Water Quality Criteria for the Protection of Human Health

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Negotiated Rulemaking

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What We Will Talk About Today

- Human Health-based Criteria (HHC)
- Exposure basis for HHC
- Details of HHC calculation
- Use of HHC in Clean Water Act programs
- Fish consumption studies
- DEQ's review of available studies
- Issues in choosing a regulatory fish consumption rate (FCR)

What are Water Quality Standards?

Water Quality Standards (WQS) define the water quality goals for state/tribal waters.

WQS are set to protect public health or welfare, enhance the quality of the water and serve the purposes of the Clean Water Act (CWA).

Provide a basis for limiting the discharge or release of pollutants under the (CWA).

See 40 CFR 131.2

WQS are composed of …

1. Beneficial uses – include aquatic life, recreation in and on the water, drinking water, etc…

2. Criteria – minimum levels of water quality that fully protect uses

- Numeric
- Narrative

3. Antidegradation Policy - ensures existing and designated beneficial uses are maintained and protected, and that waters of high quality are not degraded unless necessary and in the public interest

Also: Other policies affecting application and implementation, such as mixing zones, low flows, and variances.

Two Sets of HH Criteria

There are 2 sets of human health criteria recommended by EPA

They are based on two different exposure scenarios

1) Consumption of fish
2) Consumption of fish & ingestion of water

Exposure Basis for HH Criteria

- Eating 17.5 g/day of fish *
- Drinking 2.0 L/day of water

Various Consumption Rates

6.5 g/day = ~7 ounce meal once a month

17.5 g/day= ~4 ounce meal once a week

142 g/day = ~5 ounce meal every day

175 g/day = ~6 ounce meal every day

Association of HH Criteria & Uses

- Idaho applies criteria based on …
  - Consumption of fish (aka Fish only) to: water designated or protected for recreation use
  - Consumption on fish & drinking of water to: waters designated as domestic water supply

USE OF WATER	Human Heath Criterion	
RECREATION	Fish only	
DOMESTIC WATER SUPPLY		Water & fish

Your Dose of a Contaminant

- Is the sum of
  - Concentration of a contaminant in water x amount of water you drink

AND

  - Concentration of a contaminant in fish x amount of fish you eat

But most HH criteria are expressed as concentration in water

=

So how do we equate fish to water?

Bioaccumulation Factor

- Ratio of concentration in fish to concentration in water (units of L/Kg)
- No bioaccumulation = BAF of 1
- BAFs can reach thousands for highly bioaccumulative compounds

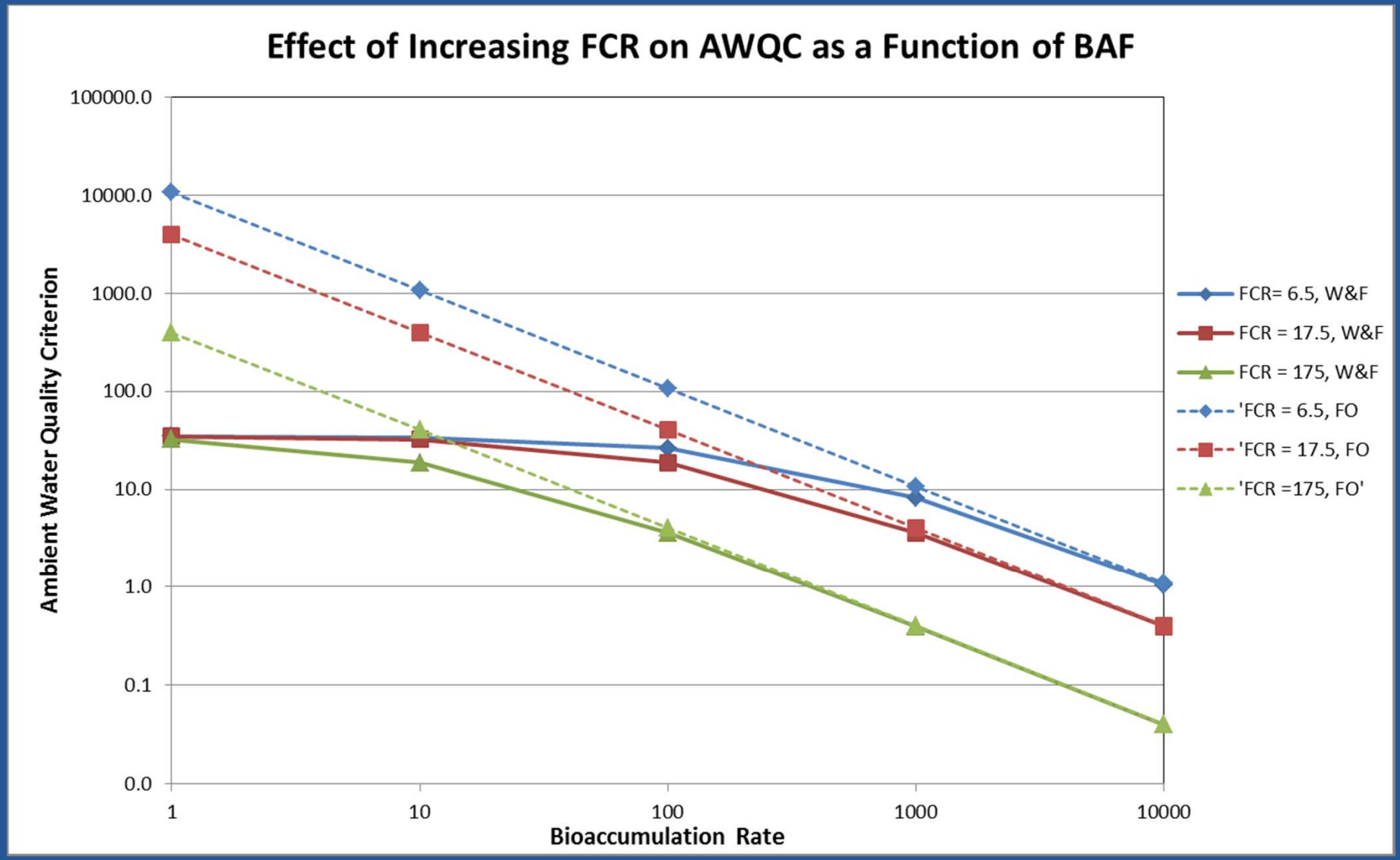
Why Am I Telling You This?

- Because if bioaccumulation is low most of your exposure comes from drinking water
- But if bioaccumulation is high most of your exposure may come from eating fish

BAF = 1	2.0 L H_2O	+	0.0175 L, fish
BAF = 100	2.0 L H_2O	+	1.75 L, fish
BAF = 10,000	2.0 L H_2O	+	175 L, fish
BAF = 1,000,000	2.0 L H_2O	+	17,500 L, fish

And Because …

- A change in fish consumption rate (FCR) used in HH criteria calculation affects the two types of criteria differently
- For fish only criteria the effect is proportional
- For water + fish criteria the effect is dependent on how strong is bioaccumulation – at low BAF, FCR matters little to criterion value


Effect of Increasing FCR on AWQC as a Function of BAF
Ambient Water Quality Criterion
100000.0
10000.0
1000.0
100.0
10.0
1.0
0.1
0.0
1
10
100
1000
10000
Bioaccumulation Rate
FCR= 6.5, W&F
FCR = 17.5, W&F
FCR = 175, W&F
'FCR = 6.5, FO
'FCR = 17.5, FO
'FCR =175, FO'

Example Criteria – FCR = 17.5 g/d

Compound	CAS Number	Water & organisms (µg/L) C1	Organisms only (µg/L) C2	BCF
Antimony	7440360	5.6	640	1
Benzene	71432	2.2	51	5.2
Carbon Tetrachloride	56235	0.23	1.6	18.75
2-Chlorophenol	95578	81	150	134
Fluoranthene	206440	130	140	1150
PCBs	n	0.000064	0.000064	31200

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

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

Input Variables

BW = *Human Body Weight* (adult = 70 kg = 154 lbs)

DI = Drinking water Intake (2.0 L/day)

FI = *Fish Intake, aka consumption rate (17.5g/day)*

BAF = *Bioaccumulation Factor* (L/Kg), chemical specific

RfD = Reference Dose, non-carcinogens (mg/Kg-day)

RsD = Risk specific Dose, for carcinogens (mg/Kg-day)

RSC = Relative Source Contribution

BCF vs. BAF, a Wrinkle

- BCF = bioconcentration, from water only to fish
- BAF = bioaccumulation, from water & food to fish
- BAF is more real & typically higher than BCF
- Thus EPA's HH Criteria guidance calls for BAF
- Mostly all we have available is BCF …. because that is what we can measure in the laboratory

Application of Surface Water Criteria

- To determine if a waterbody is impaired, needs a TMDL
- To derive load capacity and set allocations in a TMDL, so as to meet WQC
- To set effluent limits for point sources so as to meet WQC, WQBELs

Acrolein: Proposed criteria revisions

- Idaho previously used the RfD that was in the IRIS database as of May 17, 2002.
- This previous value was 0.02 mg/Kg-day.
- EPA revised the RfD in June 2003. Current value: 0.0005 mg/Kg-day.
- The critical effect observed in an oral exposure rat study was decreased survival.

Phenol: Proposed criteria revisions

- Idaho previously used the RfD that was in the IRIS database as of May 17, 2002.
- This previous value was 0.6 mg/kg-day, based on a 1983 developmental toxicity study.
- EPA revised the phenol RfD in September, 2002. Current value: 0.3 mg/kg-day.
- The new RfD is based on a 1997 developmental toxicity study.

Copper: Proposed water + organism criterion

- Currently Idaho does not have human health criteria for copper.
- EPA recommended “water + organism” criterion is 1,300 µg/L.
- This concentration is the drinking water criterion under SDWA.
- The criterion does not utilize a fish consumption rate, as copper health risk is primarily from drinking water.

FISH CONSUMPTION RATES

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Why have FCRs Become an Issue?

- EPA (2000) published a default national rate, but recommends using regional or local data
- Many regional studies over the past 20 or so years have documented higher fish consumption by some sub-groups
- This has brought protectiveness of HH criteria based on the national default FCR into question

Where Does FCR Data Come From?

- Dietary recall surveys
  - Telephone
  - Mail
  - In-person interview
- Diaries
- Creel census (angler surveys)

How is a FCR Calculated

- Frequency of consumption X meal size
- Frequency is culture/region dependent
- Meal size is age and weight dependent
- Units? g/day or mg/Kg-day

Character of Surveys

- May be national, regional or State/local
- Data may be collected for different purposes
  - Fishery management
  - Health advisories
  - Risk assessment
  - Criteria development
- Quality and specificity of survey information varies

Available FC Surveys DEQ Reviewed

- DEQ evaluated 19 surveys for their quality
- 1 was national (EPA 2002)
- 2 were local to Idaho, or had some Idaho data (ASTDR 1989, CRITFIC 1994)
- Remaining 16 were regional – that is AK, OR, or WA

Survey Quality Factors

1. Type of survey (e.g. angler or consumption)
2. Were methods reported
3. Was quality assurance/control discussed
4. Was survey representative of population surveyed
5. How did survey deal with seasonality
6. Details on fish species, source, and prep
7. Peer Review

Quality Review Results

	Quality of Survey							
Report	**FC**	**Methods Reported**	**QA/QC**	**Representative Sample**	Annual	Details on species & prep.	**Peer review**	Overall Rating
Adolfson Associates, 1995	1	1	1	1	0	1	0	9
ATSDR, 1989	1	1	0	1	0	1	0	7
CRITFIC, 1994	1	1	1	1	1	1	1	12
Harper et al, 2002	1	1	0	0	1	1		6
IDM Consulting, 1997	0	1	1	1	1	1	0	8
Landolt et al, 1985	0	0	0	0	1	1	1	4
Landolt et al, 1987	0	1	1	1	0	1	1	9
Lummi Tribe 2012	1	1	1	1	1	1	1	12
Mayfield et al, 2007	1	1	0	0	1	1	1	8
McCallum 1985	1	0	0	0	1	0	0	3
Pierce et al, 1981	0	1	0	0	0	1	0	3
Ridolfi, 2007	1	1	1	0	1	1	0	8
SRHD, 1998	0	1	0	1	1	1	0	6
Suquamish Tribe, 2000	1	1	1	1	1	1	1	12
Toy et al, 1996	1	1	1	1	1	1	0	10
USEPA, 1999	1	1	1	1	1	1	1	12
USEPA, 2002	1	1	1	1	0	1	1	11
WADOH, 1991	1	1	0	1	0	1	1	9
WADOH, 1997	1	1	0	1	0	1	1	9

Six Surveys Scored 10 or Better in our Quality Review

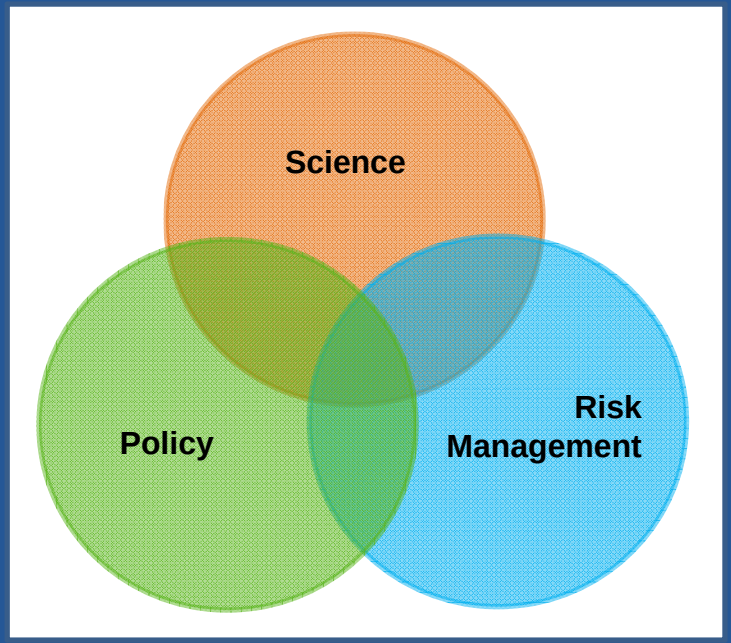
- ✓CRITFIC, 1994
- ✓Lummi Tribe, 2012
- ✓Suquamish Tribe, 2000
- ✓Toy & others, 1996
- ✓USEPA, 1999
- ✓USEPA, 2002

Factors in Relevance to an Idaho FCR

- ✓ Geographic scope, area
- ✓ Similarity of population surveyed to Idaho
- ✓ Does survey provide information on all people?
- ✓ Does survey break consumption down by species?
- ✓ Does survey identify source of fish?
- ✓ Are FCR's adjusted for body weight?

An Ideal FC Survey Would …

- Provide the distribution of long-term estimates of consumption rates
- Account for seasonality
- Characterize consumption for the general population as well as groups that consume at higher rates
- Identify all sources of fish, by species



CHOOSING A REGULATORY FISH CONSUMPTION RATE

Science, Policy & Risk Management

All three are part of criteria development

- Science provides us basic information
- Policy tells us how to apply that information
- Risk management is a matter of publicly weighing options and making a decision

Transparency

"…conclusions drawn from the science are identified separately from policy judgments and risk management decisions, and that the use of default values or methods, as well as the use of assumptions in risk assessments, are clearly articulated."

(from: USEPA. 2000. *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000)*, EPA-822-B-00-004, page 2-3)

Science

"…the extraction of data from toxicological or exposure studies and surveys with a minimum of judgment being used to make inferences from the available evidence."

Science Questions

- How much fish do people eat?
- How long do people live?
- How much do they weigh?
- What dose of a chemical causes an effect?

Science Policy

" … the decision to use animal effects as surrogates for human effects involves judgment on the part of the EPA (and similarly, by other agencies) as to the best practice to follow when human data are lacking. Such a decision is, therefore, a matter of science policy."

Science Policy Questions

- What effects concern us?
- The use of animal studies to predict effect in humans
- The selection of uncertainty factors when translating animal effect to an RfD
- Substituting BCF for BAF

Risk Management Decisions

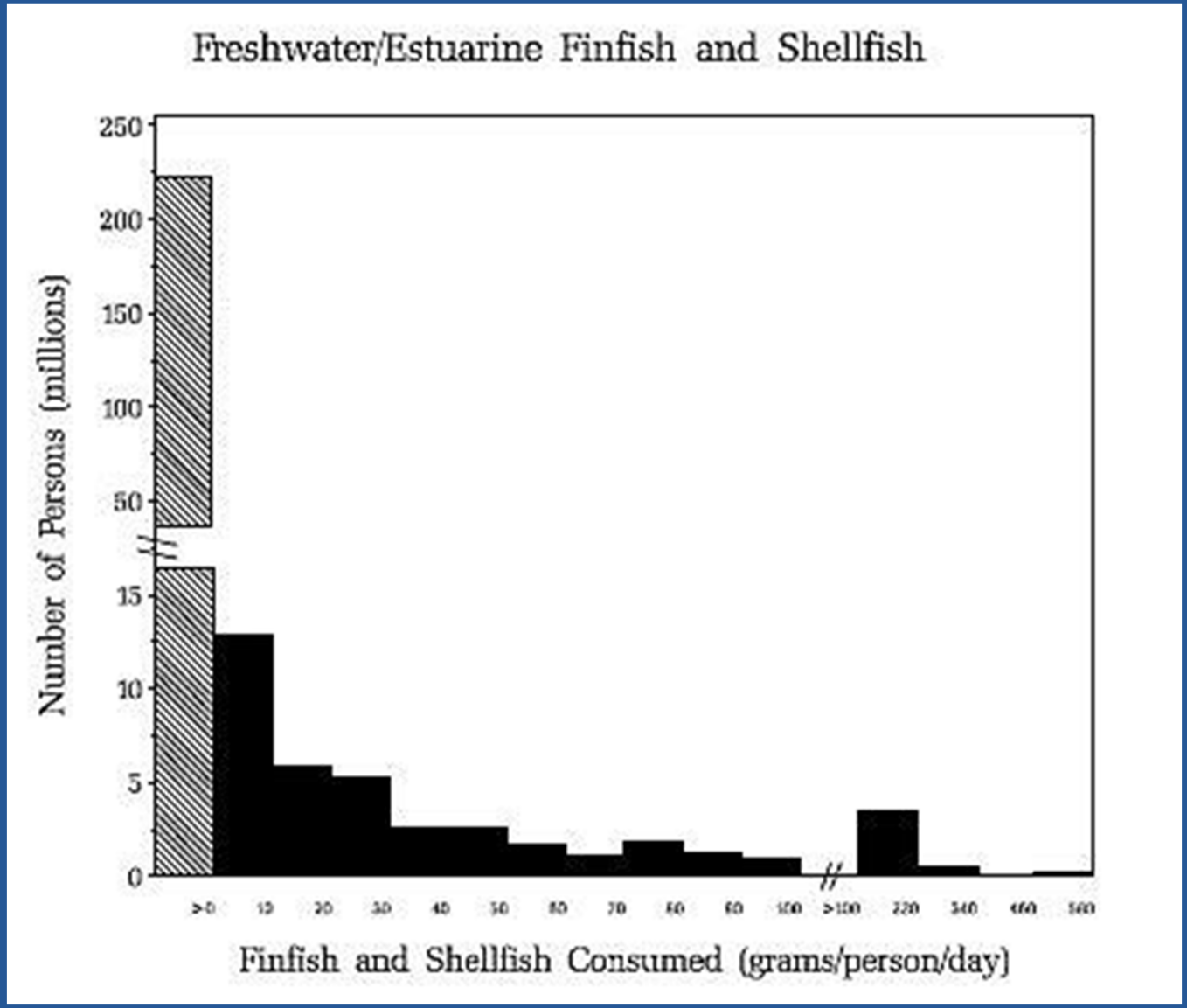
"The choice of default fish consumption rates for protection of a certain percentage (i.e., the 90th percentile) of the general population is clearly a risk management decision."

Decisions in Design of a FC Survey and Selection of a Regulatory FCR

1. Fish consumers or both consumers & non-consumers
2. Whole population or targeted sub-population
3. Inclusion of market fish
4. Inclusion of anadromous fish
5. Selection of a level of protection – what does it mean to be protected?

Fish Consumers vs Non-consumers

- Only fish consumers are exposed
- How well is it known who consumes?
- What do assumptions, data trimming, do to distribution and thus probabilities?
- How big a difference does it make?


Freshwater/Estuarine Finfish and Shellfish
Number of Persons (millions)
250
200
150
100
50
15
10
5
0
Finfish and Shellfish Consumed (grams/person/day)

Targeted Group

- Survey of a high-rate group, those at greater risk due to higher exposure
- How is it known they are a high-rate group?
- How do you put this in context of broader population?

Inclusion of Market Fish

- Your exposure comes from all sources
- How do we reconcile this with the fact we are talking about water quality criteria – which address only one source?
- Use of Relative Source Contribution?

Quotes from EPA 2000

"The Agency has recently developed the Relative Source Contribution (RSC) Policy for assessing total human exposure to a contaminant and apportioning the RfD among the media of concern, published for the first time in this Methodology."

"AWQC for the protection of human health are designed to minimize the risk of adverse effects occurring to humans from chronic (lifetime) exposure to substances through the ingestion of drinking water and consumption of fish obtained from surface waters."
[emphasis added]

Inclusion of Anadromous Fish

- Undoubtedly a source of exposure
- But how do we reconcile this with the fact that most of their body burden is acquired at sea – that is, outside Idaho's regulatory jurisdiction?
- Monitoring implications?

Level of Protection

- What level of protection is required or desired?
- Who decides this?
- Every sub-group has a different risk
- If we don't know patterns of fish consumption for all how can we communicate differences in risk?
- Carcinogens versus non-carcinogens

More on Level of Protection

- For carcinogens EPA specifies that AWQC may not result in risk greater than 1 in 100,000 for the general population AWQC and may not result in risks for high fish consuming groups exceeding 1 in 10,000.
- For non-carcinogens EPA's HH Methodology is silent on the protectiveness of the general population AWQC for high fish consuming groups.

QUESTIONS & DISCUSSION