US EPA Framework for Metals Risk Assessment

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Exponent
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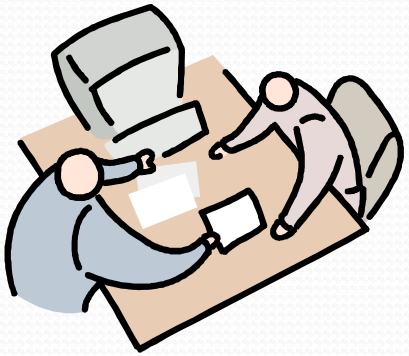
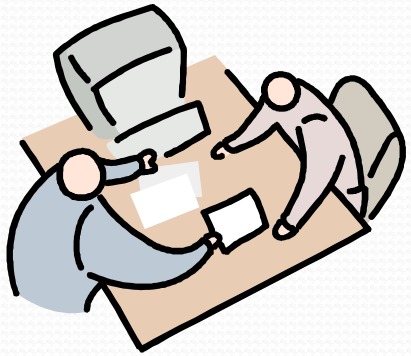
Background

- In 2002 there was considerable interest in the Agency's assessments on metals and metal compounds
  - the events surrounding promulgation of the Toxics Release Inventory (TRI) lead rulemaking
  - development of the Agency's Waste Minimization Prioritization Tool
  - Both concerned the use of the PBT screening process



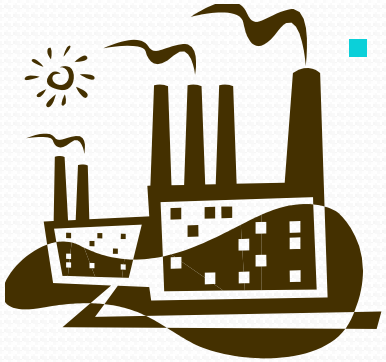
Background

- Linda Fisher, DA, initiated the development of cross-Agency guidance for assessing metal and metal compounds as a priority for EPA
  - Discussions within the Agency, with external stakeholders and with Congress
  - Provide opportunities for external input, peer review and cross-Agency involvement



Purpose

- Present key guiding principles based on the unique attributes of metals
- Describe how metals-specific attributes and principles may then be applied in the context of existing US EPA risk assessment guidance and practices
- Outline key metal principles and how they should be considered in existing human health and ecological risk assessment practices
- Foster consistency across US EPA programs and regions

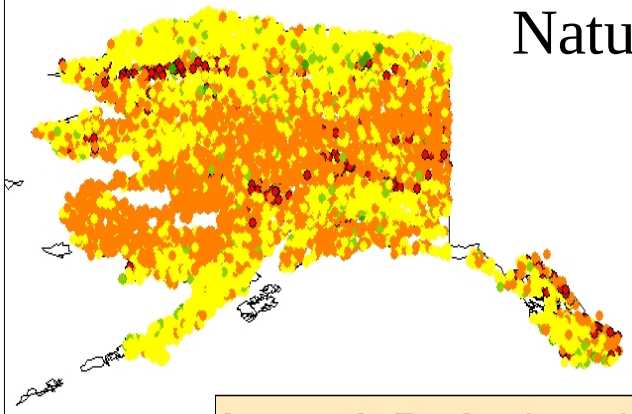


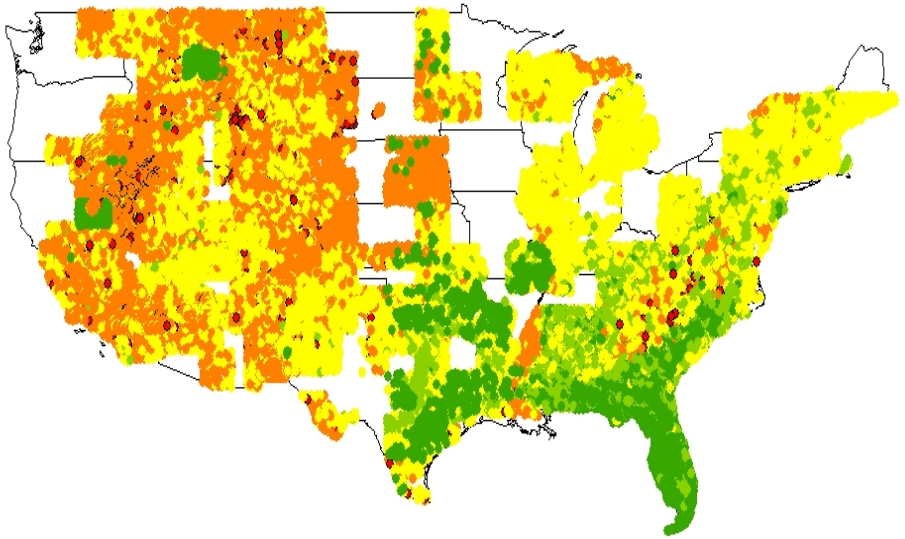
Five Principles

- Metals are naturally occurring constituents in the environment and vary in concentrations across geographic regions
- All environmental media have naturally occurring mixtures of metals, and metals often are introduced into the environment as mixtures

- Some metals are essential for maintaining proper health of humans, animals, plants, and microorganisms

Natural occurrence of barite (USGS)





Legend: Barite (ppm)

ngs

BA_ICP40

- 0.00000 - 75.00000
- 75.00001 - 225.00000
- 225.00001 - 600.00000
- 600.00001 - 1200.00000
- 1200.00001 - 9570.00000

Essentiality and Toxicity

Nutritionally Essential Metals with Potential Toxic Effects at Higher Doses	Toxic Metals With Possible Beneficial Effects	Toxic Metals With no Known Beneficial Effects
Cobalt	Arsenic	Aluminum
Chromium III	Boron	Antimony
Copper	Nickel	Barium
Iron	Silicon	Beryllium
Manganese	Vanadium	Cadmium
Molybdenum		Chromium VI
Selenium		Lead
Zinc		Mercury
		Silver
		Strontium
		Thallium
		Tin

Five Principles

- Unlike organic chemicals, metals are neither created nor destroyed by biological or chemical processes
  - they can transform from one species to another (valence states) and can convert them between inorganic and organic forms
- The absorption, distribution, transformation, and excretion of a metal (toxicokinetics) within an organism depends on:
  - the metal
  - the form of the metal or metal compound
  - the organism's ability to regulate and/or store the metal

Metals Framework

- Utilized the risk assessment process
- Listed questions assessors should consider in the phases of risk assessment
- Included chapters on
  - Introduction (bioavailability)
  - Environmental chemistry
  - Aquatic eco-risk assessment
  - Terrestrial eco-risk assessment
  - Human health

Collaboration

- Development of the Framework involved national and international experts in two workshops and five issue papers that supported the development of the document
- US EPA was active with Metals Environmental Risk Assessment Guidance (MERAG) development in Europe attending workshops and reviewing documents
- US EPA was active in Canadian Metals in the Human Environment Research Network
- Co-sponsored a SETAC workshop on metals issues

Science Policy Issues

- Incorporation of Bioavailability
- Limited use of BAF/BCF
- Application of RDA
- Environmental Chemistry
- Human Health
- Ecological

Bioavailability Issues

- Bioavailability of metals and the associated risk vary widely according to the physical, chemical, and biological conditions under which an organism is exposed
- Bioavailability should be explicitly incorporated into all risk assessments
- Where data or models are insufficient, assumptions should be clearly articulated

EPA's Bioavailability Committee

- Initiated in March, 2007
- Develops new guidance concerning site assessment and cleanup at hazardous waste sites
- Evaluates new methods and supports site specific assessments
- Identifies research needs to address data gaps relevant to contaminant bioavailability in soil site assessment activities
- EPA's Bioavailability Committee: http://www.epa.gov/superfund/health/contaminants/bioavailability/trw.htm

Background

- Background levels refers to those concentrations of metals that derive from natural as well as anthropogenic sources that are not the focus of the risk assessment
- Metal concentrations vary widely over space and time owing to differences in geology, hydrology, anthropogenic and natural loads from “nontarget” sources, and other factors
- It is recommended that, when appropriate, regional- or national- level ecological risk assessments be subdivided into metal-related ecoregions, referred to as metalloregions (McLaughlin and Smolders, 2001)

Environmental Chemistry

- Metal speciation affects metal behavior in environmental media
- pH and redox potential affect speciation
- Kd values – a coefficient for mobility in soils
  - limited use of single values
- Aging of metals in media reduces bioavailability
- Metal sorption behavior affects bioavailability

RFD and RDA Issues

- RFDs should not be below RDAs
- Essentiality should be viewed as part of the overall dose-response relationship for those metals shown to be essential
- Zinc IRIS document is an example

Human Health

- The organ or tissue in which metal toxicity occurs may differ from the organ or tissue(s) in which the metal bioaccumulates and may be affected by the metal's kinetics
  - target organs may differ by species, mainly owing to differences in absorption, distribution, and excretion.
- Both the exposure route and the form of a metal can affect the metal's carcinogenic potential and its noncancer effects
- Sensitivity to metals varies with age, sex, pregnancy status, nutritional status, and genetics

Oral Ingestion – Metal Toxicity

- Toxicity of an ingested chemical depends, on the degree to which it is absorbed from the GI tract into the body
- Metals can exist in a variety of chemical and physical forms
- Not all forms of a given metal are absorbed to the same extent
  - Physical, chemical, biological
  - Matrix: metal from a contaminated soil absorbed vs. ingestion from dietary exposure

25 March 2005 issue, *Science* Magazine, Simpson et al. The Gut: Inside out. Physiology and biology of the gastrointestinal system

Human Health

- Metals attached to small airborne particles are of primary importance for inhalation exposures.
- Adverse nutritional effects can occur if essential metals are not available in sufficient amounts
  - increases the vulnerability of humans to other stressors, including those associated with other metals.
- Because the diets of humans and other animals are diverse, there may be wide variability in the dietary intake of some metals (e.g., in seafood)
  - results in temporal, geographic or cultural variability of responses

Web Sites

- Metals Framework, March, 2007 http://www.epa.gov/raf/metalsframework
- Fairbrother et al., 2007. Ecotoxicology and Environmental Safety. 68: 145-227
- Issue papers August 2004:
  - epa.gov/raf/publications/paper risk assessment-metals.htm