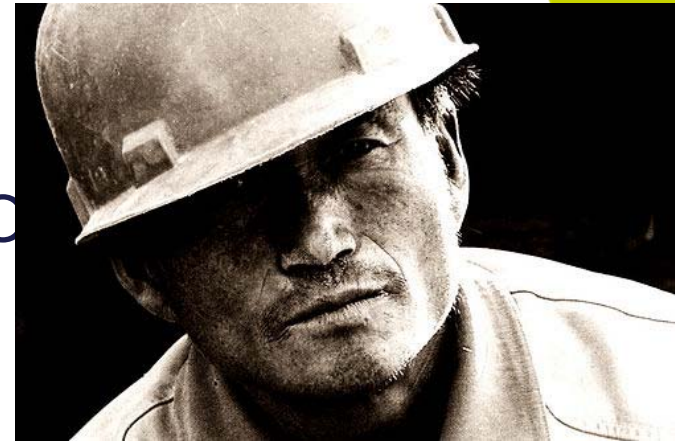
Hierarchy of exposure potential per PROC in ECETOC-TRA and CHESAR

PROC 19
PROC 10
PROC 13

PROC 11
PROC 7
PROC 6
PROC 14
PROC 12

PROC 5**
PROC 4
PROC 3*
PROC 2
PROC 20
PROC 1

PROC 8a
PROC 8b   PROC 9
PROC 15***
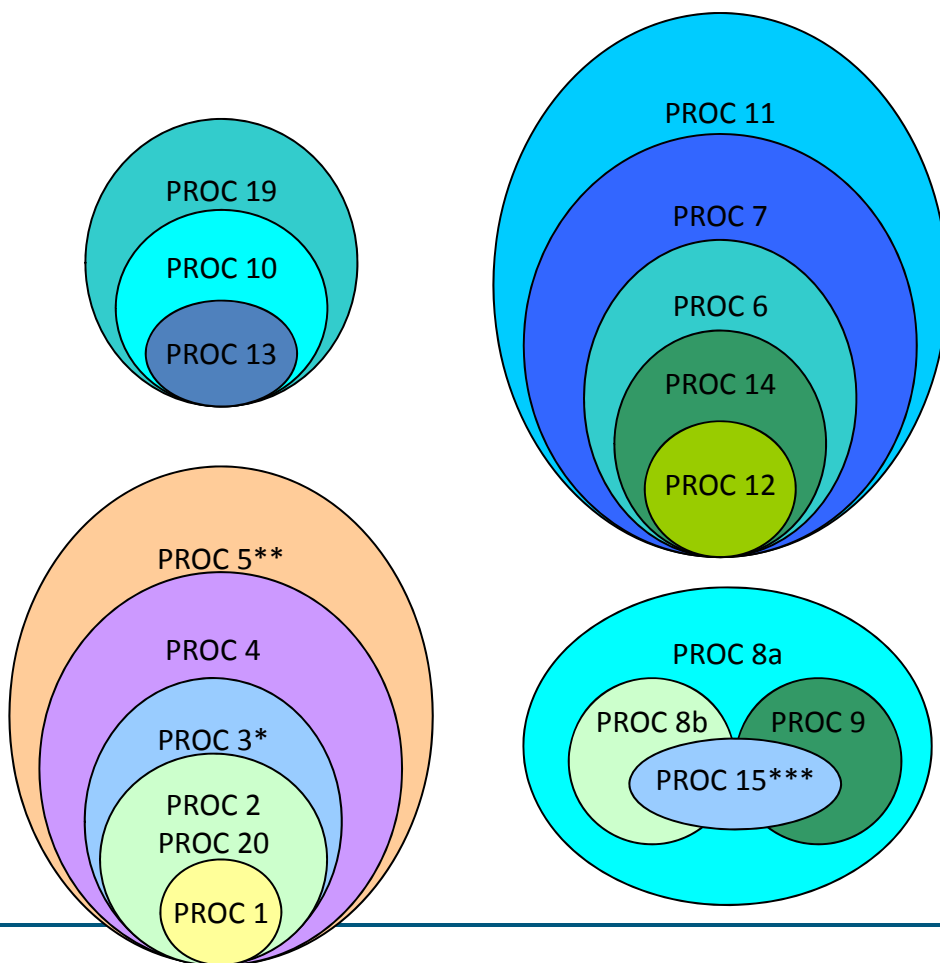
❖ Chesar exposure estimation is higher in the larger bullets (so PROC 4 also covers PROCs 1, 2, 3 and 20

❖ 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

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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

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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 higher tier tools added through determinants
- 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*

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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

- Best tool available

- Limits the amount of work
  - For similar assessments on multiple substances
  - Target DSU-er in eSDS using the same assessment
  - Grouping of uses based on potential for exposure
  - In CHESAR 3: assessment entity for "difficult substances"

- Helps in communication
  - Standard phrases
  - Adaptation of names, explanations in eSDS
  - Free format text for section 4 of eSDS
    → help for DSU-er to assess if operation is within scope

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