Department of Ecology Water Quality Standards Policy Forum #6

July 11, 2013

Yakima, WA

DEPARTMENT OF ECOLOGY
State of Washington

Policy Forums and Delegates' Table Update

- Five Policy Forums held between Fall 2012 and May 2013
- Ecology anticipates at least two more Policy Forums before draft rule language is proposed.
- Overview of June 24th Delegates' Table meeting.

Finding the Right Balance in Developing Human Health Criteria

Policy Forum #6, Yakima WA

July 11, 2013

Human Health Criteria and Implementation Tools Rule-makings

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Morning session introduction: focus on risk assessment and criteria calculation topics that specifically address whether the current criteria calculation methods result in HHC that are "overprotective" or "underprotective"

Why is it important to talk about this now?

- Draft HHC and implementation tools rules are planned for release in early 2014.
- Decisions about criteria development methods that are made in response to concerns about overprotectiveness or underprotectiveness could add time to the process.
- This information is needed to support the Delegates Table discussions and consideration by the public.

Purpose of the morning session: This session was developed to help inform and start the discussions around two criteria development issues brought up by stakeholders, specifically:

1. The issue of "compounded conservatism" in the criteria equation (which could result in perceived "overprotection"). We will talk about the term "compounded conservatism" during this presentation.

2. An interest in using the probabilistic approach to criteria development. Using the probabilistic approach can *increase the certainty that the HHC values are closely linked to the specified risk level and the population it is specifically applied to*. The "probabilistic approach" will be further defined and discussed throughout the morning session.

See, for example, October 10, 2012:

- Letter from Northwest Pulp & Paper and National Council for Air and Stream Improvement to Ecology Northwest Pulp & Paper: Transmittal letter
- National Council for Air and Stream Improvement's whitepaper: "A Review of Methods for Deriving Human Health Based Water Quality Criteria With Consideration of Protectiveness"

(At http://www.ecy.wa.gov/programs/wq/swqs/feedbkimplrule.html)

Morning presentations and discussion:

1. How the criteria equation balances overprotection and underprotection - a **qualitative** look
2. Uncertainty and variability – how are they different and why is it important?
3. Compare two HHC calculation methods: probabilistic analysis and point estimate approaches summary information.

The first three presentations are summary in nature. Further resources on variability, uncertainty, and probabilistic analysis (as used in risk assessments) can be found at the USEPA websites: http://www.epa.gov/spc/2probana.htm and http://www.epa.gov/oswer/riskassessment/rags3adt/

4. Florida's Experience with the Probabilistic Approach – Ken Weaver, Florida DEP

Expert resources available to assist with this discussion:

Toxicologist/risk assessor panel attending in Lacey

Ken Weaver (FL DEP) attending and presenting from Florida

Abbreviations used in this presentation

HHC = Human health-based criteria for surface waters
WQS = Surface Water Quality Standards (WAC 173-201A)
NTR = 1992 National Toxics Rule (40 CFR 131)
CWA = Clean Water Act
BW = Body weight
DWI = Drinking water intake
RSC = Relative source contribution (specifically discussed at Policy Forum #5)
RfD = Reference dose (specifically discussed at Policy Forum #5)
BCF = Bioconcentration factor (specifically discussed at Policy Forum #5)
BAF = bioaccumulation factor (specifically discussed at Policy Forum #5)
HQ = Hazard quotient

Special thanks to Lon Kissinger (USEPA), Rob Duff (Dept. Ecology) and Ken Weaver (FDEP) for advice and assistance with parts of the first three presentations (any errors are my own, not theirs).

How the criteria equation balances overprotection and underprotection

What is meant by "overprotection" and "underprotection" ?

- Very subjective – often a matter of opinion, and opinions vary greatly among stakeholder groups and individuals.
- Some people think the HHC are overprotective, and some people think they are underprotective.

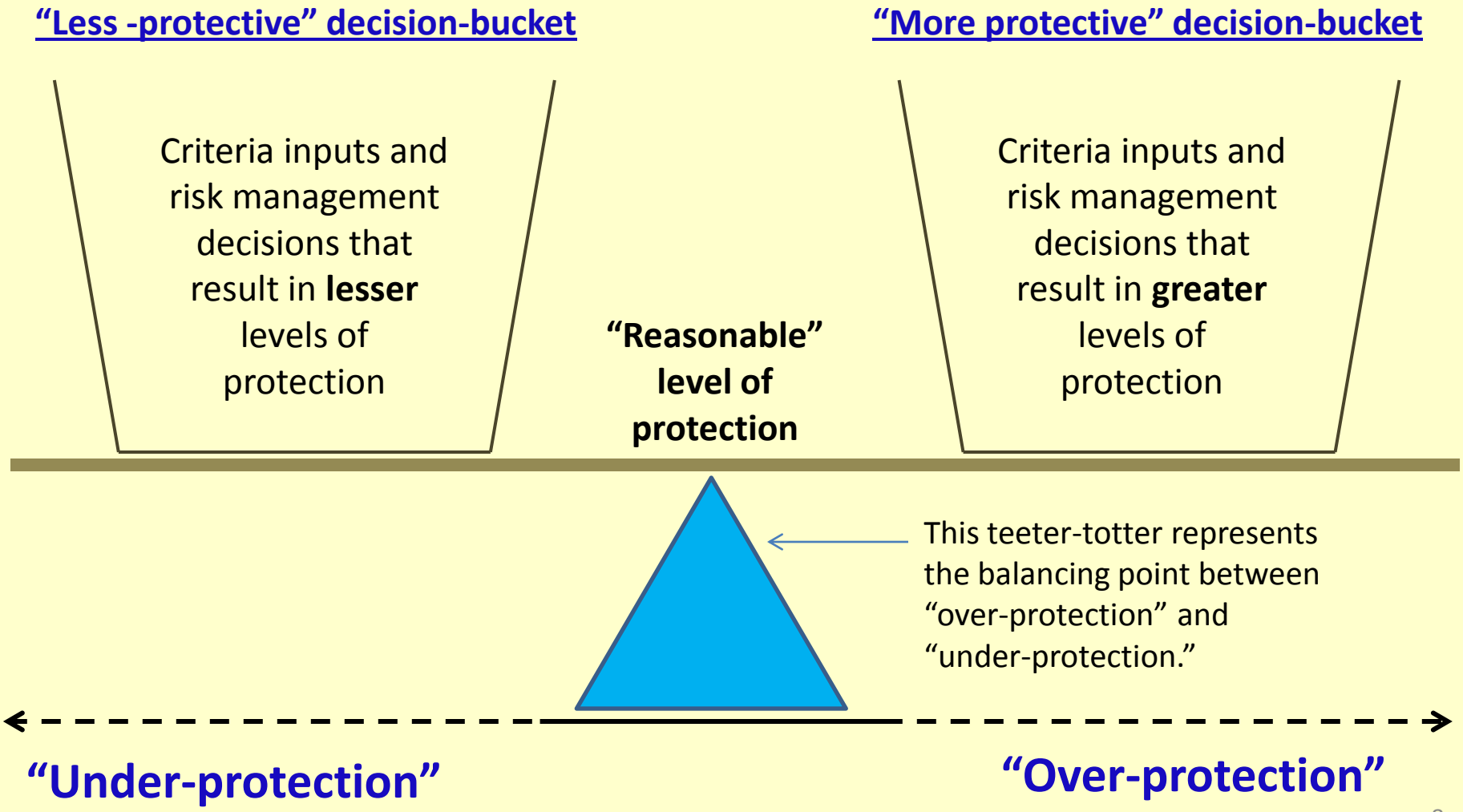
For HHC, acceptable levels of protection are somewhat defined in EPA guidance, and we know from previous Policy Forum discussions that policy and risk management choices play a large role in setting the specified levels of protection.

For this presentation:

- The terms are used in a conceptual sense, and do not refer to any specific risk or hazard level, or any particular specified level of "safety."
- For instance, this presentation will *not* say "a risk level of X is underprotective" or "a hazard quotient of X is overprotective."
- Will be making comparisons largely in terms of "less-protective" and "more-protective."

How the HHC equation balances over-protection and under-protection.

We will walk through some of the inputs and assumptions in the HHC calculation and talk about whether they confer greater or lesser levels of protection



Some equation inputs and assumptions used in criteria development (1 of 6 slides)

Input parameter	*EPA recommended value*	*(+) = a source of greater protection* *(-) = a source of lesser protection*	*Comments*
Drinking water intake (DWI)	**2 L/day** Adult drinking water rate	**(+)** based on use of a higher percentile (86th percentile)	Used in many EPA programs.
Body weight (BW)	**70 kg. (154 lbs)** Adult body weight	**(+/-)** based on use of a value close to an average adult body wt. **(+)** BW has increased, so a higher value to represent the average might be appropriate **(-)** If pregnant women are the target population 70kg might be too high.	70 kg. is used in the derivation of CSFs and unit risks that appear in IRIS. Used in many EPA programs.
Relative Source Contribution (RSC)	20% to 80%, **or**, a RSC based on information that would support a RSC between 20% and 80% (but no higher than 80%)	**(+)** Takes into account exposures from sources that are not within the scope of the CWA	Applies to the non-carcinogens for current rule-making purposes. We have addressed this at past Policy Forums in the "scope of the CWA" context.

Most information from: EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000), EPA 822-B-00-004*: http://water.epa.gov/scitech/swguidance/standards/upload/2005_05_06_criteria_humanhealth_method_complete.pdf.

Some equation inputs and assumptions used in criteria development (2 of 6 slides)

Input parameter	***EPA recommended value***	***(+) = a source of greater protection*** ***(-) = a source of lesser protection***	***Comments***
Hazard Quotient (HQ)	A HQ = 1 represents a risk level where effects should not be present *at specified exposure assumptions*	**(+)** set at a no-effects level	Applies to the non-carcinogens .
Risk Level	No greater than 10^{-4} for highly exposed populations, generally 10^{-6} or 10^{-5} for general population	**(+)** This range represents an extremely small amount of additional lifetime risk .	Applies to carcinogens. *Opinions about this risk range vary*. Please see Policy Forum #5 presentation on risk as you consider this input.

Some equation inputs and assumptions used in criteria development (3 of 6 slides)

Input parameter	***EPA recommended value***	***(+) = a source of greater protection*** ***(-) = a source of lesser protection***	***Comments***
Reference dose (RfD)	**IRIS** value	**(+/-)** Most reference doses used in HHC calculation have large "safety factors" added to them to account for uncertainty in the RfD derivation process. (Mercury is an exception – safety factor is small) For some chemicals the uncertainty factors can be quite large, but whether they are over-protective or simply sufficiently protective is a matter of debate.	Please see Policy Forum #5 presentation by Lon Kissinger (USEPA) as you consider this input.

Some equation inputs and assumptions used in criteria development (4 of 6 slides)

Other assumptions	*(+) = a source of greater protection* *(-) = a source of lesser protection*	*Comments*
Cooking effects: No chemical concentration **losses** during cooking	**(+)** for some lipophilic (fat loving) chemicals (e.g., PCBs, dioxins)	Cooking techniques that carry away fat can also carry away some chemicals (see WDOH web site: **Reduce Exposure to Contaminants in Fish**: http://www.doh.wa.gov/CommunityandEnvironment/Food/Fish/ReduceContaminantExposure.aspx)
Cooking effects: No chemical concentration **gains** during cooking	**(-)** for some non-lipophilic chemicals (e.g., mercury)	Some chemicals that are not bound to fats can increase in concentration as water and fat are lost during cooking.
Lifetime ÷ duration of exposure (70 years ÷ 70 years = 1)	**(+)** Assumes lifetime of daily exposures	
Constant exposure levels	**(+)** for most chemicals.	Exposure concentration assumed to be at constant HHC concentrations all the time

Some equation inputs and assumptions used in criteria development (5 of 6 slides)

Other assumptions	*(+) = a source of greater protection* *(-) = a source of lesser protection*	*Comments*
Multiple chemicals : Chemical effects are traditionally addressed one chemical at a time.	**(-)** Not addressing effects from chemicals that share the same effects (e.g., neurotoxicity)	Consideration of cumulative effects of multiple chemicals is allowed in the EPA 2000 HHC guidance, but thus far has not been part of the criteria calculation for the chemicals on the EPA recommended national HHC list.

Some equation inputs and assumptions used in criteria development (6 of 6 slides)

Other assumptions	*(+) = a source of greater protection* *(-) = a source of lesser protection*	*Comments*
Use of a Bioconcentration Factor (BCF) **vs.** **Bioaccumulation Factor** (BAF) *Note: Mercury is the only EPA recommended national HHC that has a BAF. Thus, other HHC still include a BCF in the calculation.*	**(+/-)** For uptake from water only **(-)** For uptake from all sources	**(+/-)**The BCF in general reflects uptake from water only. If use of a BCF is considered appropriate, then the BCFs might be a neutral factor. **(-)** BCF - If uptake from all surrounding media (the organism's food, sediments, water, etc..) is determined appropriate, then the BCFs may not reflect full uptake from all sources an organism can be exposed to, especially for highly bioacumulative chemicals.
Adult BW and DWI used to represent exposure to non-carcinogens	**(-)** for chemicals that have a toxicity factor (RfD) that is based on effects to infants or children	

How the HHC equation balances over-protection and under-protection.

Some of the criteria inputs and risk management decisions that affect protectiveness are below…

"Less -protective" decisions

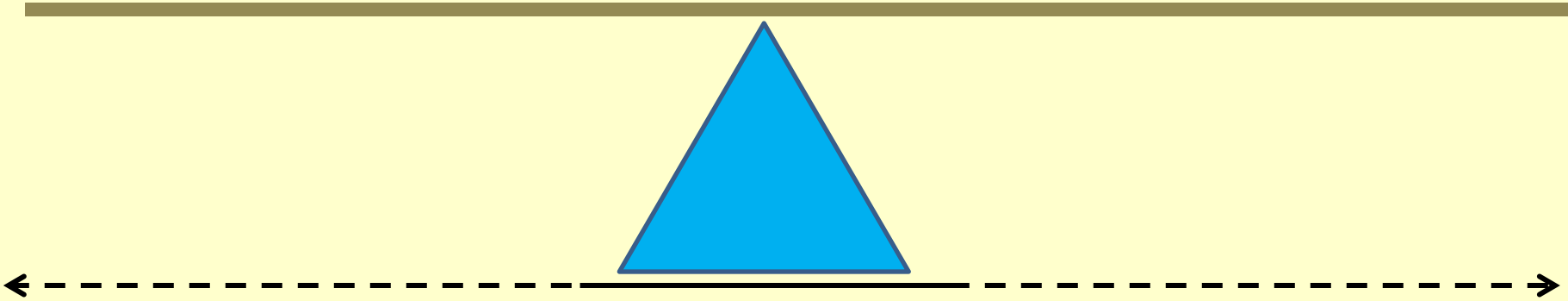
1. **Cooking effects:** No chemical concentration **gains** during cooking
2. Does not account for **effects from multiple chemicals** that share the same effects (e.g., neurotoxicity)
3. **Adult BW and DI** used to represent exposure to non-carcinogens for chemicals that can have a toxicity factor (RfD) that is based on effects to infants or children

Risk level = 10-4 to 10-6

Opinions about this risk range vary. Please see Policy Forum #5 presentation on risk as you consider this input.

"More protective" decisions

1. **Cooking effects:** No chemical concentration **losses** during cooking
2. **A lifetime of daily exposures**
3. **Exposure concentration** assumed to be at constant HHC concentrations all the time
4. **RSC** – Current EPA guidance takes into account exposures from sources of exposure that are outside the scope of the CWA
5. A **HQ = 1**
6. Adult BW has increased, so **a higher value to represent the average might be appropriate**



"Under-protection" **"Over-protection"**

Does the current approach using default inputs strike a reasonable balance?

- **Do we know when one side of the teeter totter overbalances the other?**
- **Is compounded conservatism an issue here?**

In other words: Does the use of high-percentile and other protective assumptions in the equation compound to make "overprotective" criteria?

"…EPA risk assessments are in fact a combination of both high-end and central tendency estimates. Consequently, the resulting ***risk estimates are expected to be on the high end of the range of risks but within the range of plausible outcomes.*** *The combination of default assumptions is therefore reasonable, especially for independent factors, and does not result in exaggerated estimates. "* (EPA 2004) (Boldface added)

"…consistent with its mission, EPA risk assessments tend towards protecting public and environmental health by preferring an approach that ***does not underestimate risk*** *in the face of uncertainty and variability. In other words, EPA seeks to adequately protect public and environmental health by* ***ensuring that risk is not likely to be underestimated."*** *(*EPA 2004) (Boldface added)

USEPA. *An examination of EPA risk assessment principles and practices. Staff Paper Prepared for the U.S. Environmental Protection Agency by members of the Risk Assessment Task Force, 2004*. EPA/100/B-04/001

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.

The point estimate approach to criteria calculation

Advantages of this approach:

- Can be done *quickly* using default values in the HHC equations (the "plug and play" approach)
- Can be a *low-cost* approach *if defaults are agreed up*on
- This is the *traditional* approach to HHC development.

Disadvantages of the approach:

- The full data sets for the different inputs are not used (true *variability of the population is not considered*)
- Because the variability of data sets that support the different inputs are not considered, there is *less certainty* about whether the calculated HHC closely reflects the level of protection chosen for the population it is specifically applied to.

Is it important to consider variability and level of uncertainty in criteria calculation? A matter of opinion.

For transparency during rule-making: It is important to be clear about how this is addressed.

- The current approach used to develop HHC is a point estimate approach.
- Initiating the additional work to reduce uncertainty and account for variability in this HHC rule-making process is a *policy choice*.
- It is important to understand what variability and uncertainty are, and why they could be important to HHC development, before this policy decision is made.

Variability and uncertainty– general information to support the HHC discussion

What are variability and uncertainty?

Uncertainty: Uncertainty refers to lack of knowledge about specific factors, parameters, or models. *For example, we may be uncertain about the mean concentration of a specific pollutant at a contaminated site or we may be uncertain about a specific measure of uptake (e.g., 95th percentile fish consumption rate among all adult males in the United States).*" (EPA 1997)

"Variability: Variability refers to observed differences attributable to true heterogeneity or diversity in a population or exposure parameter. *Sources of variability are the result of natural random processes and stem from environmental, lifestyle, and genetic differences among humans. Examples include human physiological variation (e.g., natural variation in bodyweight, height, breathing rates, drinking water intake rates), weather variability, variation in soil types and differences in contaminant concentrations in the environment. Variability is usually not reducible by further measurement or study (but can be better characterized)." (*EPA 1997)

"Uncertainty can be defined as a lack of precise knowledge as to what the truth is, whether qualitative or quantitative...Uncertainty — the lack of knowledge — can be reduced through additional investigation. Variability is inherent heterogeneity across space, in time, or among individuals; it cannot be reduced with additional investigation, only better understood or characterized. " (EPA 2004)

EPA/630/R-97/001, Guiding Principles for Monte Carlo Analysis, March 1997. At: http://www.epa.gov/raf/publications/pdfs/montecar.pdf

Can variability be accounted for and uncertainty reduced in HHC calculation?

Yes. Probabilistic analyses can reduce uncertainty by accounting for variability in data sets. This is a rigorous and robust modeling technique to reduce uncertainty.

This approach currently being used in Florida for HHC development (next presentation by Ken Weaver)

The traditional and default approach to HHC development is the point estimate approach. This is the approach we have talked about in prior Policy Forums.

The two approaches to consider are the "point estimate approach" and the "probabilistic approach."

Policy decision: Should WA change course from the the traditional point estimate approach and instead pursue a probabilistic analysis approach for HHC development?

Point estimate vs. probabilistic analysis – summary information

*"In a **point estimate approach**, single values (typically a mixture of average and high-end values) are input into the equation."* (EPA 2001) This is the default approach to HHC development.

*"In **probabilistic analysis** the only difference is that a probability distribution, rather than single value, is specified for one or more variables."* (EPA 2001)

Probability distributions are frequently used to characterize exposure for variables such as BW, DWI, FCR, etc..

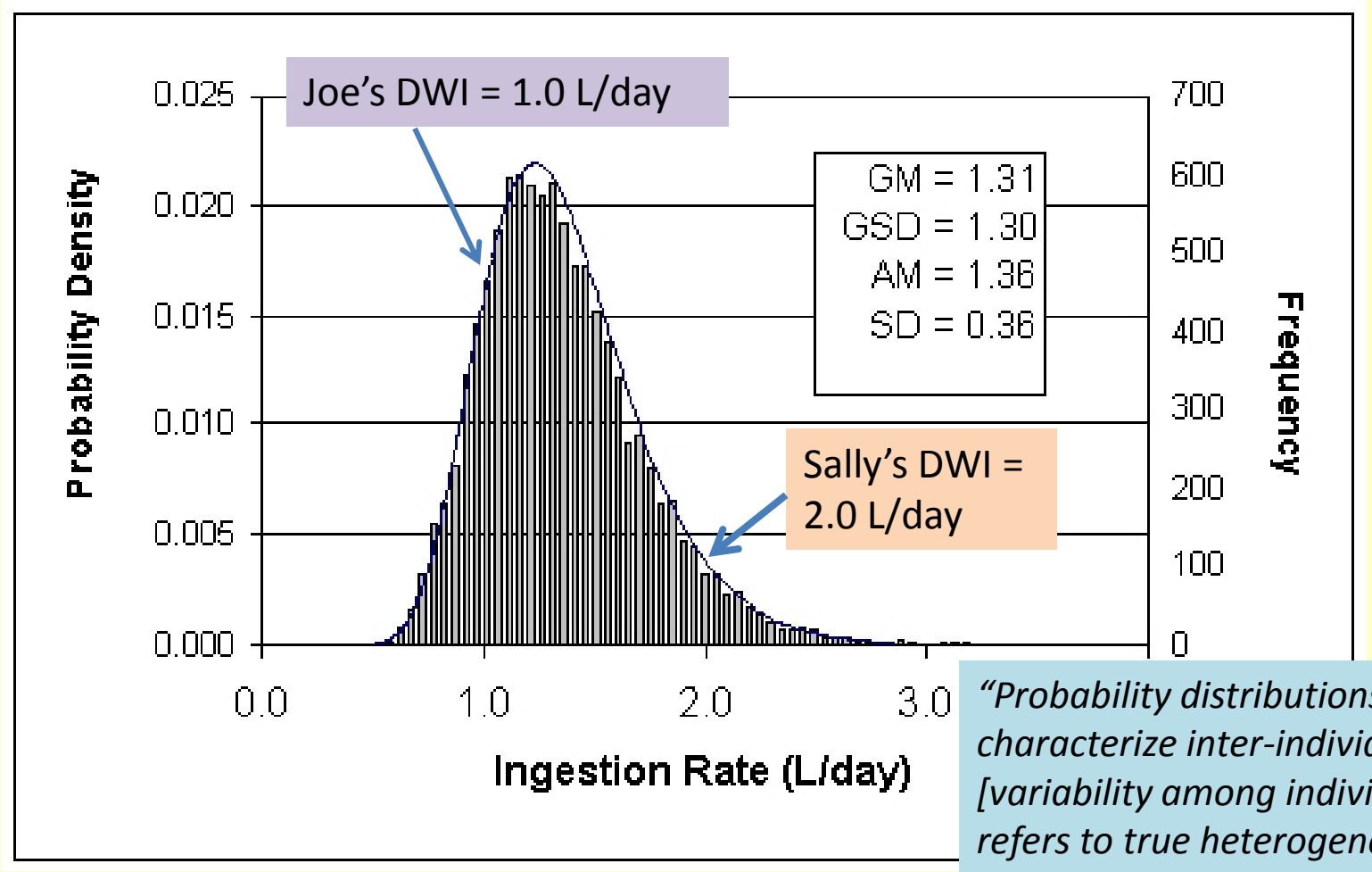
Regardless of whether a probability distribution is derived from site-specific measurements or obtained from the open literature, the distribution should be applicable to the target population of the analysis.

> *"The distribution selected should be derived from the target population or from a surrogate population that is representative of the target population at the site."* (EPA 2001)

Not all the variables in the equation have to be distributions. In some cases good distributions are not readily available for all variables. Frequently only one or a small number of variables are represented by distributions, and the other variables are represented by point estimates.

Information on Probabilistic Analysis based on ***USEPA , 2001 , Risk Assessment Guidance for Superfund, Volume 3 Part A , Process for Conducting Probabilistic Risk Assessment .***

Example of a drinking water frequency distribution overlain by a probability density function.



"Probability distributions are used to characterize inter-individual variability [variability among individuals], which refers to true heterogeneity or diversity in a population." (EPA 2001)

Adapted from: USEPA , 2001 , Risk Assessment Guidance for Superfund, Volume 3 Part A , Process for Conducting Probabilistic Risk Assessment

Figure 3-1. Example of a frequency distribution for adult drinking water ingestion rates, overlaid by a graph of the probability density function (PDF) for a lognormal distribution defined by the sample statistics. The distribution represents inter-individual variability in water intakes and is characterized by two parameters. Typically, the geometric mean (GM) and geometric standard deviation (GSD), or the arithmetic mean (AM) and arithmetic standard deviation (SD) are presented to characterize a lognormal distribution.

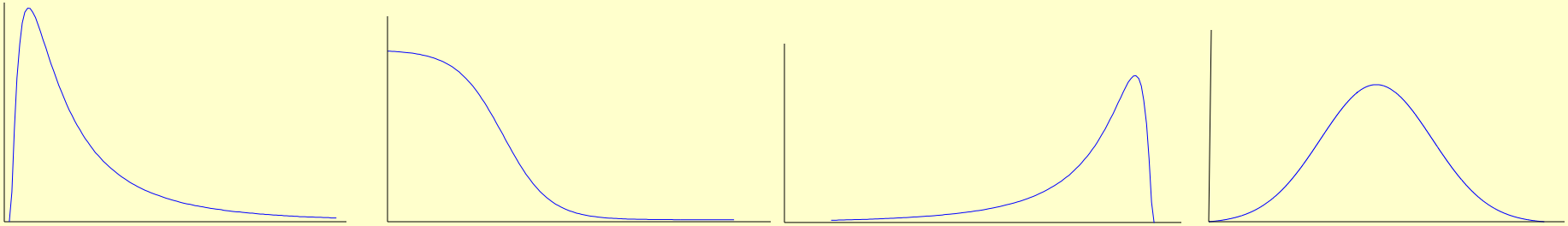
"Probability distributions are used to characterize inter-individual variability, which refers to true heterogeneity or diversity in a population. Thus, variability in daily intake, for example, can be characterized by combining multiple sources of variability in exposure, such as ingestion rate, exposure frequency, exposure duration, and body weight." (EPA 2001)

"For the majority of the exposure variables, such as exposure duration, water intake rates, and body weight, site-specific data will not be available. The risk assessor will have to either select a distribution from existing sources, or develop a distribution from published data sets and data summaries." (EPA 2001)

"A Monte Carlo simulation is executed by ***repeatedly selecting random values from each of these distributions and calculating the corresponding exposure and risk.*** *" (EPA 2001)*

A new risk distribution is developed, based on repeated calculations, using randomly drawn values from each distribution for each calculation. This is a very rigorous analysis.

Below: Examples of different types of variability shown by hypothetical distributions. In a point estimate approach one value from each distribution would be chosen to represent that parameter and calculate risk. With probabilistic analysis the entire distribution (if available) for each variable would be drawn from, over many thousands of sampling and calculation events, to develop a risk distribution.



This concludes summary information on probabilistic analysis.

This will be followed by a video of a probabilistic analysis developed by FDEP that shows how the analysis works. Ken Weaver from FDEP will introduce and discuss this video.

During the following presentation Ken Weaver will show details of how a probabilistic analysis can be used to develop human health criteria that correspond to a specified risk level and target population metric.

Questions/discussion prior to Florida DEP presentation.

Florida Department of Environmental Protection

Water Quality Standards

Florida's Experience with the Probabilistic Approach

Ken Weaver

July 11, 2013

Florida Rulemaking History

1993
- Degner's one-year fish study began.

1995
- DEP petitioned to initiate rulemaking.
- Law passed requiring Risk Impact Statements for rules sent to ERC that address human health.

1996
- The Florida Risk-Based Priority Council developed Guidelines for Risk Analysis in conjunction with rulemaking.

1997
- DEP began to develop Risk Analysis Plan.

1998
- UF initiated a three-year baseline risk analysis.
- EPA Issues Revised Criteria. 3-Year expectation of State revisions.

2001
- DEP presented baseline risk analysis.

2003
- DEP presented HHC based on EPA's risk formula.

2008
- DEP re-proposed HHC, but soon dropped effort due to nutrient criteria litigation.

2009
- EPA petitioned to initiate rulemaking.

2013
- DEP presented revised HHC to Environmental Regulation Commission, commission continued rulemaking.

Florida's Current Approach

- Probabilistic Assessment
- Input values are a mix of point estimates and distributions
- Exposure is assumed to occur at the level of the Surface Ambient Water Quality Criterion
  - Class I: Potable water supplies and Fish Consumption
  - Class III: Fish Consumption
- Results are distributions of risks calculated for the populations of interest
- Criteria were set at levels necessary to achieve target risk level

Florida Human Health Proposal

- Proposed to adopt new or revised human health-based criteria for 67 parameters (in 62-302.530, F.A.C.)
- Parameters that were considered but not added or revised include:
  - Banned pesticides: 4,4'-DDD, 4,4'-DDE, alpha-BHC, Endrin aldehyde, and Hexachlorobenzene
  - Six parameters (Endosulfan, Endosulfan sulfate, Endrin, Lindane, Selenium, and Toxaphene) with more stringent aquatic life criteria
  - Acute aquatic life criteria for Lindane are more stringent
  - Six parameters for which current toxicological data does not support criteria revision at this time (1,1,1-trichloroethane, 1,3-Dichlorobenzene, 1,4-Dichlorobenzene, Arsenic, Methyl Chloride, and Thallium)

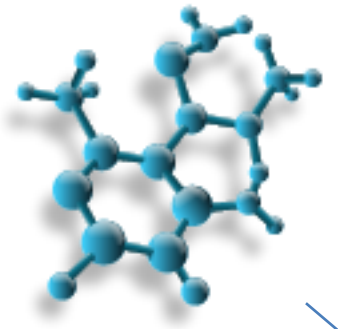
Rule Status

- FDEP took the rule to the Environmental Regulation Commission on April 23, 2013
- Commission voted to continue the rulemaking in late 2013, directed Department to
  - Further evaluate default relative source contributions
  - Evaluate state level or regional NHANES fish consumption rates, potentially using National Cancer Institute methodology
  - Consider alternative averaging periods for non-carcinogens

Deriving Human Health Water Quality Criteria

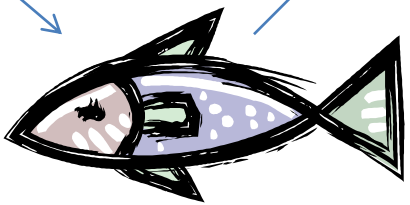
Set at levels that ensure Florida waters are safe for residents by using the following factors:

Pollutant toxicity



- Cancer Potency
- Disease

Exposure



Bioaccumulation: through food web
Bioconcentration: through gills

Human Sensitivity

Protection Goals

- EPA assumes daily exposure over the course of a lifetime
- EPA assigns a mix of average values and high end values (*e.g.*, 90th percentile) for exposure parameters such as ingestion rates and body weight
- EPA's criteria are derived to protect the majority of the general population

EPA's Default Exposure Parameters

- EPA used the following default values for the national recommended water quality criteria when chronic health effects are of concern
  - BW = 70 kg; average adult body weight
  - DI = 2 L/day; 90th percentile estimate
  - FI = 17.5 g/day; 90th percentile estimate

Deterministic Approach

- For the "standard" deterministic approach, all input variables are point values (EPA defaults or state specific)
- Point measurements are selected from a population distribution (*e.g.*, mean, median, 90th percentile, 95th percentile)
  - Typically based on conservative assumptions
  - Often represent high-end or high risk values
  - Selection is based on professional judgment or policy decision
  - Subject to disagreement
- Has the advantage of being simple to compute and easily reproduced

Deterministic Approach (continued)

- Following default approach can lead to combining several (conservative) typical/default values
  - Criticism that the approach compounds levels of conservatism
  - Can distort the risk assessment; *i.e.*, the results are unrealistic and overly stringent
  - Florida's baseline risk analysis demonstrated that layering of conservative assumptions is unnecessary
- Reliance on point values discards information about variability within and between populations
- Tendency to focus on the wrong endpoints; *i.e.*, what is the fish consumption rate, rather than what is the level of protection

Probabilistic Alternative

- Variability within the population affects exposure and thus risk
- Human health criteria are set at the highest concentration of a pollutant in water that is not expected to pose a significant risk to human health
- Thus, need to focus on assessing risk and setting criteria at levels associated with risk at no greater than the target
- Probabilistic approach can help focus the discussion on risk
  - Still requires selection and description of target populations
  - Necessitates policy decisions regarding acceptable risk levels

Probabilistic Alternative

- Point measurements do not accurately describe populations
- Populations are better described using distributions
- Probabilistic approaches replace most or all of the point estimates with distributions
- Risks are calculated for the target population based on these distributions

Probabilistic Approach Advantages

- Uses all available information including variability and uncertainty
- Can reveal and reduce compound conservatism
- Allows sensitivity analyses
  - Key professional judgments and policy decisions
  - Quantification of the influence of individual input distributions
- Provides a more complete assessment of risk
  - Fewer assumptions about the level of protection afforded
  - Communication with the public and policy makers

Probabilistic Approach Disadvantages

- More complex calculations
  - Requires programming or specialized software
  - Not easily reproduced by all stakeholders
- Difficult to explain to public and may be (mis)represented as a way of making criteria less stringent (*e.g.*, "cancer lottery")
- The results are only as good as the inputs (true for deterministic approach)
- Does not eliminate controversy
  - Protective risk levels
  - Target populations
  - Defining input distributions
  - Remaining levels of "compounded conservatism"

Should be the primary focus

FL Policy Choices on Setting Criteria

Florida Statutes for waste cleanup state (376.30701 F.S.) that levels should represent extremely low risk:

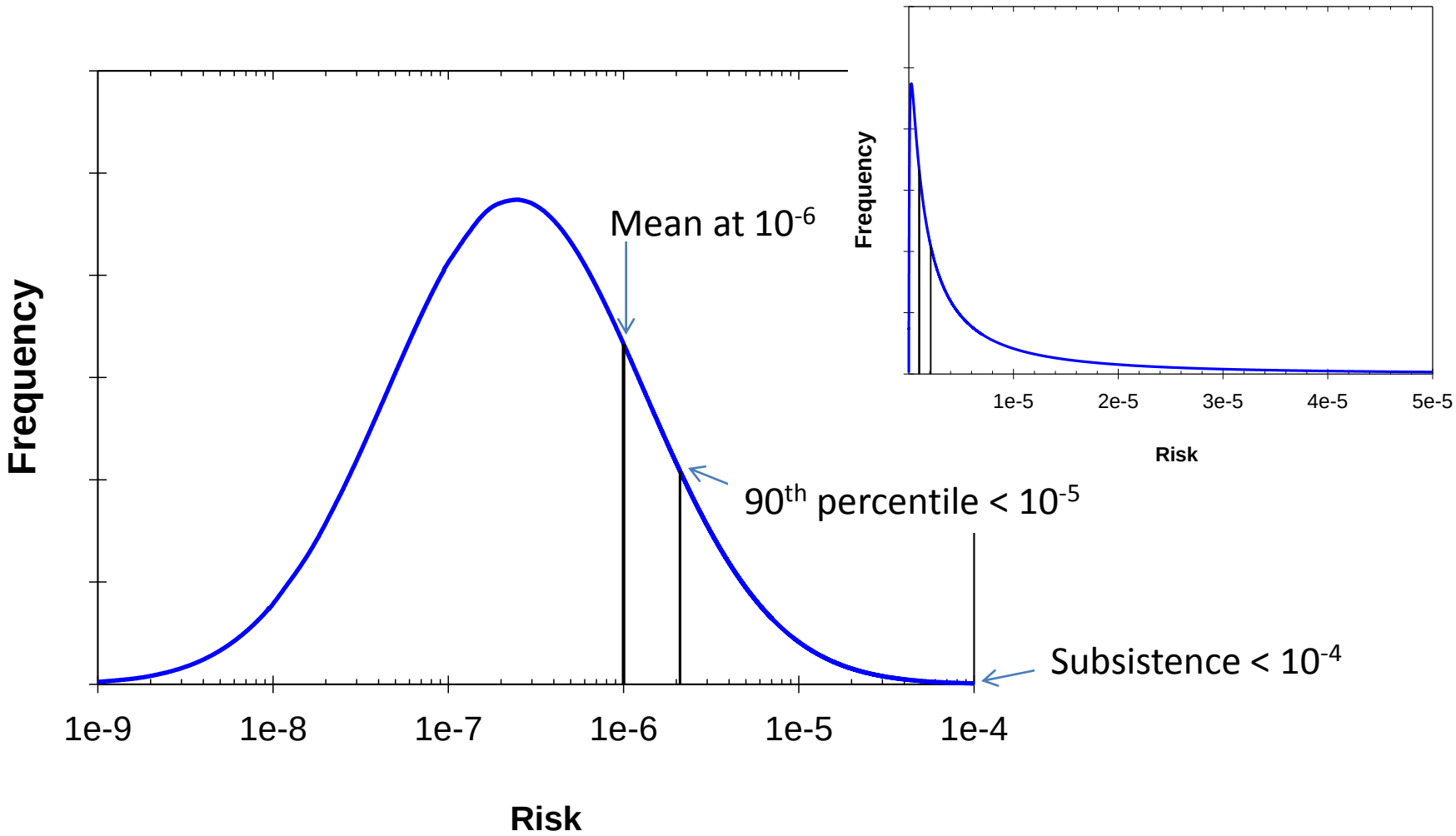
+0.000001% (10^{-6}) increase

Florida Department of Health issues fish consumption advisories at levels that represent very low risk:

+0.00001% (10^{-5}) increase.

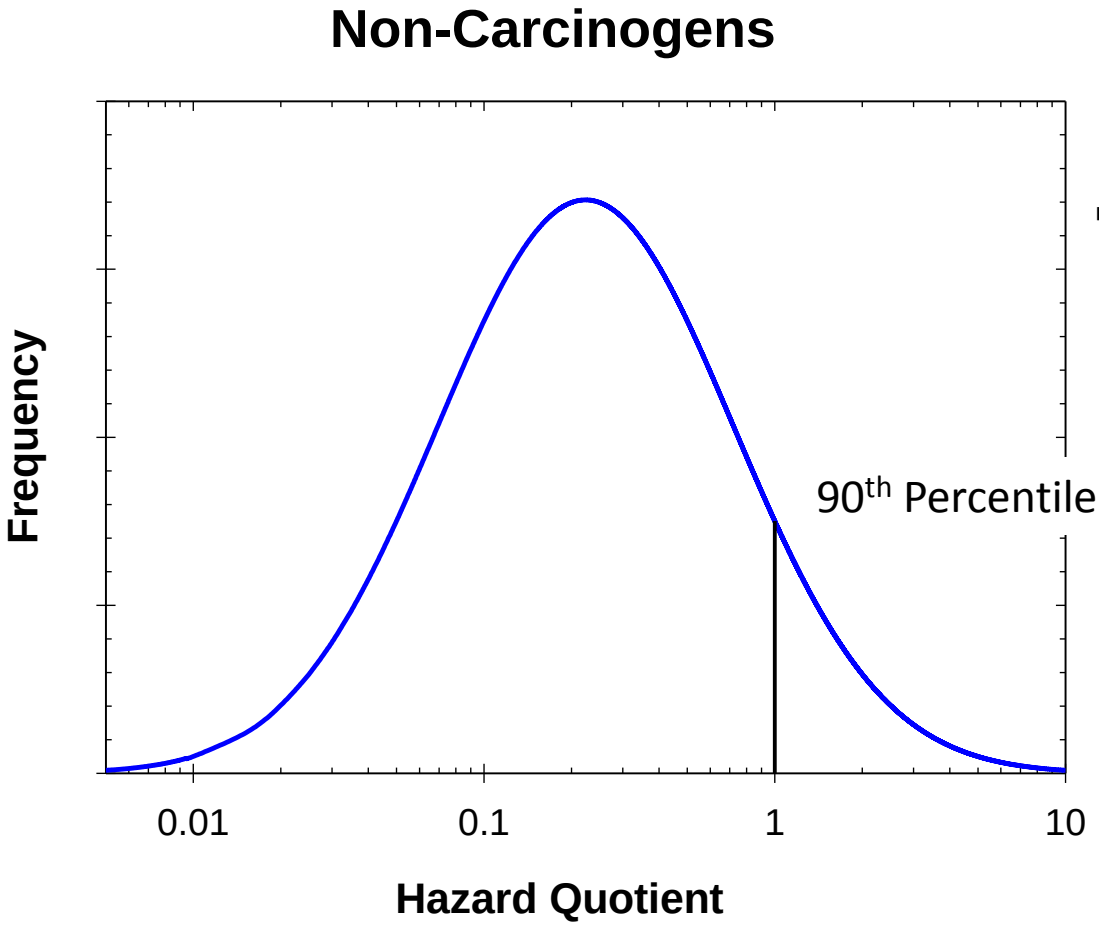
Conclusion: The average Floridian should be protected at the extremely low risk, the higher risk population should be protected at better than the very low risk, and subsistence fisherman should be protected at better than the low risk.

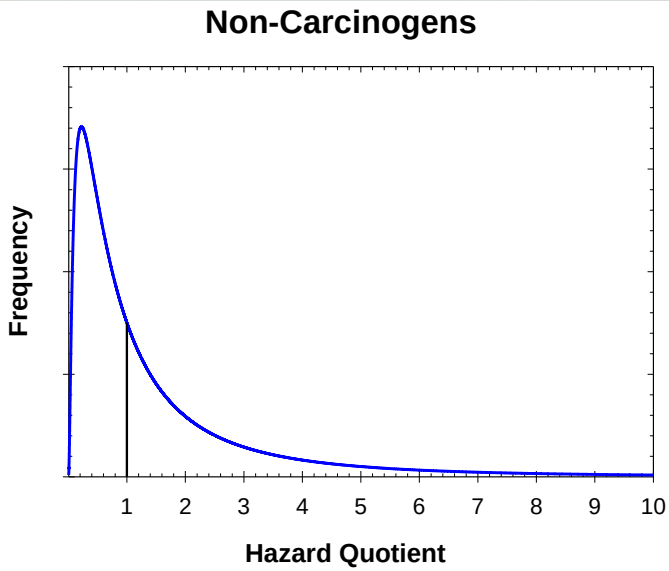
Risk Level for Carcinogen Criteria Derivation



Note: x-axis is on a log scale

Non-Carcinogen Criteria Derivation





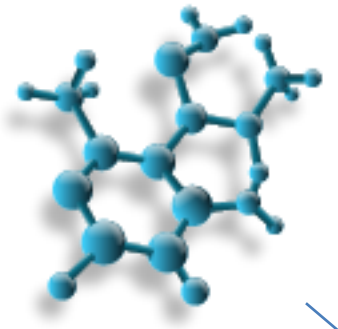
90th Percentile at HQ=1

Note: x-axis is on a log scale

Deriving Human Health Water Quality Criteria

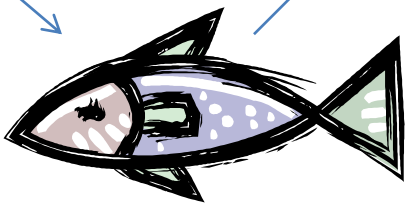
Set at levels that ensure Florida waters are safe for residents by using the following factors:

Pollutant toxicity



- Cancer Potency
-Reference Dose

Exposure



Human Sensitivity

Point Value Inputs

Parameter	Point Value Model Inputs					
	Criterion		RfD	BCF	RSC %	RSC Adjusted Rfd
	Class I	Class III				
1,1,1-Trichloroethane	9108	210000	2	5.6	0.2	0.4
1,1-Dichloroethene	227	5254	0.05	5.6	0.2	0.01
Acenaphthene	108	146	0.06	242	0.2	0.012
Acrolein	0.972	1.369	0.0005	215	0.2	0.0001
Anthracene	1213	5885	0.3	30	0.2	0.06

Criteria Values

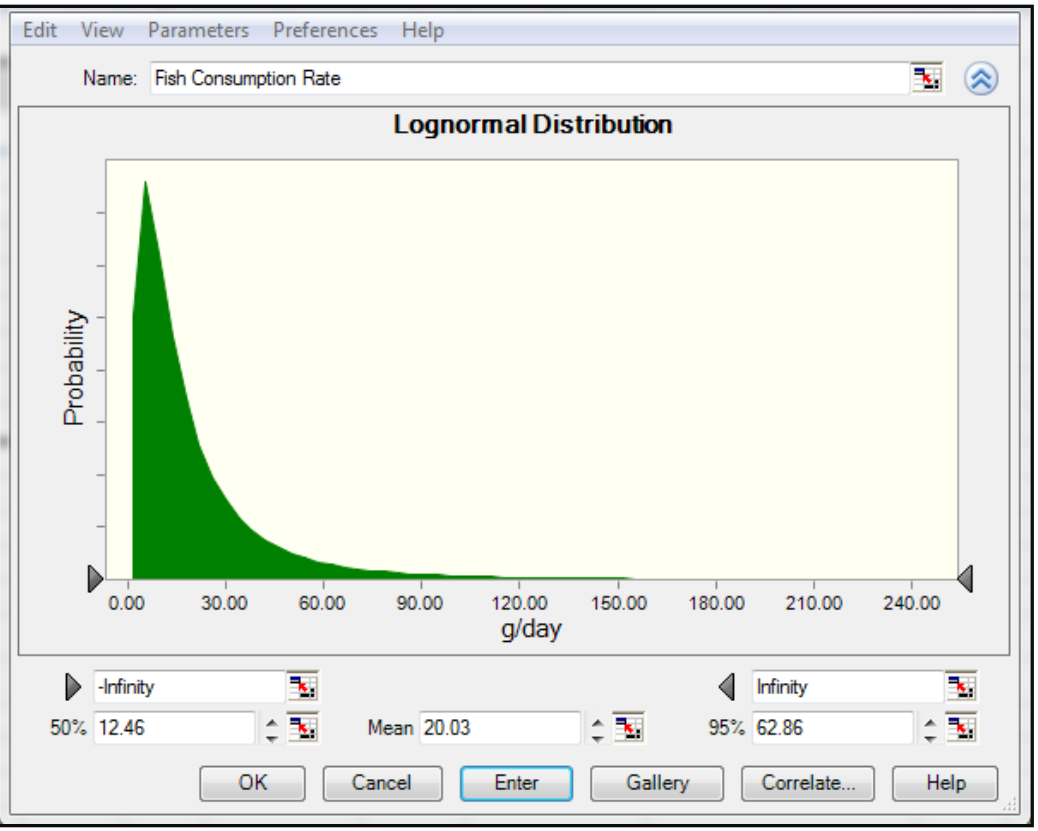
Latest Toxicity Values

Distributional Inputs

Risk Assessment for Non-Carcinogens

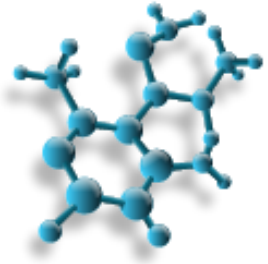
Distributional Model Inputs

Variable Type	Variable	Class I	Units
Distribution	Body Weight	70.00	*kg*
Distribution	FCR	17.50	g/day
		17.50	g/day
Distribution	Lipid Content	3.00	%
Distribution	DW Consumption	2000	mL/d
		2000	mL/d



Full Risk Assessment Approach

Pollutant toxicity



Exposure

Human Sensitivity

		Body Weight (Kg)	Drinking Water (mL/day)	Fish Consumption without Shrimp Re-apportionment (g/day)	Fish Consumption with Shrimp Re-apportionment (g/day)	Lipid (%)	Swim freq. (Event/yr)	Swim time (hr/event)
	Distribution	Lognormal	Lognormal	Lognormal	Lognormal	Custom	Custom	Triangular
Percentile	5	52	302	1.99	1.69	0.76	1.8	0.62
	10	57	506	3.41	2.88	0.87	2.6	0.81
	20	63	799	5.98	4.99	1.06	4.3	1.07
	30	68	1,043	8.53	7.14	1.25	6.8	1.33
	40	73	1,273	11.42	9.59	1.50	9.6	1.60
	50	78	1,513	14.87	12.48	1.58	12	1.90
	60	83	1,777	19.23	16.18	1.67	16	2.22
	70	89	2,093	25.23	21.20	1.75	25	2.60
	80	96	2,501	34.48	28.94	2.26	38	3.04
	90	108	3,149	52.65	44.11	3.21	58	3.61
	95	118	3,782	74.44	62.28	3.36	72	4.01

Exposure and Risk Calculations

Exposure Calculations			Risk	
Exposure through FC		Exposure through DW	Hazard Quotient	
Class I	Class III	Class I	Class I	Class III
0.8926	20.5800	18.2160	0.6824	0.7350
0.0222	0.5149	0.4540	0.6804	0.7356
0.4574	0.6183	0.2160	0.8016	0.7361
0.0037	0.0052	0.0019	0.8002	0.7358
0.6368	3.0896	2.4260	0.7292	0.7356

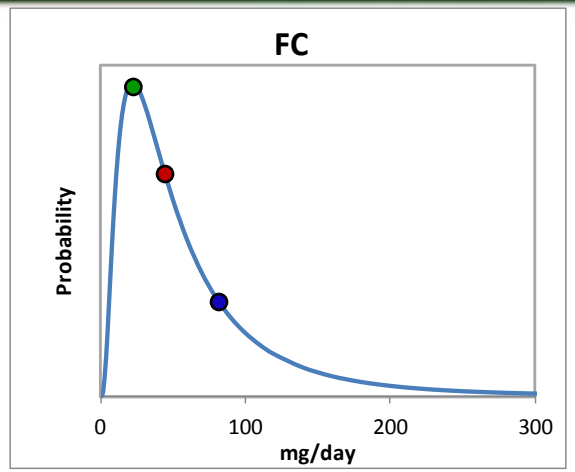
$$HQ = \frac{I_{w+}I_f + D_{Swim}}{BW \times RfD}$$

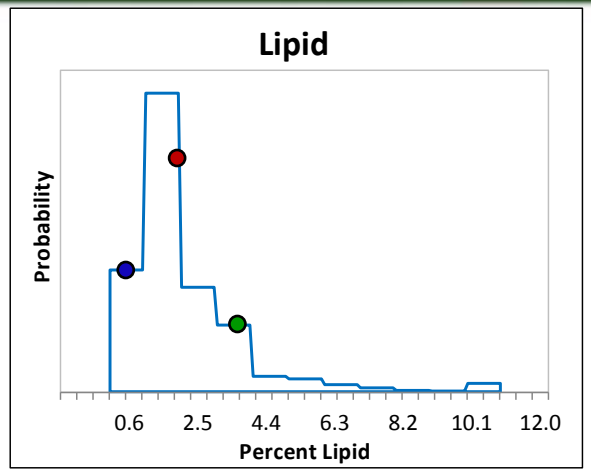
$$I_w, mg/d = SWCx\frac{DI}{1000}$$

$$I_f, mg/d = SWCx\frac{FC}{1000}xBCFx\frac{PL}{3}$$

Monte-Carlo Simulation

(Class III non-carcinogen)





Constants

Criterion

BCF

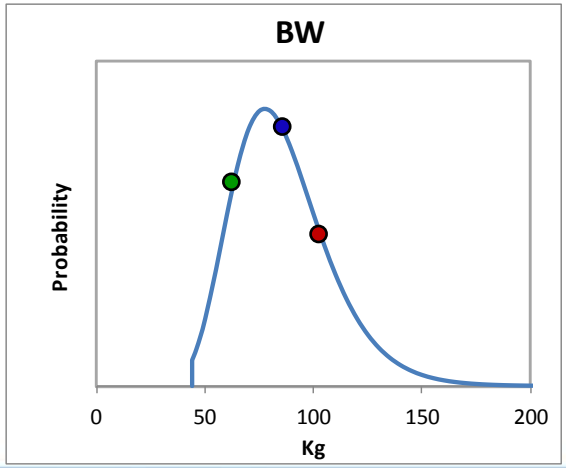
RfD

Random selections from distributions

$$I_{f,i} = SWCx\frac{FC_i}{1000}xBCFx\frac{PL_i}{3}$$

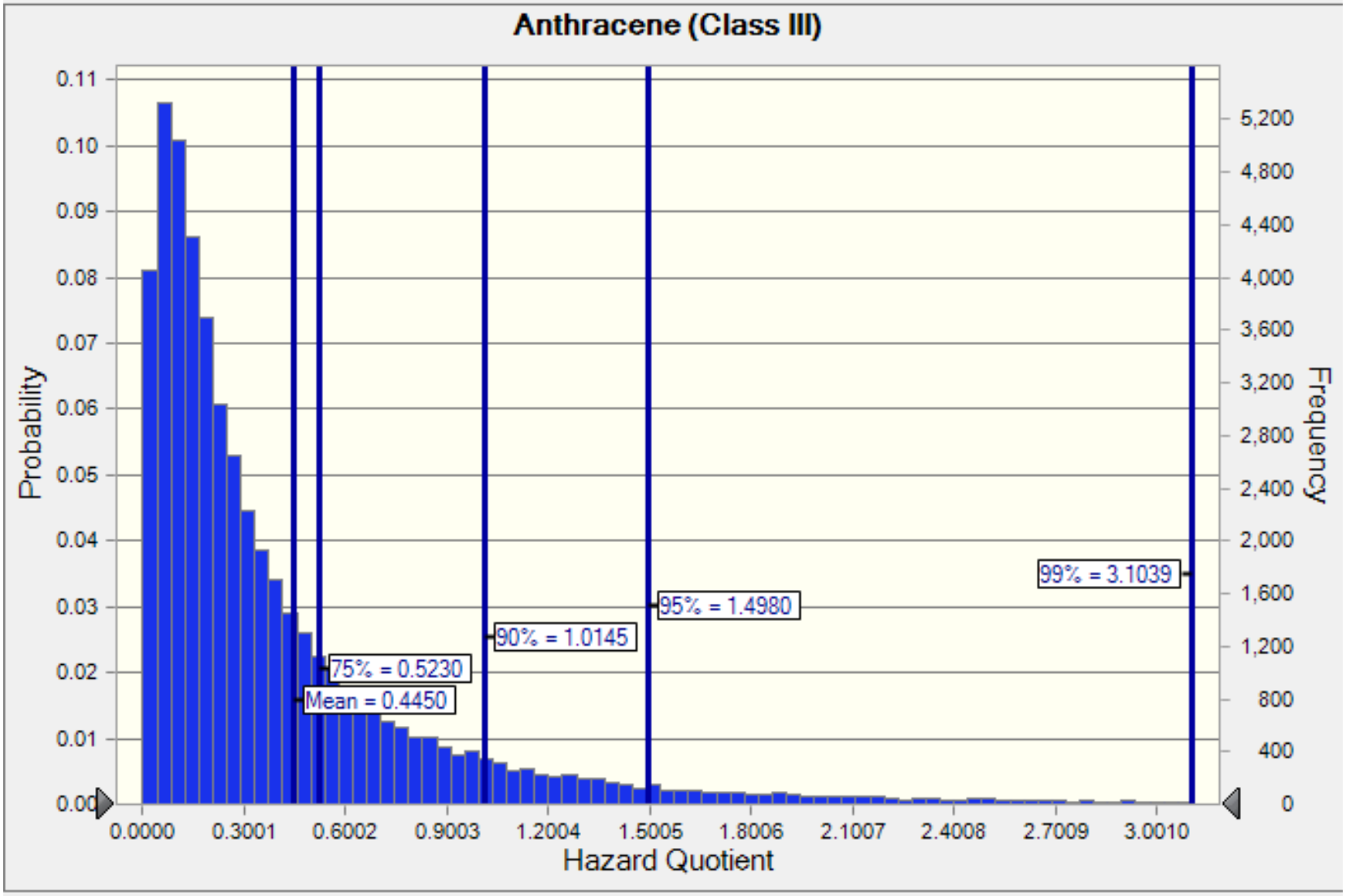
$$HQ_i = \frac{I_{f,i}}{BW_i xRfD}$$

Random selection



Run for *50,000* iterations

Risk Distribution



Criteria Derivation

- Each parameter derived independently for both Class I and Class III waters
- Surface water criterion concentration iteratively adjusted (reduced) to achieve:
  - Hazard Quotient of 1.0 at the 90th percentile for non-carcinogens
  - Mean risk of 10^{-6} carcinogens
    - Risk below 10^{-5} at the 90th percentile
    - Risk for carcinogens are all below 10^{-4} for subsistence fishers (142.4 g/day)

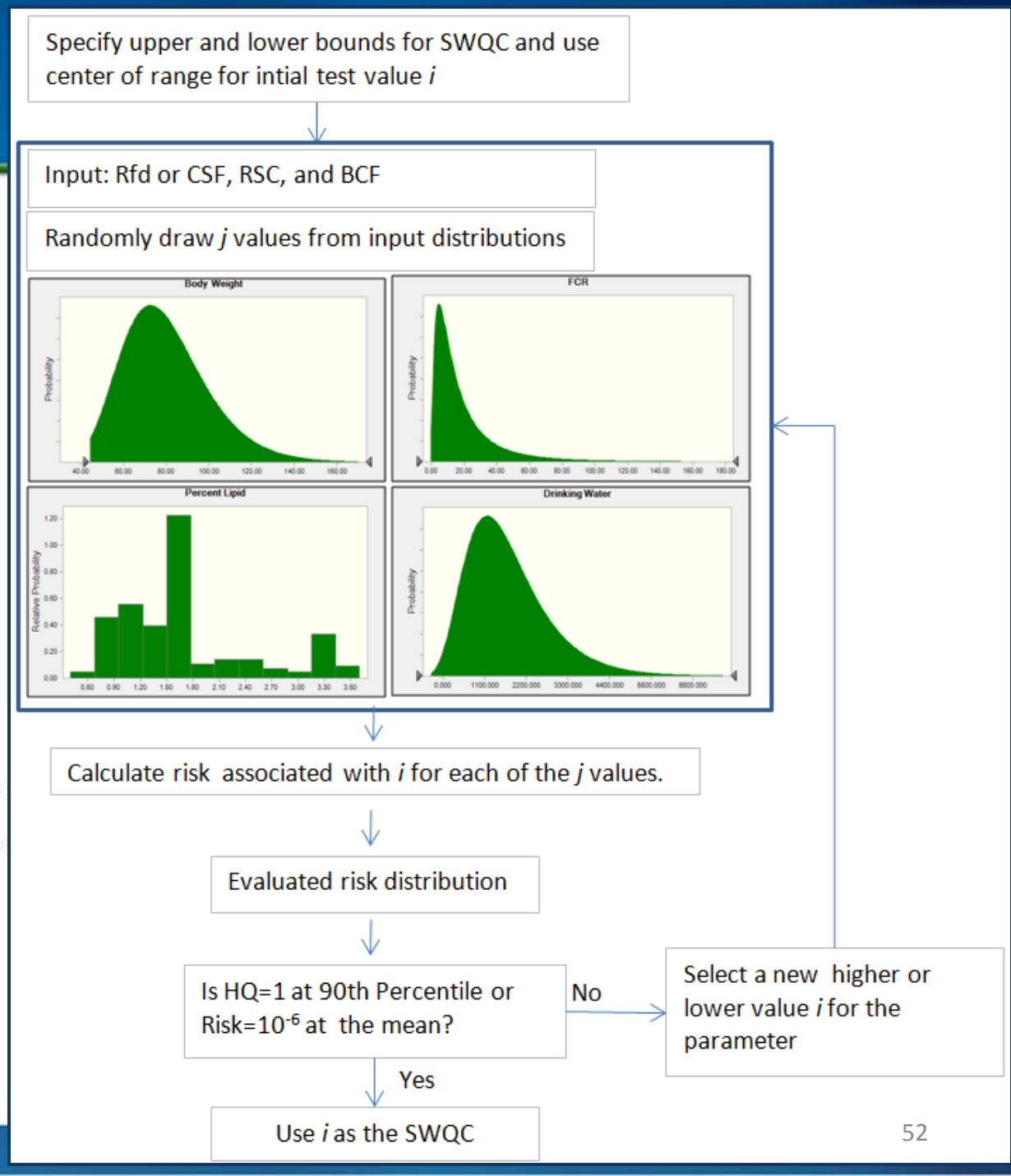
Criteria Derivation

Non-Carcinogens

$$HQ = \frac{I_{w+}I_f + D_{Swim}}{BW \times RfD}$$

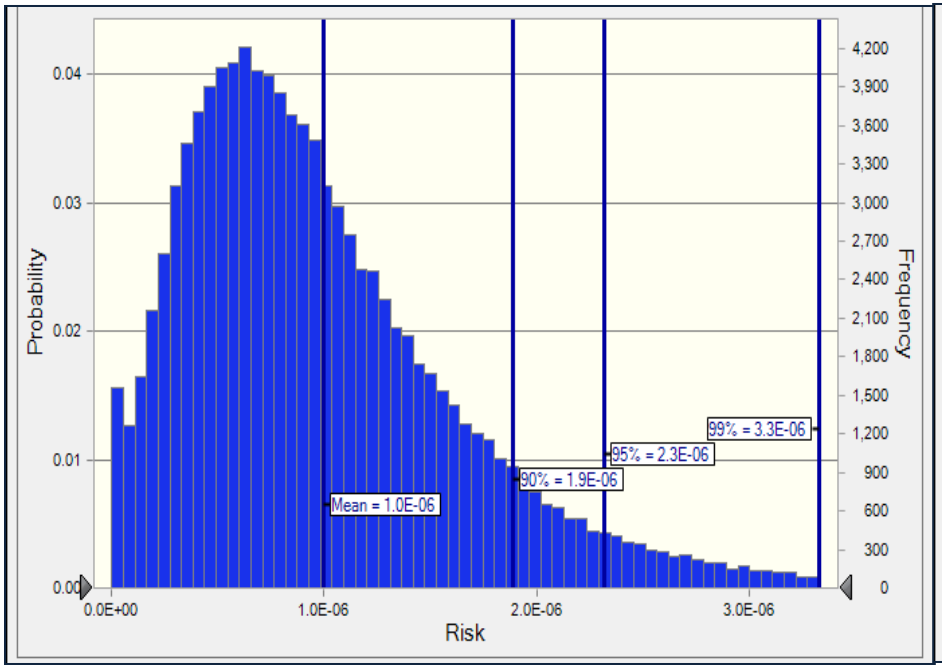
Carcinogens

$$Risk = \frac{(I_{w+}I_f + D_{Swim}) \times CSF}{BW}$$

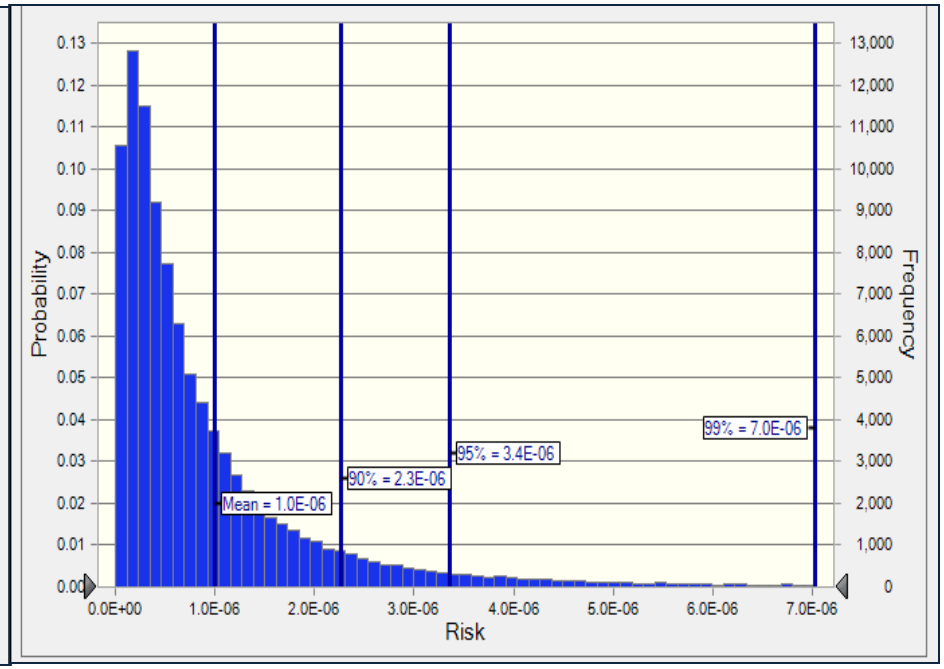


Carcinogen: Bromoform

Class I Criterion: 9.49 µg/L

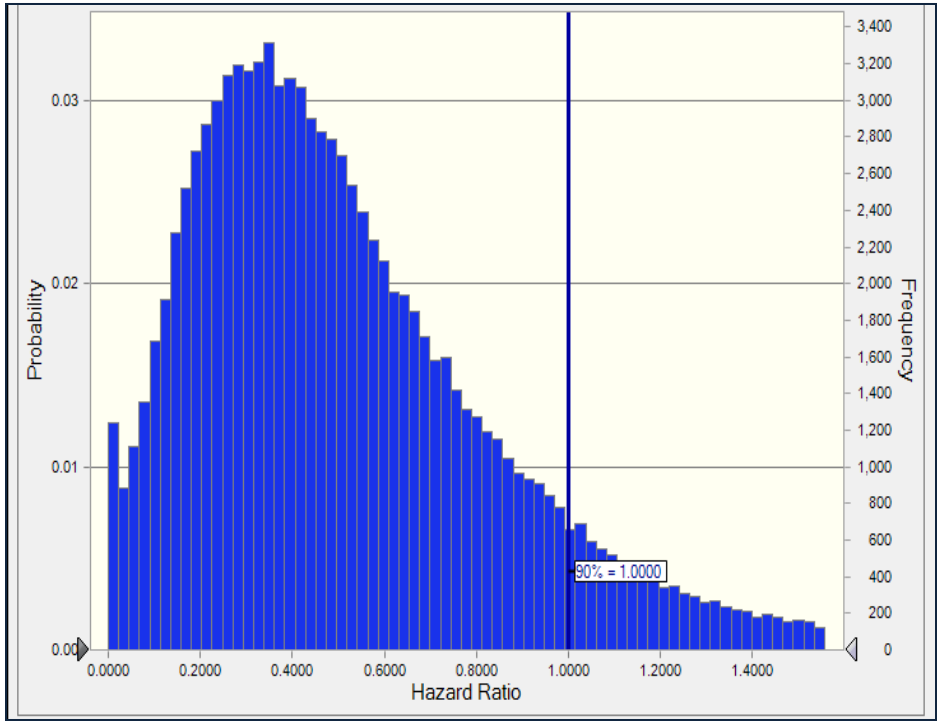


Class II/III Criterion: 390 µg/L

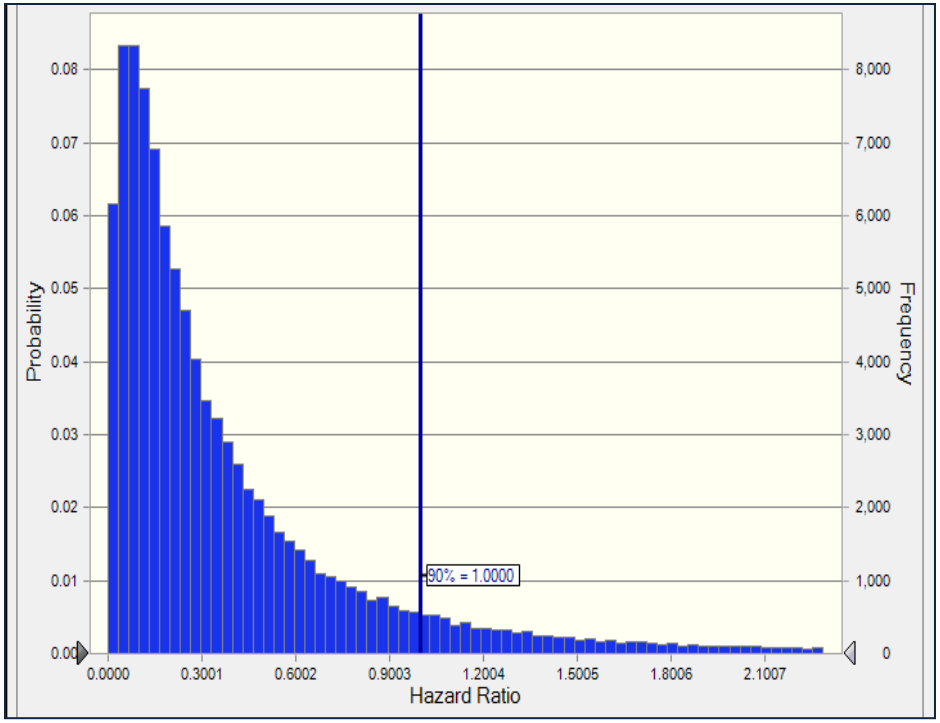


Non-Carcinogen: Chloroform

Class I Criterion: 45.9 µg/L



Class II/III Criterion: 1569 µg/L



Data Sources

- Toxicity
  - EPA's national recommendations (http://water.epa.gov/scitech/swguidance/standards/upload/2002_12_30_criteria_wqctable_hh_calc_matrix.pdf)
  - EPA Integrated Risk Information System (http://www.epa.gov/IRIS)
  - Other peer reviewed sources

Data Sources (continued)

- Exposure
  - 1995 Florida Fish Consumption Survey (Degner)
  - 2008 Baseline Risk Analysis
  - 2011 EPA Exposure Factors Handbook (http://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=236252)
  - 2004 Risk Assessment Guidance for Superfund Part E (http://www.epa.gov/oswer/riskassessment/ragse/index.htm)

Brief Fish Consumption Rate History

- Started with a Florida specific Survey conducted in 1994 (2003)
- Adjusted Florida Survey data
  - Florida species only (2005, May 2012)
  - Commercial landings adjusted Florida species (2008, July 2012)
- 2012 Peer Review Committee concluded that the Survey was outdated and should not be relied upon as the sole basis for a consumption distribution
- Peer Review Committee recommended using more contemporary national survey distributions adjusted to Florida conditions and landings

Brief Fish Consumption Rate History

- November 2012 Proposal combined two distributions
  - Commercial consumption based on national survey (NHANES 2003-2006) adjusted to Florida commercial landing; and
  - Recreational consumption based on the 1994 Florida Survey
  - Probability of being a non-consumer, consumer of commercial fish only, or consumer of both recreational and commercial fish
- EPA FAQ Sheet: *standards will be set to enable residents to safely consume from local waters the amount of fish they would normally consume from all fresh and estuarine waters*

NHANES

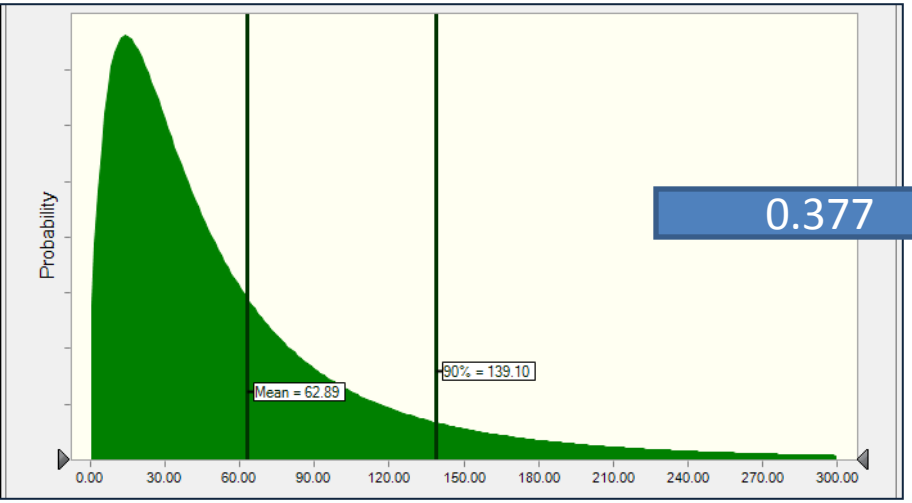
- The National Health and Nutrition Examination Survey (NHANES) is a program of studies designed to assess the health and nutritional status of adults and children in the United States
- EPA analyzed national 2003-2006 NHANES seafood consumption data and provided distributional summaries in the 2011 Exposure factors handbook
- Limitations:
  - National scale rather than state specific or regional
  - Includes marine, estuarine, and freshwater species

Revised Fish Consumption Rates

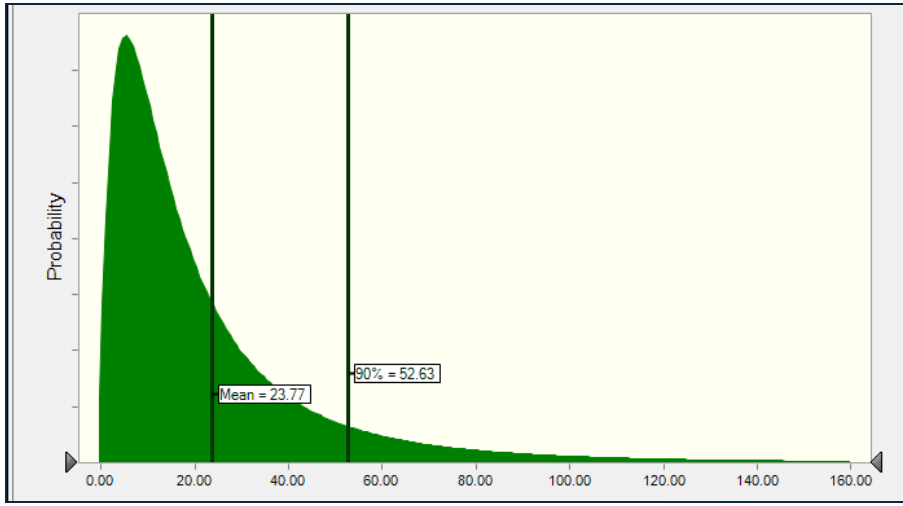
- Ratio between combined freshwater and estuarine consumption and total consumption (fresh, estuarine and marine) from the CSFII survey (EPA 2002) was applied to the national NHANES data to adjust the distribution to reflect only fresh and estuarine consumption rates
- Two new consumption distributions were developed
  - Parameters with BCF >300: NHANES adjusted to exclude marine species
  - Parameters with BCF <300: NHANES adjusted to exclude marine species with a re-apportionment of a portion of shrimp consumption to marine waters

Fish Consumption Rate 1

- NHANES adjusted to exclude marine species
  - Mean consumption of freshwater and estuarine species: **<u>7.50</u>** g/day
  - Mean consumption of marine species: 12.41 g/day
  - Mean total consumption : **<u>19.91</u>** g/day
- Fresh/Estuarine Adjustment Factor 1=7.50/19.91=**0.377**



0.377



Fish Consumption Rate 2

Habitat Apportionment

- EPA (2002) reports mean consumption rates for individual estuarine, marine, and freshwater species
- The report describes how the consumed fish component for certain species (*e.g.*, salmon, crab, unknown fish) were apportioned across multiple habitats using commercial landings reported by the U.S. Department of Commerce
- EPA methodology did not apportion shrimp between marine and estuarine habitats
  - A large fraction of shrimp are caught in marine waters (>3 miles)
  - DEP reviewed national Landings reports from the Department of Commerce and NOAA
  - Approximately 51% of shrimp are caught within 0-3 mile of shore
    - 2002-2011 Landings data, excluding 2010
    - Upper 90% confidence interval is 56%
  - DEP assigned 56% of the shrimp to the estuarine habitat

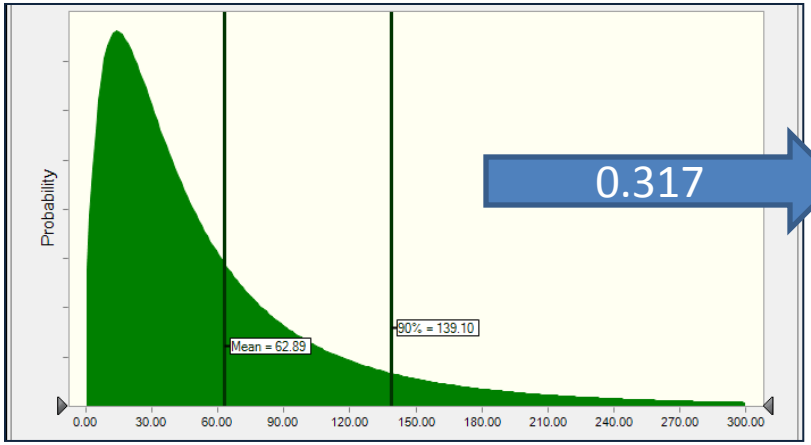
NOAA Shrimp Landings

Year	0-3 miles from shore (metric tons)			Total Landings (metric tons)			Proportion
	S. Atlantic	Gulf	Total	S. Atlantic	Gulf	Total	
2011	4902	39322	44224	10069	96162	106231	0.416
~~2010~~	~~3378~~	~~26408~~	~~29786~~	~~10238~~	~~80024~~	~~90262~~	Excluded
2009	4065	43654	47719	9447	109318	118765	0.402
2008	5474	60831	66305	10416	85410	95826	0.692
2007	5567	28543	34110	9342	80092	89434	0.381
2006	5677	57856	63533	9572	111496	121068	0.525
2005	6560	51598	58158	7077	97307	104384	0.557
2004	6299	66814	73113	11457	116519	127976	0.571
2003	8485	62290	70775	10047	115565	125612	0.563
2002	10662	54802	65464	11983	104089	116072	0.564
					Mean		0.514
					Std. Dev.		0.106
					n		9
					$t_{0.1(1),8}$		1.397
					Upper 90% C.I.		**0.560**

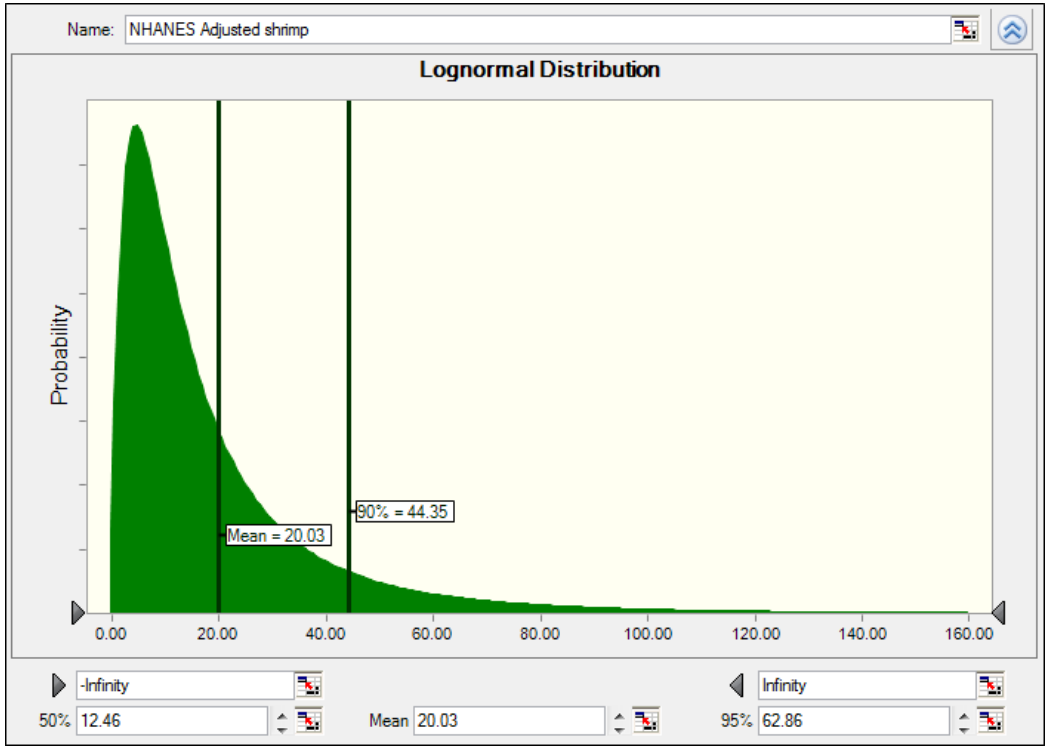
Shrimp Habitat Apportionment Factor

Source: Fisheries of the United States (http://www.st.nmfs.noaa.gov/st1/publications.html)

Adjusted NHANES Distribution with Shrimp Re-apportionment



0.317



31.7% of total fish consumption was assumed to originate from Fresh or Estuarine waters after the re-apportionment of shrimp.

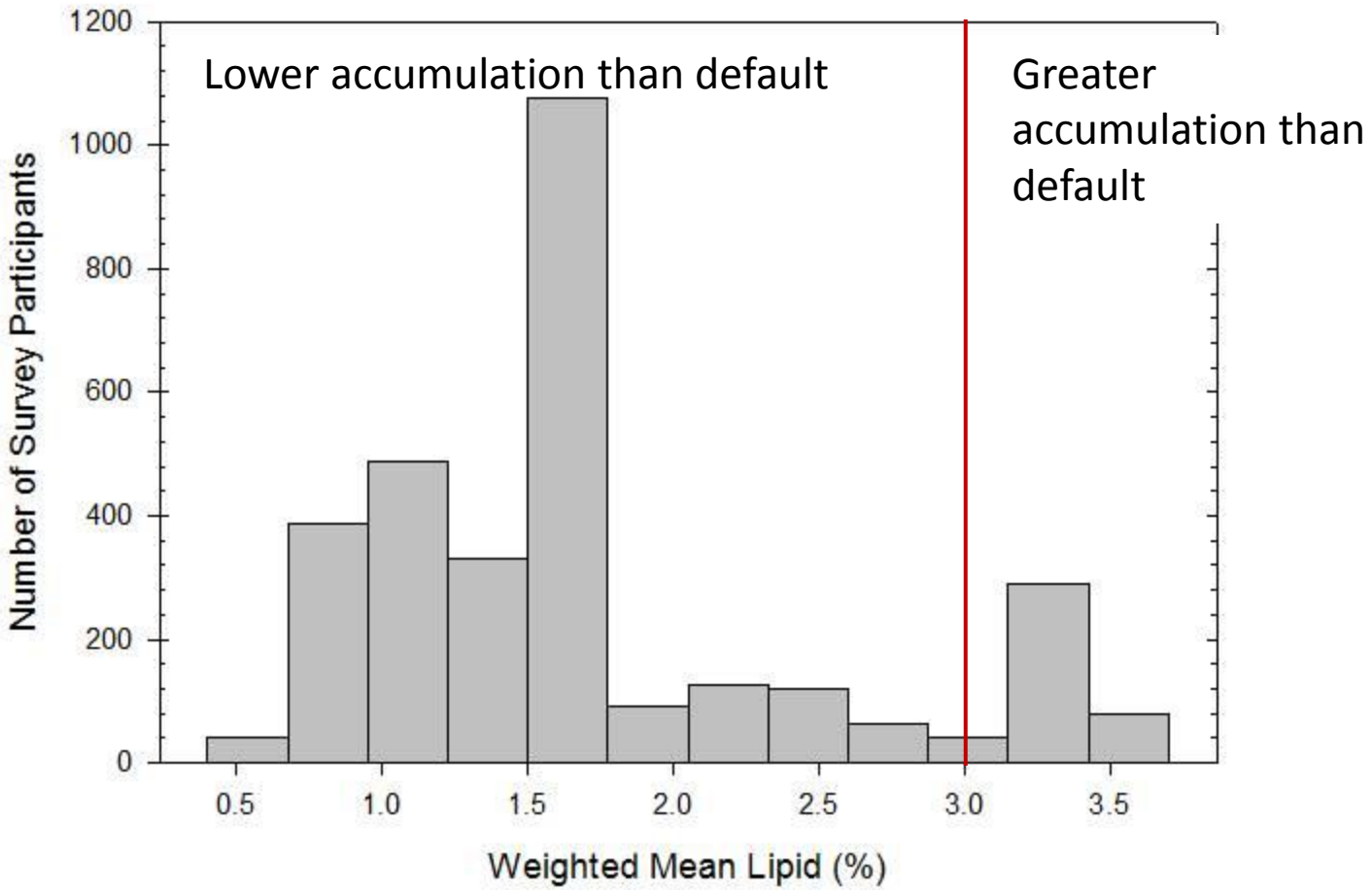
Lipid Content

- One of the most important determinants of BCF is lipid solubility of a chemical
- Chemicals with a high degree of lipid solubility tend to accumulate in fatty tissues, leading to a high BCF
- Fish with high levels of fatty tissues accumulate more of these chemicals
- U.S. EPA uses a single BCF (normalized to an average fish lipid content of 3%) for each chemical
- Lipid content of fish in the diet was entered as a distribution based on the relative proportions of different fish species being consumed and the lipid content of each species
- Lipid content was ‘turned off’ for inorganic compounds

Florida Freshwater and Estuarine Species Lipid Distribution

- Developed as consumption weighted averages
  - Consumption rates, from Degner, for Florida freshwater and near shore marine species
  - Weighted average was calculated for each consumer of Florida fish (n=3136)
  - Developed a distribution based on the individual weighted average percent lipid values
- Represents the range of species consumed from Florida waters

Florida Freshwater and Estuarine Species Lipid Distribution



Remaining Uncertainties

- Variability in contamination levels
  - Spatial and temporal variability within a water body
  - Fish consumed are not all taken from the same water body
  - Fish moving in and out of contaminated areas
  - Cooking and other losses prior to consumption
- Variability in toxic response within the human population
  - Some uncertainty factors could be handled as distributions
  - Potential to express toxicity values (RfD, CSF) as distributions

RfD Uncertainty Factors

- Five areas of consideration
  - Intraspecies variation (UF_H)
  - Interspecies variation (UF_A)
  - Uncertainty due to the duration of study (UF_S)
  - Uncertainty due to use of a LOAEL (UF_L)
  - Uncertainty due an inadequate database (UF_D)

Future potential to represent as a distribution

Remaining Uncertainties

- Exposure duration-assume a lifetime exposure
- Lack of Bioaccumulation factors
  - A bioaccumulation factor (BAF) would more accurately represent the total uptake of hydrophobic chemicals into fish tissue, and would include uptake from water, sediments, and food
  - Default BAF values have not been developed and the most accurate BAF values are developed on a site specific basis to fully account for trophic interactions
- Current approaches do not consider potential cumulative or synergistic effects from exposure to multiple compounds
- Additional and unaccounted for exposures

Summary

- Our experience is that the probabilistic approach does represent an improvement over the default approach
- Found that it is not necessary to set each input at the default value in order to achieve the desired level of protection
- Probabilistic approach does not eliminate all uncertainties, but it is a start in the right direction
  - Future potential to express toxicity inputs as distributions
  - More complex applications will reduce uncertainties

Questions or Comments

Break for Lunch

Context for the afternoon session

Presentation by Sandie O'Neill and Jim West, WDFW

WDFW will provide information on salmon. This will include what we know (and don't know) about where salmon pick up contaminants and body mass.

We have asked for information that focuses on PCBs and mercury, two of the contaminants of concern in Washington.

Why is this information important for the HHC rule-making?

This information will help inform the discussion of how salmon should be considered in criteria calculation. This is one of the more difficult issues we will deal with.

The following two important criteria equation inputs are related to this information: **relative source contribution** (RSC) and **fish consumption rate** (FCR).
(Note: FCR will be discussed at the next Policy Forum.)

This information relates directly to prior Policy Forum discussions about the "scope of the CWA."
(See Policy Forum #2 discussion on "scope of the CWA" and Policy Forum #5 discussion of RSCs)

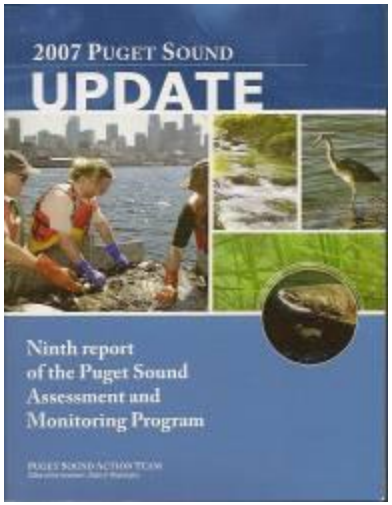
Note: Is the Florida DEP discussion on shrimp somewhat analogous to the WA discussion on salmon? Are there elements of the Florida approach that could apply to the Washington salmon issue?

photo by
Richard Bell

Sources of Contaminants to Salmon Originating from Washington

Sandie O'Neill and Jim West

Washington Department of Fish & Wildlife



PSEMP Fish Component Contaminant Focus

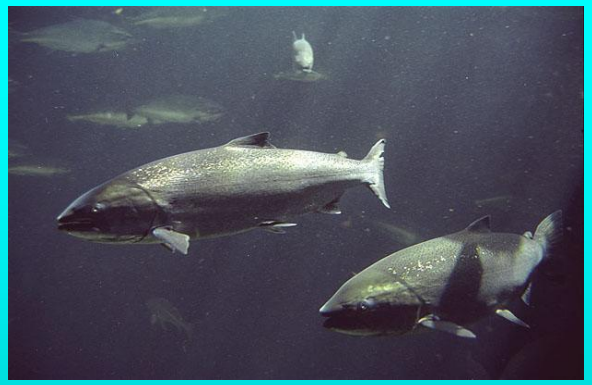
To what extent are Puget Sound fishes exposed to contaminants?

What are the effects of exposure?

Are conditions getting better or worse?

Are fish safe to eat?

PSEMP monitors toxics in sentinel species:



Coho, chinook

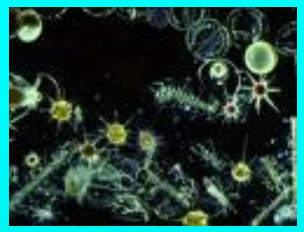
herring

3 spp of rockfish

English sole

PSEMP has also assessed:

- Plankton
- Pacific cod
- Lingcod
- Sixgill shark
- Herring eggs
- Dungeness crab
- ….and Mussels



Talk Outline

- Overview Pacific salmon life history and factors affecting contaminant accumulation
- Identify contaminant "sources"
  - Chinook salmon
  - Other Pacific salmon species
  - Trout species?

Persistent Organic Pollutants (POPs)

- toxic man-made chemicals; global distribution
- dissolve easily in animal fat (lipophilic)
- not easily metabolized
- bio-accumulate

– PCBs
– Chlordanes
– DDTs
– HCB
– HCH
– PBDE

Contaminants levels in fish are determined by…

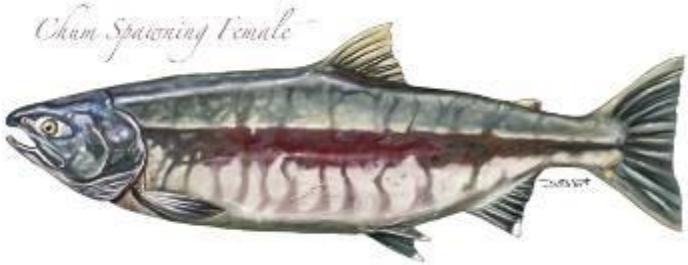
- Where they live
  - Proximity to sources, residency- migration
- What they eat
  - trophic level and diet
- How long they are exposed
  - fish age and size
- Their reproductive life history
  - gender, number of times they reproduce

- anadromous, wide-ranging, pelagic
- carnivorous
- high fat content

Chinook

Coho

Sockeye



Chum

Pink

POPs levels in salmon are determined by:

Hatcheries

Where they live …. Freshwater habitat

Marine habitat

Most of the mass of <u>adult</u> salmon is accumulated while feeding in marine habitats, thus most of their POPs are accumulated in saltwater.

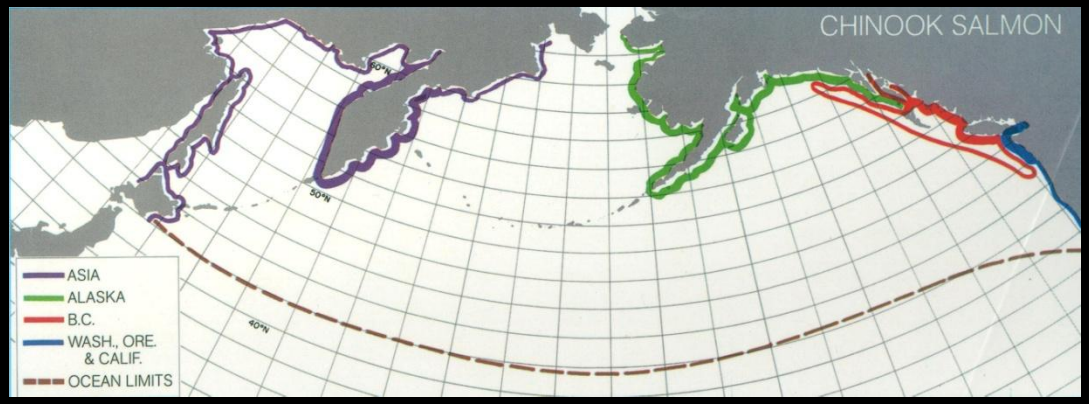
Sources of PCBs to Adult Chinook

outmigrating smolt

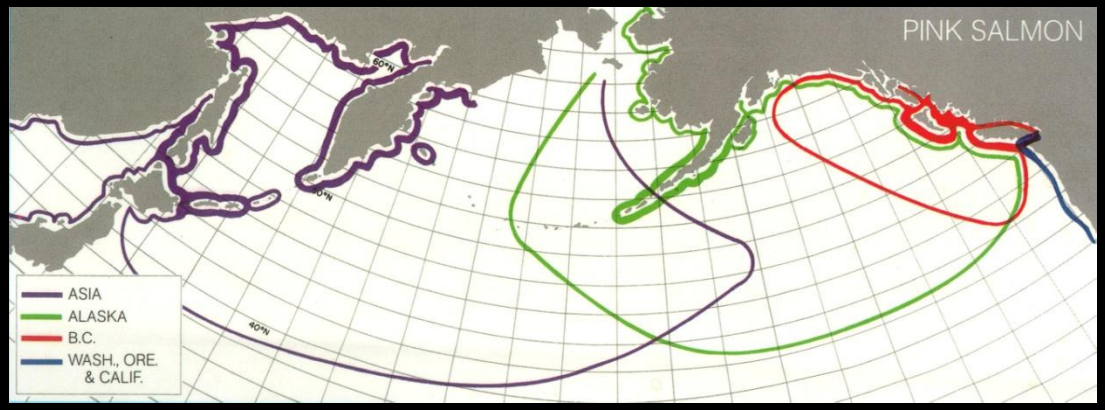
returning adult salmon

O'Neill and West (2009), Trans. Amer Fish. Soc.

BUT - salmon species differ in their marine distribution….



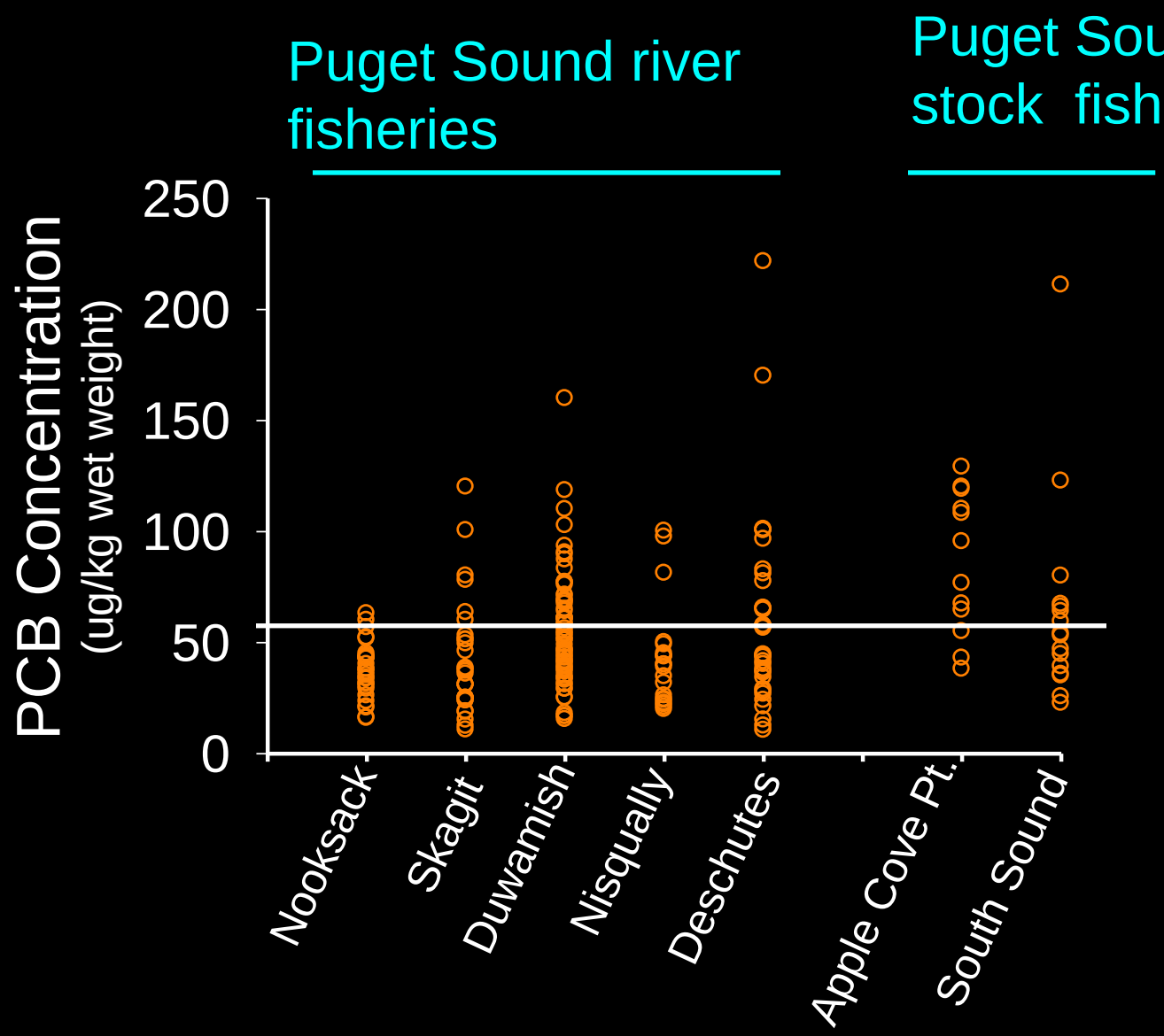
Chinook salmon – coastal distribution



Pink salmon - oceanic distribution

What are PCB levels in Puget Sound Chinook?

PCB Levels in Chinook salmon fillets



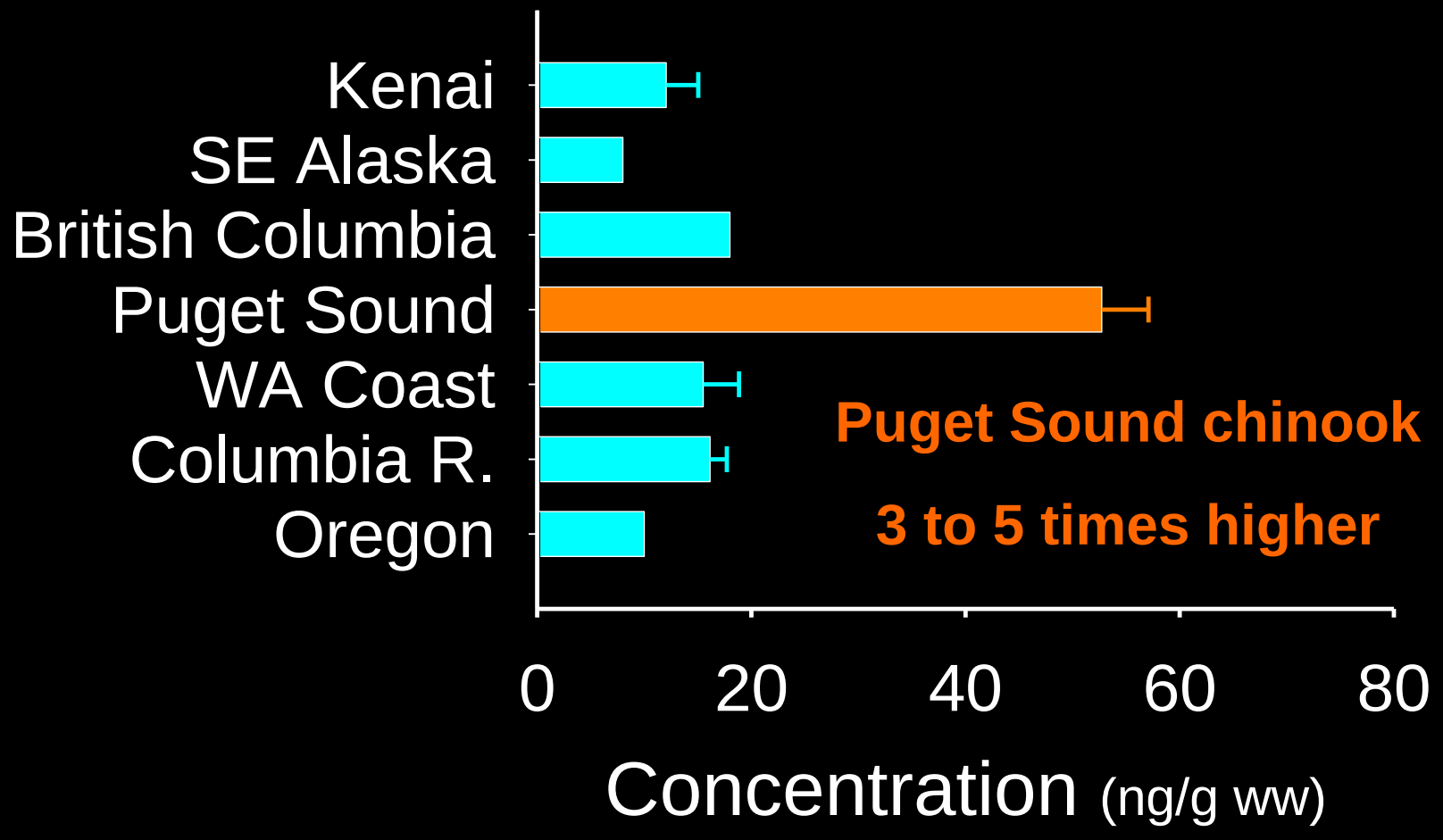
DOH (2006) recommends only 1 meal Puget Sound Chinook salmon per week to protect human health

Mean 53 ppb

PCB measured as Arochlors (modified from O'Neill and West 2009. TAFS

How do PCB levels in Puget Sound Chinook salmon compare with other Chinook salmon populations?

PCBs in Adult Chinook Salmon Fillets



O'Neill and West 2009. TAFS.

Results from an independent study by WDFW and NOAA - whole body data

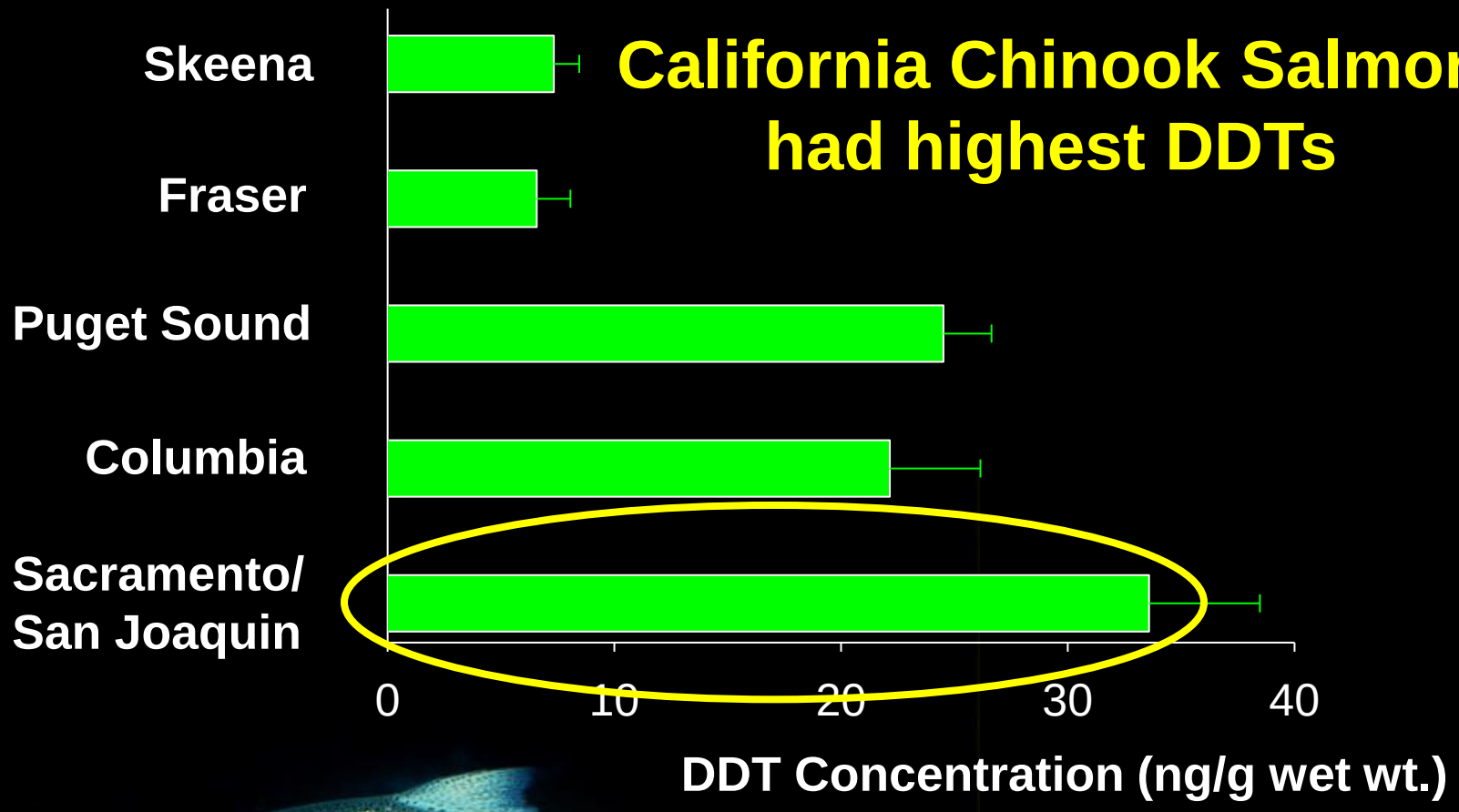
How do west coast Chinook salmon populations differ in POP concentrations?

Note: “Fraser” stocks do not include Harrison

4 classes of contaminants were analyzed in 216 whole body salmon samples:

DDTs, HCB, PCBs, PBDEs,

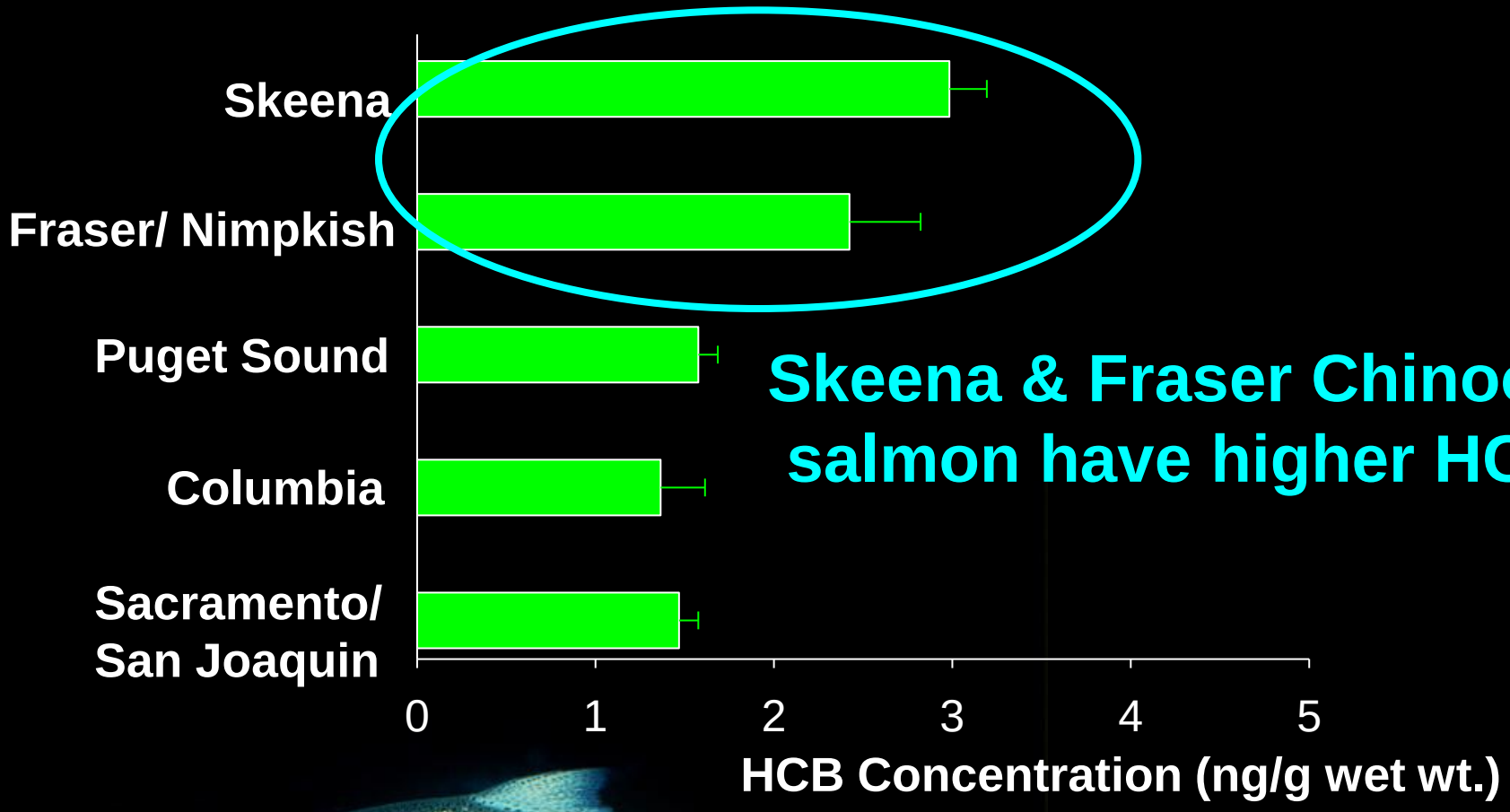
DDTs in Whole-body Chinook Salmon



California Chinook Salmon had highest DDTs

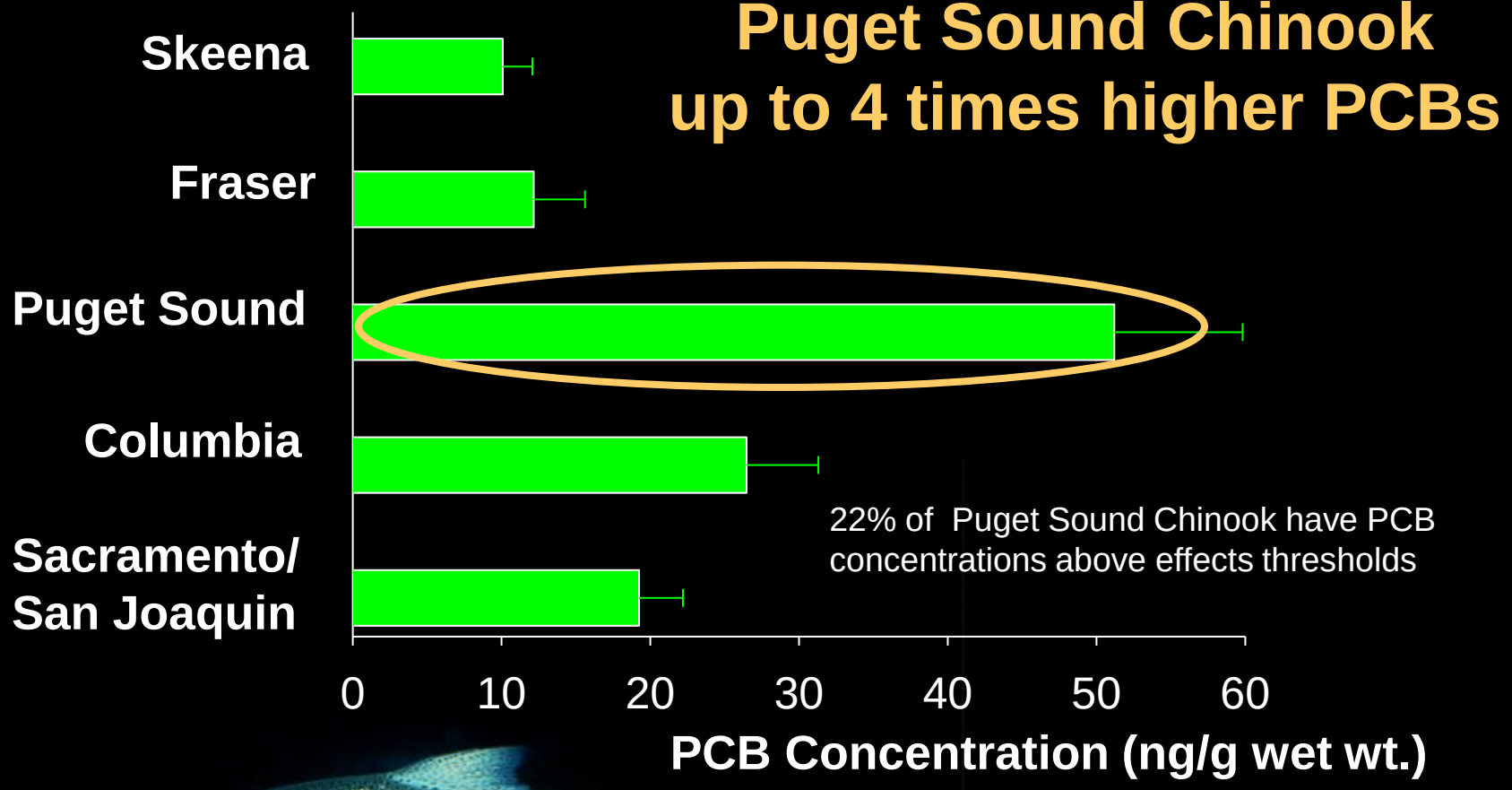
adult fish
summer/ fall run

HCB in Whole-body Chinook Salmon



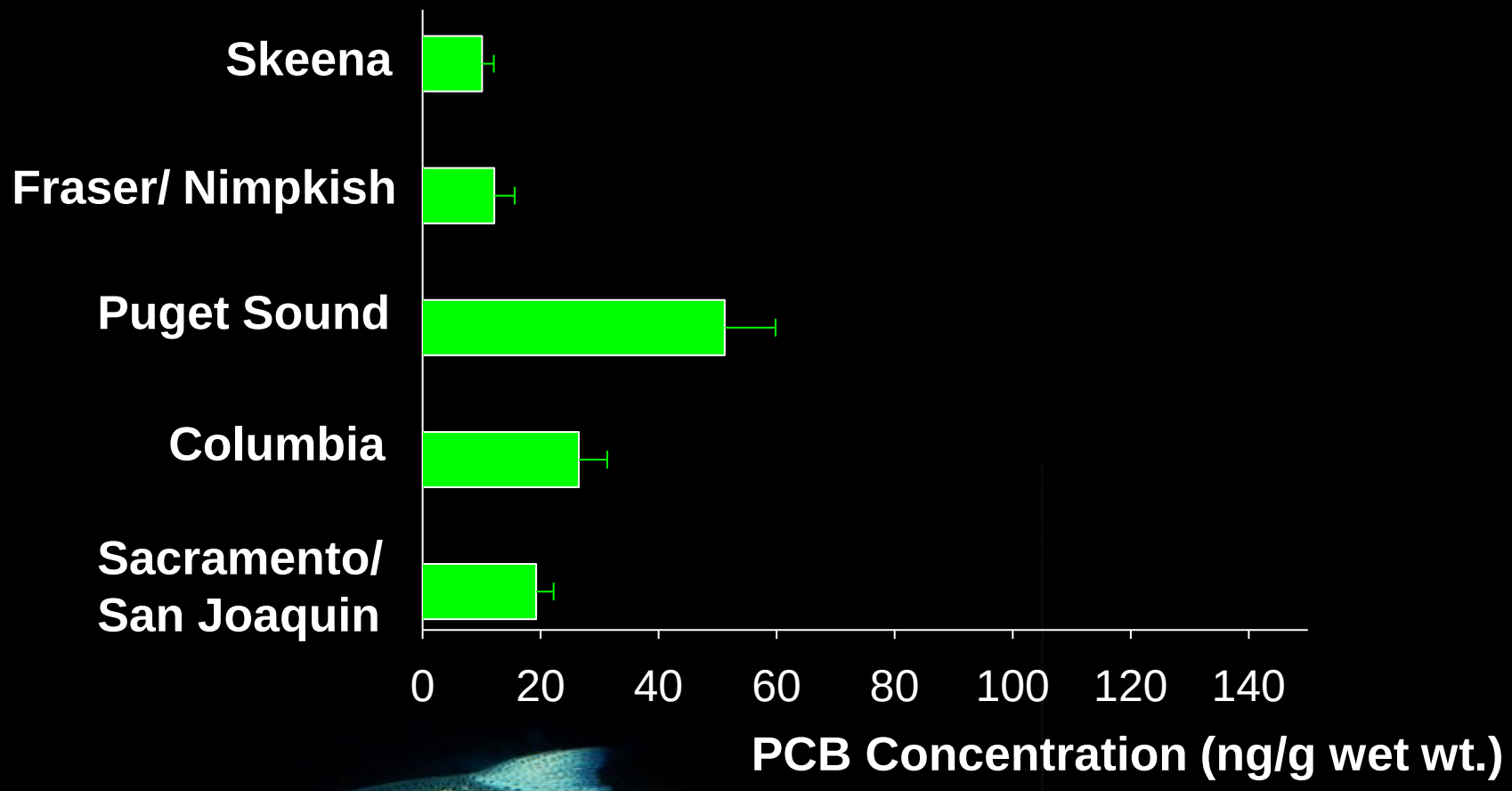
adult fish
summer/ fall run

PCBs in Whole-body Chinook Salmon



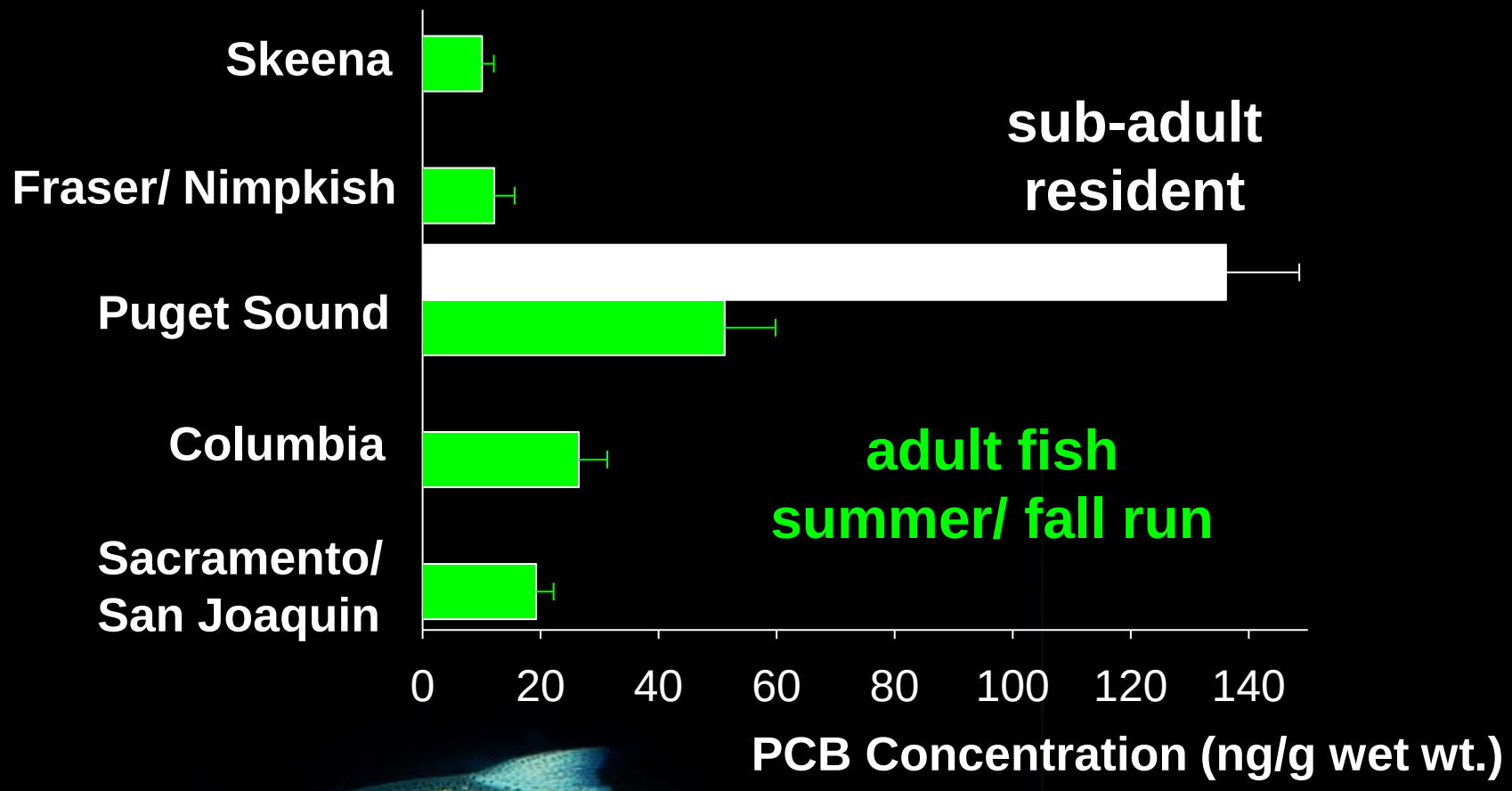
adult fish
summer/ fall run

PCBs in Whole-body Chinook Salmon



adult fish
summer/ fall run

PCBs in Whole-body Chinook Salmon

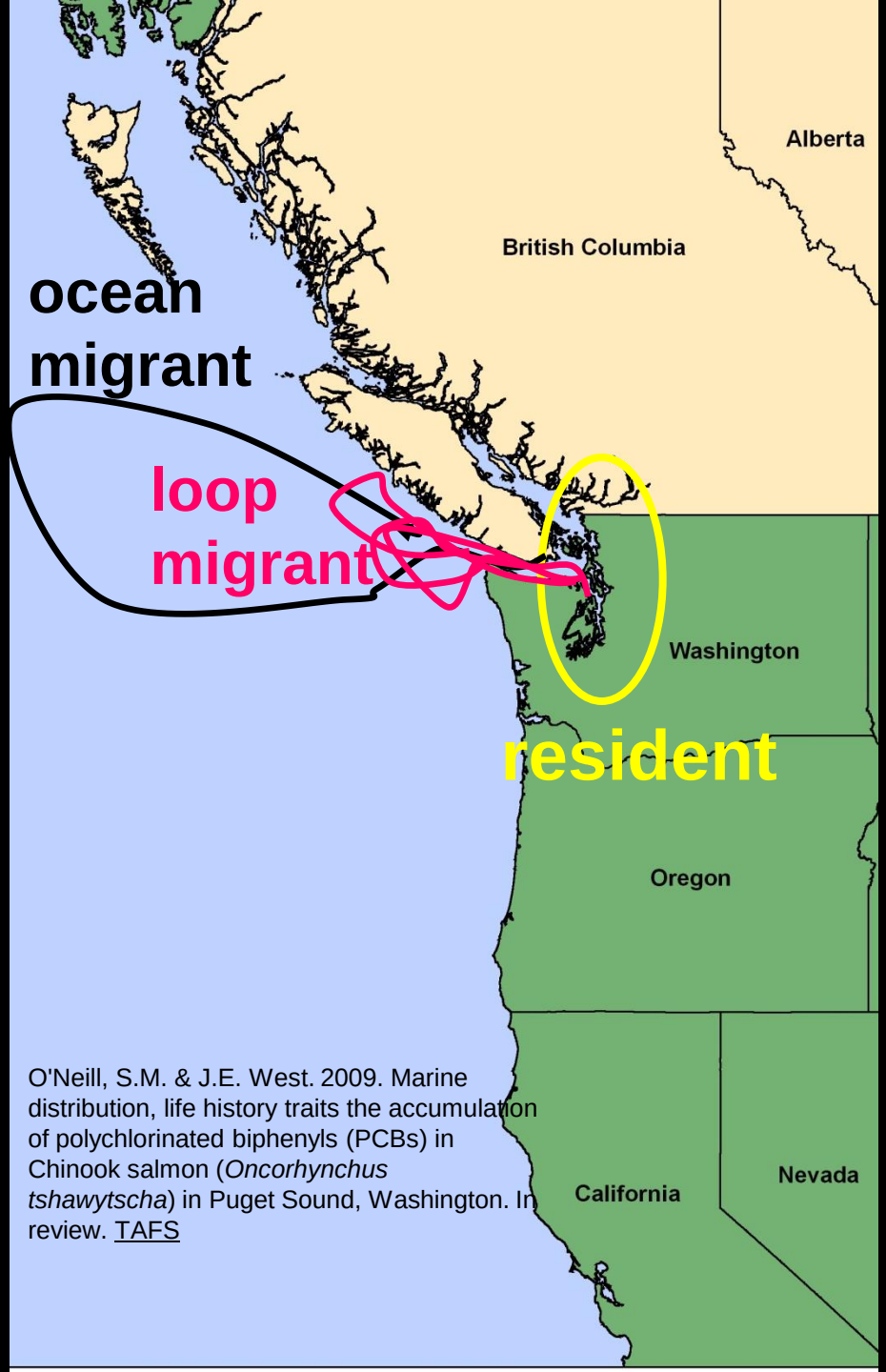


Migration patterns of Puget Sound Chinook salmon

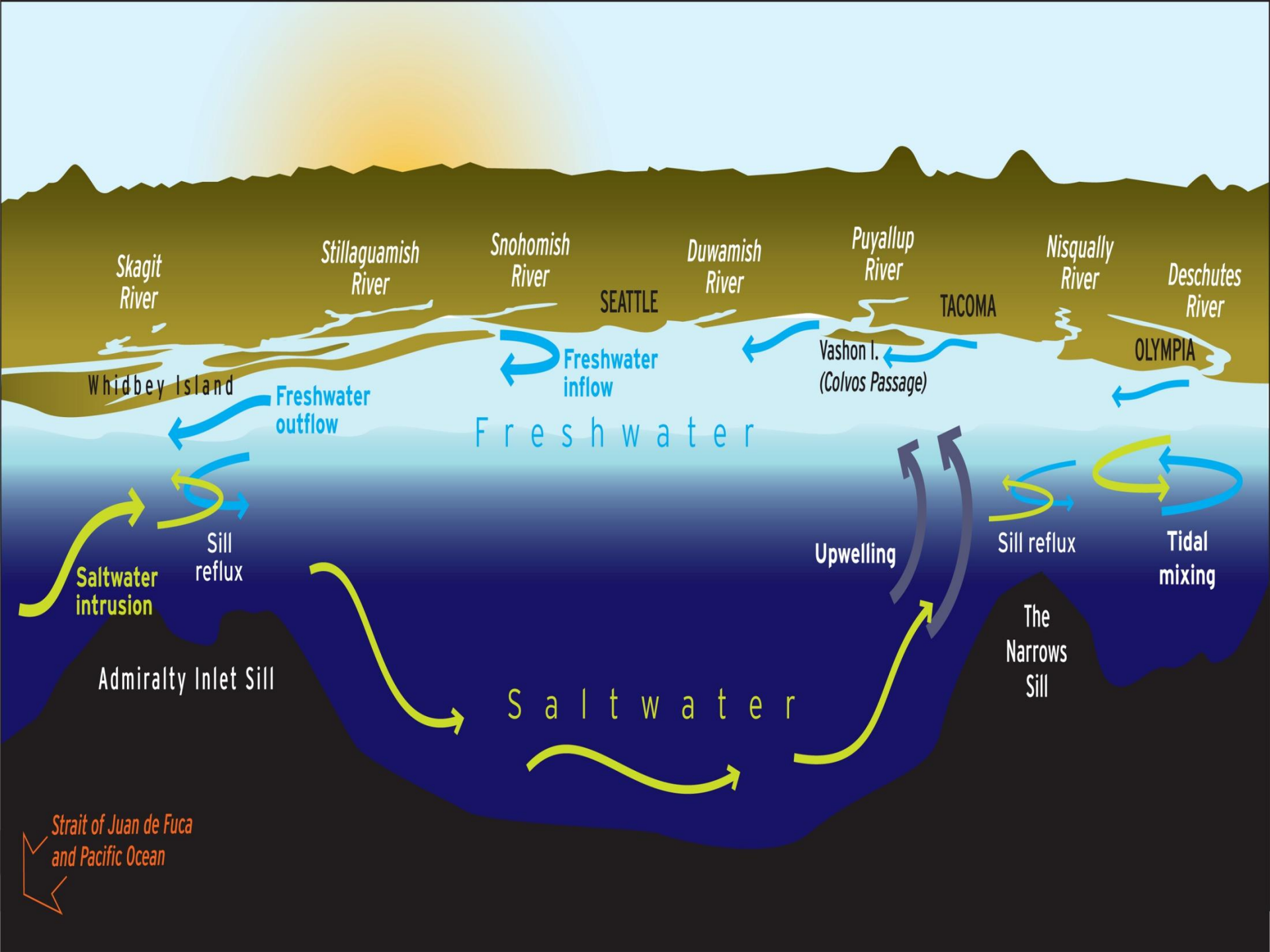
Estimated percent of recreational & commercial catch of Puget Sound Chinook salmon displaying resident behavior

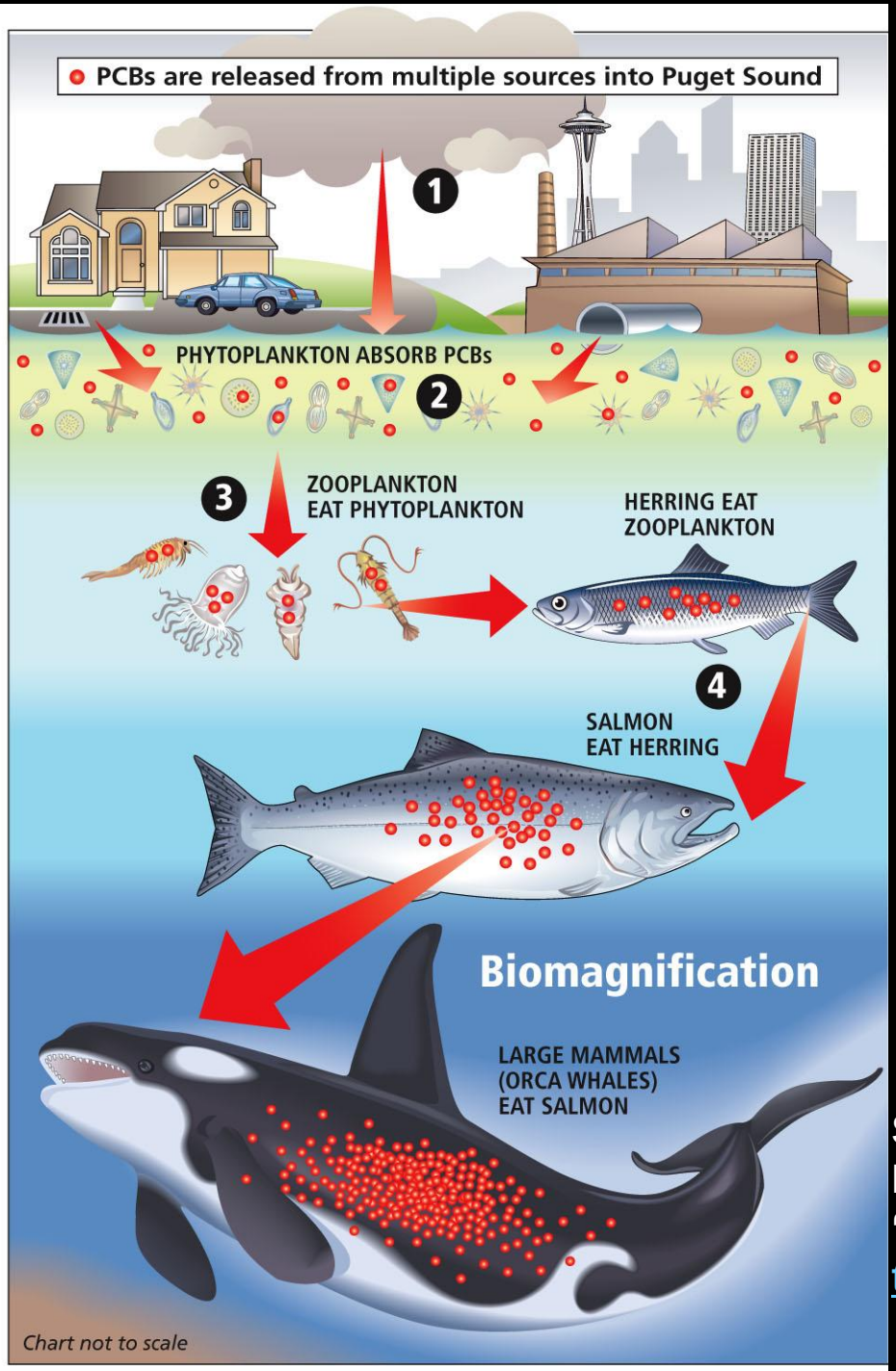
29 % of sub-yearling smolts

45 % of yearling smolts



O'Neill, S.M. & J.E. West. 2009. Marine distribution, life history traits the accumulation of polychlorinated biphenyls (PCBs) in Chinook salmon (*Oncorhynchus tshawytscha*) in Puget Sound, Washington. In review. TAFS


Skagit River
Stillaguamish River
Snohomish River
SEATTLE
Duwamish River
Puyallup River
TACOMA
Nisqually River
Deschutes River
OLYMPIA
Vashon I.
(Colvos Passage)
Whidbey Island
Freshwater inflow
Freshwater outflow
Freshwater
Saltwater intrusion
Sill reflux
Upwelling
Sill reflux
Tidal mixing
The Narrows Sill
Admiralty Inlet Sill
Saltwater
Strait of Juan de Fuca and Pacific Ocean

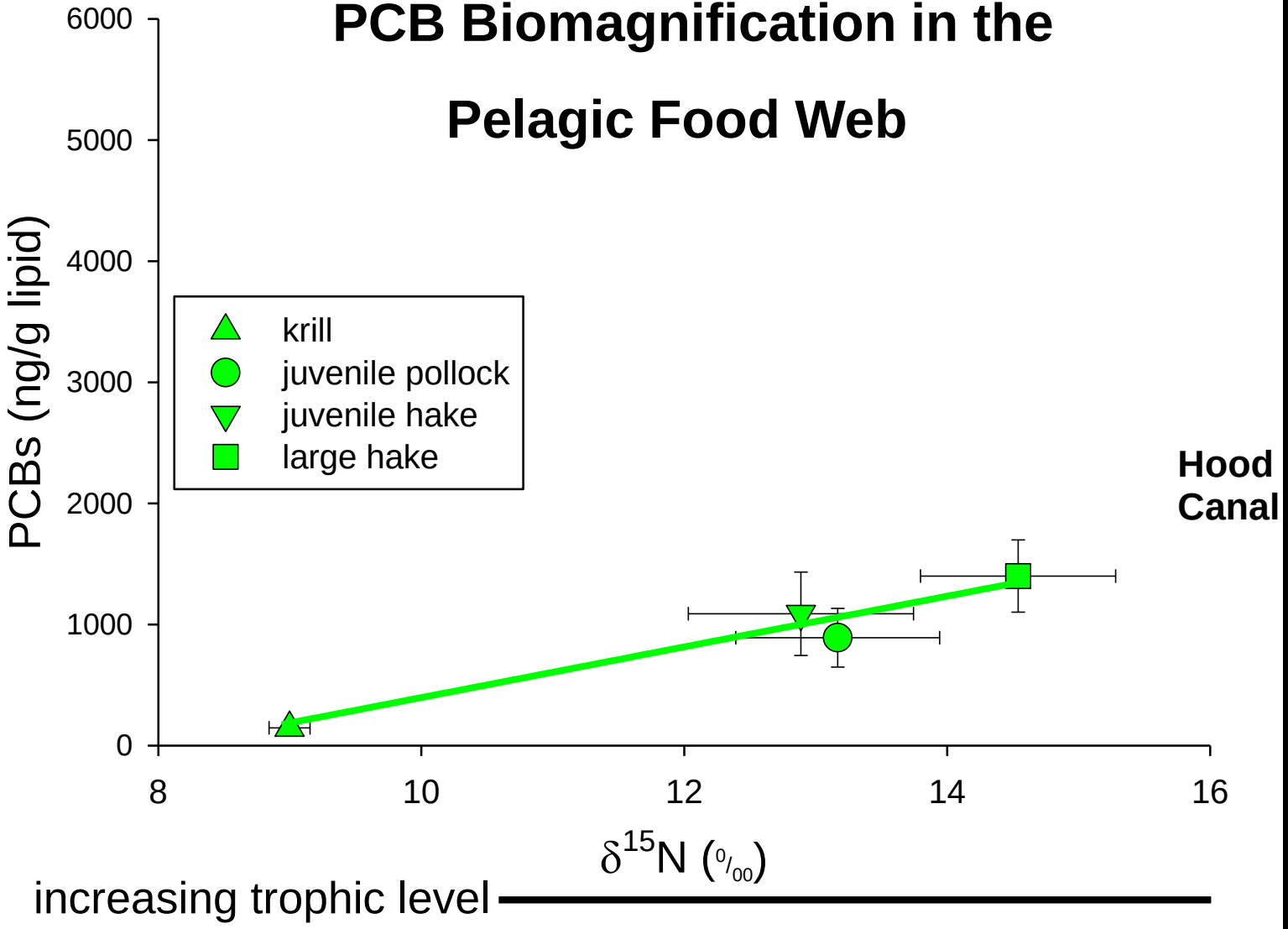


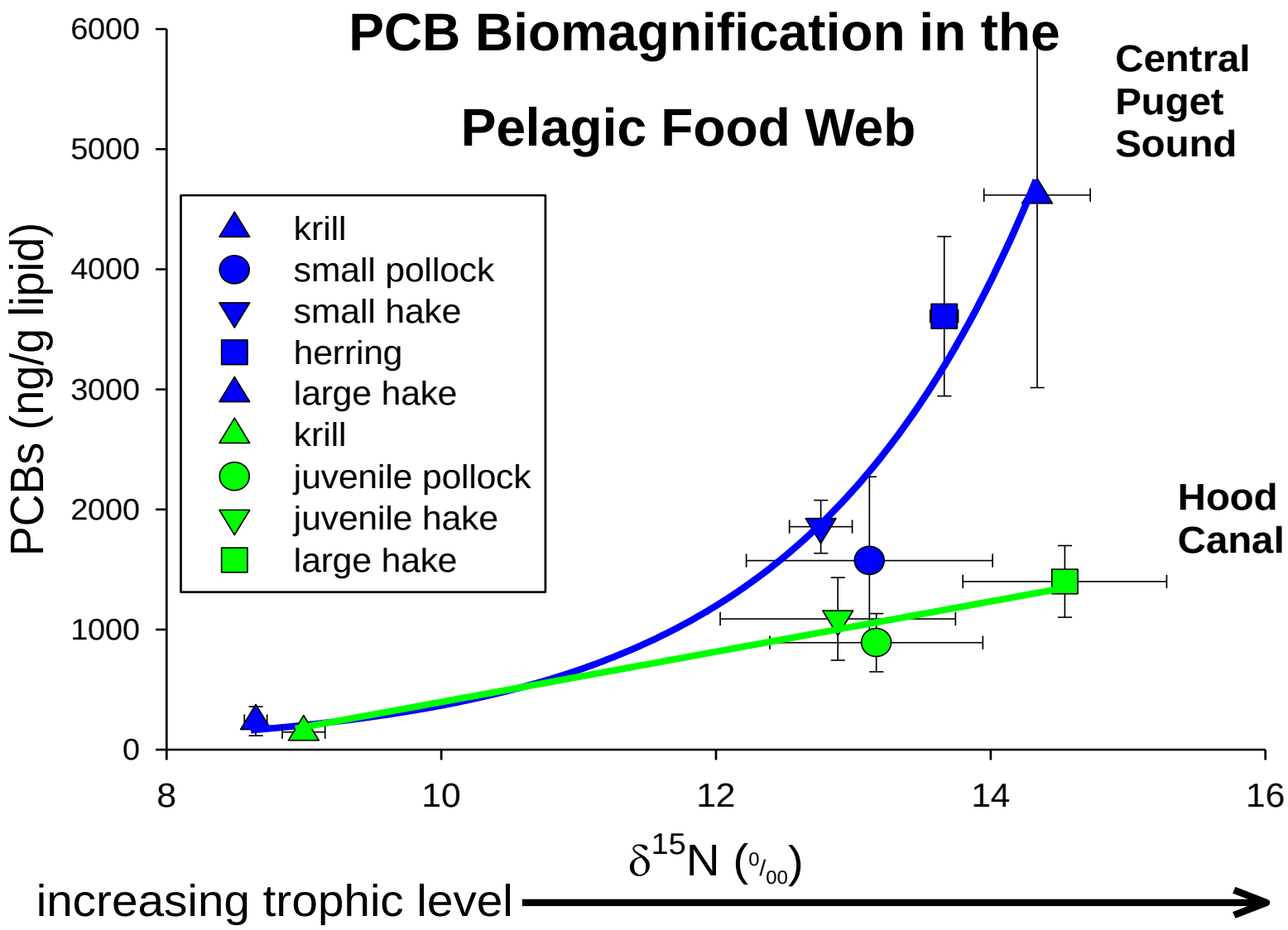
THE ZONE

Simplified pathway for PCBs entering and biomagnifying in the pelagic food web

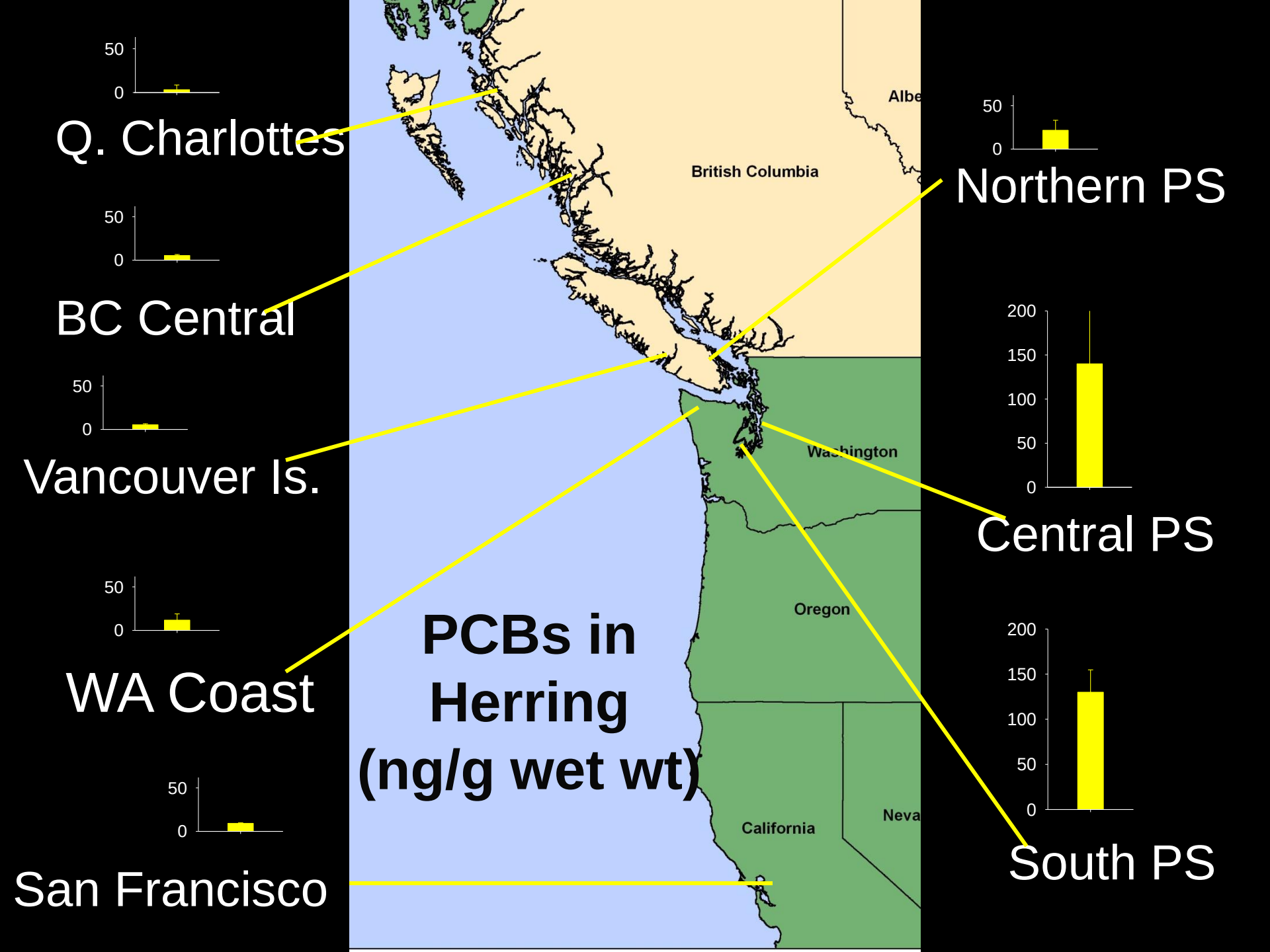
Source: Seattle Post-Intelligencer "The Zone"
thezone@seattlepi.com

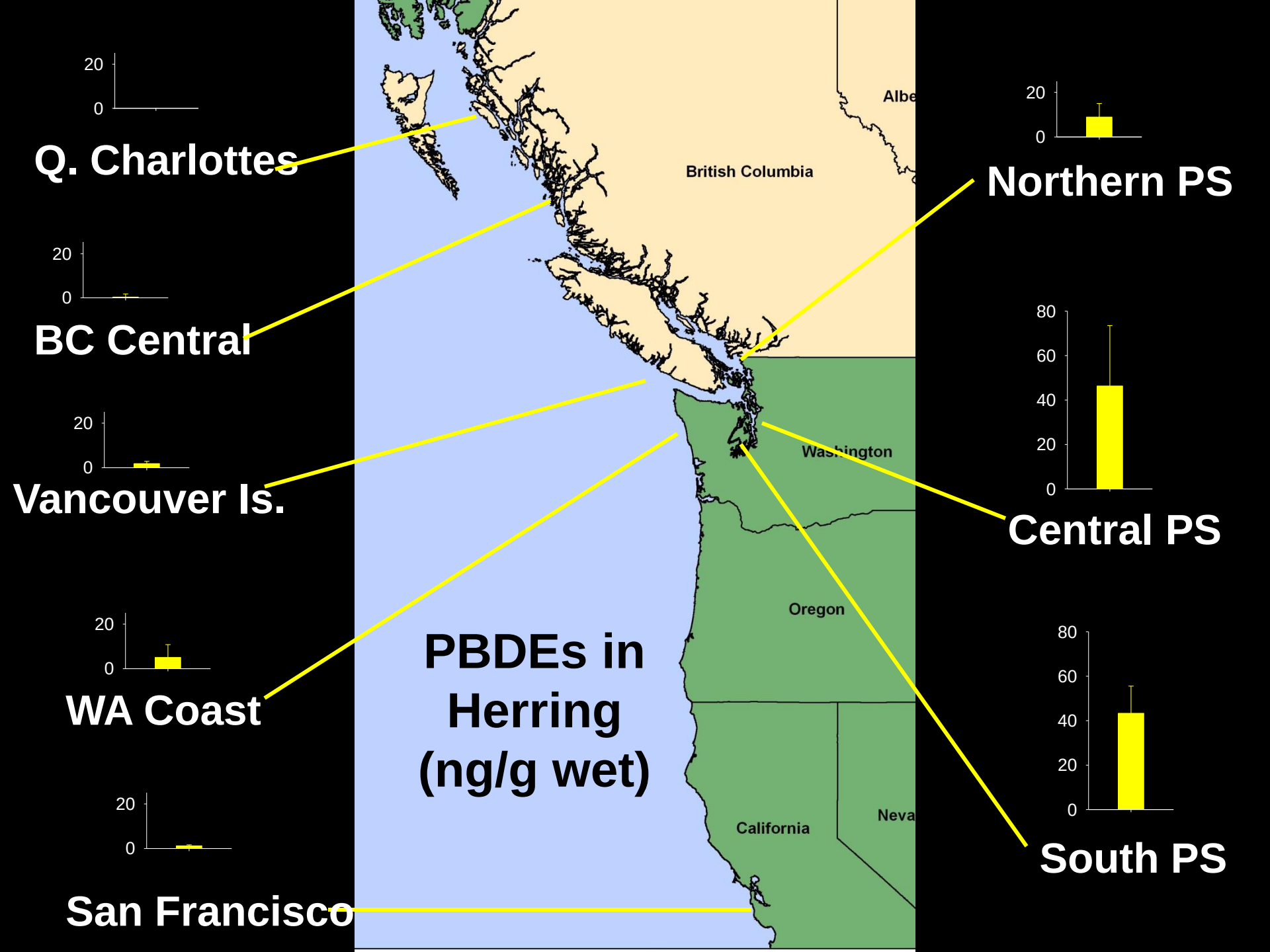
PCB Biomagnification in the Pelagic Food Web




PCB Biomagnification in the
Pelagic Food Web
Central
Puget
Sound
Hood
Canal
krill
small pollock
small hake
herring
large hake
krill
juvenile pollock
juvenile hake
large hake
PCBs (ng/g lipid)
6000
5000
4000
3000
2000
1000
0
8
10
12
14
16
δ15N (0/00)
increasing trophic level

PCBs in Herring (ng/g wet wt)

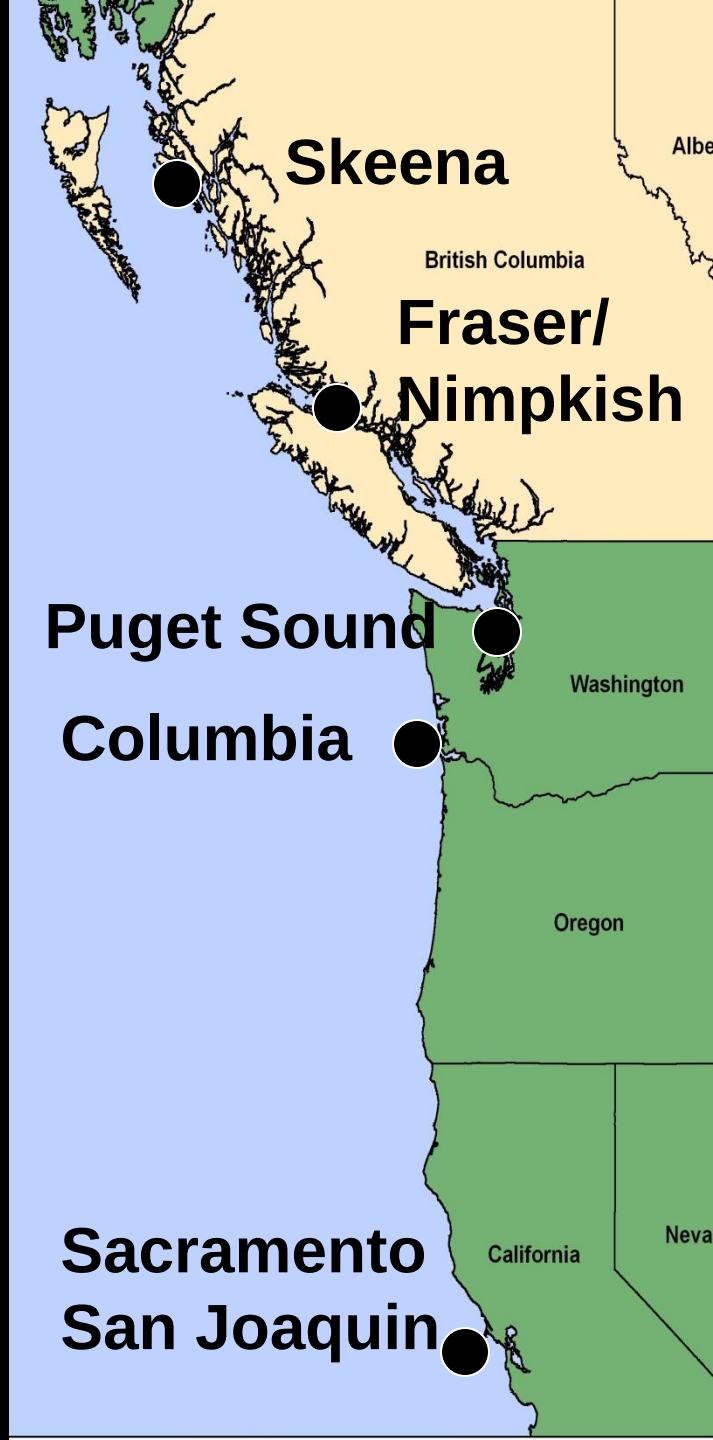



PBDEs in Herring (ng/g wet)
Q. Charlottes
BC Central
Vancouver Is.
WA Coast
San Francisco
Northern PS
Central PS
South PS
British Columbia
Washington
Oregon
California
20
0
80
60
40

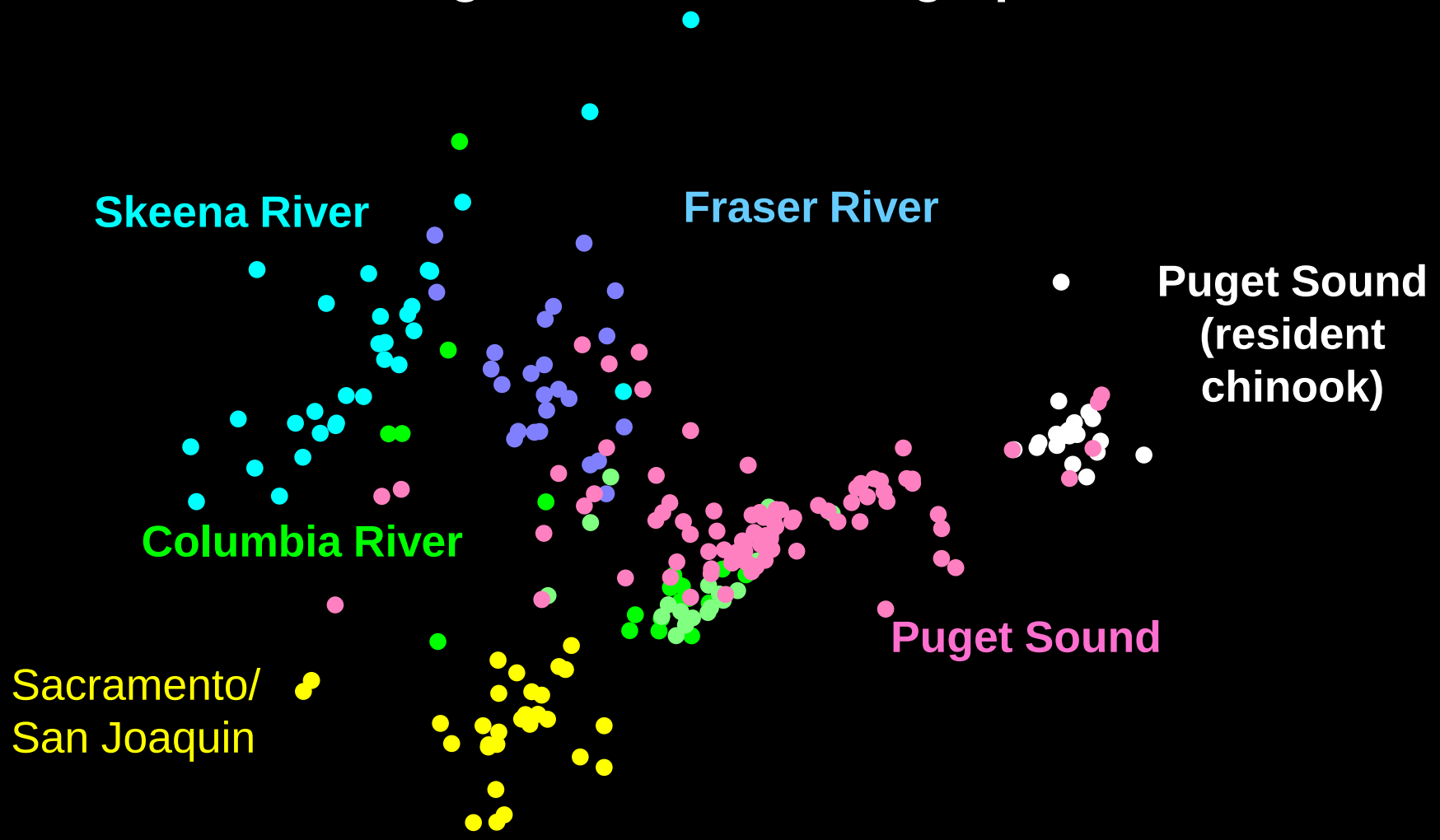
Salmon have chemical fingerprints

PCBs, PBDEs, DDTs, HCB,

Contaminant <u>patterns</u> vary by Chinook population reflecting difference in their marine distribution.



Segregation of Chinook Populations Using Contaminant Fingerprint



Multi-dimensional Scaling Plot of Four POPs

Stress=0.05

Sources of Contaminants to Chinook Salmon - Conclusions

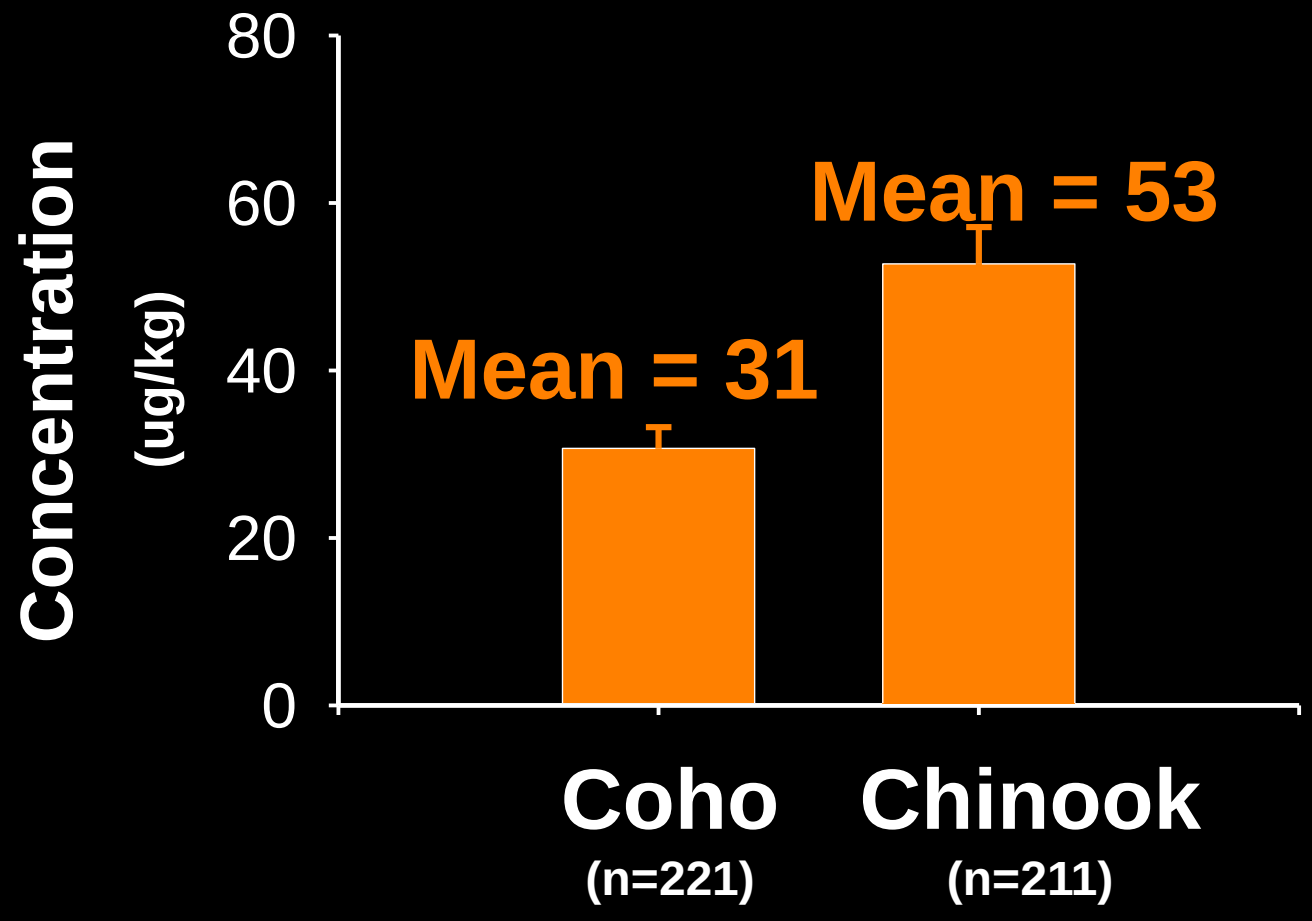
- POP- concentrations in Chinook salmon vary regionally with distinct chemical fingerprints associated with each population.

- Marine distribution is the main factor affecting POP levels in Chinook salmon.

- Puget Sound is a significant source of contaminants to Puget Sound Chinook salmon because 30% reside in Puget Sound

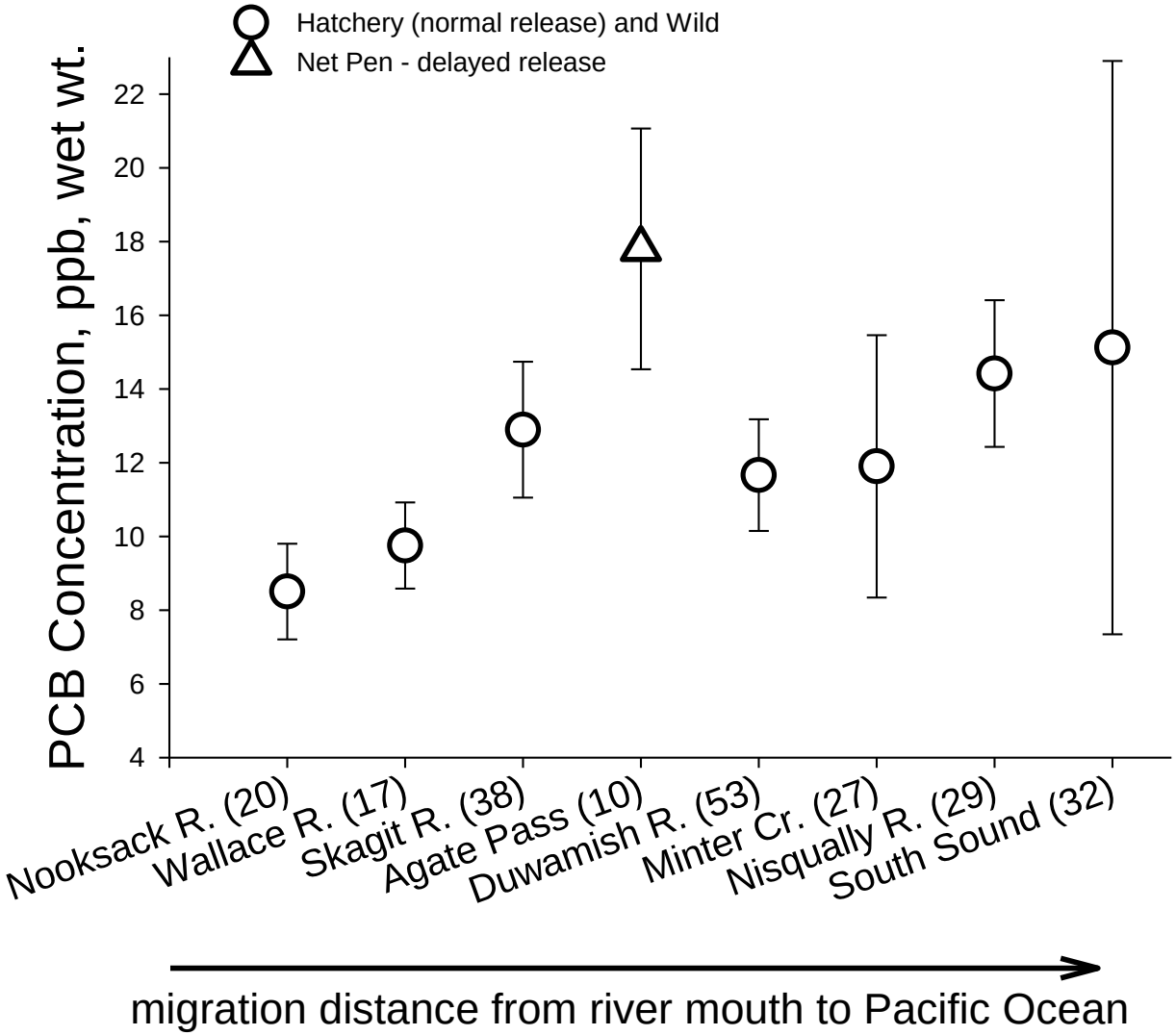
What about contaminant levels and sources in other species of Pacific salmon?

PCBs in Adult Coho and Chinook Salmon Fillets Caught in Puget Sound



Based on Aroclor: 92-'98samples

PCBs in Coho Salmon Fillets 1998-2002

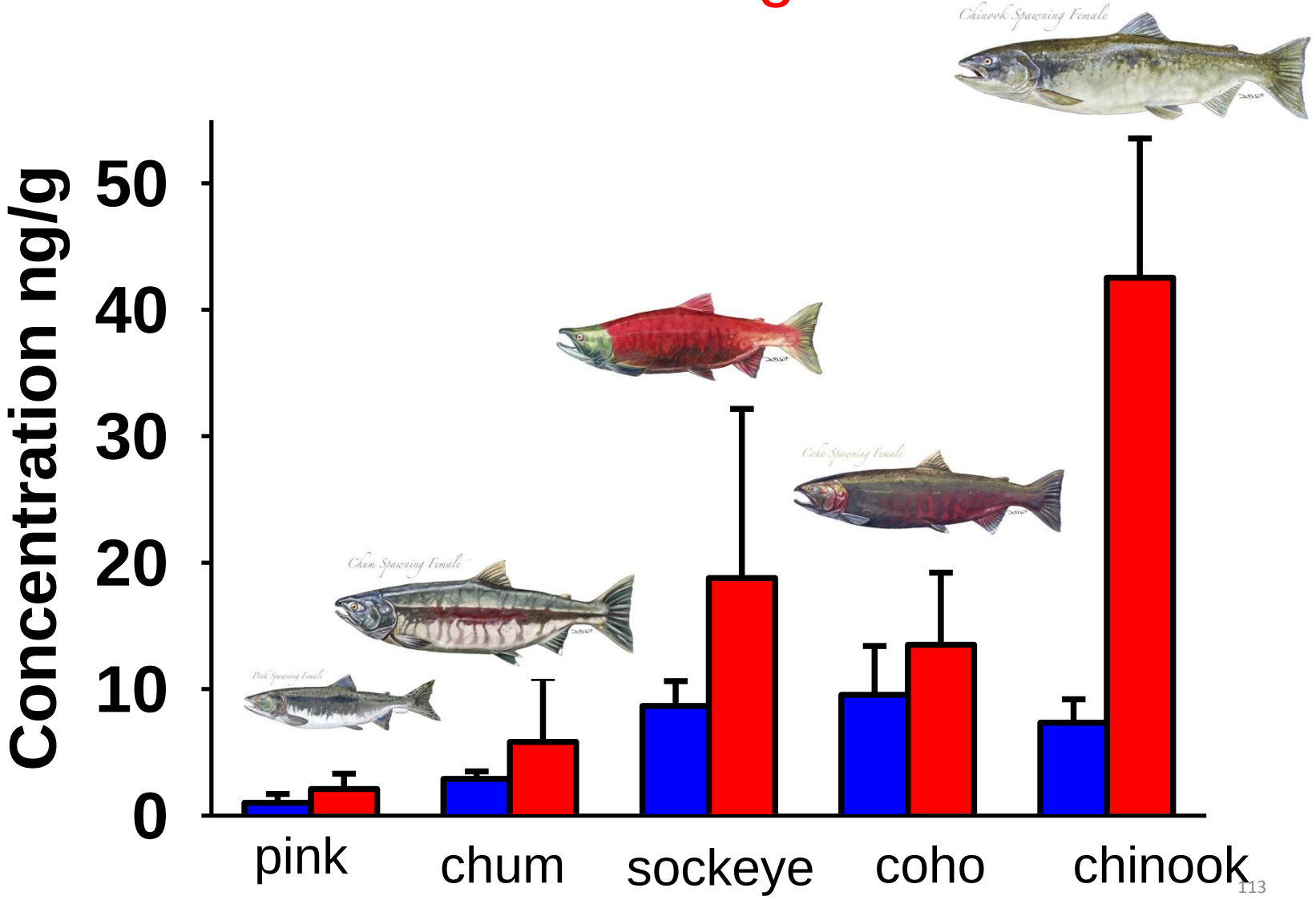


Values based on PCB congeners

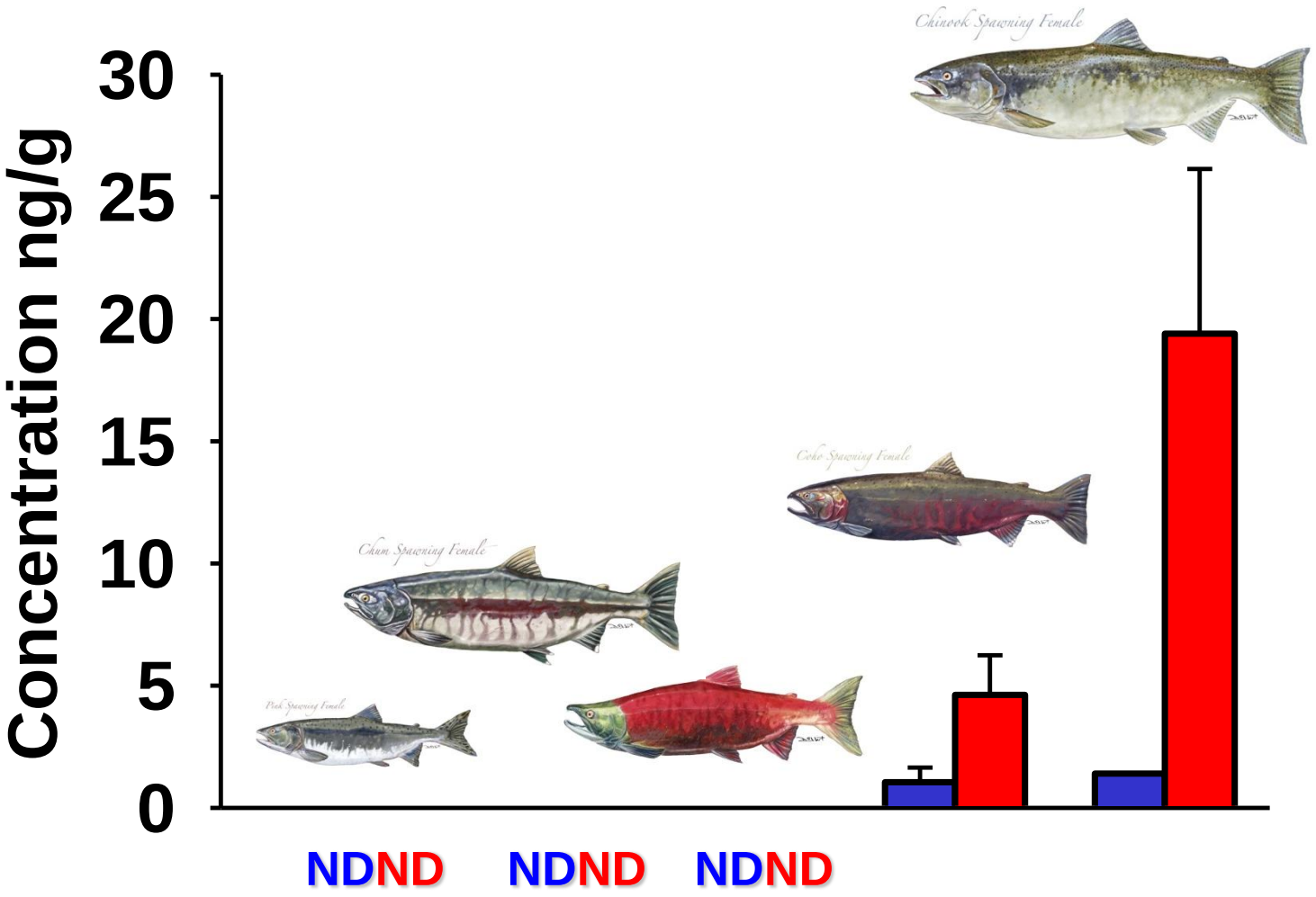
WDFW- NOAA Study to Measure Toxics in West Coast Pacific Salmon

Compare contaminant levels among coho, Chinook, pink, chum and sockeye salmon from lightly and heavily populated areas.

PCBs in 5 Pacific salmon species from north/central BC and Puget Sound/SJF



PBDEs in 5 Pacific salmon species from north/central BC and Puget Sound/SJF



Contaminant Levels and Sources for Pacific salmon - Conclusions

- Adult Chinook, coho and sockeye salmon accumulate higher contaminant concentrations than pink and chum.
- For all species, contaminant levels in fish from Puget Sound/ SJF origin are higher than north/central BC.
- For all species originating from Puget Sound, Puget Sound is a source of contaminants
- For Puget Sound Chinook which are more resident, the Puget Sound is a <u>major</u> source of contaminants

What about contaminant levels and sources in trout species?

Steelhead Trout

Contaminant levels likely to be significantly lower than Puget Sound Chinook salmon

- Anadromous
  - fish do not reside in Puget Sound
- Off-shore marine distribution
- Repeat spawners
  - fish spend more time rivers than Pacific salmon
- <u>Major</u> source of contaminants for Puget Sound fish is Pacific Ocean

Bull Trout..

Contaminant levels may be higher than Puget Sound Chinook

- Anadromous –
  - but Puget Sound fish do not migrate to Pacific Ocean.
- Repeat spawners –
  - fish spend more time in freshwater than Pacific salmon
- <u>Major contaminant sources</u> to Puget Sound fish is Puget Sound rivers & marine waters.

Cutthroat Trout..

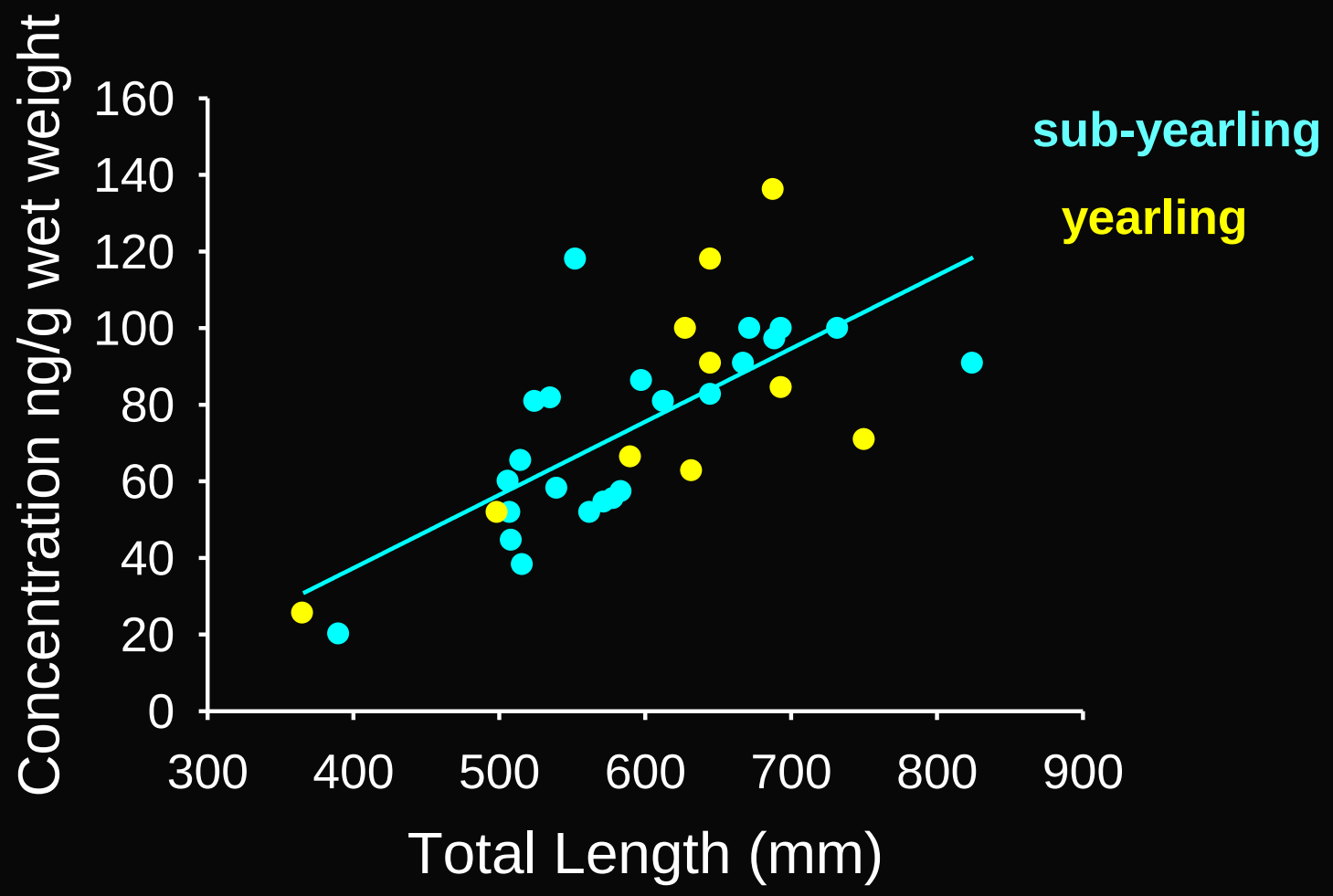
Contaminant levels likely to be higher than Puget Sound Chinook salmon and bull head trout.

- Anadromous –
  - but Puget Sound fish do not migrate to Pacific Ocean.
- Repeat spawners
  - fish spend more time in freshwater than Pacific salmon but spend more time in Puget Sound than bull trout.
- <u>Major contaminant sources</u> to Puget Sound fish is Puget Sound rivers & marine waters.

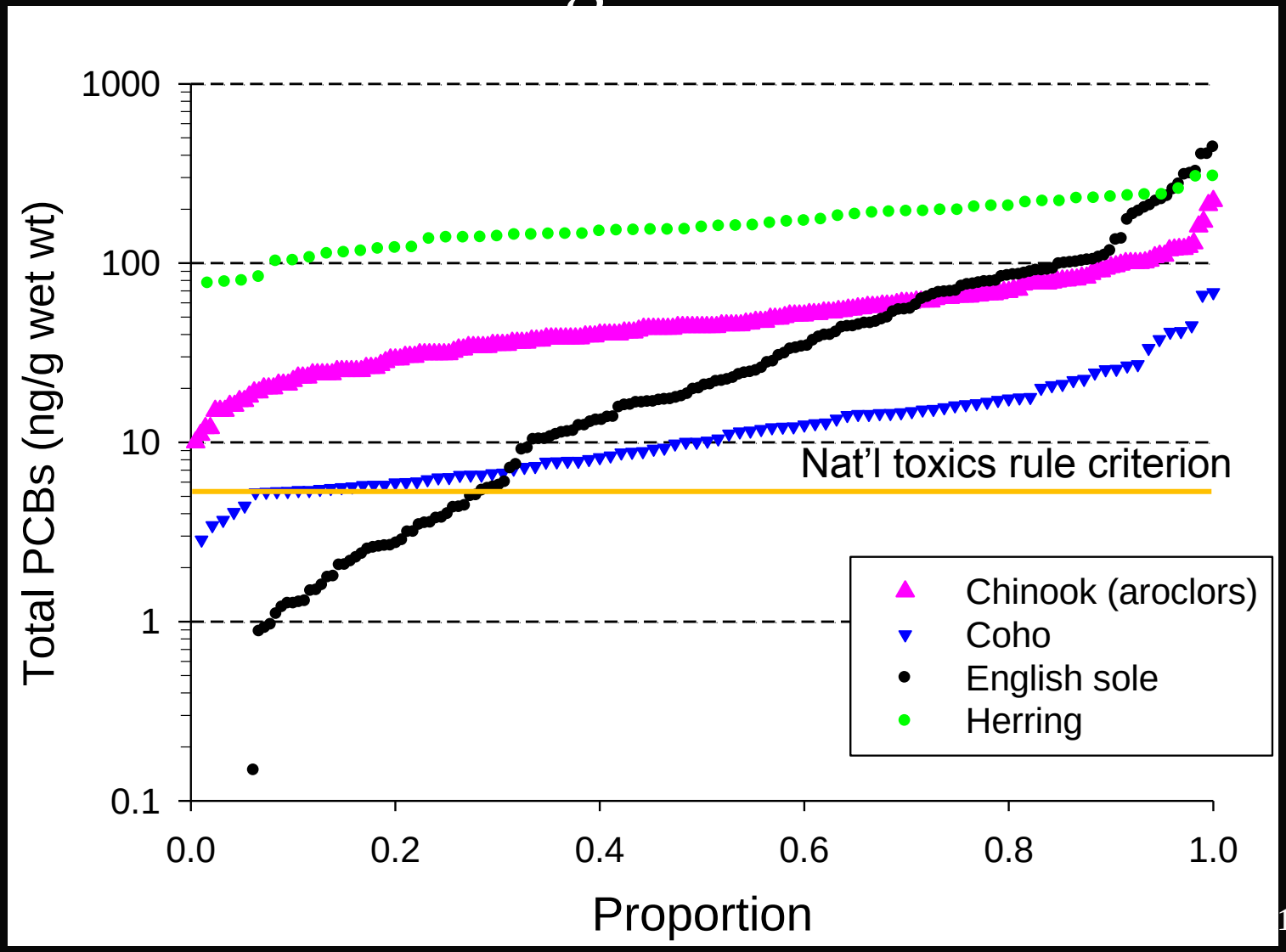
Life history determines if Puget Sound is a major contaminant source for our salmon species….

END

Estimated PCB Accumulation in Blackmouth Fillets



PCB Levels in Marine & Anadromous Fish from Washington 2001 to 2008



Questions/Comments/Discussion

THANK YOU!