Transparent reporting of more complex cases: the assessment entity

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Se Al Cu Ni Pb Sn Zn Au Ag Pt Sb W Be Si Cr Co Mo Ge V Mn Ir Ru Rh Ta

Background

As industry, we are keen to have « efficient » registrations:

- compliant
- balanced workload (including for updates)
- allowing a good understanding of the data & followed approaches (e.g. by evaluating authorities)

Some dossiers are more **complex** to compile

- 'intrinsic properties' of the material/substance
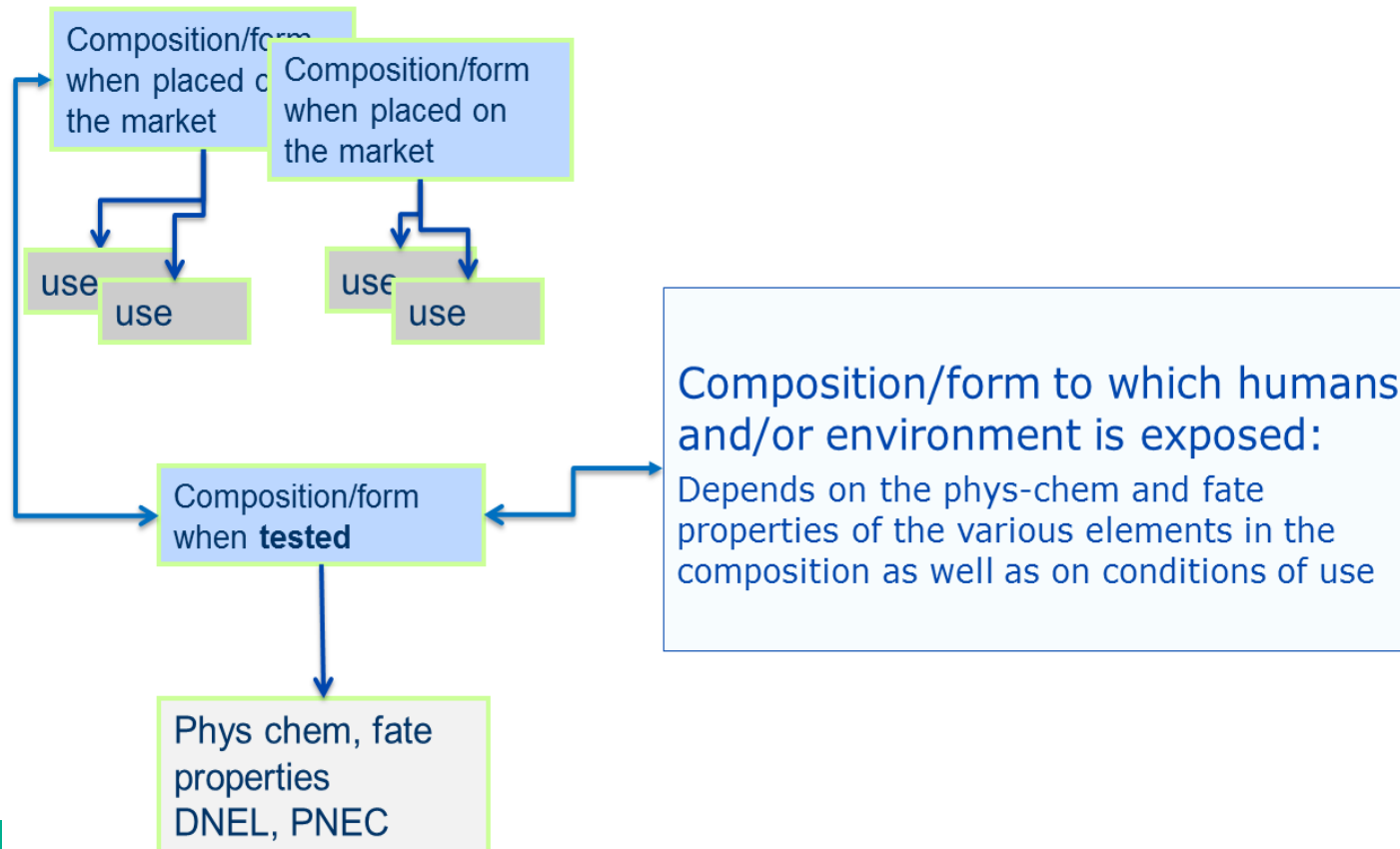- fate
- specific approaches

For example…

- **Inorganic UVCBs** characterised by varying concentrations of a number of constituents, assessed in parallel

- **Substances transforming** and both parent and transformation product(s) play a role in the assessment
  - *Unintended transformation*: e.g. under the conditions of use due to energy applied in the use process or dissociating in water subsequent to the use of the substance
  - *Intended change of form or composition* along the lifecycle with a new form/composition placed on the market
  - The substance is *meant to react* for delivering its technical function

- Different **forms** and **compositions** of a substance with different hazard properties in same registration/different **forms** in different uses

The assessor needs to…

- Consider <u>and link</u> the following aspects to ensure consistency between the form/composition of the substance placed on the market, the available information to determine the properties of this composition/form and the conditions of use

Composition/form when placed on the market

Composition/form when placed on the market

use

use

use

use

Composition/form when **tested**

Composition/form to which humans and/or environment is exposed:

Depends on the phys-chem and fate properties of the various elements in the composition as well as on conditions of use

Phys chem, fate properties
DNEL, PNEC

Issues

In such situations:

- **several sets of information/data per endpoint** may be needed for the safety assessment of a substance
- the approach followed needs to be reported **transparently** and 'grasped'

However

- IUCLID 5 has no default record or field to explain the followed approach
- Information on substance as registered and information on the transformation products (e.g. metal carboxylates dissociate in metal and carboxylic acid) is hard to combine in IUCLID/CSR
- In case of substance assessed via multiple sets of eco/toxicological data, information disseminated on the ECHA website is confusing

Solution: the assessment entity (AE)

- wrapper for a set of substance property data (across endpoints) used for assessment purpose

- facilitating transparent organisation and reporting of data in IUCLID and CSR

- allowing documentation of the followed assessment approach and better dissemination

- data object created/used when needed (not mandatory, opportunity for the assessor to make his case more transparent)
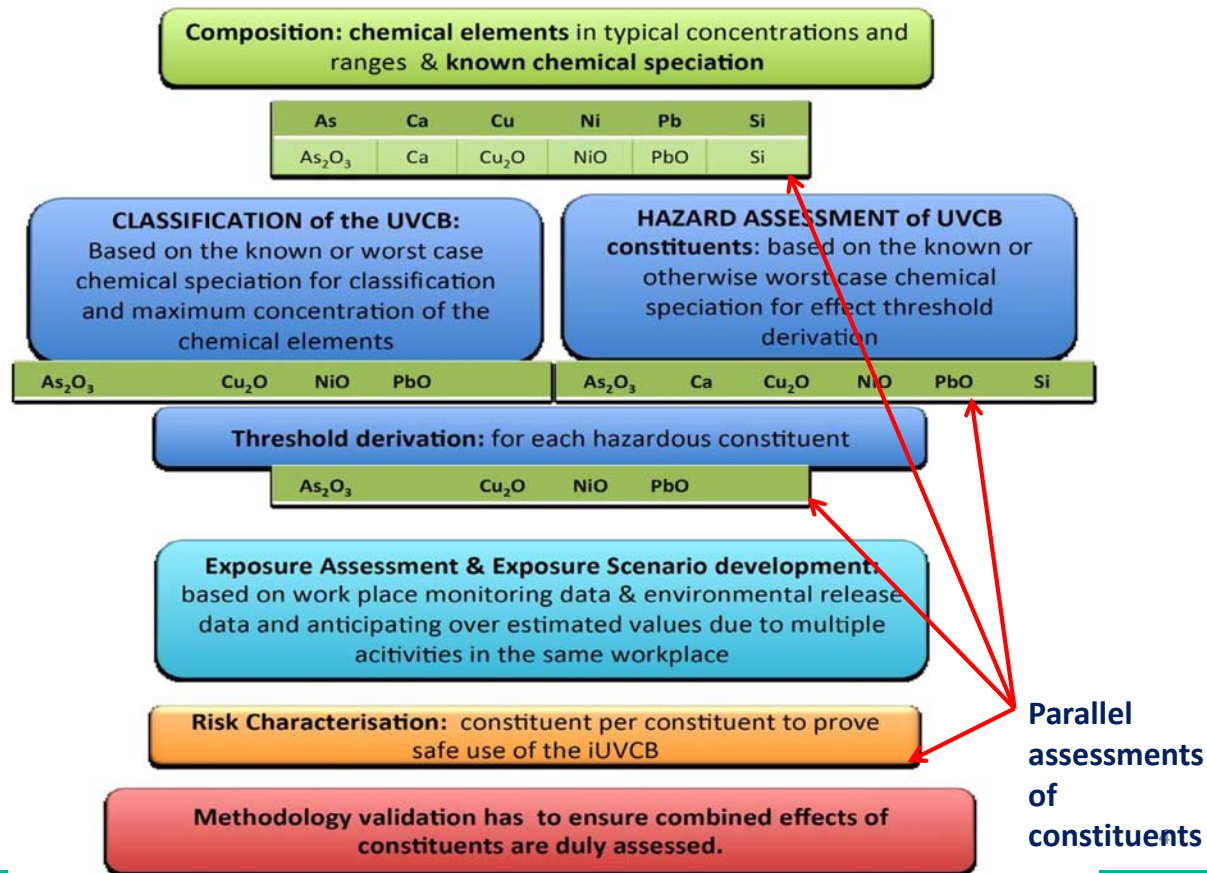
Illustration: the risk assessment of an inorganic UVCB
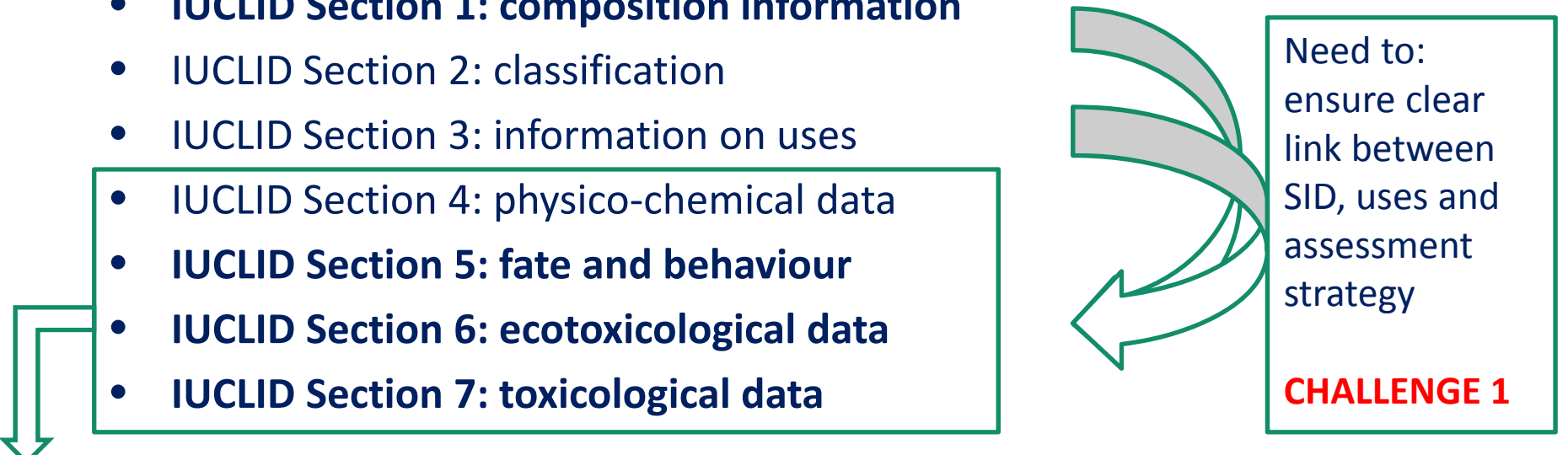
Assessment approach

- The assessment relies on the assessment of its constituents.
- In each parallel assessment the properties of a given (group of) constituents will be used
- Need to easily identify the set of properties per (group of) constituents

Overview of iUVCB experience in IUCLID 5 & CSR

- **IUCLID Section 1: composition information**
- IUCLID Section 2: classification
- IUCLID Section 3: information on uses
- IUCLID Section 4: physico-chemical data
- **IUCLID Section 5: fate and behaviour**
- **IUCLID Section 6: ecotoxicological data**
- **IUCLID Section 7: toxicological data**

Need to: ensure clear link between SID, uses and assessment strategy

CHALLENGE 1

Need to:
- Create dossiers compliant with regulatory requirements/in line with ECHA Guidance
- Allow a good understanding of the substance/constituents data & the followed approaches (from SID to Risk Management)
- 'stand alone' IUCLID dossier from constituents dossiers but still with 'all information at hand'
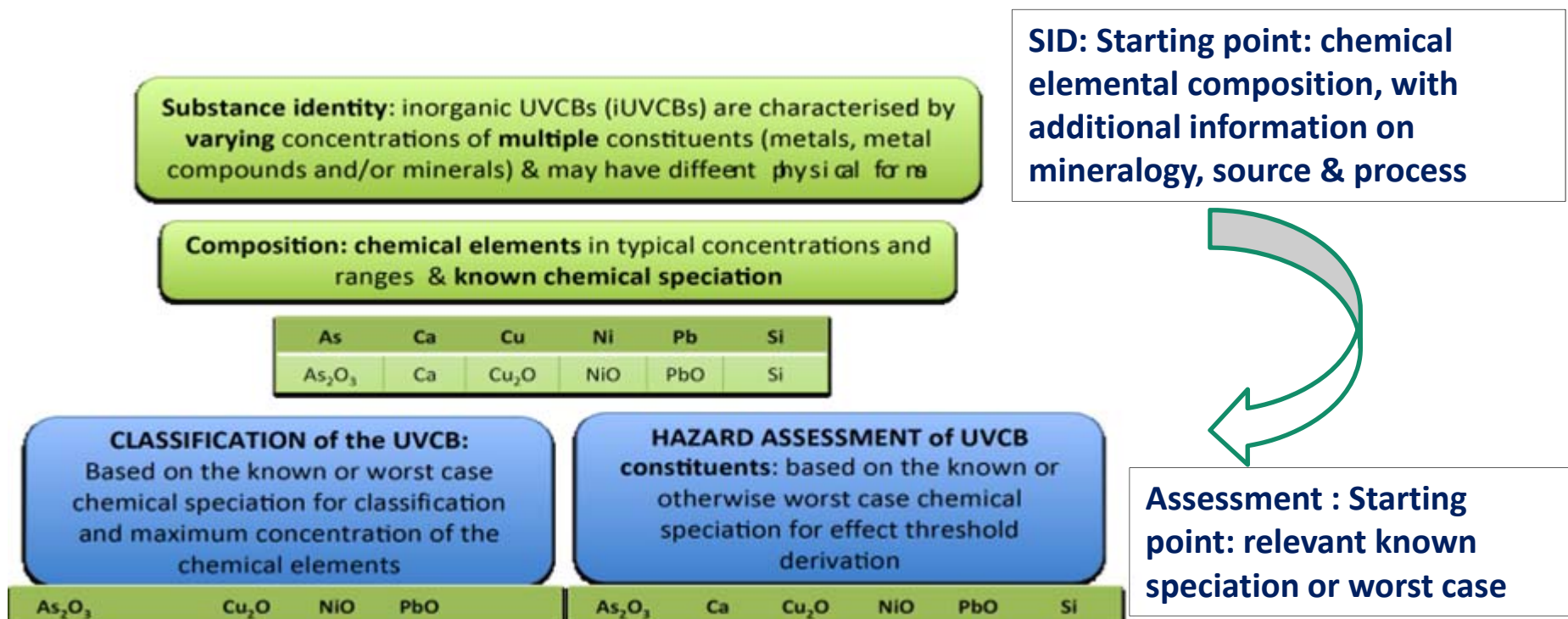
In practice:
- Tweaking of IUCLID **CHALLENGE 2**
- CSR iUVCB template required quite some adaptations to create a readable template **CHALLENGE 3**

Challenge 1 : from SID to assessment

Example based on an iUVCB dossier, where iUVCB substance is identified based on its composition and manufacturing process. Being a **UV**CB, the substance presents *variable* composition (reflected in constituents ranges) & *unknown* speciation for some constituents.

The assessment accounts for the above: transparency between SID & assessment approach!

Substance identity: inorganic UVCBs (iUVCBs) are characterised by **varying** concentrations of **multiple** constituents (metals, metal compounds and/or minerals) & may have diffeent physical forms

Composition: chemical elements in typical concentrations and ranges **& known chemical speciation**

As	Ca	Cu	Ni	Pb	Si
As_2O_3	Ca	Cu_2O	NiO	PbO	Si

SID: Starting point: chemical elemental composition, with additional information on mineralogy, source & process

CLASSIFICATION of the UVCB: Based on the known or worst case chemical speciation for classification and maximum concentration of the chemical elements

As_2O_3		Cu_2O	NiO	PbO	

HAZARD ASSESSMENT of UVCB constituents: based on the known or otherwise worst case chemical speciation for effect threshold derivation

As_2O_3	Ca	Cu_2O	NiO	PbO	Si

Assessment : Starting point: relevant known speciation or worst case

How can the AE address it ?

- AE can **highlight the link between iUVCBs SID and the risk assessment**:
  - ↳ All iUVCB constituents are regularly reported in SID
  - ↳ Each constituent relevant for the assessment will be reflected in an AE entry
  - ↳ Each AE will be linked to properties (phys-chem, fate, PNEC, DNEL) and exposure assessment
  - ↳ Parallel assessment of the iUVCB constituents/AEs

- AE can **help in transparently clarify constituent speciation** used in the assessment:
  - ↳ E.g. AE assessed *As_2O_3 for HH* & *As ion for ENV*

- AE **does not impact on SID, only develops an additional step in IUCLID** to ensure understandability of complex substance's assessment
  - ↳ AE tool wraps & summarises 'assessment strategy' of complex substances (IUCLID 0 level)
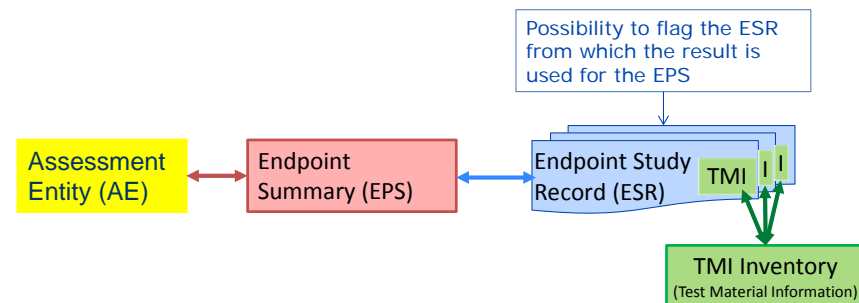
Challenge 2: readable IUCLID Sections 4-7?

- The constituent based approach requires identification of all hazardous constituents & metal substances are generally data rich, leading to increase IUCLID size and complexity

- "Tweak":
  - Key data to report for each constituent were identified and IUCLID "discussion" boxes in endpoint summaries were used for clarifications on assessment strategy
  - Effects assessment is dealt with in the summary sections:
    - ↳ *Summaries (PNEC/DNEL summaries) are provided for the constituents driving the assessment using a template workaround*
    - ↳ *Per endpoint, summaries are given for the iUVCB , indicating the C&L for individual composition profiles*

    => *BUT dossiers are difficult to apprehend…Updates? Dissemination?*

How can the AE address it?

- AE can **transparently** report and organise data relevant for risk assessment:

  ↳ Each AE created for a iUVCB constituent is linked to its fate, ecotoxicological and toxicological data

  ↳ AE properties data base is based on existing:
    ↳ Endpoint Summary (EPS)
    ↳ Each Endpoint Summary is linked to its set of Endpoint Study Record (ESR)

Possibility to flag the ESR from which the result is used for the EPS

Assessment Entity (AE)	Endpoint Summary (EPS)	Endpoint Study Record (ESR)	TMI

TMI Inventory
(Test Material Information)

Challenge 3: CSR generation

- The UVCB CSR required manual amendments/filling compare to usual IUCLID automated extraction
    - CSR Section 4-5-7: because of complexity of the assessment
    - CSR 9- 10: was manually filled according to Chesar 2.3 template

- Creation of explanatory notes that would provide ad hoc introduction to the different CSR sections
    - Overall effort to create templates useful for iUVCB dossiers
    - Summarising assessment approach (e.g. explanation, table of constituents and highlighting speciation used in the human health/environment hazard assessment)
    - Providing concentrations data used for calculations

How can the AE address it?

- The **AE** is meant to enable **logical grouping of data** to enable IT processing and a transparent documentation of the safety assessment in IUCLID and the CSR (for complex assessment cases)

- AE structure should enable logic CSR generation via IUCLID report generator:
  ↳ **One CSR** type should be used for the several constituents contributing to the iUVCB chemical safety assessment

  ↳ AE use in Chesar 3.0 should also help in generating 'easier' CSRs

  ↳ Manual adaptation would be expected to be minor even in complex cases as iUVCBs

To conclude

The AE can help with

- data sorting in IUCLID

- increasing transparency of the information provided to regulators (via IUCLID and CSRs) or to the generic public (dissemination website, brief profiles)

For complex cases, this concept is essential to ensure understanding/readability of the approach & appropriate data use

Looking forward to using it!

Thank you

Eurometaux
European Association of Metals

www.eurometaux.eu | www.callforaction.eu
Avenue de Broqueville 12 | B-1150 Brussels | Tel: +32 (2) 775 63 11 | eurometaux@eurometaux.be