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Experience of Metals Risk Assessments in the Existing  
Substances Regulation Process:  
Technical Committee for New and Existing Substances  
discussions

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# Environmental Compartments covered by ESR

- Freshwater



- Protection of FW ecosystems widely accepted

- Marine



- Protection of marine ecosystems increasingly emphasized

- Sediment



- Sediments accumulate many contaminants
- Good sediment quality essential for good FW ecological quality

- Soil



- Protection of natural and agricultural soil quality is recognized

For all compartments, PNECs are calculated based on dissolved and dietborne exposures (via secondary poisoning assessment)

# Metals in the EU Risk Assessment Process

- **Metals involved :**
  - Cd, Cu, Ni, Pb, Sb<sub>2</sub>O<sub>3</sub>, and Zn
- **Recent developments:**
  - Discussions completed
    - Zn: Rapporteur ESR = NL
    - Ni: Rapporteur ESR = DK
    - Pb: VRAR ESR, Review Country = NL
    - Cu: VRAR ESR, Review Country = Italy
    - Cu: Rapporteur BPD = France
  - **Extensive, comprehensive** written and oral discussions on all aspects of metals risk assessment took place, involving many EU member states
- **Key Results**
  - **Bioavailability** was used extensively (soil, water, sediments, and secondary poisoning) in both Cu and Ni RAs
  - **Bioavailability scenarios** (also known as **Ecoregions**) were used to calculate ranges of PNECs based on typical conditions of abiotic factors within the EU (e.g., 10P – 90P)
  - **Tiered Approaches** allowed for increasing use of bioavailability concepts with increasing amounts of information



# EU Environmental Existing Substances Risk Assessment: Next Steps

- The Scientific Committee on Health and Environmental Risks (SCHER) released their review on the ENV Zn, Cu, Pb, and Ni RAs
- SCHER was overall highly complimentary of the technical quality of the RA:

*“According to the SCHER, the [author] has performed a very good job on this difficult task and should be congratulated with the final result achieved. SCHER is aware of the complexities in this work and appreciates the efforts that have been carried out in the preparation of this [Risk Assessment Report].”*
- The SCHER identified the following aspects of the ENV Ni RA as “state of the science”:
  - Bioavailability normalization;
  - The Ecoregion approach (i.e., use of bioavailability scenarios);
  - Probabilistic risk characterization

# EU Environmental Existing Substances Risk Assessment: Next Steps

- OECD:
  - The Ni RA was presented by the Danish Environmental Protection Agency to the OECD SIAM in October, 2008
  - OECD Member Countries accepted the datasets, and the use of bioavailability normalization as the basis for setting appropriate PNECs for water, sediment, and soil
  - Acceptance at OECD level means that OECD countries (Japan, Australia, Korea, U.S.A, Canada, etc.) will have to recognize the databases and approaches used in the ENV Ni RA
- REACH:
  - Efforts are underway for adoption of RA guidance for metals under REACH (RIP's)
  - Application of new concepts under REACH