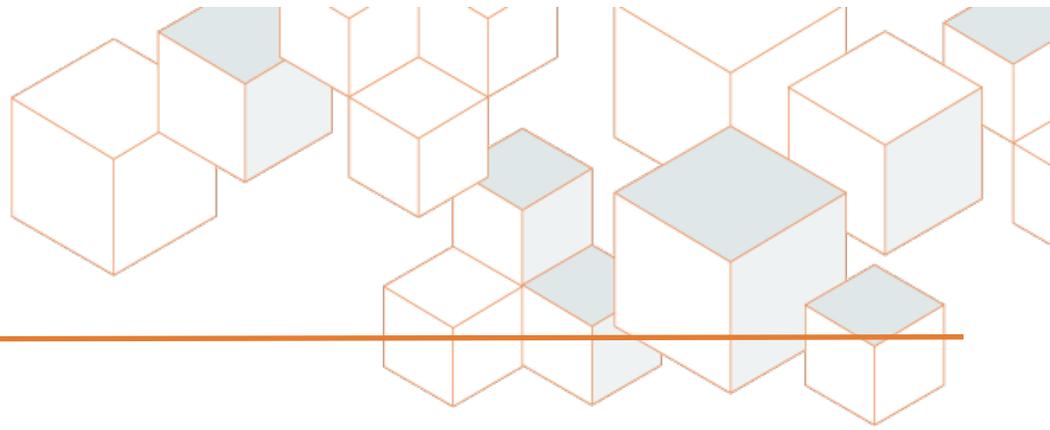


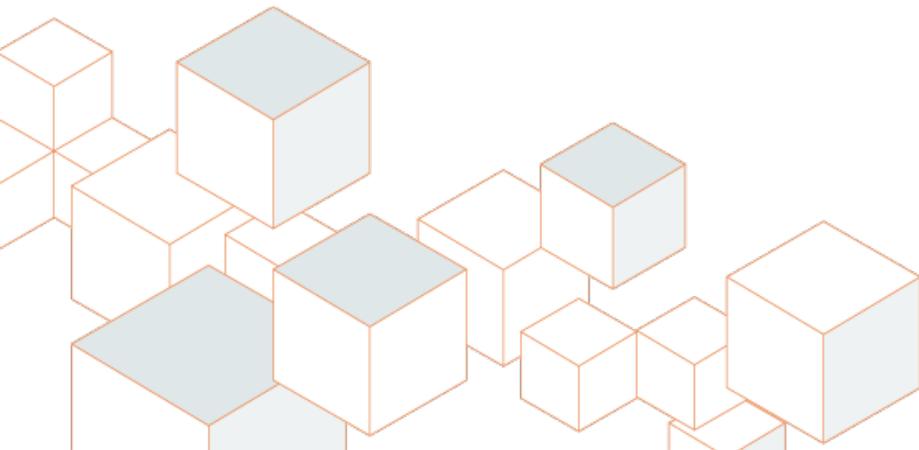
Consideration of Unreasonable Risk under the

Lautenberg Chemical Safety Act

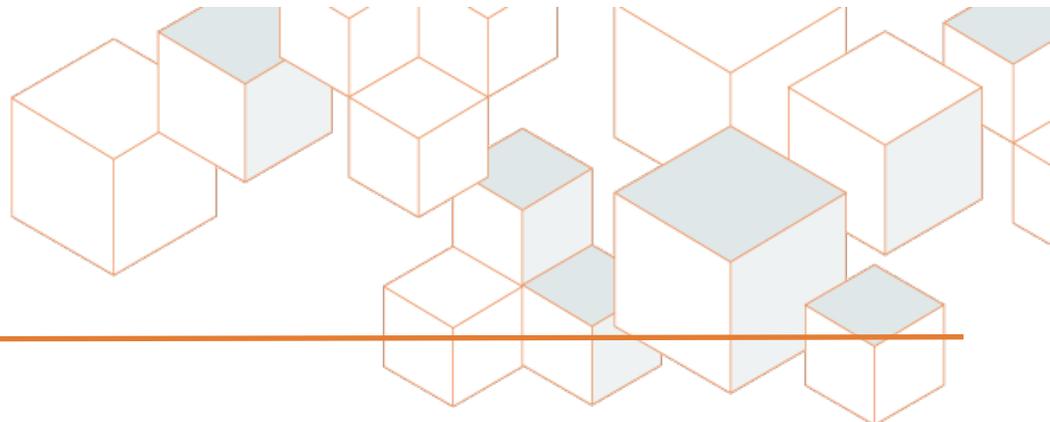
Unreasonable Risk



- **Key concept in Toxic Substances Control Act (TSCA) and Lautenberg Chemical Safety Act (LCSA)**
- **We will first look at what unreasonable risk meant under “old TSCA” before the LCSA amendment of summer 2016, and then review the new amendment**



Risk in TSCA



- TSCA enacted in 1976
- “unreasonable risk” is critical concept
- EPA given authority to restrict or ban a chemical that “presents or will present an unreasonable risk [of injury to health or the environment]”
- Regulation by rule; record must be supported by substantial evidence
- Subordinate concepts:
 - *significant* health risks, not insignificant ones
 - *imminency* and *degree of certainty* (presents vs. may present)
 - requirement to impose least burdensome requirements



Imminency and Certainty of Risk

Different articulations when regulatory authority attaches based on how the risk presents:

4: “may present”

5(b)(4): “presents or may present”

5(e): “may present”

5(f): “presents or will present”

6: “presents or will present”

7: imminently hazardous substances - “presents” an imminent and unreasonable risk of serious or widespread injury

Initial Applications of Unreasonable Risk

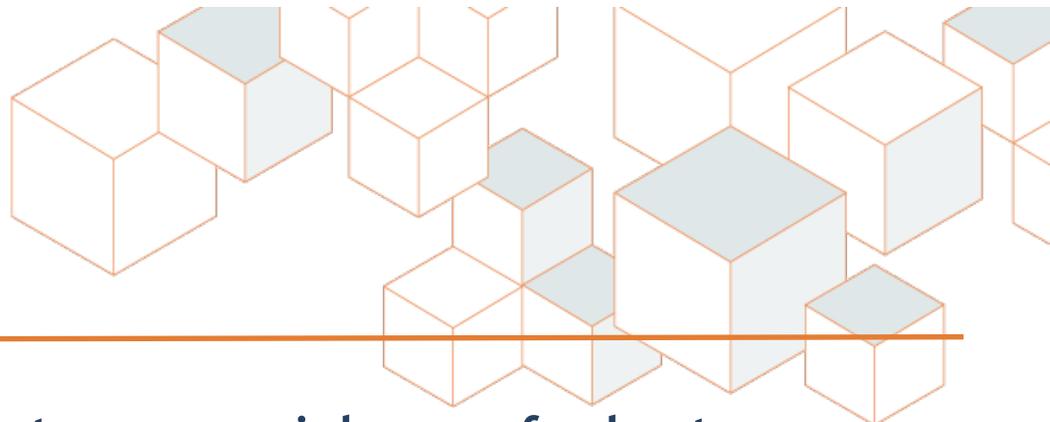


EPA took early regulatory action for several chemicals

- 1978, halogenated chlorofluoroalkanes
- 1980, TCCC (2,3,7,8-Tetrachlorobenzo-p-dioxin)
- 1984, metalworking fluids PMN restrictions
- 1990, hexavalent chromium

No judicial challenges were made to these actions

Asbestos



- EPA issued a “three stage” ban of most commercial uses of asbestos
 - Bans of asbestos-containing products were to phase in over a period of years
- Rule followed a decade long rulemaking process
- Lawsuit filed - Corrosion Proof Fittings v. EPA
- 1991, Fifth Circuit court of appeals struck portion of rule
- First time court had interpreted the “presents or will present an unreasonable risk” standard
- agency improperly relied on “flawed methodology” and failed to consider “factors and alternatives that TSCA explicitly requires it to consider”

Basis of Decision in *Corrosion-Proof Fittings*



- Focus not on the “health risk” side of the unreasonable risk equation
 - Court concluded that EPA had failed to
 - Show that a total ban was the least burdensome requirement
 - Make an adequate consideration of the availability of substitutes
 - Conduct a properly supported economic analysis of the costs and benefits of the proposed ban
 - **Least burdensome: EPA required to use the “least burdensome” method of achieving (1) an “*acceptable level*” of “*non-zero*” risk**
 - “TSCA imposes a least-to-most burdensome hierarchy”
 - “EPA must show not only that its proposed action *reduces the risk of the product to an adequate level*, but also that [less burdensome actions] would not do the job”
 - “[EPA should] consider each regulatory option, beginning with the least burdensome, and the costs and benefits of regulation under each option”
- 

After *Corrosion-Proof Fittings*

- Made clear that the “unreasonable” part of the “unreasonable risk” concept includes consideration of economic, social risks under TSCA
- EPA subsequently preferred to use its separate authority under Sec. 5(a)(2) to regulated by “Significant New Use Rules”
- No requirement to find that a substance “presents or will present an unreasonable risk” for SNURs, but limited to “new uses” and could not be used for “existing uses”
- Difficulty of regulating under Sec. 6, following the decision, was a key precipitator for reform of TSCA by LCSEA

RISK = HEALTH/ENVIRONMENTAL RISK (severity and likelihood of injury)
“severity of injury that may result from the product, factored by the likelihood of the injury, offsets the harm the regulation itself imposes upon manufacturers and consumers”

UNREASONABLE = (largely) ECONOMIC, SOCIAL FACTORS

“Unreasonable Risk” concept in other Statutes



Risk as general legal concept

- Restatement of Torts

Unreasonable Risk concept in health and environmental statutes

FHSA

- Hazardous substances

CPSA

- Consumer products

FIFRA

- Pesticides

TSCA

- Chemicals in commerce
- 

Restatement of Torts



General U.S. legal principles articulated in Restatement Sec. 291

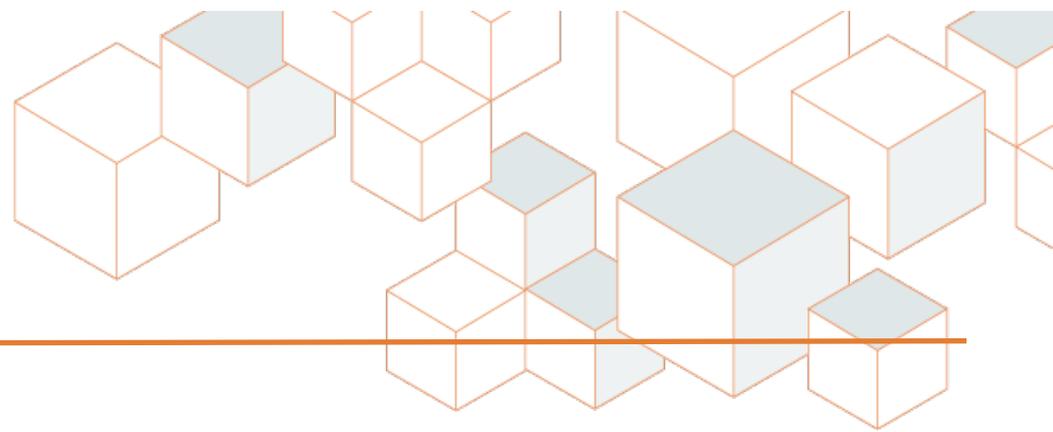
Risk is “unreasonable” if the risk:

“is of such magnitude as to outweigh what the law regards as the utility of the act or of the particular manner in which it is done”

Four factors for magnitude of risk:

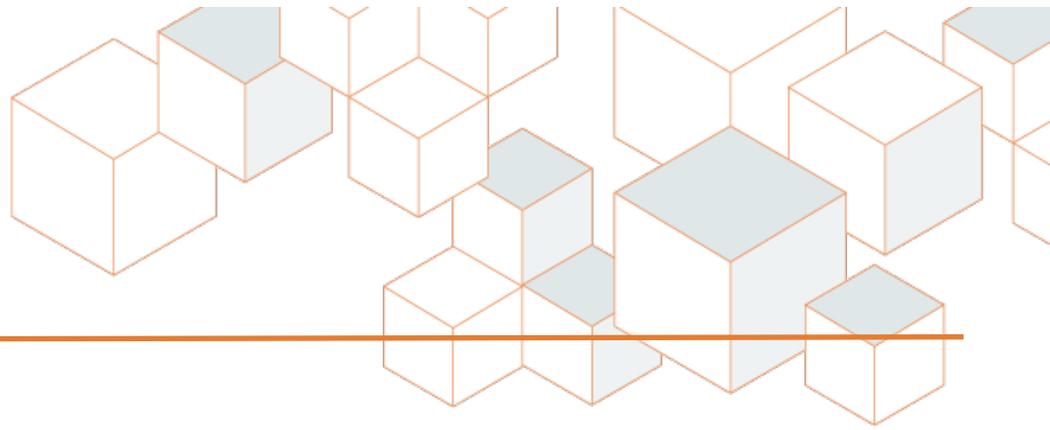
- (1) Social value of the activity/product
- (2) Chance that the activity/product will hurt another party
- (3) Extent of harm likely to be caused to the activity/product
- (4) Number of people likely to be affected if harm materializes from the risk

FHSA



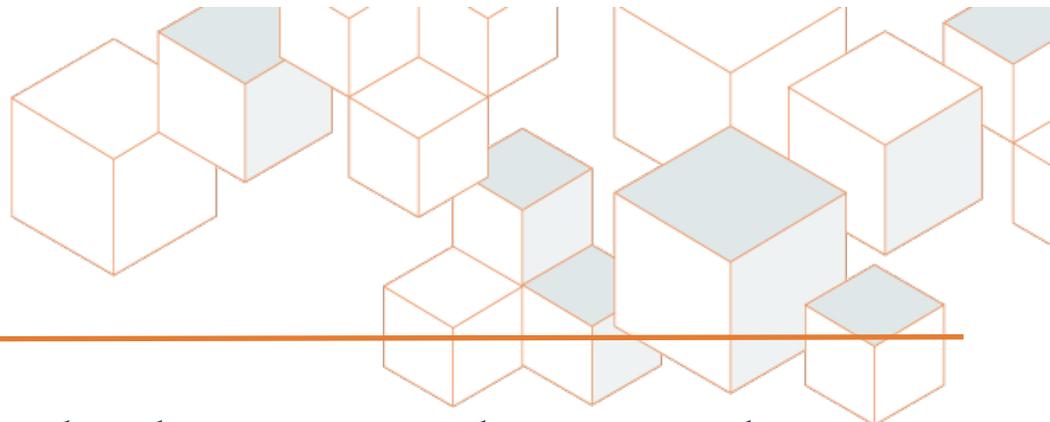
- Commission power to regulate “unreasonable risk” of consumer injury
- Commission must determine that
 - risk is unreasonable, and
 - There is a “sufficient nexus” between regulation and hazard it addresses
- Commission may regulate if
 - *severity of injury* factored by *likelihood of injury* offsets the harm of the regulation on consumers and manufacturers

CPSA



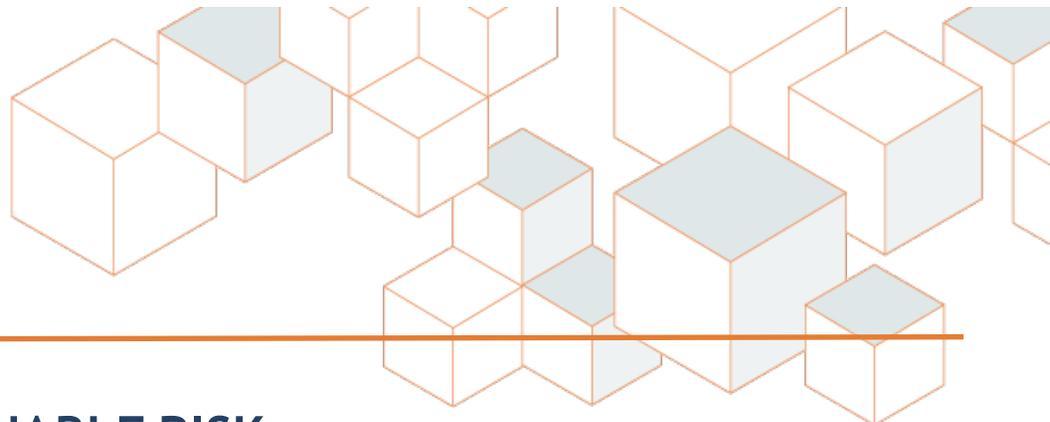
- Commission power to issue standards that are “reasonably necessary to prevent or reduce unreasonable risk of injury”
- “unreasonable risk” not defined by statute
- “risk of injury” is defined
 - “risk of death, personal injury, or serious or frequent illness”

FIFRA



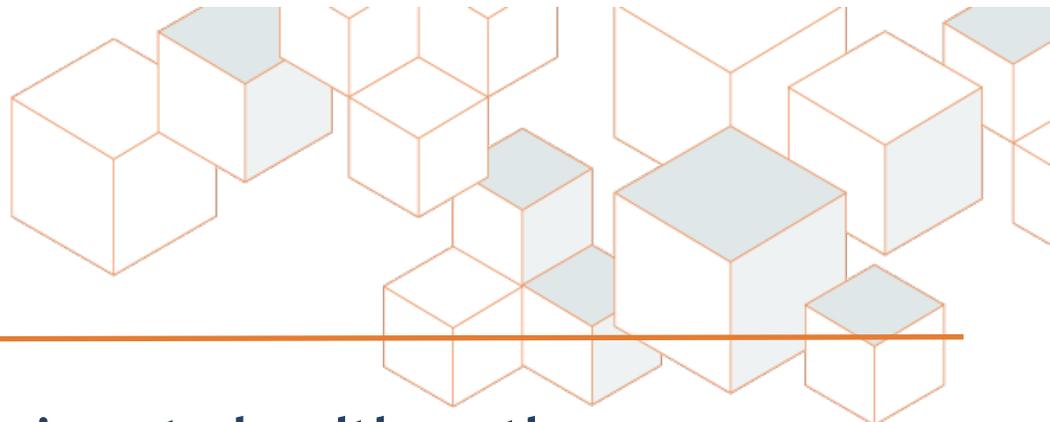
- EPA power to regulate “to the extent necessary to prevent unreasonable adverse effects” on the environment
- “unreasonable adverse effects on the environment” is defined by statute to mean “unreasonable risk”
 - Includes “any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits or the use of any pesticide”
- Proof of actual harm not needed
- But EPA must show *significant* probability of harm occurring

LCSA



- Retains critical concept of **UNREASONABLE RISK**
- But addresses *Corrosion-Proof Fittings* issues by bifurcates risk evaluation and risk management
- Unreasonable risk determination is contained in the risk evaluation step
 - UR is “pure” health/environmental risk decision.
 - Includes consideration of conditions of use
 - Conditions of use includes consideration of potentially exposed or susceptible subpopulations
- Considerations of cost and non-risk factors are decoupled from the risk evaluation (UR) stage and moved to risk management stage
- Note: Risk evaluation step can also yield agency determination that chemical does NOT present unreasonable risk.

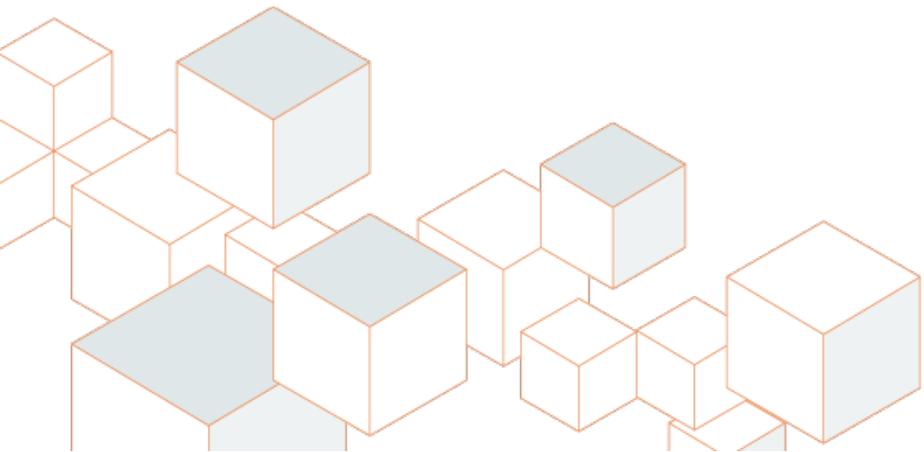
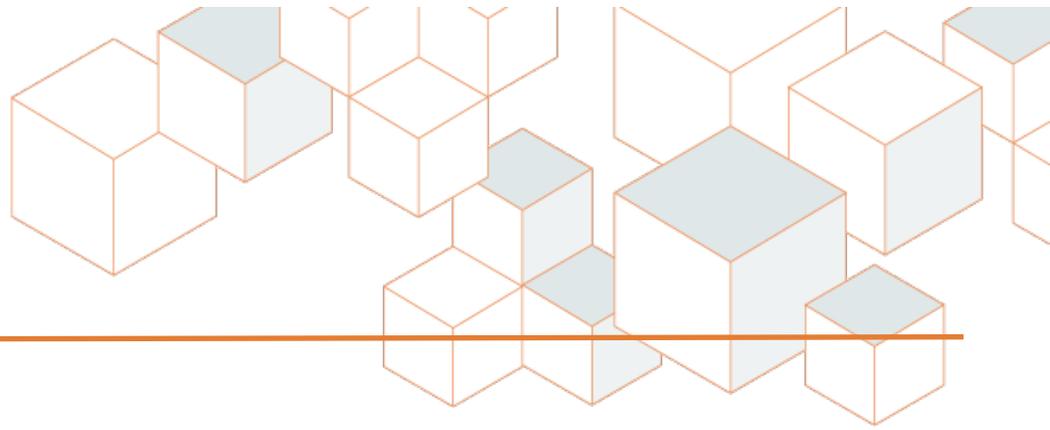
LCSA



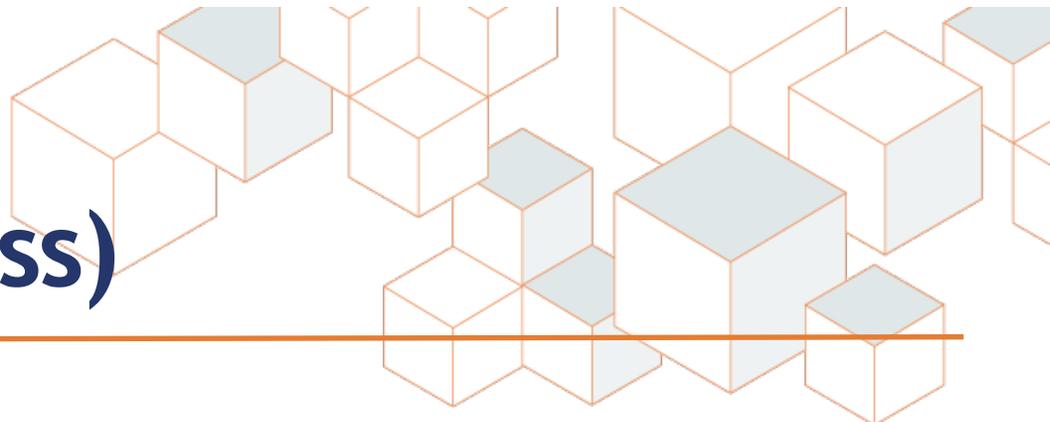
- Retains “unreasonable risk of injury to health or the environment” as the standard
- But the unreasonable risk determination must be reached “without consideration of costs or other nonrisk factors”
- Traditional meaning of “unreasonable” (consideration of costs, alternatives, etc. does not apply) in risk evaluation phase
- Risk determination followed by risk management
- *What likelihood (probability) of injury and severity of injury supports an unreasonable risk determination?*

Other

- Health-based air standards
- Other health standards (values)



Severity (Seriousness)



LCSA: determination of unreasonable risk (following risk evaluations under Section 6) must include

- “an unreasonable risk to a *potentially exposed or susceptible subpopulation*”
 - “under *conditions of use*”
 - **Factors will necessarily vary from chemical to chemical**
 - Case-by-case determination
 - Occupational setting vs. children’s product
 - E.g., Benzene decision: 10^{-3} “definitely significant”; 10^{-9} “definitely insignificant”
 - Material
 - Significant
- 

Probability (Likelihood)

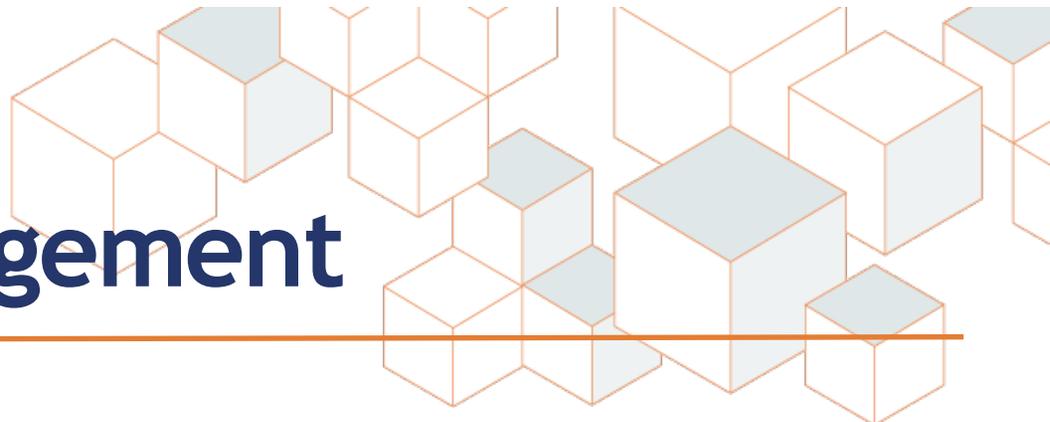
- > 0 (Corrosion-Proof Fittings - non-zero)
- “not insignificant”
- significant



Application of Science Standard

- Unreasonable risk determinations under LCSA are necessarily science-based decisions
- These determinations are subject to new standards under Sec. 26 of LCSA
- EPA shall use ...measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science”
- Application to EPA’s guidelines and frameworks for risk assessment
- Scientific determinations
 - Probability (science of uncertainty)
 - Seriousness

Nexus to Risk Management



Standard for regulation:

Action taken to the “extent necessary so that the chemical no longer presents unreasonable risk”

Observations:

- No requirement to eliminate all risk; some risk can remain
 - But expectation that “unreasonable” risk will be removed
 - Acceptable health risk - case by case
- 