Strictly controlled conditions discussion

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Status on interpretation SSC for intermediates

→ **CEFIC** provided an interpretation note on
"how to interpret the SSC requirements for intermediates"

→ **Member states**
- ✓ felt guidance not far too liberal and requested ECHA to clarify the interpretation.
- ✓ Requested a more restrictive interpretation
- ✓ Proposed to prepare series of indicative examples

→ **Eurometaux guidance** :
- ✓ less liberal as CEFIC guidance but
- ✓ may require updating based on outcome of ECHA review

This guidance update raises high stakes !!!! Since any different interpretation may result in the need to prepare full Registration dossiers for Intermediates !

Guidance on strictly controlled conditions (1)

- **ECHA will update guidance in Spring** including 7-12 examples on SCC and exposure-based waiving
- **Consortium** of TNO, DHI, Milieu, ...is developing examples in cooperation with industry
- **Opportunity** for industry to:
  - Provide some ***metals examples*** AND concepts:
    - Relative to (non-) releases of substances of concern from articles like batteries
    - Approach for intermediates using bio-elution, dustiness
  - Metal ***strictly controlled conditions***: in some cases = adequate control (see next slide)

Guidance on strictly controlled conditions (2)

- **Metal Intermediates**: strictly controlled or adequate control conditions?
  - SSC was invented to cover for the **lack of information on Hazard / effects**
  - In the metals sector, we often have some ***information on the hazard*** (on the intermediate/constituents) profile. We are definitively not starting from NO information on hazard of the intermediate or its constituents
  - Can this be used as an argument with e.g. ***bio-elution and dustiness data*** to plea for adequately controlled conditions rather than SCC demonstration.

Guidance on strictly controlled conditions (3)

If you have a ***substance X***	-> to be registered	hazard profile will be known	-> and there will be no risk	then, REACH speaks about Adequate Control (AC)
If you have an ***intermediate***	-> to be registered	usually the hazard profile will be not or less well known	can we say there is no risk??	no, so need for Strictly controlled conditions
For a metal intermediate	-> to be registered	the hazard profile is often well known	can we say there is no risk??	in theory should be AC rather than SCC, as hazard profile is known
For a metallic Intermediate XYZ	-> to be registered	hazard profile reasonably known (using additivity rule) In case not, bio-elution /Tdp can make the bridge (very conservative)	can we say there is no risk??	are SCC not equal to AC?

Timing:

- **December 2009**: indicate willingness/commitment from industry + rough outline of the examples we would provide to consortium
- **End of January**: provide detailed examples (existing template): batteries (interest from Recharge, meeting January), Ni-matte
- **ECHA Workshop** February 10 2010: selection of examples

CONCLUSION : Carefulness is recommended in applyting the SSC principle for Intermediates. While Eurometaux will try to raise recognition for the specific concerns of the metals intermediates, it is expected that **national implementation authorities WILL conduct reviews of the SSC principle**