

## Legal Lookout: EPA Issues Metals Risk Assessment Framework

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Businesses have long believed that assessing potential risks from metal and inorganic chemical exposures are qualitatively and quantitatively different from assessing potential risks from organic chemical substances. On March 8, EPA capped off an intensive effort that fundamentally recognized these differences in announcing the availability of its final *Framework for Metals Risk Assessment*. The framework is available at [www.epa.gov/osa/metalsframework/pdfs/metals-risk-assessment-final-3-8-07.pdf](http://www.epa.gov/osa/metalsframework/pdfs/metals-risk-assessment-final-3-8-07.pdf).

### Metals are unique

In EPA's words, metals "present unique risk assessment issues." Industry groups have long urged federal and state agencies to specify risk assessment principles, assumptions and paradigms for the risks associated with metals.

In announcing the framework's availability, EPA stated that its purpose was "to present key guiding principles based on the unique attributes of metals (as differentiated from organic and organometallic compounds) and to describe how these metals-specific attributes and principles may then be applied in the context of existing EPA risk assessment guidance and practices."

The agency notes that the framework "is not a prescriptive guide on how any particular type of assessment should be conducted within an EPA program or regional office." Rather, the framework "outlines key metal principles and describes how they should be considered in conducting human health and ecological risk assessments to advance our understanding of metal's impact and foster consistency across EPA programs and regions."

Primarily addressing issues that EPA risk assessors expect to encounter, the framework also communicates principles and makes recommendations for metal risk assessments to stakeholders and the public. EPA will use the framework "in conjunction with guidance developed by the programs and regions for use in site-specific risk assessments, criteria derivation, ranking or categorization and other similar agency activities related to metals." Because EPA assessments can vary in details from simple screening analyses to complex assessments, the agency noted that "[m]ore complex scientific tools and metal specific methods should be applied as the complexity of the hazard assessment or risk assessment increases."

According to the framework, the following principles are more generalized, fundamental properties of metals and "should be addressed and incorporated into all inorganic metals risk assessments:"

- Metals are naturally-occurring constituents and vary in concentrations across geographic regions;
- All environmental media have naturally occurring mixtures of metals, and metals are often introduced into the environment as mixtures;
- Some metals are essential for maintaining proper health of humans, animals, plants and microorganisms;

- The absorption, distribution, transformation, and excretion of a metal within an organism depend on the metal, the form of the metal or metal compound, and the organism's ability to regulate and/or store the metal.

The agency's Risk Assessment Forum oversaw the development of the framework, which included input from stakeholders and experts throughout EPA, obtained through several expert workshops, followed by peer review by EPA's Science Advisory Board.

### **Implications**

That metals and inorganic compounds pose different potential risks and invite different risk assessment principles is clear. The availability of the framework heralds the hope of improved consistency in the application of risk assessment principles uniquely suited to risk assessments pertinent to metals and inorganic substances. This is essential in conducting scientifically valid and defensible assessments of all kinds involving metals.

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