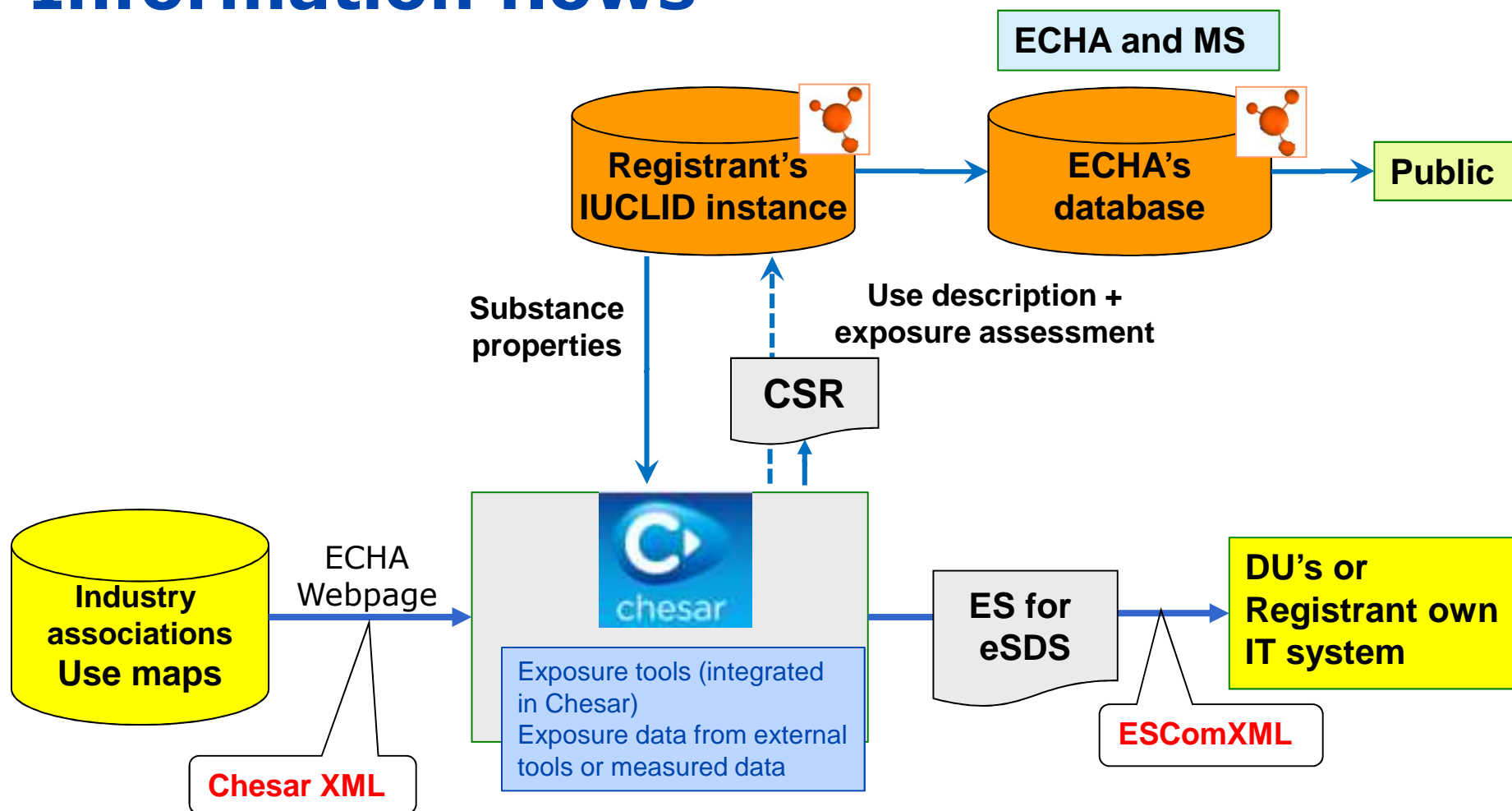


# Creating Chesar 3 files for use maps packages

3 May 2017



# Information flows



## Current trends in use of Chesar for registration dossiers

- Recent indication that higher share of the market (intend to) use Chesar:
  - 40% of dossiers with CSR chapter 9-10 submitted between July 2016 and March 2017 have been flagged as done with Chesar in section 13 of IUCLID
  - Small survey with current 2018 registrants (220 companies having created a “joint submission object”, i.e. intend to register as a lead; 59 respondents indicated needed for exposure assessment).
    - 75% of them intend to use Chesar for their 2018 registration (for some or all substances)
    - 60% said they have used it for past registrations

## Today's objective:

- Exchange experience among sectors
- Provide practical support on remaining issues
- Some topics for deeper insight
  - Conditions of use beyond TRA: approach and possible solutions
  - Standard phrases in ES for communication: default in Chesar
  - Measured data as part of SWEDs
- Update on Chesar 3.2 new functionalities
- Collect improvement needs for Chesar 3.3
  
- Discuss next steps towards finalisation

## Use maps developers network so far...

16/01(Workshop) and 2/02 (WebEx):

First steps in Chesar: How to create files?

- Hands on with Chesar
- preliminary observations

31/03 (WebEx):

- State of play of further development
- How to use Chesar for basic 'validation' of the input data for TRA and EUSES

3/05 (Workshop): TODAY

- Further support
- Next steps towards finalisation

- Cefic's pilot project
    - Objective: test the "machinery" developed under the ENES work programme and propose improvements/further guidance if needed
    - Use map-> registrant CSA/ES for communication->Formulators
    - Kick off on 4 May
  - ENES "technical group" to get common understanding on critical interactions between the tools and find compatible technical solutions
    - ESCom xml and phrase catalogue
    - Use maps: use description, SCED, SPERCs, SWEDs
    - Chesar
    - Formulator's tool/ SUMI
- Exploratory discussion tonight

# Feedback from sectors



- See separate slides
  - ARCHE consulting for EFCC / FEICA / Cosmetics europe / ESIG / Eurométaux
  - Fertilisers Europe
  - EuPC-EuMBC
  - Resin Technical Platform (RTP)
- Additional feedback provided orally by
  - AISE
  - ATIEL
  - Catalyst sector
  - Concawe
  - ECPA
  - I&P



# Specific topics for discussion



# **Conditions of use beyond TRAs' in SWEDs: approach and possible solutions**



## Background

- SWED template
  - mainly supports the description of the conditions of use as ECETOC TRA inputs
  - provides some flexibility for reporting other conditions of use
- Assumption:
  - A sector decides to support registrants in using e.g. ART because for certain substances or use conditions control of risks cannot be demonstrated with the TRA
- Objective:
  - Provide guidance (and possibly expended template and Chesar files) to sectors on how best to set up their SWEDs (excel and Chesar files)
- Proposal based on analysis of EFCC use map

## Approach for the analysis

- **Constraint:** a SWED cannot be modified by the registrant's assessor (except for the concentration in mixture)

### Looking for a solution where

- The proposed changes in the current template do not require update of the SWEDs already available
- An ECETOC TRA dataset can be generated in Chesar when the SWED is converted into a Chesar file
- The ES for communication generated from a SWED reflects the existing CoU independent of the exposure estimation tool used by the registrant
  - formulator receives the same ES for the various ingredients of his mixture

# ES independent of exposure estimation tool: illustration

**Example 1. Fume cupboard** is assumed (eff 99% in ART)

- Need for fume cupboard is communicated.
- ART exposure estimates obtained using effectiveness of 99%
- TRA exposure estimate obtained using its standard LEV effectiveness: 95%. Possibly overestimate of the exposure

**Example 2: Canopy hood** is assumed (eff 50% in ART)

- Need for canopy hood (and not high standard LEV) is communicated
- ART exposure estimates obtained using effectiveness 50%
- TRA exposure estimate obtained with setting LEV to NO; 50% effectiveness of canopy hood disregarded (and thus overestimate of exposure).
  - Reason: TRA LEV 95% would lead to underestimation of exposure.

# Information necessary for an ART assessment

- Activity class
- Conditions of use in ART
  - also existing in ECETOC TRA (e.g. LEV, general ventilation); can be more or less effective than the ECETOC TRA options.
  - Not existing in TRA
    - General applicable to all/most of the activity classes
    - specific to Activity Classes

# Proposed changes SWED template

- Guidance: report the relevant Activity class in the field "1.4.2" (Short description of factors during use that may influence selection of modelling tool -> advise to assessor)
- CoU (inputs) only relevant for ART
  - Can be added as non mandatory fields in the SWED template
  - *Conditions of use templates* can be generated in Chesar to be used by all SWED developers
  - ECHA has developed a proposal
    - To be shared for feedback (from you? ; to see how feedback from ART developers could also be obtained)
    - For EFCC use map, specific conditions of use in Chesar format have been shared

# “Common CoU” between TRA and other tools

For conditions of use which also exist in ECETOC TRA (common CoU) such as

- LEV
- General ventilation
- Respiratory protection...

we have thought of 3 options:

- Option 1: No duplication of CoU
- Option 2: Duplication of CoU (preferred option for now as better supporting harmonisation across SWED developers ?)
- Option 3: Mapping/Harmonisation across tools: probably best solution but for longer term



## Description of the solution

- Keep only the CoU as described currently for the TRA.
- SWED developer describes the values for the ART assessment in the free-text field “details on”.
  - assessor is made aware of the input he can use for his assessment in ART (and in TRA of course)
- The phrase for the ES for communication is to be set according to the more stringent measure (usually ART)

## Disadvantage

- The ART values and text for communication are not standardised (guidance could be provided).
- Guidance needed for the consistency between the values used for the 2 tools

## Advantage:

- Only one condition of use set per type of measure (clearer CSR?)

## Description of the solution

- Add a new row in SWED template to report the “LEV for ART” ART value not mandatory.
- In Chesar, two conditions of use for LEV. Both TRA and ART values are available for assessment (and are listed in the CS for the CSR).
- When an ART value is provided, only one of the two CoUs has to be communicated (usually ART as being more stringent)

## Disadvantage:

- Does not “look nice” in the CSR [for Chesar to reflect whether to report in the CS which CoU is relevant for which expo tool]
- guidance should be provided for the consistency between the values used for the 2 tools

## Advantages:

- The ART values can be standardised (dropdown) including the information to be communicated
- Can facilitate IT exchange of data between Chesar and ART (if this is once implemented)

## **Description of the solution**

Increase harmonisation/consistency between the solutions.  
Include the ART values as part of the dropdown.

- Option 2a: Map the TRA values to ART values (solutions on how to set the effectiveness to be found)
- Option 2b: TRA and ART values are alternatives with their respective effectiveness.

Such solution would be more effective if a “modified” TRA is implemented in Chesar i.e. exposure estimates calculated from the baseline TRA and “more flexible RMM”.

For example in case the LEV from ART is of lower efficiency (e.g. canopy hood), TRA can run using 50% efficiency.

In this case a TRA and ART estimates can always be obtained.

## Disadvantage

- Requires a mapping between tools (needs the involvement of tool owners)
- Further changes required in Chesar

## Advantages:

- The ART values can be standardised (dropdown) including the information to be communicated
- No duplication of CoU with different values in CSR

## Conclusion

- Initial set of “ART conditions of use” shared with EFCC for their use map
- “Solution” proposed by ECHA to be shared
  - Feedback from you (SWED group)? Cefic pilot project?
- Publication of “current solution”
  - Guidance/specific template made available on ECHA website (use map page)
  - *Chesar CoU template* could be available on Chesar website (library)

**Standard phrases in ES for  
communication: default in Chesar**





## Background

- Communication for “standard” conditions of use in SPERC/SCED/SWED:
  - Which CoUs to include in the ES for Com (some systematically, some not, some depending on value)?
  - Which standard phrases to associate to the CoU to be communicated ?
- Initial proposal prepared by ECHA for “defaults” in Chesar (*see document distributed*)
- Solution to be agreed for implementation in Chesar/ESCom/SWED/(SCED/SPERC) templates

## Illustration for environment

Daily use amount at site	Daily amount per site 10076084403 tonnes/day 15193135620	
Biological STP	<ul style="list-style-type: none"> <li>• Municipal Sewage treatment plant is assumed 11133170613</li> <li>• Provide onsite wastewater treatment 11133171638</li> <li>• Not needed</li> </ul>	<p>Proposal to replace both phrases by new phrase: <i>Biological sewage treatment assumed</i></p> <p>Presently Chesar works with existing phrases. However the key information (<u>biological</u> treatment) does not get clear.</p>

Dermal protection	Not needed	<p>We are not really satisfied with the current phrase, as the <b>dermal exposure may go beyond the hands</b> (see also PROC dependent assumptions in TRA). Sleeves, apron or coverall may be relevant as well. Proposal: Check whether other phrases exist, potentially extent phrase at least regarding arms.</p> <p>On top there may be technical measures, more suitable than gloves. To be discussed with SWED group.</p>
	<p>Wear suitable gloves tested to EN374. 10133224896</p> <p>For further specification, refer to section 8 of the SDS.</p> <p>12355002165</p>	
	<p>Wear chemically resistant gloves (tested to EN374) in combination with 'basic' employee training.</p> <p>11133171457</p> <p>For further specification, refer to section 8 of the SDS.</p> <p>12355002165</p>	
	<p>Wear chemically resistant gloves (tested to EN374) in combination with specific activity training.</p> <p>11133171458</p> <p>For further specification, refer to section 8 of the SDS.</p> <p>12355002165</p>	

## **Measured data as part of SWEDs**



- Last meeting
  - Downstream sectors could collect representative measured data and provide them via the SWED
  - It has not been tested so far how the data structure of the SWED template and Chesar can support that type of assessment. Concrete cases for testing are welcome
- Next steps?

## Chesar 3.2



## New functionalities for use maps - 1

- The way to create use map has been changed **to support update** of use map by sectors (minimum impact on users of use map)
  - New “use map developer” role to create and manage use maps
  - Unique IDs are set up by the system for comparison when update is made
    - When an updated use map is imported by assessor, he can see the differences with previous version and previous assessment is kept when no changes are made
    - The functionality will only be effective if use map created in Chesar 3.2
    - Update of use map created in 3.1.1 to 3.2 use map can be done in few clicks

## New functionalities for use maps - 2

- Specific phrase can be assigned to SPERC/SWED conditions of use (replace previous work around in Box 5)
- Versioning:
  - Field “last modification date” available in SPERC/SCED/SWED
  - Chesar version information separate
- Assignment of SWED/SPERC for use in rigorously contained system clearer



## Release plan

- Release foreseen for 31 May
  - (limited) external testing on going till mid May
- Update of user manual for sectors planned
  - New way of creating use map
  - “migration” from 3.1 to 3.2
  - New functionalities
  - “Validation” advice
- Publication in Chesar library?
  - Validation substances (liquid/solid)
  - Conditions of use relevant for ART

# Demo

## Chesar 3.3



## Chesar 3.3 plans

- To be released early November 2017 (alignment to IUCLID)
- Use map related functionalities:
  - Use map report creation (useful to have soon ?)
  - SWED report aligned to template?
  - Align SCED data structure/functionalities to SPERC/SWED (conditions of use added from library)?
    - Enable to have specific phrases/ systematic explanations
    - Prepare for future (adding other conditions of use)
    - Few open questions on how to do it
  - Generate SCED report
  - Feedback from Cefic pilot
- Extended TRA

# Conclusions



## Conclusions (1)

- Good progress made by sectors.
- For 'standard cases' input into Chesar relatively straightforward.
- Clarifications:
  - solid/liquid mixtures: the conditions of use to handle a solid and a liquid mixture are usually different and the exposure levels to the substances in the mixture are not the same if the mixture is solid or liquid. Therefore different SWEDs have to be developed for mixture of different physical forms (liquid/solid). Note that a SWED can be used to assess exposure of substances of any physical form (although ECETOC TRA will not provide exposure estimates for solid substance in liquid mixture)

## Conclusions (2)

- Clarifications:
  - Ambient temperature: the default operating temp. is set to 40°C in Chesar to prevent that DUs would be outside the conditions e.g. in summer in southern EU. It is up to each SWED developer to decide whether it fits the real conditions or if it needs to be changed (some mixtures cannot be used at such high temperature). In general it was felt that 40°C is a too high temperature for workers to work, and that 30°C would be more appropriate.

## Conclusions (3)

- Alternative approach to the SWEDs developed by the “plastic sector” (EuPC) in the form of a guidance document to registrants:
  - Registrant set the CoU following an approach(order) proposed in the guidance depending on substance information
  - Up to the formulator or converter to compile the information received and set the CoUs for the mixture (SUMI not expected)Pros and cons may be analysed.
- Some sectors have been working with slightly different formats/approach (e.g. GES from ATIEL, ESIG). Work towards harmonisation needed.



## Conclusions (4)

- SWED/SPERC code: need to ensure that it will be communicated. Requirement will be brought to the attention of ESCom/Chesar/templates representatives via 'ENES technical group'? (see slide 6)
- Frequency of use over the day for infrequent use in SCED: need to clarify the example where current Chesar implementation appears not fit for purpose
- Can information from external tools (e.g. for environment) /measured data be provided as part of use map: requirement to be clarified. Further example needed.
- How to best support the selection of uses/CAs by registrants? Where to put information (in activity name, in (a) new field(s), in the applicability domain of the SPERC/SWED/SCED)? Solutions to be worked out. Alignment between sectors expected.

## Conclusions (5)

- Bugs/inconsistencies observed in Chesar: Don't forget to report your observations to the Chesar team so that Chesar can be improved!
- Need to explore how feedback on use maps could be provided where assessors encountered issues with the data provided
- Need to explore ways to make registrants aware when uses maps information are updated by the sectors
- A number of companies (in particular smaller ones) are not aware about the ENES tools. Need to provide more explanations.

- **Standard phrases for ES for communication – default in Chesar:** sectors to reflect on how feedback could be provided on ECHA's proposal. Topics will also be brought to the attention of 'ENES technical group' (see slide 6)
- **Measured data:** exploration work on how to make use of existing datasets could potentially be initiated in some sectors (tbc)
- Not so clear how the system would work when data on mixture are available (e.g on one endpoint only such as sensitisation): topic to explore in a next step?

# Thank you!

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