Policy Discussion #7

Risk Management and Protection of Human Health

Outline

- Introduction: AWQC for protection of public health
- Exposure to noncarcinogenic chemicals; relative source contribution
- Risk from exposure to carcinogens
- How much risk be considered acceptable?
- 1×10^{-6} as acceptable risk
- Regulatory perspective on acceptable risk
- Developing reasonably achievable criteria while maintaining health protectiveness

Human Health Criteria Formulas

Noncancer Effects[2]

$$AWQC = RfD \cdot RSC \cdot \left(\frac{BW}{DI + \sum_{i=2}^{4} (FI_i \cdot BAF_i)} \right)$$

Cancer Effects: Linear Low-Dose Extrapolation

$$AWQC = RSD \cdot \left(\frac{BW}{DI + \sum_{i=2}^{4} (FI_i \cdot BAF_i)} \right)$$

$$RSD = \frac{Target\ Incremental\ Cancer\ Risk}{Cancer\ Potency\ Factor}$$

Introduction

- AWQC are a way to manage risk associated with chemicals in surface water.
- Many human activities discharge these chemicals.
- Exposure cannot be completely eliminated
  - Risk cannot be zero.
  - What level of risk is acceptable?

Exposure to noncarcinogenic chemicals

- Exposure is compared to a reference dose (RfD) expressed as mg/kg-day.
- Daily exposure that doesn't exceed the RfD is likely to be without risk of adverse health effects for a lifetime.
- Exposure that comes from media other than fish and water is accounted for by the relative source contribution (RSC).
- EPA guidance recommends a default RSC of 0.20 (20%) in the absence of chemical-specific exposure data.
- The Florida DEP has estimated RSC values between 0.20 and 0.80 for a number of chemicals

Exposure to carcinogenic chemicals

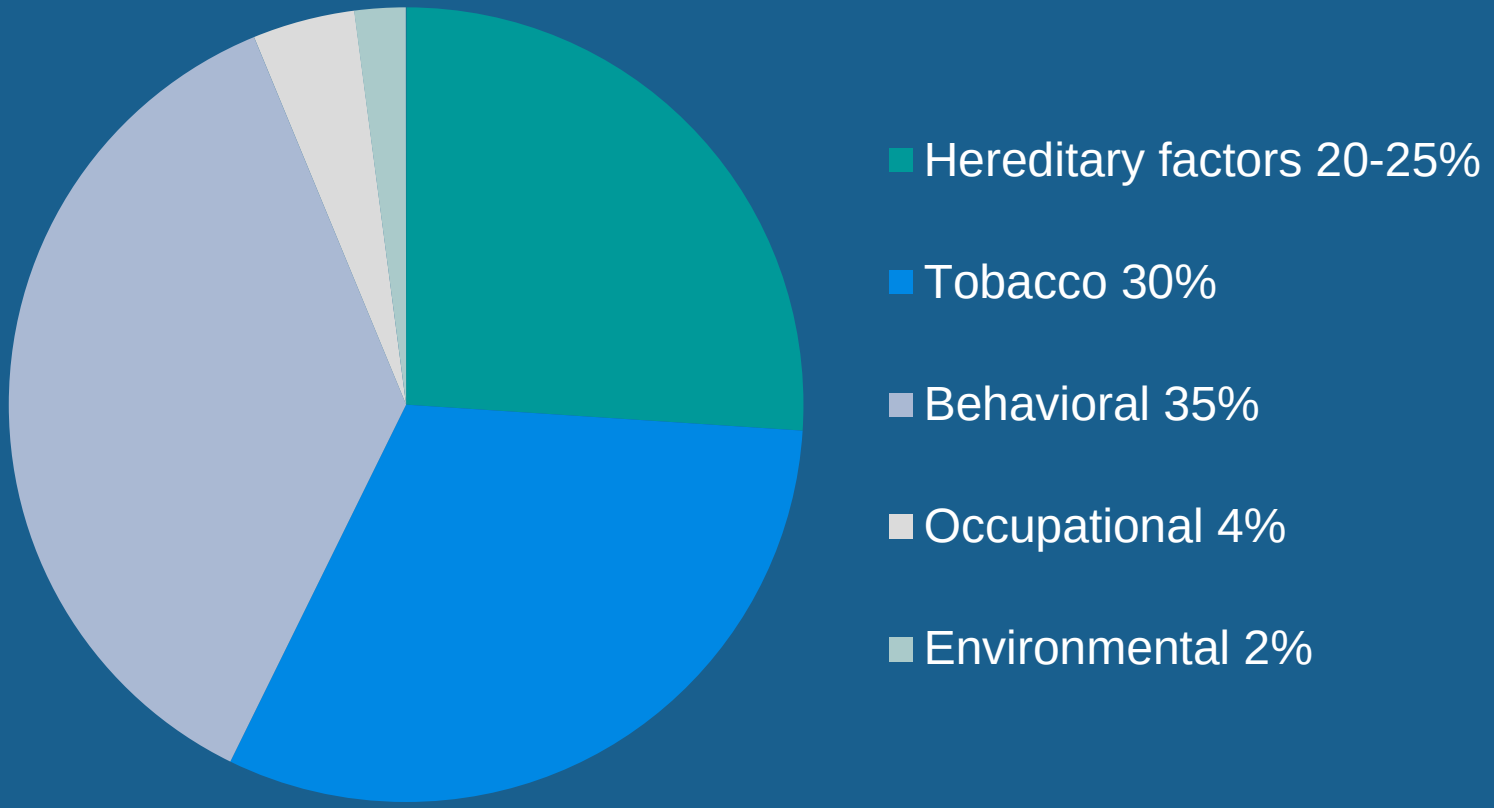
- For a given exposure, the risk of cancer is represented as a probability.
- Example: one in a million or 1×10^{-6}
- It is assumed there is no exposure threshold below which there is no risk.
- Risks from exposure to multiple chemicals are additive.
- Because estimates are uncertain, one significant figure is used, e.g. 3.8×10^{-5} becomes 4×10^{-5}.

Lifetime Probability of Developing Invasive Cancer

Females: 38% or 3.8×10^{-1}

Males: 44% or 4.4×10^{-1}

Cancer Causes



Source: American Cancer Society, Cancer Facts and Figures 2014

10^{-6} and the Concept of Acceptable Risk

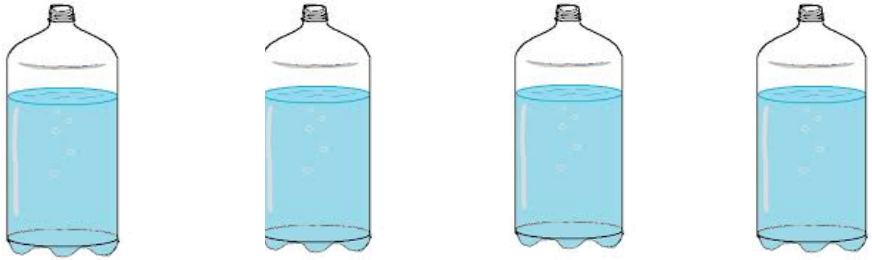
One in a million risk was originally incorporated into a US FDA regulation as a screening level that is essentially no different than zero risk.

It was a *de minimis* risk, a level of risk that is below regulatory concern.

But, now it is often interpreted as a risk level that must not be exceeded.

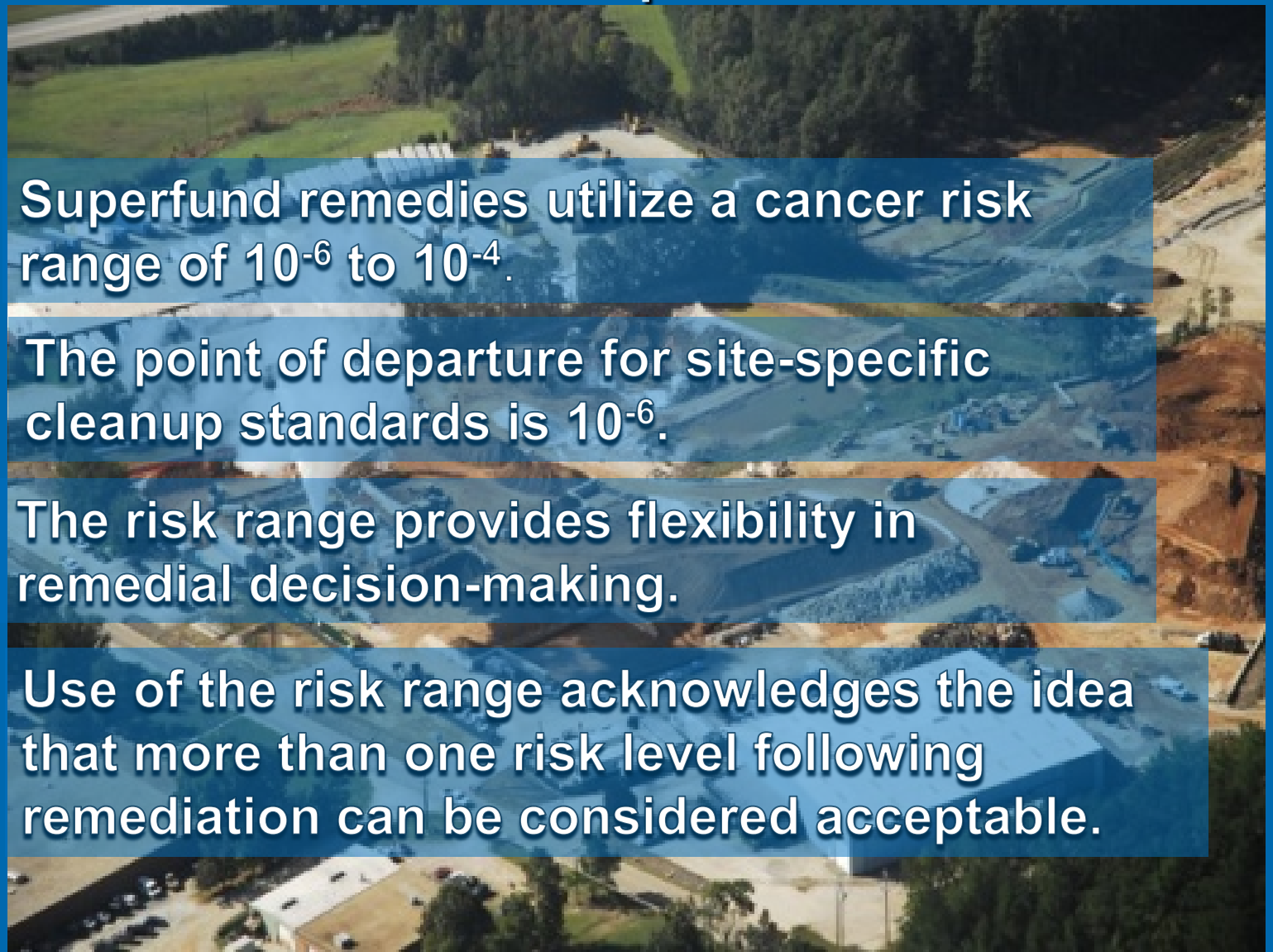
Incremental Risk

1 drop = 1 x 10^{-6} incremental risk



4 gallons = ‘baseline risk’

Regulatory perspectives on acceptable risk - Superfund



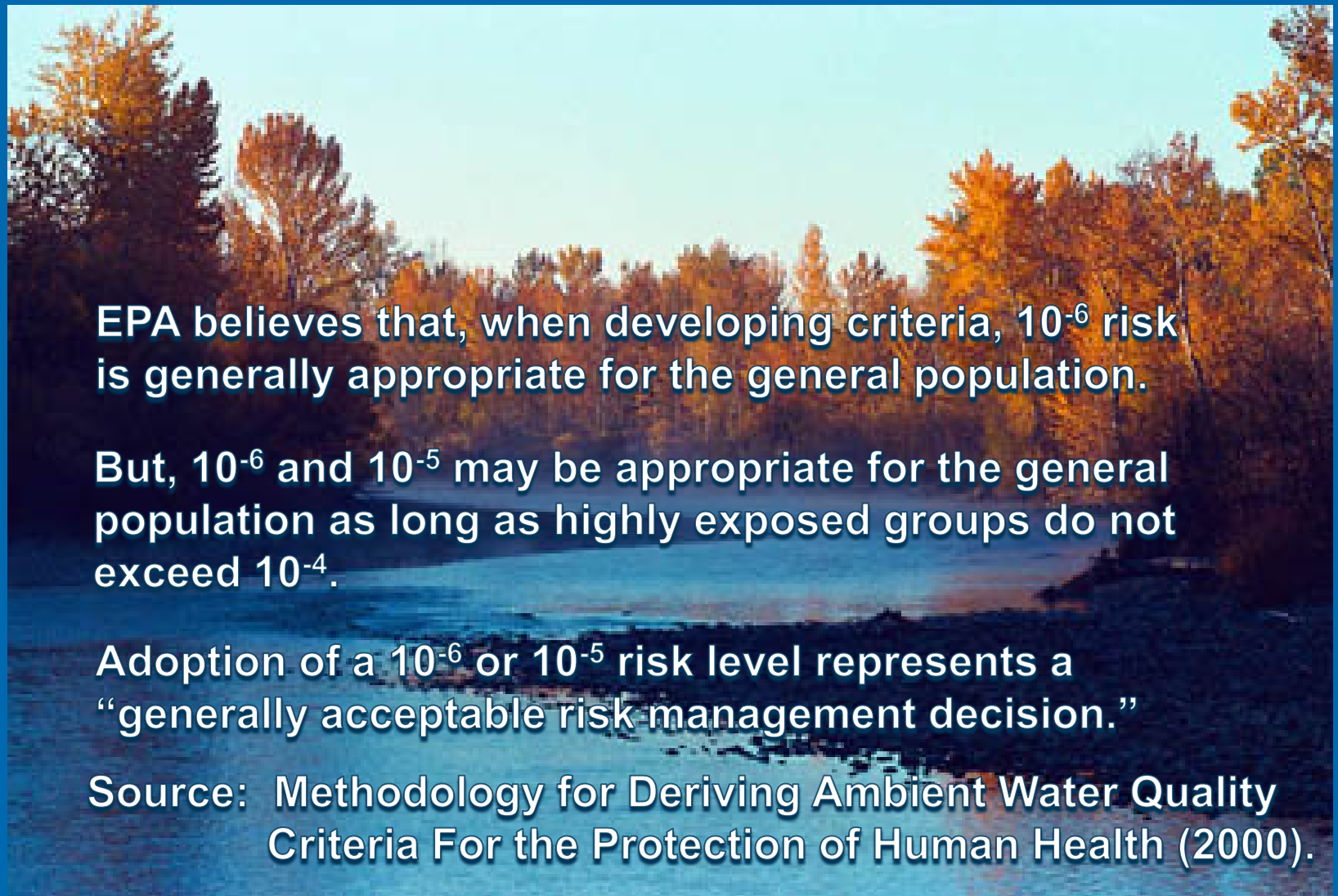
Superfund remedies utilize a cancer risk range of 10^{-6} to 10^{-4}.

The point of departure for site-specific cleanup standards is 10^{-6}.

The risk range provides flexibility in remedial decision-making.

Use of the risk range acknowledges the idea that more than one risk level following remediation can be considered acceptable.

Regulatory perspectives on acceptable risk - water quality criteria



Comparing risk levels

Are Washington's proposed water quality standards based on 175 g/day FCR and 10^{-5} risk protective?

Compared fish consumption rates included:

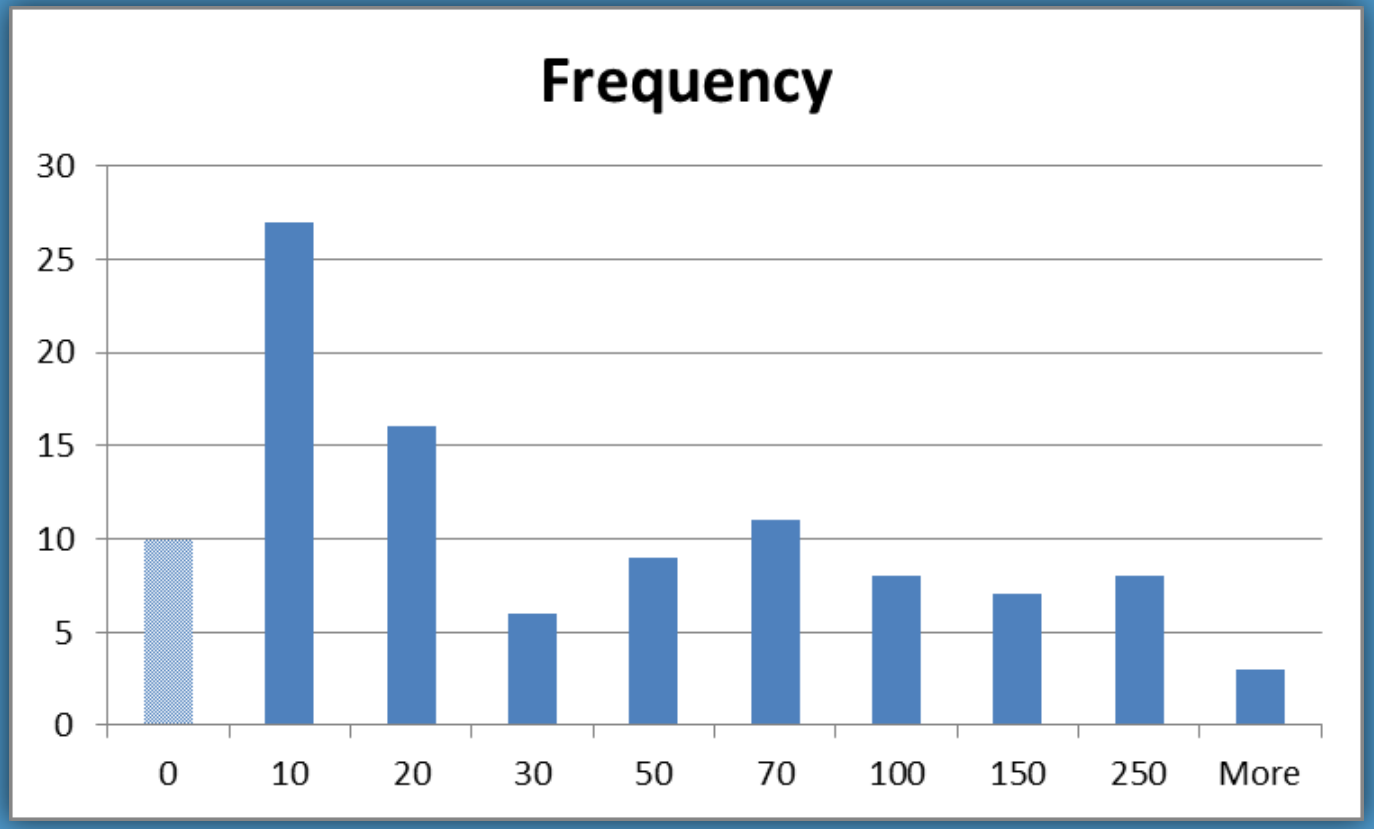
- Suquamish tribal members: mean FCR of 214 g/day (1.2×10^{-5})
- Squaxin Island 90th percentile FCR of 206 g/day (1.2×10^{-5})
- Tulalip tribal members 90th percentile FCR of 193 g/day (1.1×10^{-5})
- Recreational fishers upper percentile of 200-250 g/day (1.1 to 1.4×10^{-5})
- Japanese 95th percentile FCR of 188 g/day (1×10^{-5})
- Korean 95th percentile FCR of 230 g/day (1.3×10^{-5})

Source: http://www.irehr.org/issue-areas/treaty-rights-and-tribal-sovereignty/583-washington-department-of-ecology-caters-to-big-business

General Population Distribution

Hypothetical example:

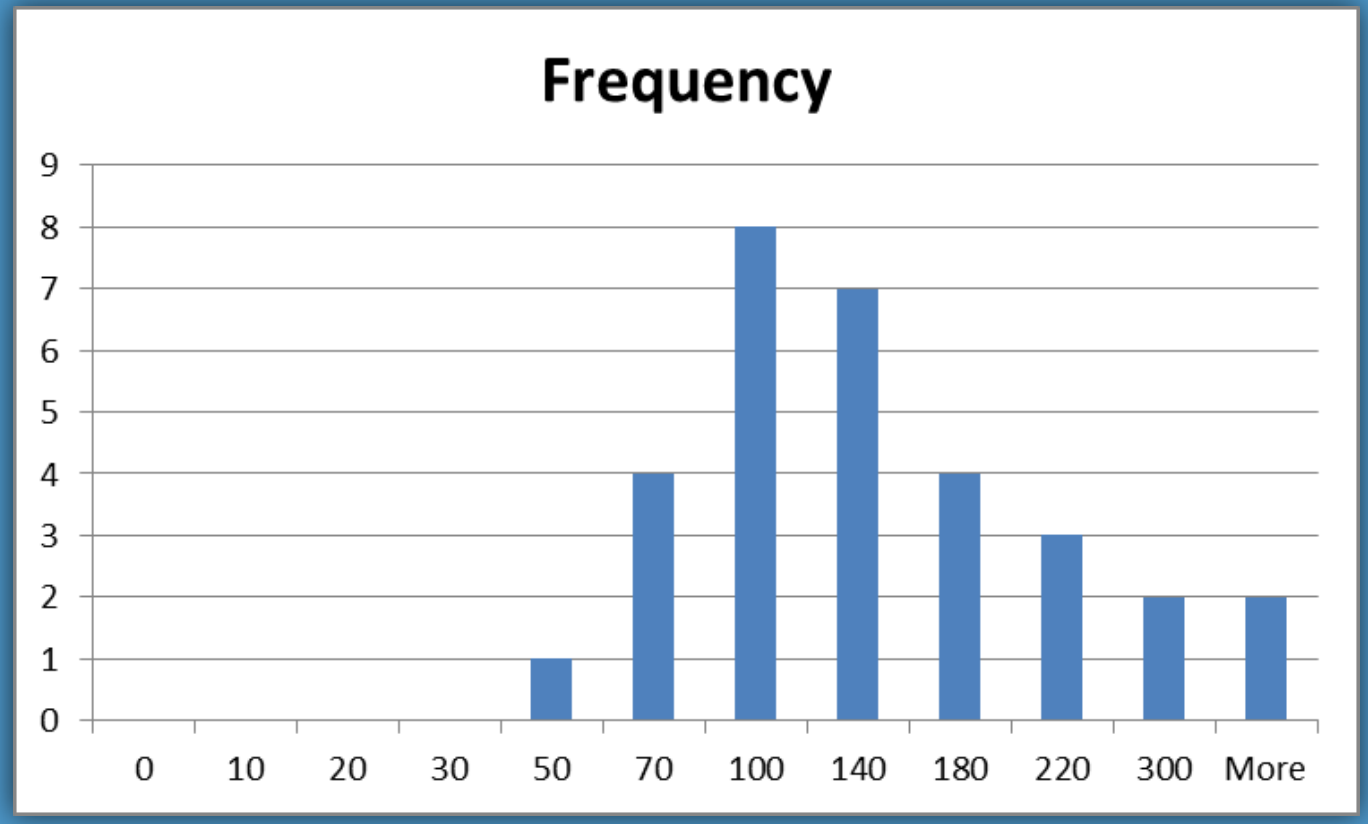
ALL data	
Median	20.0
Mean	52.7
90th %ile	144.6
95th %ile	186.6
99th %ile	343.1



Targeted Subpopulation Distribution

Hypothetical example:

Top 30	
Median	112.0
Mean	140.4
90th %ile	248.0
95th %ile	321.5
99th %ile	377.9



A comparison…

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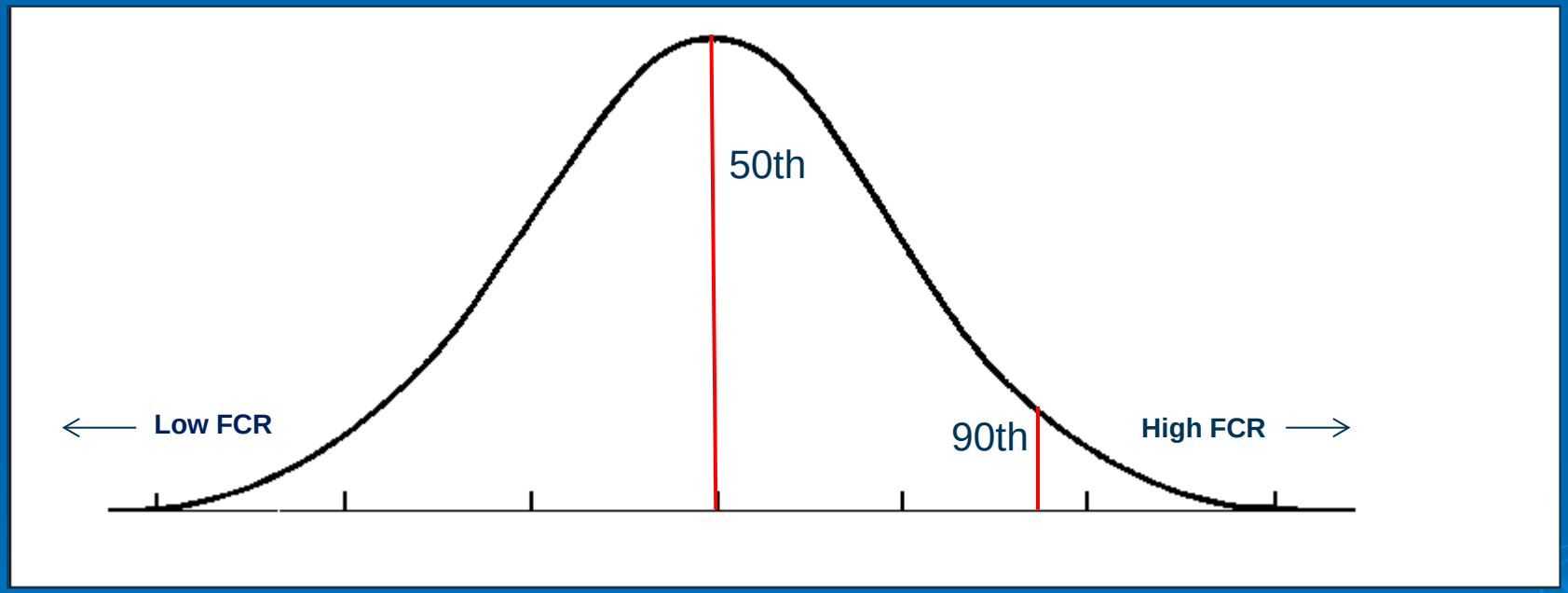
If 1×10^{-6} risk is set at the 90th percentile of the general population, risk for the 90th percentile of the subpopulation is 1.7×10^{-6}.

Cumulative effects

- Water quality criteria are chemical-specific, and do not account for combined effects of exposure to multiple chemicals.
- Additional exposure occurs to chemicals that do not have criteria.
- Criteria only apply to chemicals that have permitted (point source) discharges. They don't apply to nonpoint sources.
- These are reasons to be conservative (more protective) in criteria development.

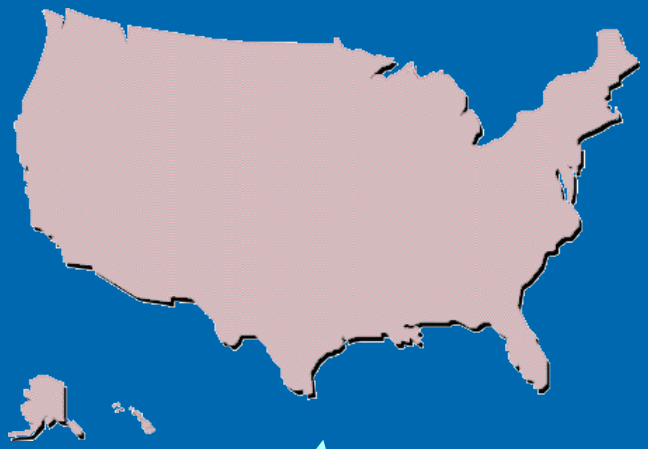
Population FCR Distribution



What can we accomplish with water quality criteria?

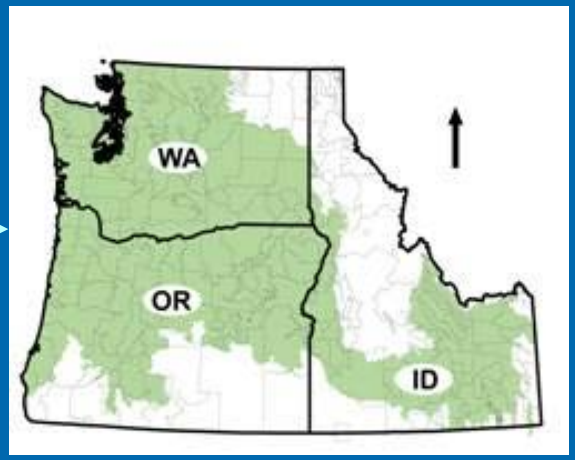
- In developing human health criteria, the goal is to be health-protective.
- Problems can arise when criteria are below detection limits, or background levels.
- In some cases, adopting stricter (lower) criteria is not likely to lead to significantly lower levels of contaminants in fish. Example: mercury.

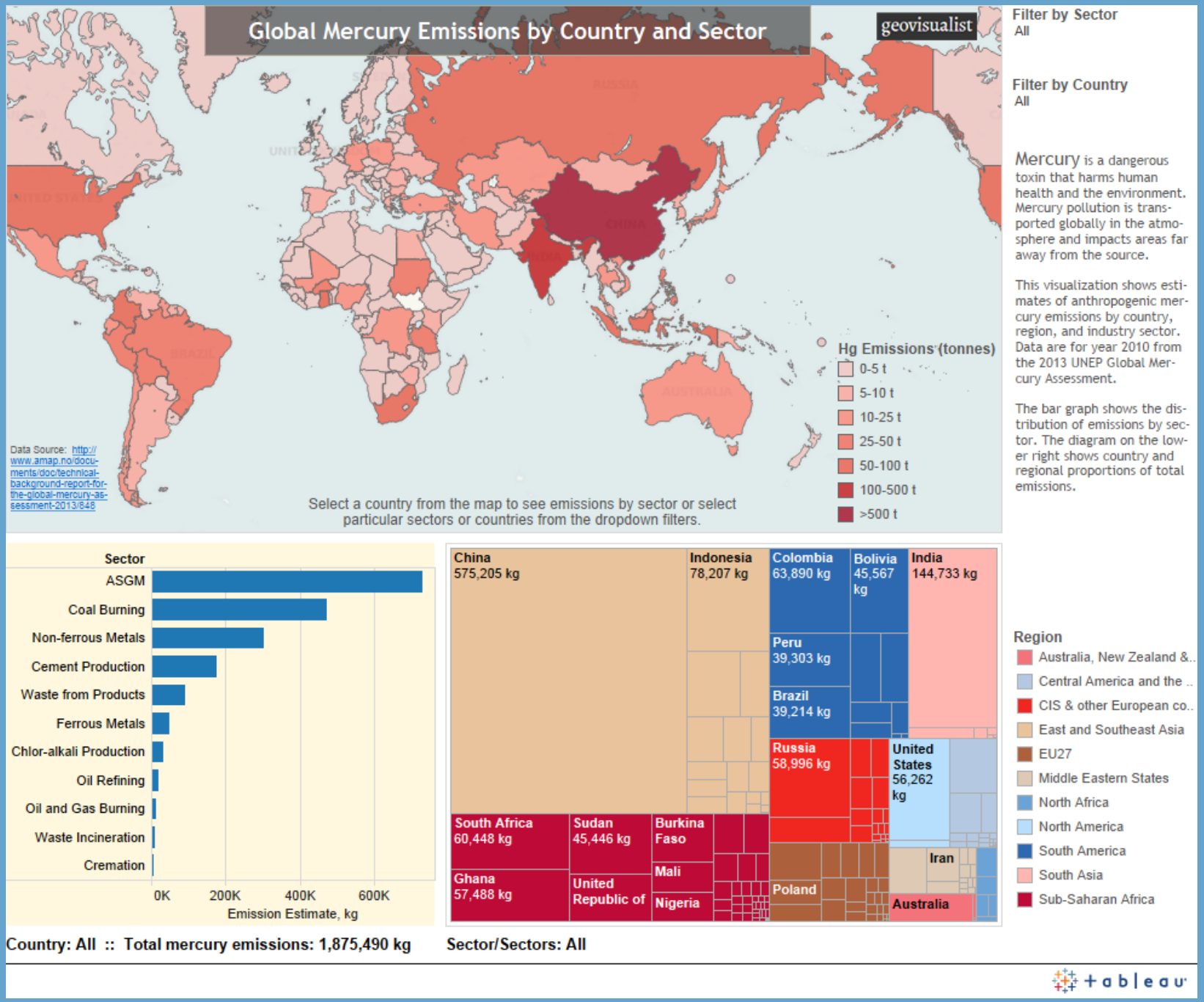
Location of most air sources of mercury:



… than here or here

More from here





Source: http://geovisualist.com/2014/05/09/updated-global-mercury-pollution-viz-and-graphics/

Voluntary and involuntary risk

- Fish are good for us, but mercury is not.
- We can perform a cost-benefit analysis when we eat fish that contains mercury.
- If we choose to eat large quantities of fish with high mercury levels, we are voluntarily exposing ourselves to greater risk.
- The presence of mercury in fish is not voluntary, but our consumption decisions are.

ALARA

- ALARA is a radiation safety principle as well as a regulatory requirement in the nuclear industry.
- It stands for “As Low As Reasonably Achievable.”
- It means making every reasonable effort to maintain radiation exposures as low as possible.
- This concept has some relevance to development of water quality criteria.
- However, there may be disagreement about what is reasonable, and what is achievable.

Conclusions

- Consuming fish has known health benefits and significant cultural importance.
- There are limits to what we can accomplish with water quality criteria.
- We have to make a number of risk management decisions.
- The decisions are informed by FCR data as well as policy considerations.
- The challenge is to develop criteria that are both health protective and achievable.