

## Session 4.1: IT Tool developments for use and exposure information

ENES 7

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European Chemicals Agency

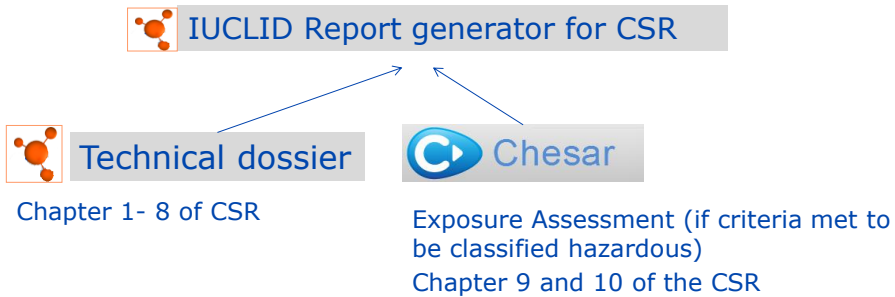
### **The (extended) tool context**



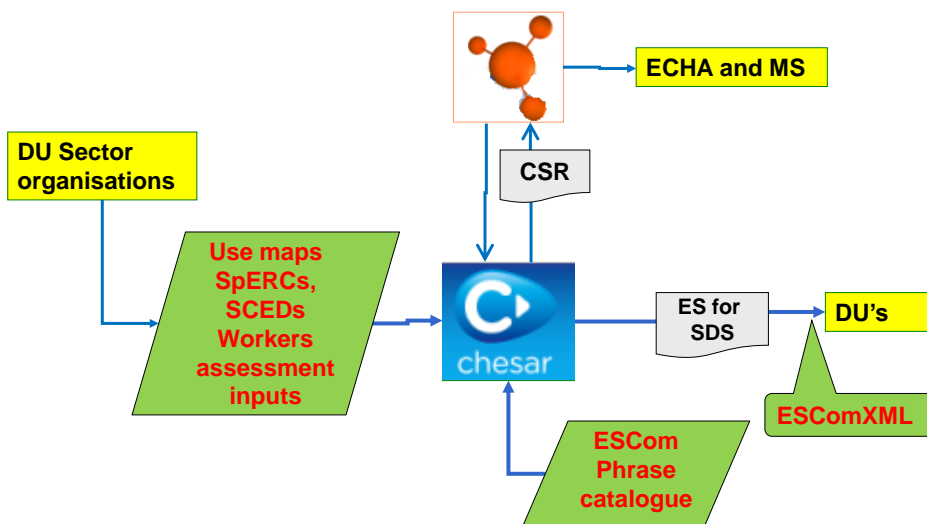
## Elements of the registration dossier

Technical Dossier  **IUCLID 5**  
(INTERNATIONAL UNIFORM CHEMICAL INFORMATION DATABASE)

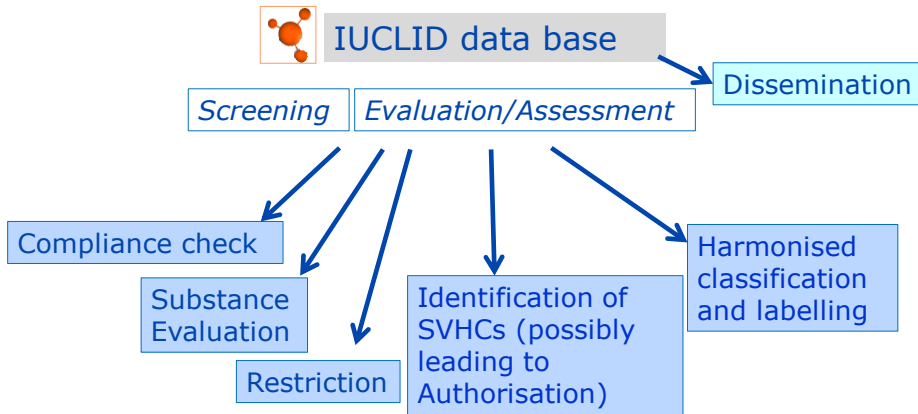
Chemical Safety Assessment (> 10 t) reported in **Chemical Safety Report** (attached document in technical dossier)



## Chesar, IUCLID, CSA elements and ECom



## Registration dossiers: main source of information for the authorities



**IUCLID 6**



## IUCLID 6: objectives

- Improve exchange with other IT systems and facilitate further development
  - > new architecture
- Modify data structure to give an opportunity to registrants to provide information in their registration dossier in a clearer and more transparent way.  
Ultimate goal:
  - reduce number of substances selected for further scrutiny or risk management action on wrong basis and
  - reduce number of draft decisions due to lack of clarity on the dossier

## IUCLID 6 Use and exposure information



## OECD harmonised template on use and exposure

- Very largely based on current IUCLID 5.4 sections 3.5 and 3.7. Some new possibilities for reporting :
  - Details on tonnage per use
  - Contributing activity names and related use descriptors
  - Link between compositions and uses
  - regulatory exemptions
  - uses in strictly controlled conditions (for Art 10 registrations)
  - details on release/exposure estimates

## OECD harmonised template on use and exposure: process

- Developed over 2014; agreed at TFEA in September 2014
- Involved parties: Canada, Denmark, Germany, Japan, Netherlands, United States, BIAC: EUROMETAUX, CONCAWE, VCI/CEFIC, ACC, ECHA, OECD
- Consultation
  - 3 drafts and 2 responses to comments documents by ECHA
  - 3 web-conferences with whole subgroup
  - 1 face to face meeting and 1 web-conference among EU members of subgroup

## **Additional changes related to use and exposure**

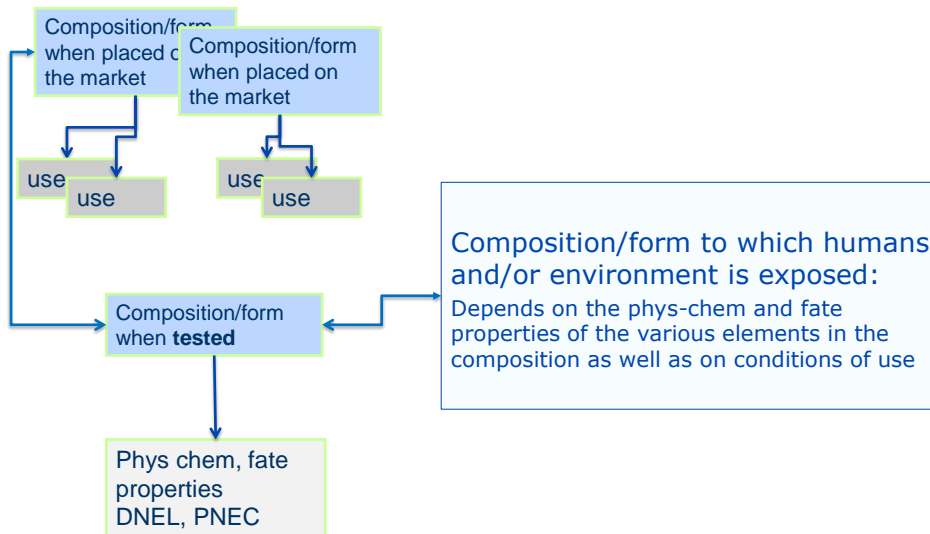
- Enhanced reporting for Intermediates
- Additional field for explanation on tonnage information
- Conditions of use information for substances < 10 t/a
  
- Consultation via OHT EU subgroup, CEFIC ES group and ES/CSR roadmap coordination group

## **IUCLID**

### **Assessment Entity Concept for improving transparency**



## Challenges for a consistent safety assessment



## Challenge for “complex” substances

More than one set of substance properties may play a role for the assessment:

- Several compositions/forms with different levels of hazard supplied into different type of uses
- Substance transforming during use or in the environment: assessment of parent and/or transformation products
- Constituents in a substance have significantly different fate properties: parallel assessment of (group of) constituents needed

IUCLID 5 does not support transparent links, e.g. between

- Composition and uses
- Composition and endpoint studies

## Proposal for IUCLID 6

- Better support transparency of the assessments and traceability of the related substance properties => **“Assessment Entity”** concept
- Grouping property data together (phys-chem/fate/hazard) representative for one or more compositions (or forms or constituents)
- Transparent links needed between composition/form and endpoint study records, endpoint study summaries and classification
- IUCLID data set can be sorted and CSR generated with report generator gets properly structured without manual intervention
- No additional complexity for "classical" cases where no such differentiation is needed

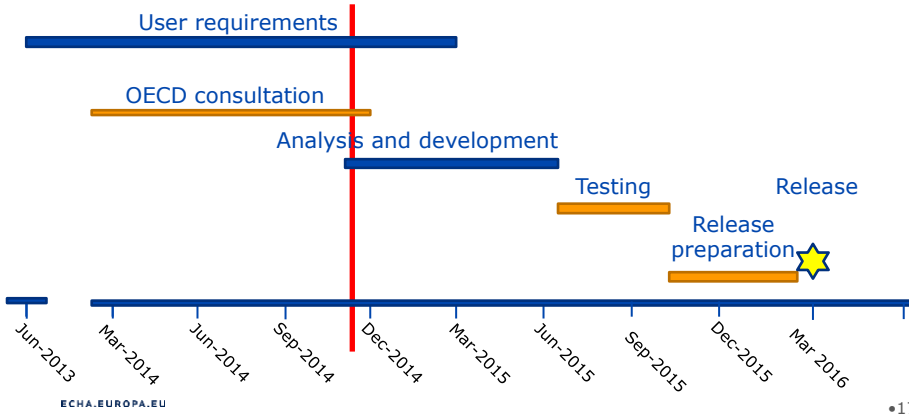
## Consultation process for “assessment entity”

- Discussion started in the context of the OHT on use and exposure
- Meeting organised by industry end of August 2014
- Development of solution in IUCLID by ECHA with the help of test cases by industry
- “wrap up” meeting organised by industry: 10 December 2014



## IUCLID 6 schedule

IUCLID 6 format to be used for data submission to ECHA from 2016 on



## Chesar 3



## Chesar 3 scope

- Improved communication with IUCLID 6, in particular for the export of information from Chesar to IUCLID section 3.5/3.7 (use and exposure)
- Better support assessment of “complex cases”: Parallel assessment can be carried out for:
  - Substance of complex composition with (group of) constituents behaving differently
  - substance dissociating/transforming on use or in the environment
- Align and improve implementation of the existing CSA elements on the basis of the latest developments done under industry initiatives:
  - Use maps, exposure assessment inputs, ECom phrase catalogue and EComXML, short title for communication

## Use maps and Chesar

In Chesar 2

- Industry associations can generate use maps (with or without full exposure assessment input) in Chesar format (XML) for import by registrants
- Registrants can make use of the use maps generated by sectors in their assessment
- Registrants can export the use description to IUCLID

Plans for Chesar 3:

- Adapt to use map format once agreed
- Find solutions for: tonnage information, multiple SPERCs relevant for one contributing activity

## Exposure assessment inputs and Chesar

In Chesar 2:

- Industry associations can generate exposure assessment inputs (SPERCs, SCEDs, GES) in Chesar format for import by registrants
- Registrants can make use of exposure assessment inputs generated by sectors in their CSA:
  - To perform release and exposure estimation
  - To report the conditions of use and all rationale to CSR
  - To generate an ES for communication if standard phrases available

Plans for Chesar 3:

- Adapt format of SpERCs based on latest development
- Implement format for workers assessment input once available

## ESCom and Chesar

In Chesar 2 it is already possible to:

- Import ESCom phrase catalogue
- Assign standard phrases to use/contributing activity names as well as to “determinants” (conditions of use)
- Generate an ES for communication using ESCom standard phrases

Plans for Chesar 3:

- Enable export of ES for communication in ESComXML format
- Enable generation of ES for communication in other EU languages if ESCom catalogue translations are available in Chesar format

## Short title for communication and Chesar

In Chesar 2

- the short title for communication is already based on identifier 1 and 2 (+ use name)
- The ES for communication contains a table of contents based on all short titles for communication

Plans for Chesar 3:

- Adapt content of short title and implement automated rules
- To be solved: identify source for information for the 3<sup>rd</sup> identifier

## Chesar 3 development

- Release of Chesar 3 planned together with IUCLID 6.
- Requirements/specifications consulted within Chesar consultation group. Timing: Q1/Q2 2014  
→ interest to be flagged to [chesar@echa.europa.eu](mailto:chesar@echa.europa.eu)

## Concluding remarks

- IUCLID and Chesar are developed to integrate/align with on going initiatives
- Objective is to increase the clarity and the consistency of CSR and ES for communication
- Would Chesar 2 be helpful in testing the various CSA elements developed by industry?
- ECHA is working on a training and promotion strategy for Chesar
  - Includes a targeted cooperation with sectors for developing CSA elements in Chesar format

Thank you!

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