Information on the Fish Consumption Rate (FCR) input to the criteria equations.

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Human Health Criteria and Implementation Tools Rule-makings

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Additional Information

Thank you to the toxicologists and risk assessors, our expert resource group, who are attending today.

Abbreviations used in today's presentations:

HHC = Human health-based criteria for surface waters

WQS = Surface Water Quality Standards (WAC 173-201A)

NTR = 1992 National Toxics Rule (40CFR131)

CWA = Clean Water Act

RfD = Reference dose (specifically discussed at Policy Forum #5)

RSC = Relative source contribution

FCR = Fish consumption rate

BW = Body weight

DWI = Drinking water intake

BCF = Bioconcentration factor

BAF = bioaccumulation factor

HQ = Hazard quotient

What do the different FCR numbers mean? A basic refresher.

We talk about many different FCRs when considering HHC development, for example:

6.5 g/day is the **average of the per capita distribution** (the NTR FCR, based on national data).

17.5 g/day is the **90th percentile of the per capita distribution** – (EPA's recommended 2000 FCR used for national HHC calculation, based on national data.

0 g/day is the **median of the per capita distribution** from EPA 2000 based on national data.

Each of these FCRs includes information about (1) a population, and (2) a specific statistic of that population.

Why is it important to know specifically what these numbers represent?

The FCR values help define the specific group that the additional cancer risk level or HQ are applied to in criteria calculation.

The FCR input value has a big effect on the criteria value outcomes (as do the cancer risk level and the RSC). The greater the FCR, the more protective and stringent the criteria concentrations are.

Different populations can be sampled to develop a data set of FCRs.

Examples:

General population: This includes everyone

Per capita: This is the population that is sampled for a particular parameter. This could be all people sampled for fish consumption, yearly income, education, weight, etc.

For purposes of FCR studies (or other dietary studies that support FCR development), per capita data are often further subdivided by age, sex, region, consumers and non-consumers, etc…

Consumer-only intake rates refer to the quantity of finfish and shellfish consumed by individuals during the survey period. Does not include non-consumers.

Highly-exposed sub populations:

These include sub-population that eat large amounts of fish/shellfish. These sub-populations can include recreational fishers, subsistence fishers, tribal populations, etc. These groups can be specifically targeted for sampling in FCR studies.

Fish Consumption Rate Data

For HHC development purposes, the data set from a FCR study or other type of food survey can be used as:

- the basis of a frequency distribution from which a specific FCR can be chosen (deterministic approach); or
- the FCR distribution can be used as an input to a probabilistic analysis.

What is a Frequency Distribution: a set of values and their frequency (how often each value occurs). (*Will show these in later slides*)

Date sets from different studies can be combined if the data are comparable or can be transformed to be comparable.

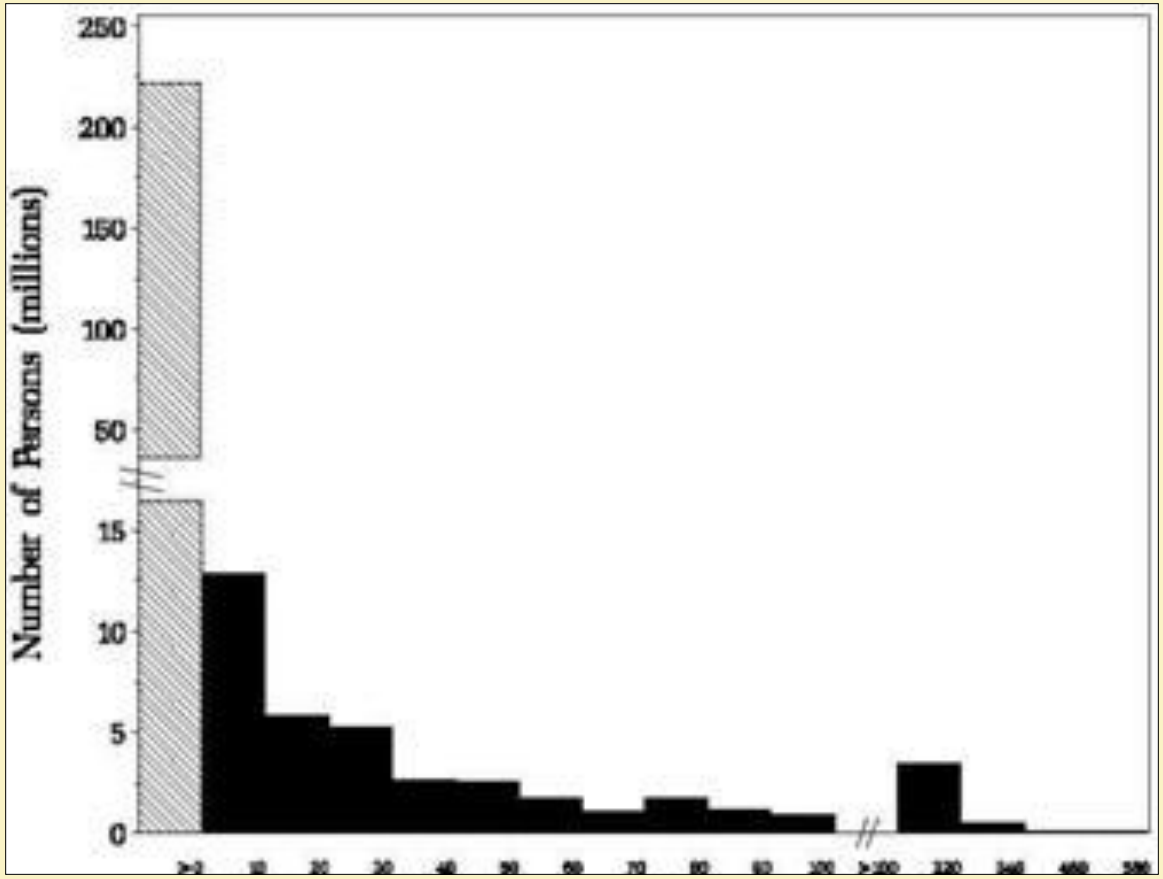
For example, for estimates based on national data, the methodology developed by the National Cancer Institute provides improved accuracy for episodically consumed foods: allows better comparison with longer term studies. (Refer to earlier Lon Kissinger presentation).

How are FCR data displayed?

Frequently a histogram or bar chart.

For example, USEPA 2002: Histogram of uncooked fish consumption for U.S. Population: Freshwater/Estuarine and shellfish.

Freshwater/Estuarine Finfish and Shellfish



Finfish and Shellfish Consumed (grams/person/day)

Crosshatch = Persons reporting zero consumption

Black = Persons reporting > zero consumption

Figure from: *USEPA 2002. Estimated per capita fish consumption in the United States.* EPA-821-C-02-003. (Page 5-8, Section 5.1.1.1, Figure 1)

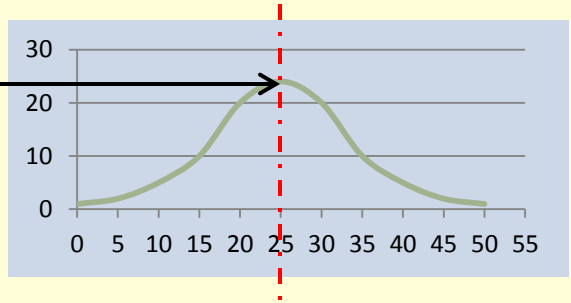
A statistic specifies a specific value within a distribution.

The statistics that are frequently used for FCRs are:

Arithmetic mean (= "average")

Median (= 50th percentile)

Median and average are measures of "central tendency." They are both common ways of characterizing a distribution by looking at a "central" value.



Percentile –indicates the value below which a given percentage of observations in a group of observations fall. For example, the 20th percentile is the value (or score) below which 20 percent of the observations may be found.

The arithmetic mean is frequently called "the average"

There are different kinds of means, e.g., arithmetic means, geometric means.

The arithmetic mean (average) is calculated by *adding together all the observed values and dividing by the number of observations.*

Example:

Sample distribution for the number of miles jogged per month by each of 7 individuals:

0	16	18	20	33	48	68

Using the data set above, the average for the data set is calculated as follows:

$$\frac{0 + 16 + 18 + 20 + 33 + 48 + 68}{7} = \frac{203}{7} = 29 \text{ miles jogged per month}$$

Median

Median = 50th percentile = whatever value splits a distribution in half.

Example: Sample distribution for the number of miles jogged per month by each of 7 individuals.

0	16	18	20	33	48	68

Median = **20**

Maximum = 68
Minimum = 0
Range = 0 to 68
Average = 29
Median = 20

If you remove one of the observations…

0	16	18	20	33	48

Median = the value half-way between 18 and 20 = **19** (even if 19 does not exist in the data set)

Also note the maximum, the minimum, and the range, as shown on the upper data set.

Percentiles

Percentiles are frequently used to describe a data set.

The percentile indicates the value **below** which a given percentage of observations in a group of observations fall.

For example:

The 20th percentile is the value below which 20 percent of the observations may be found.

The 90th percentile is the value below which 90 percent of the observations may be found.

Percentiles split a set of ordered data into hundredths.

The median is the 50th percentile (half the data points below and half above).

Examples of percentiles:

In a distribution of 100 data points, all consecutive whole numbers from 1 to 100 (sample size = 100), and the desired percentile is…	The percentile value is:	Number of data points above the percentile	Number of data points below the percentile
95th	95	5	95
90th	90	10	90
75th	75	25	75
50th (median)	50	50	50
20th	20	80	20
5th	5	95	5
In a distribution of 400 data points, all consecutive whole numbers from 1 to 400 (sample size = 400), and the desired percentile is…	**The percentile value is:**	**Number of data points above the percentile**	**Number of data points below the percentile**
95th	380	20	380
90th	360	40	360
75th	300	100	300
50th (median)	200	200	200
20th	80	320	80
5th	20	380	20

Percentiles (cont.)

A smaller data set will have fewer values below and above the percentile than a larger data set.

FCR data are derived from surveys that sample many different sized populations, and have different sample sizes.

Sample size is generally taken into account when different data sets are compared.

FCR data are frequently presented as averages, medians, and various percentiles.

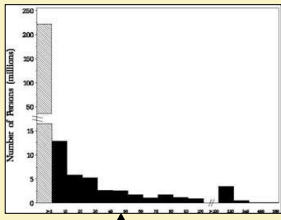
“Bell shaped” curve and the average, median, and 90th percentile

The graph below is not perfectly “normal”, but approximates the bell-shaped curve from a normal distribution.

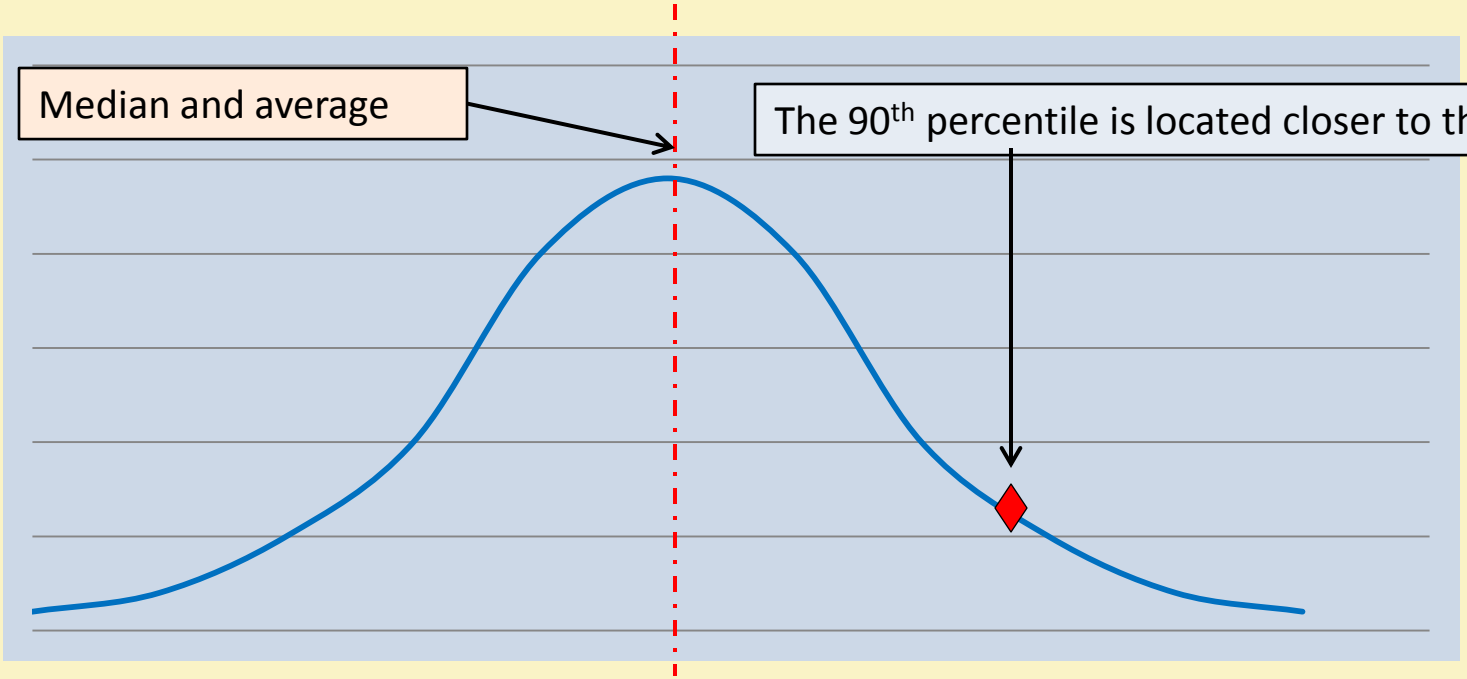
The normal distributions are a very important class of statistical distributions

All normal distributions are **symmetric** and have **bell-shaped density curves with a single peak**.
The curve below approximates a normal distribution.

In a normal distribution the median and average are the same number.



FCR distributions generally do not have a bell shape. See the histogram of the national FCR data in box above.

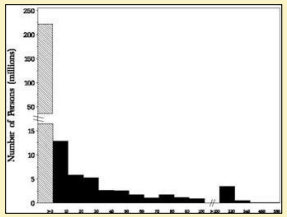


What about other type of distributions that are not bell-shaped?

Example: a distribution **with over half of the observations at zero**

Below is a *distribution* of 100 hypothetical observations (52 observations are zero)

(20 observations in each row, 5 rows X 20 = 100 observations)



The histogram of the national FCR data shown earlier has greater then half of the values at or near zero.

Median = the middle of the data set = **0**

0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
0	0	0	0	0	0	0	0	0	0	0	0	1	1	1	1	1	1	2	2
2	3	3	4	4	5	5	6	7	7	8	9	9	10	11	12	13	14	15	16
18	19	20	21	22	23	25	26	27	29	30	31	33	34	36	37	39	41	43	45

Average = $\frac{\text{sum of observations}}{\text{number of observations}} = \frac{772}{100} = \mathbf{7.72}$

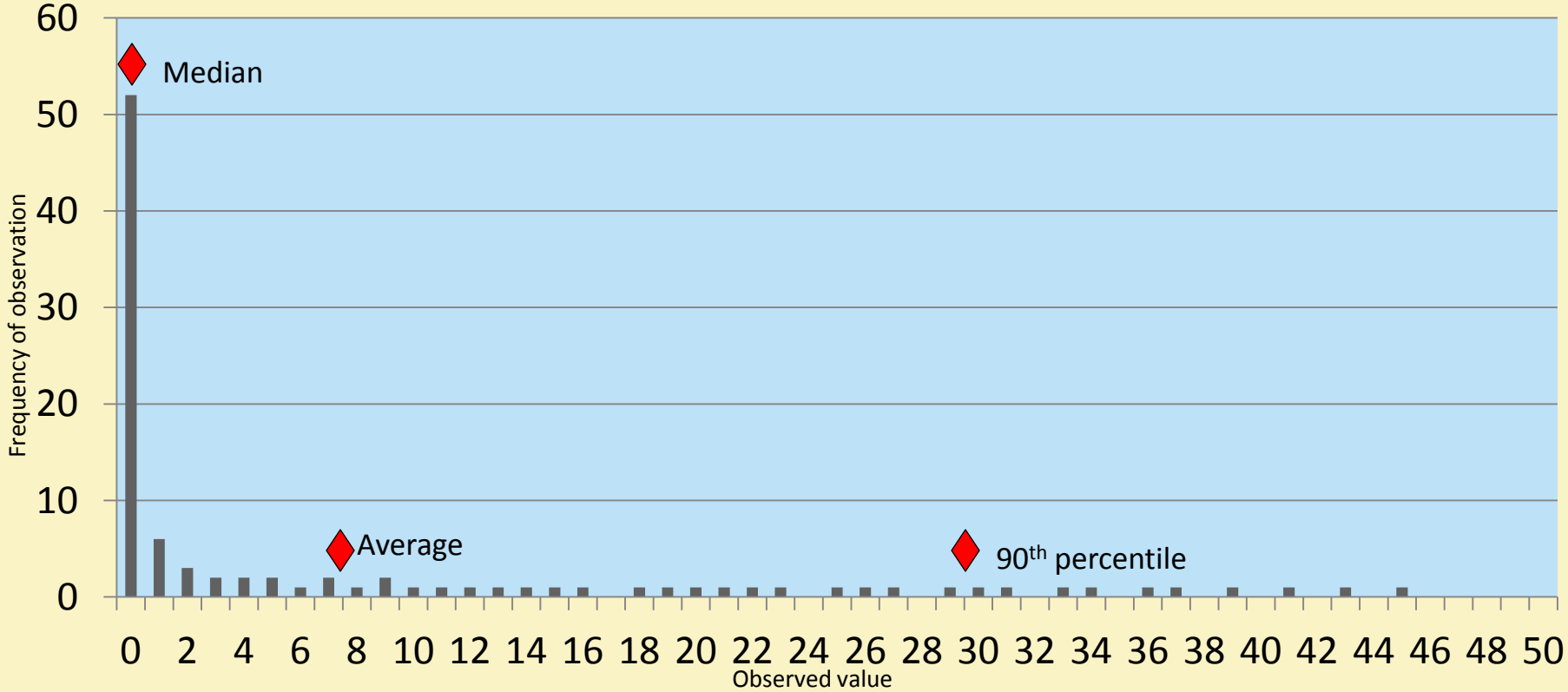
90th percentile = 90% of data below and 10% above = **29.5**

frequency distribution table from prior slide

Observation	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	18	19	20
Number of times observed	52	6	3	2	2	2	1	2	1	2	1	1	1	1	1	1	1	1	1	1

Observation	21	22	23	25	26	27	29	30	31	33	34	36	37	39	41	43	45
Number of times observed	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1

Median = the middle of the data set = 0	Average = $\frac{\text{sum of observations}}{\text{number of observations}} = \frac{772}{100} = 7.72$	90th percentile = 90% of data below and 10% above = 29.5



Another example:

Prior distribution **without zeros** **(this is similar to removing non-consumers from a data set of FCRs)**

(100 observations – 52 observations of zero = **48 remaining observations**)

Median = the middle of the data set = 12.5

1	1	1	1	1	1	2	2	2	3	3	4	4	5	5	6	7	7	8	9
9	10	11	12	13	14	15	16	18	19	20	21	22	23	25	26	27	29	30	31
33	34	36	37	39	41	43	45												

Average = $\frac{\text{sum of observations}}{\text{number of observations}} = \frac{772}{48} = \mathbf{16.08}$

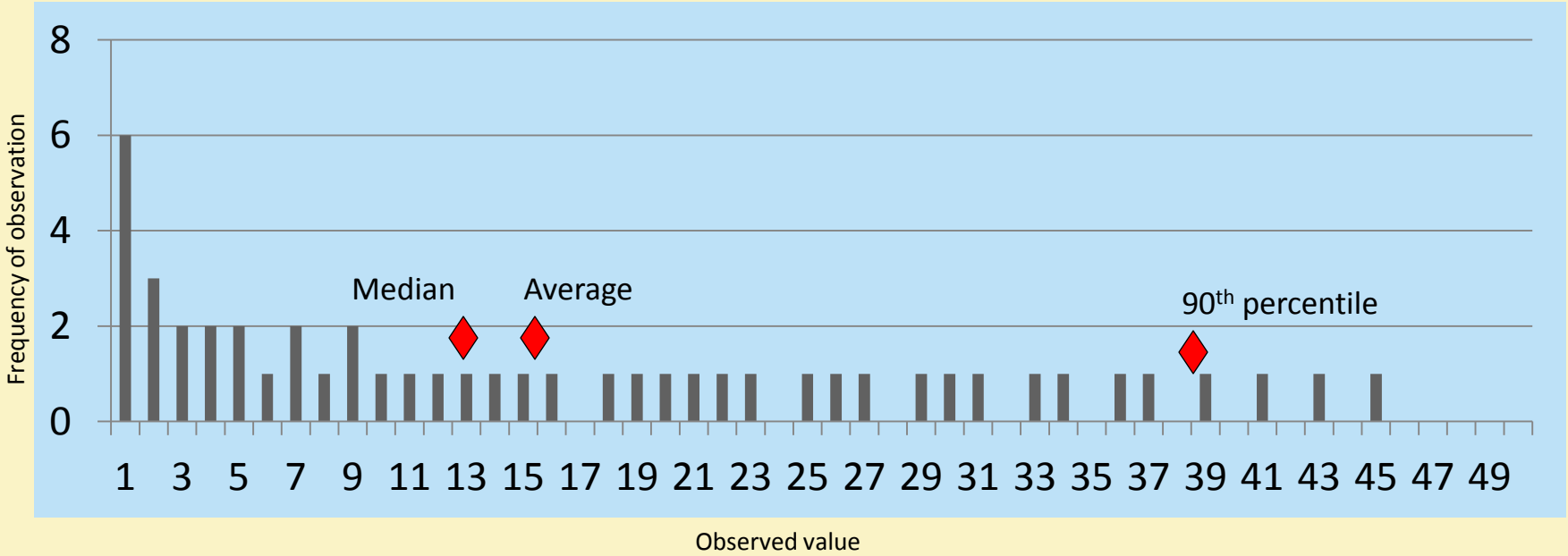
90th percentile = 90% of data below and 10% above = **38**

frequency distribution table from prior slide

Observation	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	18	19	20	22
Number of times observed	3	2	2	2	1	2	1	2	1	1	1	1	1	1	1	1	1	1	1

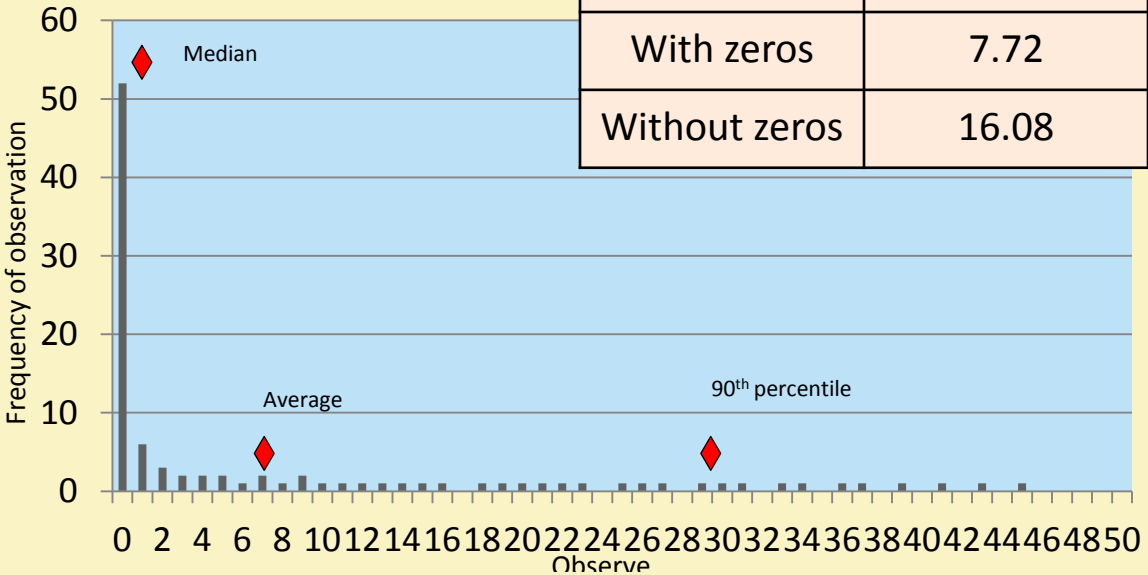
Observation	23	25	26	27	29	30	31	33	34	36	37	39	41	43	45
Number of times observed	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1

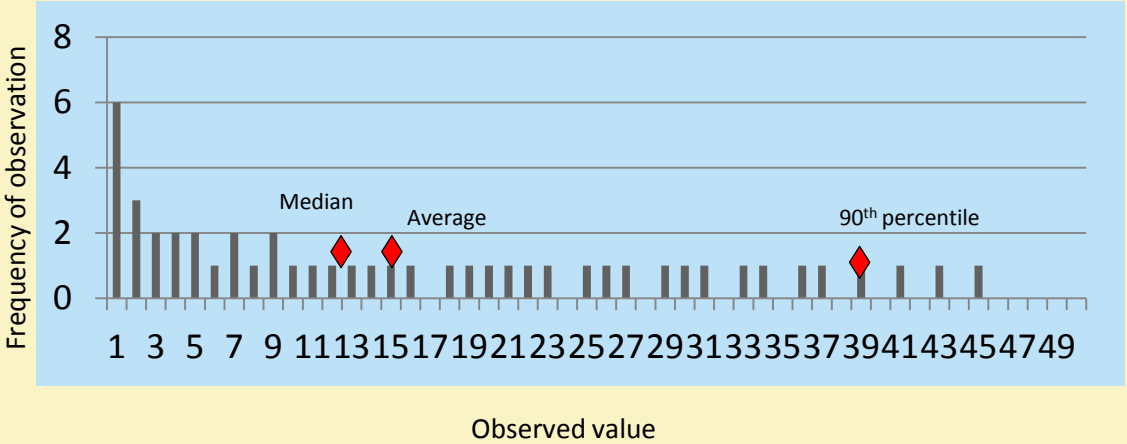
Median = the middle of the data set = 12.5	Average = $\frac{\text{sum of observations}}{\text{number of observations}} = \frac{772}{48} = 16.08$	90th percentile = 90% of data below and 10% above = 38



How do zeros affect the statistics on a distribution with many zeros (right skewed)?

Distribution	Average	Median	90th percentile
With zeros	7.72	0	29.5
Without zeros	16.08	12.5	38





Why is this important?

Recommendations for choosing FCRs are sometimes specific about whether rates should be based on:

- Consumers + non-consumers (this includes the zeros); or,
- Consumers–only (zeros removed).

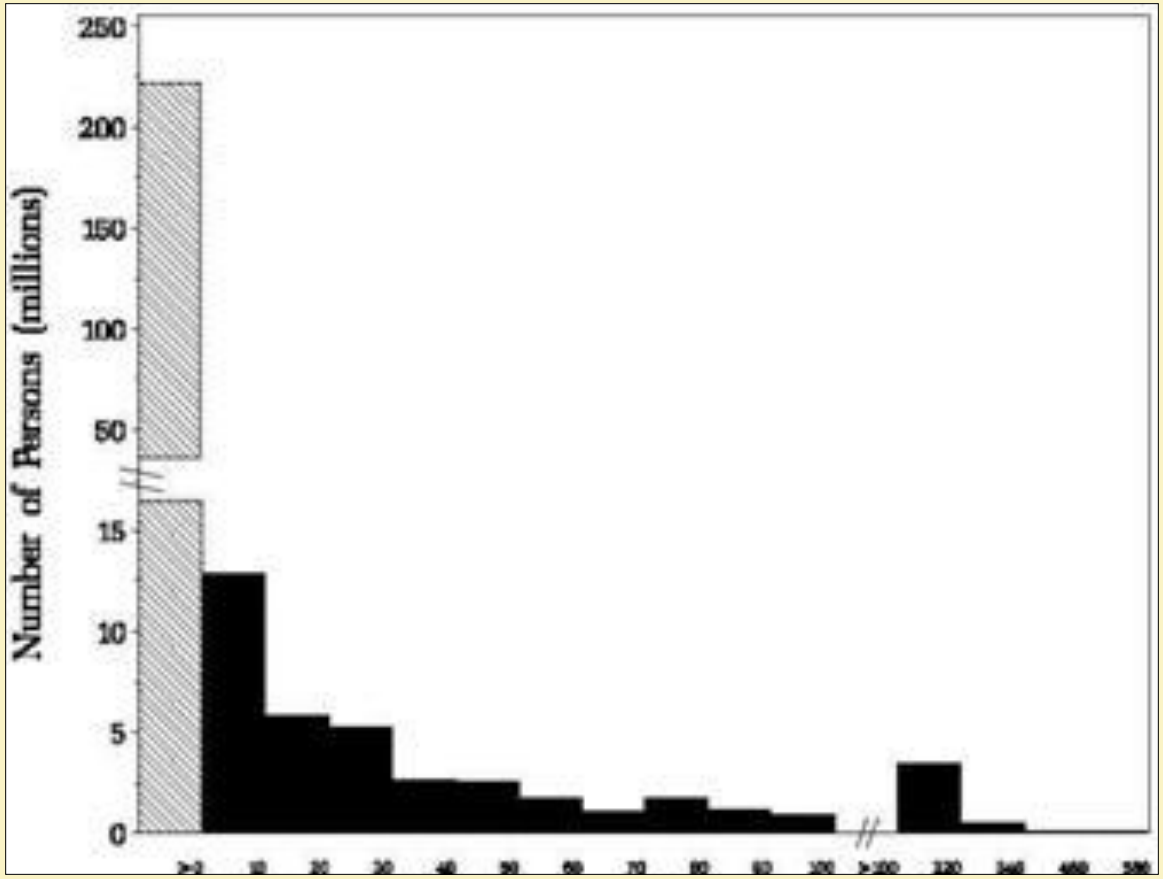
EPA national recommended FCRs are based on consumers + non-consumers.

The NTR criteria are based on consumers + non-consumers.

National per capita adult FCR data: consumers + non-consumers, over half the data set are zeros

USEPA 2002: Histogram of uncooked fish consumption for U.S. Population: Freshwater/Estuarine and shellfish.

Freshwater/Estuarine Finfish and Shellfish



Finfish and Shellfish Consumed (grams/person/day)

Crosshatch = Persons reporting zero consumption

Black = Persons reporting > zero consumption

Figure from: *USEPA 2002. Estimated per capita fish consumption in the United States.* EPA-821-C-02-003. (Page 5-8, Section 5.1.1.1, Figure 1)

Some examples of FCRs from EPA 2000:

EPA's FCR statistics from 2000 guidance (based on per capita data that includes consumers + non-consumers). The data have not been transformed using the NCI method.	Value (g/day) Freshwater and estuarine data only.	EPA rates used for deriving national criteria.
Average	7.50	
Median	0	
90th percentile	17.53	EPA recommended default for general adult population and sport fishers
95th percentile	49.59	
99th percentile	142.41	EPA recommended default for subsistence fishers (may reflect the "average" FCR of these consumers)

Questions/Comments/Discussion

What FCR statistics have been developed from Washington and national survey data? Some summary information on FCRs from the 2012 Ecology FCR Technical Support Document

In 2013 Ecology's Toxics Clean-up Program published the *Fish Consumption Rates FINAL Technical Support Docu*ment, *A Review of Data and Information about Fish Consumption in Washington* , Version 2.0

The FCR TSD compiles information relevant to development of FCRs in WA, as well as broadly applicable information. Topics covered include:

- Washington Fish Resources and Fish-Consuming Populations
- Methodology for Assessing Fish Consumption Rate Information
- Fish Consumption Survey Data that Apply to Washington Fish Consumers
- Sources of Uncertainty and Variability
- Using Scientific Data to Support Regulatory Decisions

Much additional information is also part of the report, including information on bioaccumulation, salmon life history, etc.

The information in this report, as well as additional information submitted, will inform the discussion and the final risk management decisions on FCRs for HHC development in WA.

Information from: Ecology 2013. *Fish Consumption Rates FINAL Technical Support Docu*ment, Version 2.0

Fish Consumption Survey Data that Apply to Washington Fish Consumers

National data – general population across the nation

PNW tribal surveys

At the writing of the FCR TSD, results of three tribal-specific finfish/shellfish dietary surveys of tribes along the Columbia River basin and in the Puget Sound area of Washington were available for review.

Columbia River Inter-Tribal Fish Commission survey: the Umatilla, Nez Perce, Yakama, and Warm Springs Tribes of the Columbia River Basin

Tulalip and Squaxin Island Tribes of the Puget Sound Region

Suquamish Tribe

(Full citations for these studies can be found in the FCR TSD).

In addition, several technical publications provided information on tribal fish consumption

Although the technical publications provided useful information for specific regulatory decisions, it is the published tribal fish consumption surveys that provide the relevant information on tribal fish consumption.

Information from: Ecology 2013. *Fish Consumption Rates FINAL Technical Support Docu*ment, Version 2.0

Fish Consumption Survey Data that Apply to Washington Fish Consumers (cont.)

Overall:

The three surveys employed a well-defined, standardized, dietary survey methodology, data analysis, and reporting of results.

Ecology reviewed and analyzed the data from these surveys, looking specifically at species consumed and where the fish were obtained.

The fish dietary surveys provide credible information on the types and amounts of fish consumed by Native American populations in Washington State.

Generally, the fish dietary surveys indicate that these populations consume large amounts of finfish and shellfish harvested from marine and freshwater environments throughout Washington.

These tribal surveys characterize high rates of fish consumption in WA.

Information from: Ecology 2013. *Fish Consumption Rates FINAL Technical Support Docu*ment, Version 2.0

What FCR statistics have been developed from Washington and national survey data? Some summary information on FCRs from the 2012 Ecology FCR Technical Support Document

Table below shows all fish and shellfish, including local and non-local, and salmon.

Table 1. Summary of Fish Consumption Data, All Finfish and Shellfish (g/day)

Population	Source of Fish	Number of Adults Surveyed	Mean	Percentiles		
				50th	90th	95th
General population (consumers only)	All sources: EPA method	2,853	56	38	128	168
	All sources: NCI method	6,465	19	13	43	57
Columbia River Tribes	All sources	464	63	41	130	194
	Columbia River	–	56	36	114	171
Tulalip Tribes	All sources	73	82	45	193	268
	Puget Sound	71	60	30	139	237
Squaxin Island Tribe	All sources	117	84	45	206	280
	Puget Sound	–	56	30	139	189
Suquamish Tribe	All sources	92	214	132	489	797
	Puget Sound	91	165	58	397	767
Recreational Fishers (compilation of multiple studies)	Marine waters, WA State	–	11–53	1.0–21	13–246	
	Freshwater, WA State	–	6.0–22	–	42–67	

Sources: Adapted from Polissar et al., 2012, Table E-1. Data for recreational fishers is from Table 3, Technical Issue Paper: *Recreational Fish Consumption Rates* (Ecology, 2012). General population data are for consumers only, as opposed to per capita. See Chapters 4 and 6.

Information from: Ecology 2013. *Fish Consumption Rates FINAL Technical Support Document*, Version 2.0

The FCR TSD also breaks out, where information is available, different species groups and sources of fish and shellfish. For example, the Tulalip Tribal FCRs in the table below.

Table 23. Tulalip Tribal Adult Fish Consumption Rates by Species Group and Source

Population Tribal	Species Group	Harvest Source of Fish	Descriptive Statistics (g/day)				
			50th Percentile	Mean	75th Percentile	90th Percentile	95th Percentile
Tulalip	All Fish	All Sources	44.5	82.2	94.2	193	268
	Finfish	All Sources	22.3	44.1	49.1	110	204
	Shellfish	All Sources	15.4	42.6	40.1	113	141
	Non-anadromous	All Sources	20.1	45.9	52.4	118	151
	Anadromous	All Sources	16.8	38.1	43.3	92.1	191
	All	Puget Sound	29.9	59.5	75.0	139	237
	Finfish	Puget Sound	13.0	31.9	33.1	78.4	146
	Shellfish	Puget Sound	14.2	36.9	40.1	111	148
	Non-anadromous	Puget Sound	14.8	35.5	38.8	109	145
	Anadromous	Puget Sound	11.8	30.4	32.4	66.0	148

See Polissar et al., 2012, Table E-1.

Information from: Ecology 2013. *Fish Consumption Rates FINAL Technical Support Document*, Version 2.0

The FCR TSD is a very useful compilation of information that will inform the HHC development process.

Questions/Comments/Discussion

FCRs used by other states

Please see handout – thanks to EPA Region 10 for providing this information.

The range of FCRs used by states and tribes is large.

Entity	Range of CWA approved rates
Tribal rates	6.5 - 389
State rates	6.5 - 175

How do the rates used in other states affect WA risk management decisions on FCRs?

The national and state information help provide context for WA as the risk management decisions on FCRs are made.

Questions/Comments/Discussion

HHC development and FCRs – important policy questions and decisions

There are many important policy questions that are associated with FCRs. These include questions (and subsequent decisions) on:

Risk level
Target population
Target statistic

Geographic variability
Salmon
Sources of fish and shellfish

Note: This presentation does not provide decisions – instead it poses specific questions that need answers before criteria can be calculated. In some cases possible answers/alternatives are provided for consideration.

EPA provides guidance to states on these policy issues

U.S. EPA's national water quality criteria are aimed at protecting the majority of the general population from chronic adverse health effects.

National consumption studies and high-end consumption rates from such studies of the entire general population (consumers and non-consumers) are considered protective in this case.

These FCRs may not be adequately protective of state or local target populations.

U.S. EPA has developed a series of preferences for states selecting consumption rates to use to develop water quality criteria (e.g. 17.5 g/day).

The EPA methodology allows for both upper percentile and central tendency policy choices. (Refer to earlier talk).

EPA provides guidance to states on these policy issues

The preferred option for states is to use regional or local consumption studies and consumption rates to adequately protect the most highly exposed population when developing state or local criteria.

"The four preference hierarchy is:

(1) use of local data;
(2) (2) use of data reflecting similar geography/population groups;
(3) (3) use of data from national surveys; and
(4) (4) use of EPA's default intake rates." (EPA 2000)

"The recommended four preference hierarchy is intended for use in evaluating fish intake from fresh and estuarine species only. Therefore, to protect humans who additionally consume marine species of fish, the marine portion should be considered an *other source of exposure* when calculating an RSC for dietary intake." (EPA 2000)

Question:
What population and what statistic of that population is the target of the risk level for a HHC? (Remember, there are many inputs to the HHC equations)

Risk level
Target population
Target statistic

Once this risk management decision is made, HHC that directly reflect this decision can most accurately be developed using a **probabilistic approach** (see PF #6). Using this approach allows a fuller assessment of the input variables.

If a **point estimate approach** is used then the choice of equation inputs is less likely to get to a HHC that specifically addresses this specific risk management decision. In this case the risk management decision would take into account the factors discussed at PF #6 : *Finding the Right Balance in Developing Human Health Criteria*

This slide is from PF#6: *Finding the Right Balance in Developing Human Health Criteria*

How closely do the HHC reflect the risk management decisions?

When a selection of default inputs is chosen, do we have certainty that the HHC calculated from those inputs matches the specific level of protection, and target population, that it is intended to? Is the resultant HHC "overprotective" or "underprotective" for the risk management decisions that have been made?

"Because of data gaps, as well as uncertainty and variability in the available data, risk cannot be known or calculated with absolute certainty." (EPA 2004)

"On balance, while the resulting estimates are likely to be reasonable, without a detailed uncertainty analysis it is not possible to determine where on the range of plausible outcomes the estimates actually reside." (EPA 2004)

The criteria calculation approach we have talked about thus far is called a "point estimate" or "deterministic" approach.

This means one value is chosen to represent each input to the equation.

Back to the Question:
What population and what statistic of that population is the target of the risk level (or HQ) for a HHC?

If we <u>only look at FCRs</u> (and ignore other inputs to the equation), then:

<u>For carcinogens:</u>

For the NTR this is:

The **10^{-6}** additional cancer risk level is targeted at the **average of the general population, consumers + non-consumers.**

<u>For non-carcinogens</u>

For the NTR this is:

The HQ=1 is applied to the **average of the general population, consumers + non-consumers.**

However, remember that there are other inputs that also help define the targeted level of protection, such as body weight and drinking water ingestion.

Geographic variability
Salmon
Sources of fish and shellfish

Variability in FCRs, how salmon and other anadromous fish are considered, and the sources of fish and shellfish also can effect FCRs.

The following slides will briefly address these issues.

Salmon and sources of fish and shellfish have all been discussed in more detail at past Policy Forums. Those PFs will be referenced.

Geographic variability - WA

Fish/shellfish consumption rates vary among different areas of WA

Table 1. Summary of Fish Consumption Data, All Finfish and Shellfish (g/day)

Population	Source of Fish	Number of Adults Surveyed	Mean	Percentiles		
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Within-Puget Sound survey data show varying rates of finfish consumption.

Shellfish consumption is very high in some areas of Puget Sound (e.g. Suquamish Tribe and Tulalip Tribe data). (g/day)

Tribal Population	Sample size	Species Group	Source	50th	Mean	75th	90th	95th
Tulalip	71	Shellfish	Puget Sound	14.2	36.9	40.1	111	148
Suquamish	91	Shellfish	Puget Sound	52.4	109	118	294	499

Shellfish consumption is lower in E. WA. Data from the WA outer coast ?

Information from: Ecology 2012. *Fish Consumption Rates FINAL Technical Support Document*, Version 2.0

Within-Puget Sound survey data show varying rates of finfish consumption (all finfish).

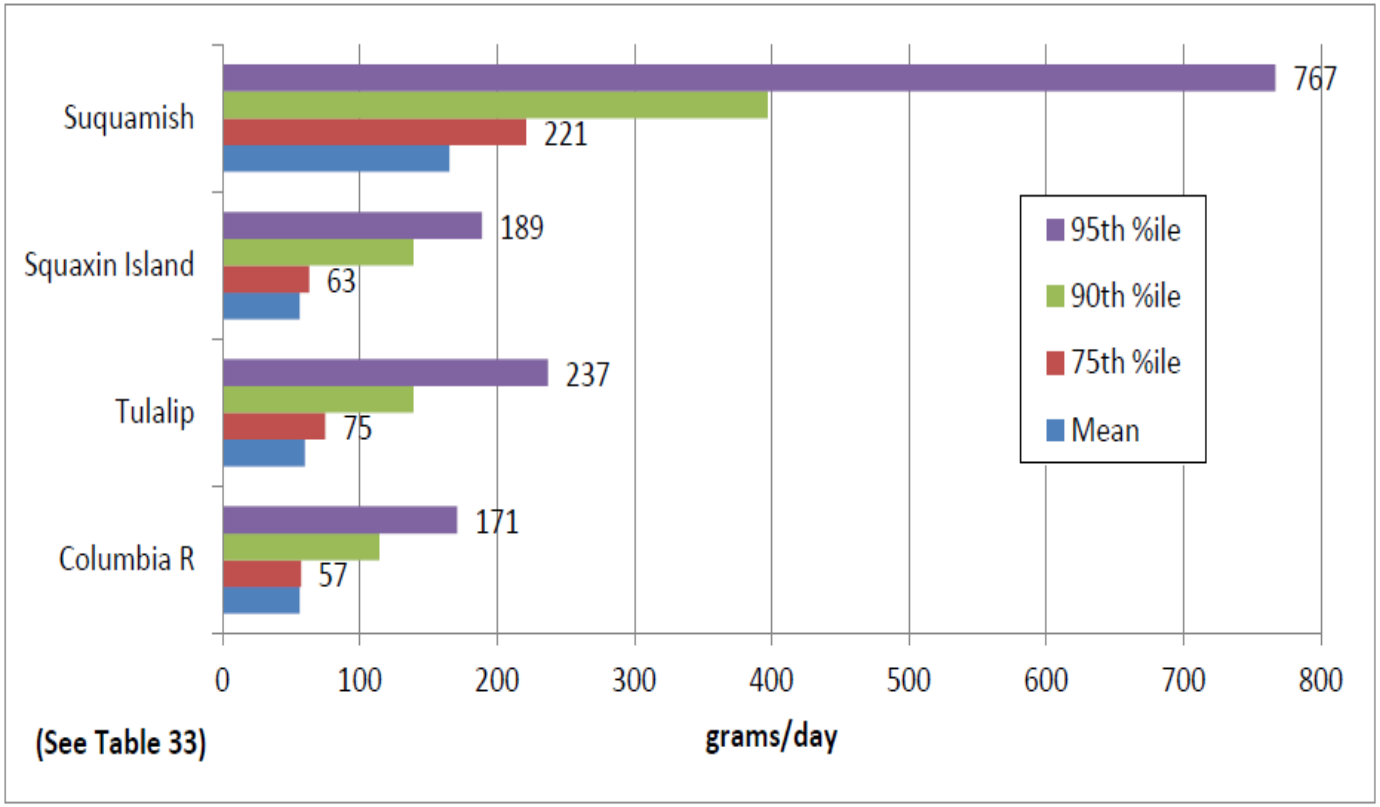


Figure 13. Regional-specific Adult Fish Consumption Rates, Harvested from Local Sources

Information from: Ecology 2012. *Fish Consumption Rates FINAL Technical Support Document*, Version 2.0

Salmon and Sources of fish and shellfish

Scope of the CWA: Why is the geographic scope important?

Designated uses and **water quality criteria** are applied to waters within Washington's jurisdictional authority.

Washington's WQS do **not** apply to marine waters outside the 3-mile limit or to waters of other states.

CWA-authorized source controls occur within this geographic boundary

Scope of the CWA discussed at PF #2

Salmon

Salmon are a large part of the FCR, and salmon do not accumulate their contaminants equally among all geographic areas.

(See O'Neill and West presentation from Policy Forum 6)

Most biomass and analyzed contaminants are accumulated in salt water

Puget Sound and Straits have salmon spending time there and picking up contaminants. Some salmon are resident, others spend varying amounts of time in Puget Sound/Straits during migrations.

Other waters in WA have much less influence on biomass growth or accumulation of the analyzed chemicals in salmon.

We have a situation where salmon pick up a varying amount of their body burden in WA waters, based on their life history.

Sources of fish and shellfish

Scope of the CWA (Discussed at PF #2)

Washington cannot regulate sources of contaminants to fish that originate outside Washington's boundaries.

CWA WQS apply to waters within Washington's jurisdiction and to sources addressed in the CWA.

WA can regulate some specific sources of contaminants that largely affect <u>resident</u> fish.

Questions:

Should WA develop 2 sets of HHC: One set based on Puget Sound fish consumption and the other based on fish consumption outside of Puget Sound?

Example:

Apply a translator to the salmon portion of the FCR to remove (1) an estimated fraction of salmon consumption that derives from fish outside waters of the state and/or (2) an estimate of that fraction of contaminants that derives from growth and accumulation occurring outside state waters.

What FCR will Ecology use?

Choosing a FCR or a specific distribution of FCRs is a policy/risk management decision.

A decision on this has not been made yet.

These decisions will need to be made to support development of the draft rule.

EPA 2000 guidance: information on risk management:

"Risk management is the process of selecting the most appropriate guidance or regulatory actions by integrating the results of risk assessment with engineering data and with social, economic, and political concerns to reach a decision. In this (EPA 2000) methodology, the choice of a default fish consumption rate which is protective of 90 percent of the general population is a risk management decision. The choice of an acceptable cancer risk by a State or Tribe is a risk management decision."

(EPA 2000, page 2-4)

Criteria calculation: Past practice and new opportunities

Past practice and default approach: Deterministic approach

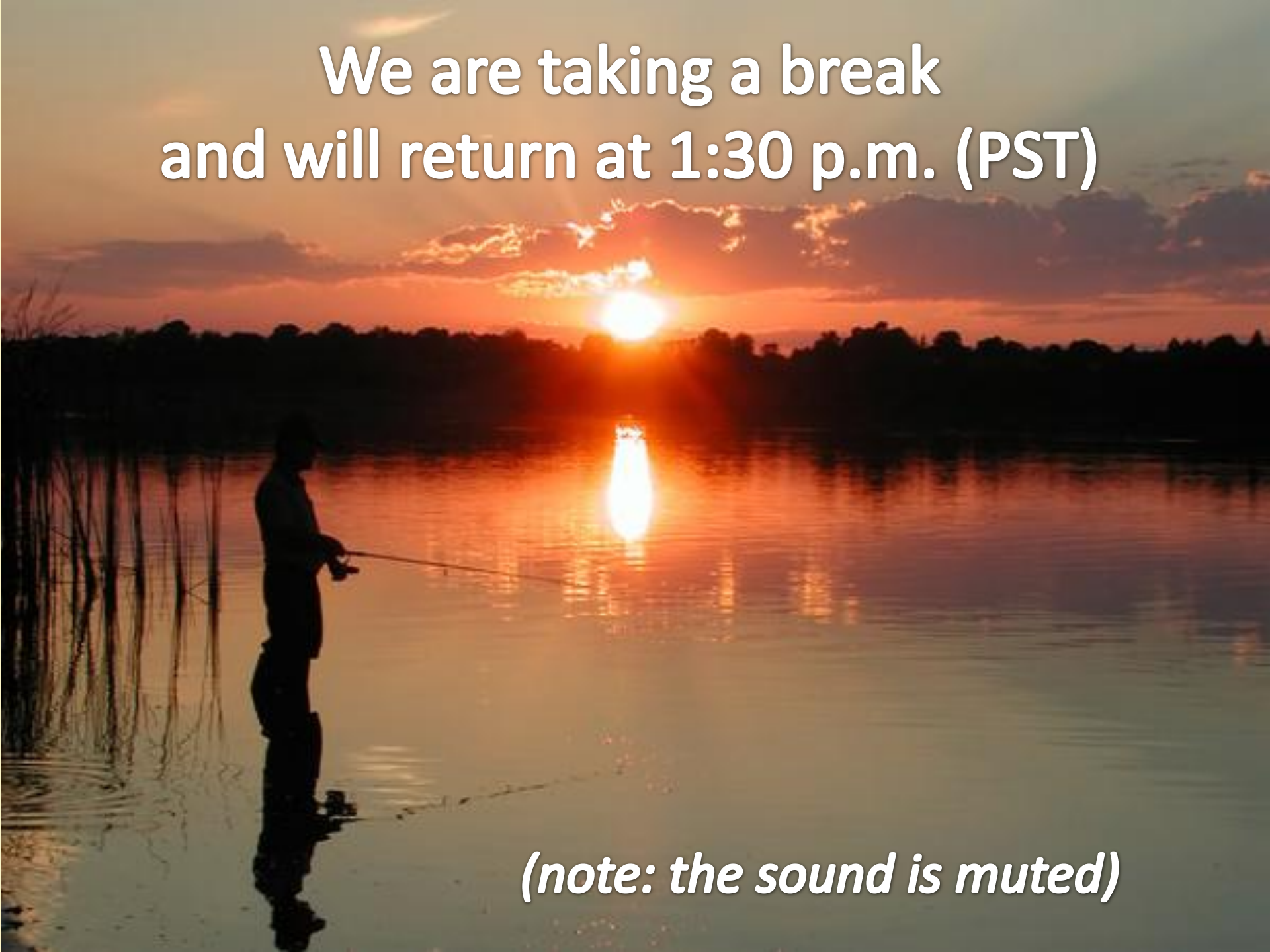
New opportunity: Probabilistic approach

Both approaches were discussed at Policy Forum #6.

Both approaches have pros and cons.

No decision has been made yet on taking a probabilistic approach, or on staying with the default.

Questions/Comments/Discussion


We are taking a break
and will return at 1:30 p.m. (PST)
(note: the sound is muted)

EPA 1980 and 2000 HHC guidance, the NTR, and choices

Policy Forum #7, Lacey WA

September 12, 2013

Human Health Criteria and Implementation Tools Rule-makings

Cheryl Niemi

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Where we are with the NTR

The federal NTR criteria were based on the EPA 1980 HHC guidance

The policy decisions incorporated into the NTR criteria inputs are Washington's current "baseline" of policy decisions – formalized and issued to WA from the USEPA

These include

- risk level (adopted into WAC 173-201A),
- target population,
- specific statistic of the target population,
- cost considerations,
- the RSC value, and
- how salmon are treated.

- WA will make many policy decisions before HHC are developed.

- The following tables compare the NTR criteria with newer guidance, and point out some differences.

How do the EPA 1980 guidance, early criteria documents (basis of NTR) and the newer EPA 2000 guidance compare?

Input	EPA 1980 and/or early criteria docs/NTR NTR is the current default	EPA 2000	Effect of new guidance on protection/stringency?
Flexibility in inputs to the equation?	Yes – can be modified to accommodate other information or state needs	Yes – can be modified to accommodate other information or state needs	Equal
Risk level (WA risk level adopted into WAC 173-201A)	NTR = 10^{-6} for WA 10^{-7} to 10^{-5} range presented in earlier criteria docs	10^{-5} to 10^{-6} for general population, <= to 10^{-4} for highly exposed subpopulations	Equal

Input	EPA 1980 and/or early criteria docs/NTR NTR is the current default	EPA 2000	Effect of new guidance on protection/stringency?
Target population to which risk level or HQ is applied	General population, per capita	General population, per capita,	Equal
		4-stage hierarchy of FCR data	Equal, or, more protective /stringent
Specific statistic of the target population	Average	90th percentile	More protective /stringent

Input	EPA 1980 and/or early criteria docs/NTR NTR is the current default	EPA 2000	Effect ?
Cost	Cost **cann**ot be taken into account in criteria derivation: *"Potential social or economic costs and benefits are not considered in the formulation of the criteria (pp79347)*	Cost-related factors **can** be taken into account when developing specific inputs to the criterion equation: *"Risk management is the process of selecting the most appropriate guidance or regulatory actions by integrating the results of risk assessment with engineering data and with social, **economic**, and political concerns to reach a decision. In this (EPA 2000) methodology, the choice of a default fish consumption rate which is protective of 90 percent of the general population is a risk management decision. The choice of an acceptable cancer risk by a State or Tribe is a risk management decision." (EPA 2000)*	Could make less protective /stringent , but not aware of this being formally used by other states

Input	EPA 1980 and/or early criteria docs/NTR NTR is the current default	EPA 2000	Effect of new guidance on protection/stringency?
Relative source contribution (RSC)	1.0 used in criteria docs supporting NTR	0.2 default, no greater then 0.8	More protective /stringent
How anadromous fish (salmon) are treated	No anadromous fish	No anadromous fish in national recommended criteria	Equal
Bioconcentration or bioaccumulation	BCF	BAF	Equal (at present)
Body weight	70 kg	70 kg	Equal
Drinking water intake	2 L/day	2 L/day	Equal

Questions/Comments/Discussion

Summary of what we have covered so far: Where we are after 7 Policy Forums and 2 Implementation Tools Workshops.

Policy Forum #7, Lacey WA

September 12, 2013

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The Policy Forums

The Policy Forum process is designed to give all interested persons an opportunity to learn about the rulemaking processes to adopt new human health-based water quality standards and implementation tools in WA.

All interested persons are welcome to attend the Policy Forum.

Ecology is hosting the Forums on the current rulemaking work to provide a structured dialog throughout the rulemaking process.

PF Goal 1. To help clarify many of the issues/factors that work together when we consider how criteria are developed and subsequently implemented – this is complex from beginning to end.

PF Goal 2. To build a level playing field of knowledge - to help interested people understand enough about the issues so that they can talk with each other and understand each others concerns. This is an important public policy and economic issue.

The Policy Forum process has received technical and policy assistance from other agencies and from many programs within Ecology

Expertise	Who
CWA WQS information, EPA policies, and information on the Oregon HHC development process	Matt Szelag and Angela Chung - EPA Region 10
Toxicology and risk assessment	Lon Kissinger - USEPA Region 10 Dave McBride - Washington Department of Heal**th** Rob Duff (EAP), Gary Palcisko (Air), Matt Kadlec (Air), Craig McCormack (Clean-up), Damon Delistraty (Haz. waste, toxics reduction) – Ecology
Florida's experiences using probabilistic analysis to develop HHC	Ken Weaver – Florida DEP
Economics	Kasia Patora and Allen Chen – Ecology
Environmental contamination in Washington	Dale Norton (EAP) Ecology
Anadromous fish, contaminants in anadromous fish, and fishery resources in Washington	Sandy O'Neill and Jim West - WA Department of Fish and Wildlife
NPDES permitting (individual and general permits)	Nancy Kmet, Bill Moore, Jeff Killalea, and Vince McGowan (Water) - Ecology
Chemical Action Plans and other source reduction approaches	Carol Kraege and Holly Davies (Waste to Resources) - Ecology

Also –
The diverse opinions, and the many issues that the Policy Forum participants have brought up, have resulted in extremely rich discussions on both criteria development and on implementation.

The issues and factors we've discussed include many of the important building blocks of information that we need to consider in order to fully engage in the discussion around criteria development and future criteria implementation.

Timeline: Draft rule language will be filed in early 2014.

What follows is a table listing many of the factors we have discussed and presented information on at 9 public meetings. All those factors play key roles in this rule-making.

Public meetings were:

2 Implementation Tools Workshops (12/2011 and 1/2012),
The Public Workshop on Reducing Toxics in Fish, Sediment, and Water (8/28/13); and,
7 Policy Forums (11/12 through 7/13)

Discussion topics.

Topics		Venue
WQS – what they are and how they are developed		Workshop PF3
The differences between science, science policy, and risk management decisions in HHC development		Workshop PF 2
How cost could be considered in HHC calculation		PF1
How cost and benefit are considered in rule-making under the WA Administrative Procedures Act *(thanks to Kasia Patora, Ecology, for her presentation)*		PF 1
Information on the criteria equations, including specific input variables	The HHC equations for carcinogens and non-carcinogens, for the exposure pathways of "organisms-only" and "water + organisms"	PF 2 Workshop
	Balancing the inputs of the equation	PF
	Risk levels and history of levels commonly used in regulatory programs	Workshop PF's 2, 3, 5
	Hazard Quotient (HQ)	Workshop PF 5
	Cancer slope factors and reference doses *(thanks to Lon Kissinger, EPA Region 10, for his presentation)*	Workshop PF 5

Discussion topics (cont.)

Topics		Venue
(cont.)	Relative source contribution	PF's 3, 5
	Lifespan and duration of exposure	Workshop
	Fish consumption rates (*thanks to Lon Kissinger, USEPA Region 10, for his talk today on this topic*)	Workshop PF 7
Priority pollutants and criteria pollutants	What they are and their history	PF 4,5
Different methods of criteria development	Deterministic and probabilistic approaches and their advantages and disadvantages *(thanks to Ken Weaver from FDEP for his presentation on Florida's HHC development process using probabilistic analysis)*	PF 6,7
CWA vs. other programs	How CWA criteria are developed and implemented, compared to other programs (e.g. SDWA, clean-up.)	PF 5
Chemicals of concern	Chemical-specific and Washington-specific information on three chemicals : PCBs, arsenic, and mercury.	PF's 4, 5
	PCB sources and reduction efforts (thanks for Adriane Borges from Ecology ERO for her presentation)	PF 4

Discussion topics (cont.)

Topics		Venue
WDOH fish advisories in WA *(thanks to Dave McBride from WDOH for his presentation)*		PF 4
Environmental contamination	Information about contaminants in WA salmon, and where those salmon put on their body mass and accumulate contaminants *(thanks to Sandy O'Neill and Jim West - WA Department of Fish and Wildlife, for their presentation)*	PF 6
	Contaminants in Washington waters and fish (*(thanks to Dale Norton, Ecology, for his presentation)*	PF 3
Bioconcentration and bioaccumulation factors		PF 3,5
Scope of the CWA and what WA can address	Preliminary and continuing discussion on the scope of the source controls that the state can address under the CWA regulations and within state geographic jurisdiction	PF's 2, 3, 5, 7
Implementation tools and NPDES permitting	Compliance schedules and variances, what they are and why Ecology is looking at rule-making to provide longer timelines for them.	ITW 1 & 2 PF1, 2

Discussion topics (cont.)

Topics		Venue
Implementation tools and NPDES permitting	Discharge scenarios	PF's 1, 2, 3
	Current and possible future implementation tools, and where they would make a difference.	ITW 1 & 2 PF's 1,2,3
	How variances and compliance schedules apply to existing, new, and expanding discharges	PF's 2,3
	The Pinto Creek Decision and how it affects permitting for new and expanding discharges	PF's 2, 3
	Detection and quantification levels for chemical analytical methods used for NPDES permitting, and uncertainty around use of new methods (in particular for PCBs)	PF's 2, 3,5
	Municipal and industrial stormwater permits – effects of new HHC on current permits, and, when those permits expire	PF's2,3
303(d) listings	303(d) listings	PF's2,3,4,5
	The impact that 303(d) listings and TMDLs have on effluent limits	PF's 2,3,5
	Implications of lower concentration criteria and additional 303(d) listings on existing, new and expanding discharges	PF's 2,3
Implementation tools developed in Oregon *(thanks to Andrea Matzke- Oregon DEQ, for her presentation)*		ITW 1& 2

Where are we now?

This concludes the educational workshop phase of this process.

Future workshops will likely focus on alternatives and draft rule discussion.

Everyone should start thinking about how all the pieces fit together to make a picture that includes HHC that reflect Washington's risk management decisions for CWA regulation, and the suite of implementation tools that can be adopted that are within the bounds of law and regulation and that provide for toxics reductions, adequate timelines to make those reductions, and compliance for dischargers while progress is being made.

Materials developed for the Delegates' Table meetings, and discussions at those meetings, will be helpful in considering the development of the draft rule.

Now - Time to begin the process of making the policy /risk management choices that will guide development of the draft rule.

Questions/Comments/Discussion

Thank You!