Chesar training
Box 3

chesar

17 May 2011

Outlines

- Exposure assessment: general concepts
- Scope and type of assessment for workers and Environment
- Worker exposure assessment: quantitative (TRA) and qualitative
- Default environment exposure assessment: EUSES + Chesar release module

Organisation of Chesar

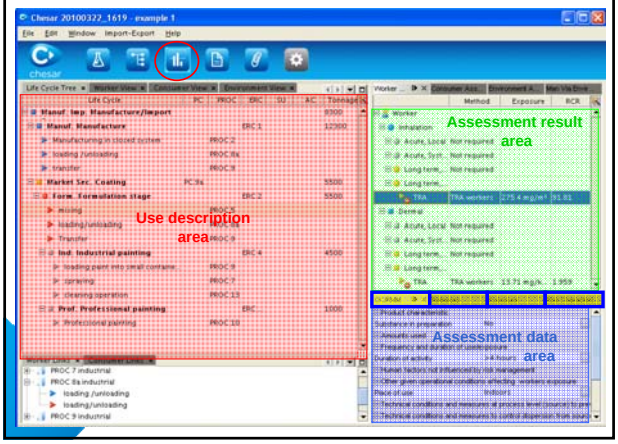
1. Manage substances
2. Reporting of uses
3. **Manage assessment**
4. ES building and CSR generation
5. Generation of ES for eSDS
6. Administration tools

Exposure assessment – general concepts

- REACH requires industry to **document** that manufacture, use and subsequent life cycle stages of substances is "**safe**" for humans and environment. Thus industry is expected to describe the condition of use under which risks are controlled.
- An exposure assessment has to be carried out for "**all identified hazards**" for the following targets:
  - **Workers** and/or **consumers**
  - **Environment**
  - **Man via the environment**
- The exposure assessment should describe the **conditions of use** and calculate the **exposure estimates** (if relevant)
- The **risk characterisation** identifies if the risks arising from all life cycle stages of a substance are adequately controlled.

Box 3 – Chesar exposure assessment

1. **internally plugged-in** Tier 1 exposure estimation tools:
   - **ECETOC TRA** (Targeted Risk Assessment) for Workers (Consumers not yet available)
   - **EUSES** + **Chesar release module** (Environment)
2. **external sources** and manual reporting in Chesar (only for Worker/Consumer)
   - **external** exposure estimation tool
   - **measured** release or exposure data sets
3. **determinant** concept



Exposure assessment: quantitative

- The exposure assessment aims to describe conditions of use (OC/RMM) and to generate corresponding **exposure estimates** based on measured or modelled data.
- These exposure estimates are then compared to derived/predicted no-effect-levels for human health and the environment (DNELs and PNECs) to get a **quantitative** risk characterization.
- The objective of exposure assessment and characterization under REACH is to describe the conditions under which a substance can be **safely used**
- Chesar provides particular functionalities to systematically describe the **determinants** of exposure, rather then only calculating release - exposure estimates.
- **Determinants** of exposure = Operational conditions (OC) and risk management measures (RMM)

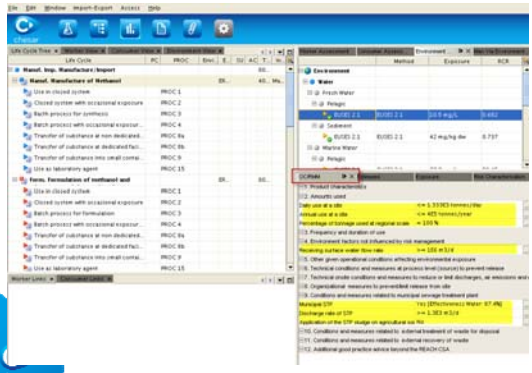
Exposure assessment - Qualitative

- For certain substance properties it may not be possible or useful to derive an **exposure threshold at which no adverse effects are expected to occur**.
- This for example applies for example to corrosive substances or PBT/vPvB substances
- In this case, the risk characterization justifies in a **qualitative** way that the level of exposure minimization achieved under the conditions described in the exposure scenario is appropriate

Conditions of use – determinants (Box 6)

- The **conditions of use** and **risk management measures** (OC/RMM) are the so-called "**determinants**" in Chesar.
- A determinant is a defined **set of information** which describes conditions of use in exposure scenarios. Such conditions may
  - Correspond to input parameters of a plugged-in or external exposure estimation tool
  - Be related to measured concentrations
- **General scope** of Chesar Determinants
  - Can be used in a **consistent way across different assessments,** supporting **harmonization** in the description of safe conditions of use
  - Facilitate **reuse** of already created information on conditions of use

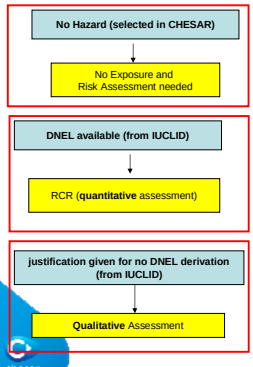
“Determinants” in Chesar

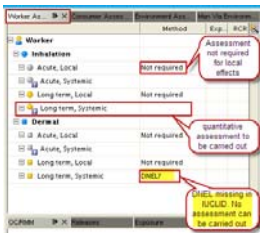


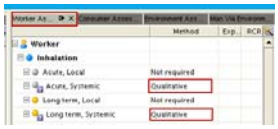
Workers: Exposure assessment

- To perform an assessment for worker, the first step is to select a **specific use** in the life cycle tree
- Then the **scope and type of assessment** per route of exposure and type of effect will be determined:
  - **Not required**: The assessment is not required since no hazard identified.
  - **DNEL?**: A DNEL is missing in IUCLID 5 (due to lack of data) and consequently no assessment can be carried out
  - **Qualitative**: no DNEL can be derived (justified by a IUCLID picklist entry: e.g. no dose descriptor available) and a qualitative risk characterization is required
  - Empty field: a **quantitative** risk characterization is to be carried out.

Expected results from hazard assessment for workers/consumers





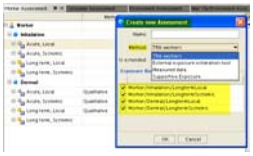


Exposure assessment for workers-> methods available

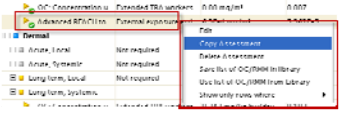
- **TRA Worker** (+ TRA Extended)
- **External exposure estimation tool** (e.g.Stoffenmanager)
- **Measured data** in case the exposure estimates have been obtained using measured data
- **Supportive exposure**: to report exposure measurement to support a specific estimated concentration by a model
- **Condition of use (RMM/OC)**: to support **qualitative** risk characterisation

Exposure assessment for workers - tips

- the user can select **several routes** of exposure and **type of effect(s)** to which the newly created assessment applies.



- An assessment can be
  - Edited
  - Copied and pasted
  - Deleted
  - And the list of OC/RMM defined copied to the library

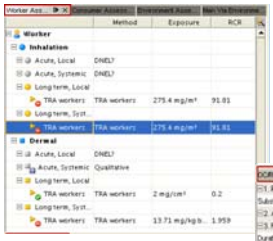


ECETOC TRA worker assessment

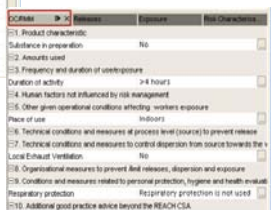
- The workers exposure estimations provided by Chesar are calculated using the workers **ECETOC TRA** tool (available on http://www.ecetoc.org/tra.)*.
- **Basic information from IUCLID**: molecular weight, physical state, vapor pressure
- **Default assessment** is carried out
- **Default set of RMM/OC** is visible in the RMM/OC tab

* For more information see also the Guidance on Information Requirements and Chemical Safety Assessment Chapter R14 Occupational exposure estimation.

ECETOC TRA worker assessment

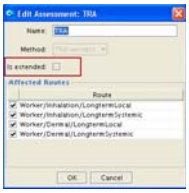


If the RCR is > 1 **iterations** of the determinant values are possible



Extended TRA workers

- The TRA workers assessment can be extended by adding determinants **outside the model** in order to **refine the assessment**.
- When using this functionality you should be extremely careful not to use additional determinants that are (in fact) already covered by the TRA tool
- For example if you want to add a new determinant with effectiveness (for example use of personal protection equipment such as gloves with a given effectiveness), **the exposure estimation is recalculated taking into account the effectiveness of the added determinants.**



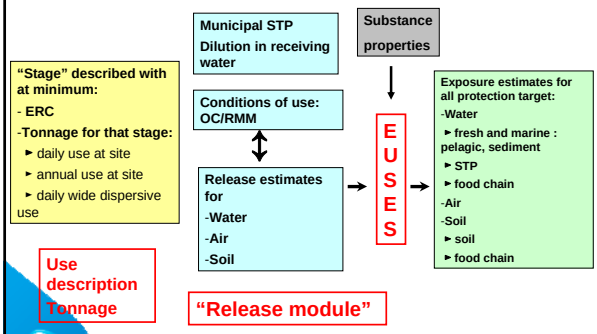
Output of HH exposure assessment

- If the predicted exposure is lower than the derived no-effect levels (DNELs) the **risk can be considered as controlled** (**quantitative** risk characterization)
- For the substances for which there is no possibilities to derive an exposure threshold (corrosive, PBT/vPvB …), the OC/RMM should aim to **prevent/minimise** the exposure (**qualitative** risk characterization)

Environment exposure assessment

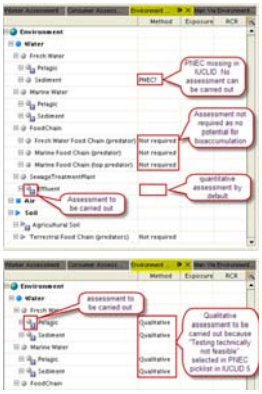
- The exposure concentrations in the different compartments (to which the different protection targets will be exposed) is the result of estimates of releases to water, air, soil and/or the result of fate
- Chesar estimates the exposure concentrations in the different compartments, based on the release rates to water, air and soil fed into the EUSES 2.1 fate model
- Predicted Environmental Concentrations (PECs) are estimated taking into account the so-called “local concentrations” and “regional concentrations”
- In Chesar it is not possible to perform more than one assessment for one given stage (and hence the tonnage associated to it). A registrant who wishes to derive several exposure scenarios (describing the conditions of use) for a given stage should “split their stage” assigning a tonnage fraction to each of the different conditions of use

Environment exposure assessment in Chesar – general concept



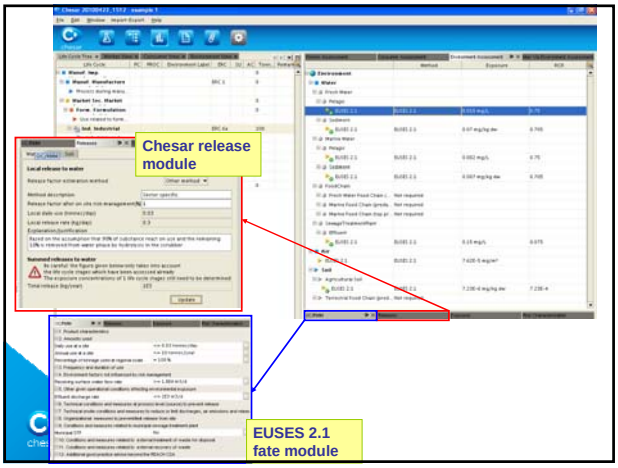
Expected results from hazard assessment for the environment

- No hazard related to the environment
  - no assessment needed for secondary poisoning or
  - no assessment needed for all environment
  - assessment of man via environment always required
- hazard to the environment but **not PBT**
  - **PNEC**
    - Quantitative assessment (risk characterisation ratio)
  - Absence of dose descriptor
    - qualitative assessment
- hazard to the environment and **PBT**
  - Qualitative assessment (emission minimisation)



Default environmental assessment - EUSES

- For non PBT/vPVB substances the default assessment consists of:
  - release estimation performed by Chesar **release module**
  - the exposure estimation performed by the EUSES 2.1 **distribution and fate module**
- The default assessment carries the set of default determinants. They appear under the **OC/RMM tab** of the assessment data area



Environmental determinants in Chesar (1)

- **Amount related** determinants:
  - **Daily use at a site** (for uses in industrial settings) or daily wide dispersive use that are calculated by default from the tonnage assigned to the stage
  - **Annual use at a site** (only for uses at industrial settings), which is by default the tonnage for that stage
  - **Percentage of tonnage used in a region** (for uses in industrial settings), which is by default 100%

Environmental determinants in Chesar (2)

- **Dilution related** determinant:
  - **Receiving surface water flow rate**: set by default to 18 000 m3/day as in EUSES
- **Municipal sewage treatment plant** (STP) related determinants:
  - **Availability of the STP** "yes" by default
  - **Discharge rate of STP** 2000 m3/day by default as in EUSES
  - **Application of the STP sludge on agricultural soil** "yes" by default leading to soil exposure

Chesar default release module

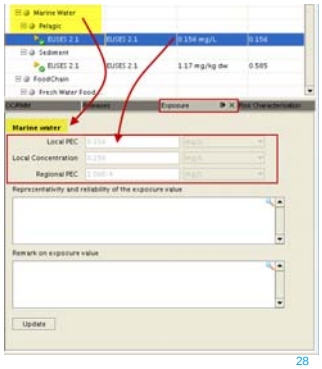
- The **release estimation** is based on**:**
  - **Release factor** defined for each **ERC**
  - **Daily use at the site** directly calculated from the tonnage of the site
- The release rate at **local scale** is: **daily use x ERC release factor**
- The release rate at **regional scale** is:
  - **100% of the registrant's EU level tonnage for that stage x ERC release factor** ("industrial settings" ERC 1 to 7 and 12),
  - **10% of the registrant's EU level tonnage for that stage x ERC release factor** ("wide dispersive use" ERC 8 to 11).

In case RCR >1 - Refinement options

- **Modification of amounts used**
  - daily use,
  - annual use,
  - tonnage used in a region for industrial setting
- **Modification of release factor**:
  - Introducing **RMM** with effectiveness determinant
  - **SPERC** option (to be discussed in a special session)
  - **Other method** (+ adding relevant determinants in the OC/RMM tab of the assessment area)
  - **Release rate** (+ adding relevant determinants in the OC/RMM tab of the assessment area)
- **Refinement of other determinants** impacting on exposure
  - receiving water / discharge flow rate (giving the dilution factor)
  - parameter related to STP (application of sludge in agriculture, etc.)

Output of default exposure assessment

- in the **Exposure tab** in the assessment window reports the:
- **predicted environmental concentrations** (**PECs**) for each protection target for environmental risk assessment



Assessment for men via environment

- Indirect exposure of general population via the environment may occur by consumption of food (fish, crops, meat and milk), drinking water and by inhalation of air.
- It has always to be performed, assumed chronic systemic hazards have been identified for humans.
- **EUSES** makes an **estimation** of the doses to which humans are exposed, based on the concentrations in the different environmental compartments,
  - **food consumption**
  - **drinking water**
  - **air inhalation**

  These values are then compared with the **DNEL values** (long term systemic oral and long term systemic inhalation exposures) for the general population, respectively.

Thank you for your attention
Questions?