# Department of Ecology Water Quality Standards Policy Forum #5

May 23, 2013

Lacey, WA

DEPARTMENT OF ECOLOGY
State of Washington

# Status of rule-making process and Policy Forums

- Four Policy Forums held between Fall 2012 and March 2013
- Ecology anticipates at least three more Policy Forums before draft rule language is proposed.
- Ecology is working towards proposing draft Water Quality Standards rule language at the end of 2013.

# Status of Delegate's Table

- Ecology submitted a work request to contract a Delegate's Table facilitator.
- Delegate's Table facilitator: Elizabeth McManus (Ross Strategic).
- Ms. McManus will work to re-start the Delegate's Table dialogue.
- Tentative Schedule: four Delegate's Table meetings between now and the end of the calendar year.

# Continuation of the mercury discussion from the March 28 Policy Forum

Policy Forum #5

May 23, 2013

Human Health Criteria and Implementation Tools Rule-makings

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# 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 (40CFR131)
**CWA** = Clean Water Act
**RfD** = Reference dose
**RSC** = Relative source contribution
**FTR** = Fish Tissue Residue
**Hg** = Mercury
**WDOH** = Washington Department of Health
**FA** = Fish advisory
**FTEC** = Fish Tissue Equivalent Concentration

# What we will cover in this discussion:

Review the maps – 303(d) listings and WDOH fish advisories

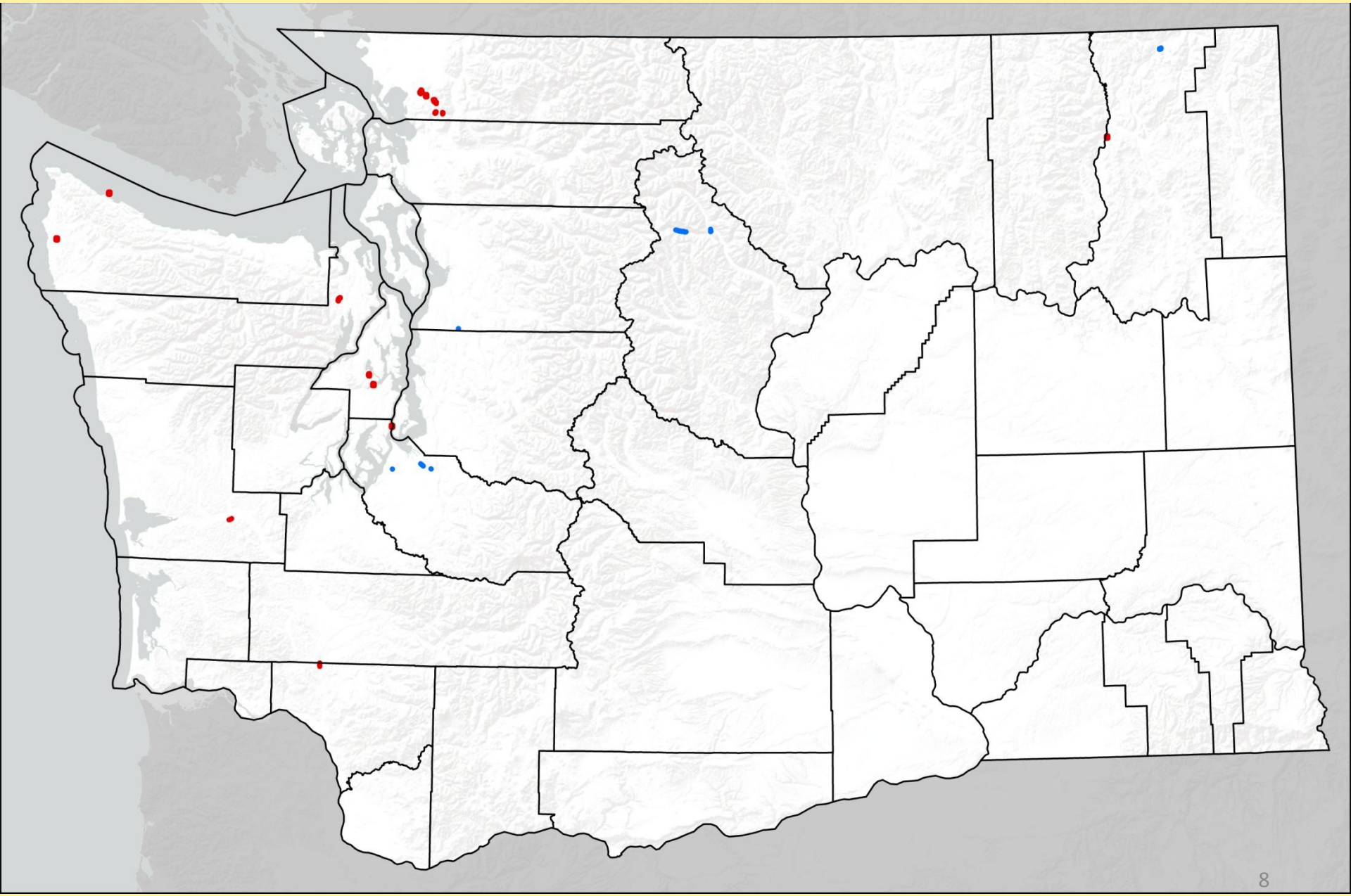
Discuss two comments made at the last Policy Forum

Examine some of the differences between the 1992 NTR HHC, WDOH's fish advisory level, and EPA's new recommended criterion

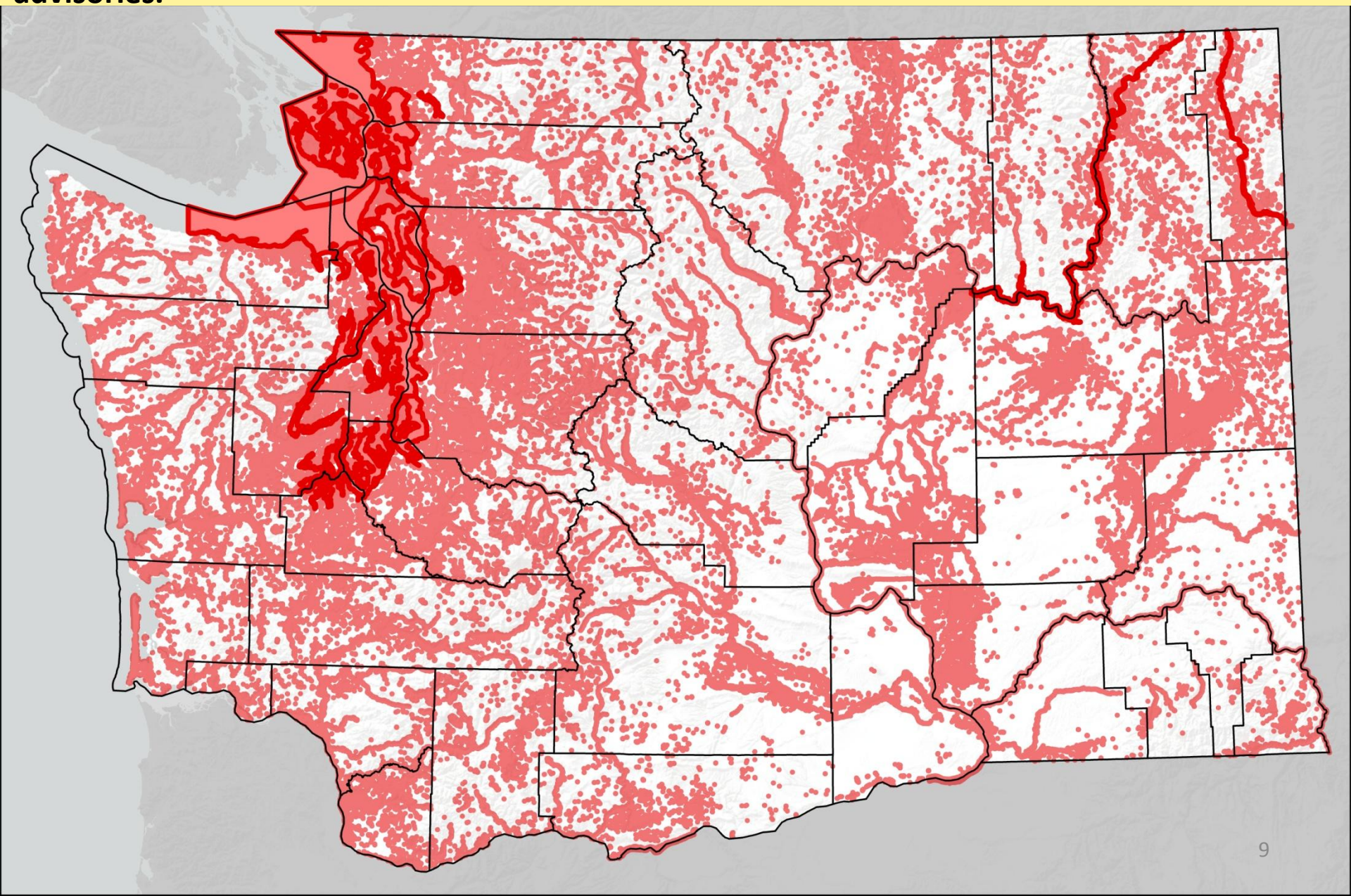
303(d) listings – current approach and future approaches

The new EPA approach to mercury criterion development is a Fish Tissue Residue criterion (not water), and this will add some complications to NPDES permit limit development

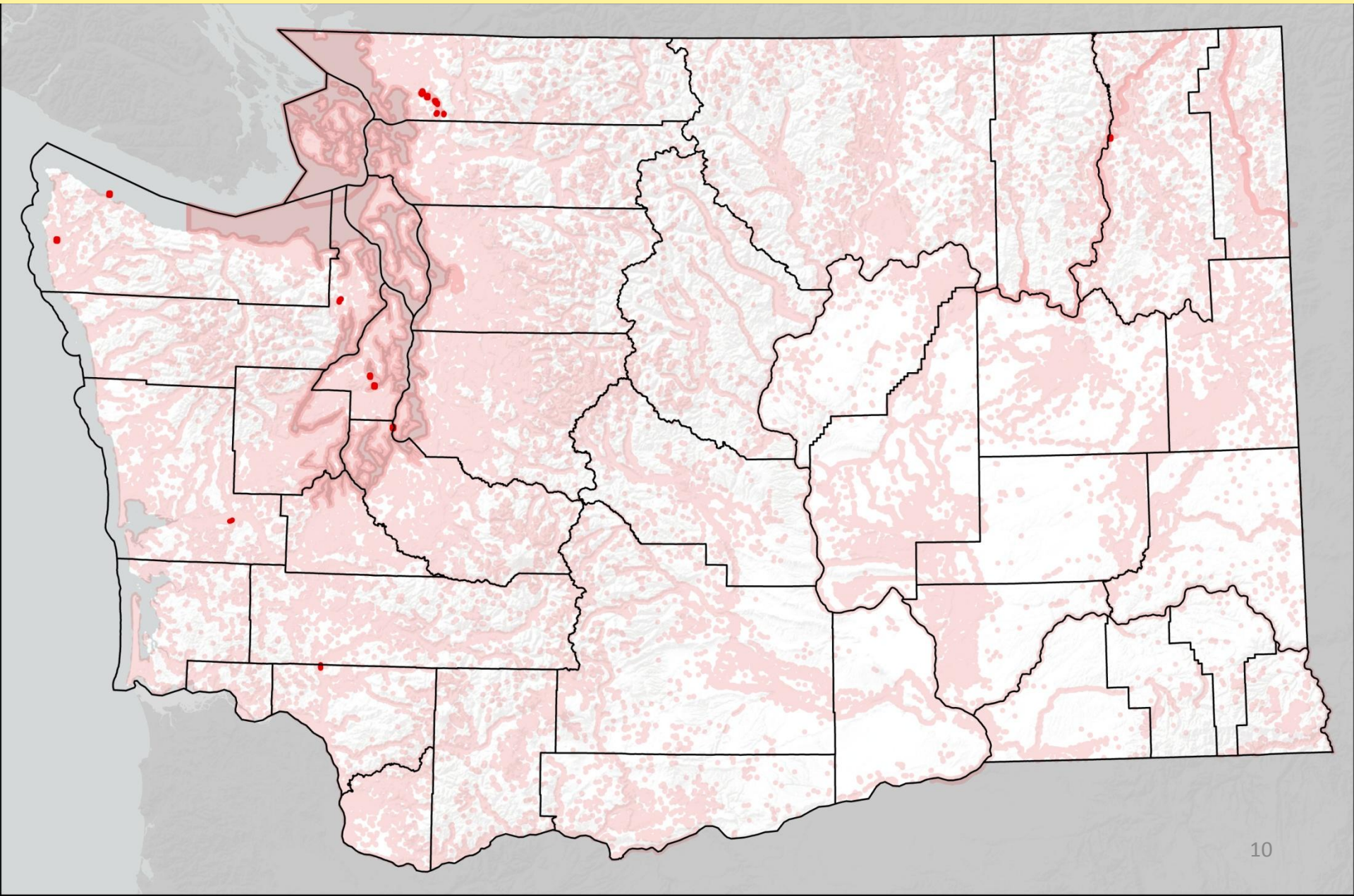
**This map represents all 25 Category 5 Listings for Mercury from the 2012 WQ Assessment, distinctly by medium (red: tissue, blue: water). Category 5 = the 303(d) list.**



**This map represents the Dept. of Heath Fish Consumption Advisories for Mercury: Includes individual waterbody advisories and a representation of Statewide water advisories.**



**Map of the 16 Category 5, (303d) tissue-based Listings for Mercury overlying a representation of the statewide Dept. of Heath Fish Consumption Advisories and the waterbody-specific Advisories for Mercury.**



# Additional information on two comments, about mercury from the March 28 Policy Forum

**Comment 1:**

"Where do the mercury tissue concentration values used by Ecology in the 303(d) listing process come from? Specifically the value of 825 ppb (as opposed to the WDOH advisory level of 101 ppb.)"

**Comment 2:**

"The aquatic life-based (AQL) criteria for mercury are more protective than the NTR HHC, so the Washington AQL criteria are providing some extra protection beyond the NTR HHC."

These comments were part of the discussion surrounding WDOH fish advisories and comparisons with the NTR HHC for mercury.

# Comment 1:

"Where do the mercury tissue concentration values used by Ecology in the 303(d) listing process come from? Specifically the value of 825 ppb (as opposed to the WDOH advisory level of 101 ppb.)"

| **Regulation/advisory/ recommendation** | **HHC** | **BCF** | **Tissue Concentration (ppb)** | |
|---|---|---|---|---|
| Organisms-Only NTR HHC (estuarine and ocean) | 0.15 ug/L | 3765 L/kg<br>9000 L/kg | 565 (estuar.)<br>1,350 (ocean) | (for 303(d) listing) |
| Water & Organisms NTR HHC (freshwater) | 0.14 ug/L | 5500 L/kg | 770 ppb | |
| WDOH Fish Advisory Level | NA | NA | **101 ppb** | |
| EPA recommended national HHC – **fish tissue residue** | NA | Use a BAF instead | **300** ppb | |

Note: the new recommended EPA criterion for Hg is a **<u>Fish Tissue Residue</u> (FTR)** value.

825 ppb is an older value used for listing – based on use of freshwater BCF with the organisms-only criterion.

**Question- Why are all the tissue concentration levels so different?**

**Answer:** **Because the equation inputs are different. All these numbers come from equations. With updates to WA's CWA HHC some of the inputs will become more similar – but not all.**

| Regulation/advisory/ Recommendation for mercury | Examples of some of the equation inputs | | | |
|---|---|---|---|---|
| | Reference dose (RfD) | Fish Consumption Rate (FCR) (g/day) | Body Wt. (kg) | Relative Source Contribution (RSC) used? |
| NTR HHC | ?? LOEL/uncertainty factor = 20 ug/day (EPA 1980 criteria doc: EPA 440/5-80-085) | 18.7 (this FCR was used only for Hg in the NTR – represents fresh, estuarine, and marine species) | 70 | No |
| WDOH fish advisory (statewide) | 0.1 µg/kg-day | 60 | 60 | No |
| EPA recommended national HHC (FTR) | 0.1 µg/kg-day | 17.5 | 70 | Yes - accounts for marine fish consumption |

**What about the listing situation?** **Future Hg 303(d) listings likely based directly on a Hg Fish Tissue Residue, which might or might not be similar to the WDOH fish advisory level of 101 ppb.**

| WDOH Statewide Bass Hg Advisory Trigger | Alternative mercury FTR criteria, based on EPA's current recommended national criterion calculation for mercury, calculated at various fish consumption rates. Rates w/ percentiles are from EPA's per capita fish consumption rate estimates (EPA 2000, page 4-27) | | | | | |
|---|---|---|---|---|---|---|
| | 6.5 g/day (NTR – WA 303(d) listing trigger –not a criterion) | 7.5 g/day (est. mean) | 17.5 g/day (est. 90th) | 49.6 g/day (est. 95th) | 142.4 g/day (est. 99th) | 175 (Oregon FCR) |
| 101 ppb | 825 ppb | 680 ppb | 300 ppb | 103 ppb | 35.9 ppb | 29.2 ppb |

WDOH advisory information: *Statewide Bass Advisory*. Washington Dept. Health. DOH 334-290, September 2003
1980 EPA Hg criterion doc - FCR: Ambient Water Quality Criteria for Mercury, EPA-440/5-80-058, pages C-102 to C-107.
EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000)*:
http://water.epa.gov/scitech/swguidance/standards/upload/2005_05_06_criteria_humanhealth_method_complete.pdf.



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# Comment 2

"The aquatic life-based (AQL) criteria for mercury are more protective than the NTR HHC, so the Washington AQL criteria are providing some extra protection."

Here are the CWA regulatory levels for mercury in Washington:

| NTR HHC Organism + Water (ug/L) | NTR HHC Organism Only (ug/L) | WA AQL WQS (WAC 173-201A) Acute Marine (ug/L) | WA AQL WQS (WAC 173-201A) Chronic Marine (ug/L) | WA AQL WQS (WAC 173-201A) Acute Freshwater (ug/L) | WA AQL WQS (WAC 173-201A) Chronic Freshwater (ug/L) |
|---|---|---|---|---|---|
| 0.14 (total) | 0.14 (total) | 1.8 (dissolved) | 0.025 (total) | 2.1 (dissolved) | 0.012 (total) |

The **red arrows** show the most protective Hg criteria for fresh and marine/estuarine environments. The comment is accurate.

| Freshwater | Marine and estuarine |
|---|---|

Draft

| Regulatory or advisory concentration in yellow | Calculated "equivalent" concentration in blue |
|---|---|

| Regulatory or advisory program | Water concentration (ppb in water) | Tissue concentration (ppb) | Tissue concentration (mg/kg) |
|---|---|---|---|
| CWA - National Toxics Rule HHC – **total** mercury (organisms only – **marine and estuarine** scenario)<br>HHC x BCF = tissue conc.<br>BCFs: 3765 (estuarine), 9000 (open ocean) | 0.15 | 565 (estuarine)<br>1,350 (ocean) | 0.56475 (estuarine)<br>1.350 (ocean) |
| CWA - National Toxics Rule HHC – **total** mercury (organisms + drinking water – **freshwater** scenario)<br>HHC x BCF = tissue conc.<br>BCFs: 5500 | 0.14 | 770 | 0.770 |
| CWA - EPA recommended national criterion - **methyl**mercury | NA | 300 | 0.3 |
| WDOH fish advisory – total mercury | NA | 101 | 0.101 |
| CWA - WA WQS – **freshwater** chronic aquatic life criterion – **total** recoverable<br>0.0005 = QL for permit monitoring | 0.012 | 1000 | |
| CWA - WA WQS – **marine** water chronic aquatic life criterion – **total** recoverable<br>0.0005 = QL for permit monitoring | 0.025 | 1000 | |
| US Food and Drug Administration - Action Level- methyl-mercury expressed as Hg (limited to contaminants in food shipped and marketed in interstate commerce - 1979) | NA | 1000 | 1.0 |
| Safe Drinking Water Act – Maximum Contaminant Level – "at source" requirement | 2.0 | NA | |

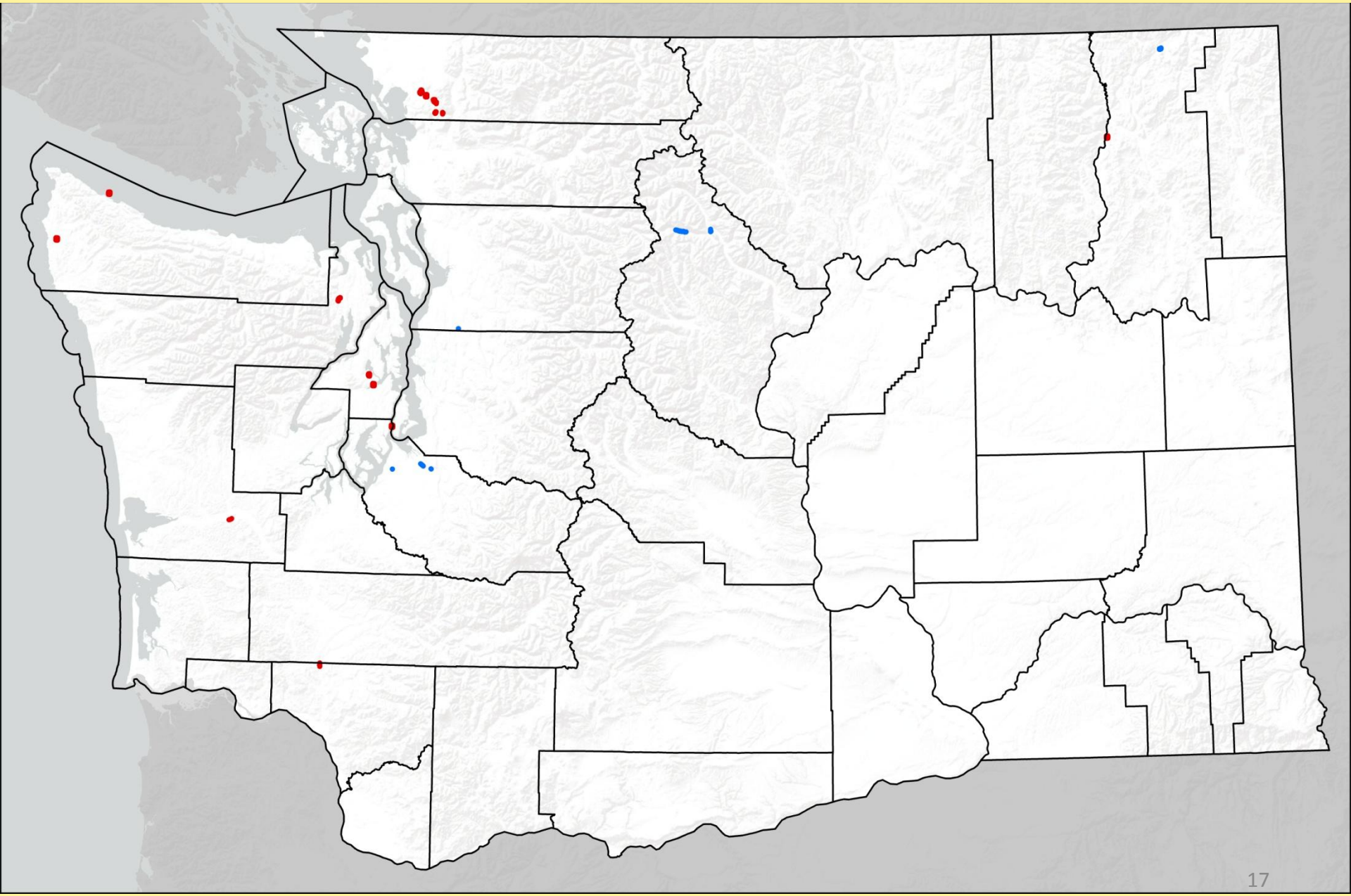
USFDA. NSSP 2009 Section IV Chapter II .04. Action Levels, Tolerances And Guidance levels for Poisonous or Deleterious Substances in Seafood.
http://www.issc.org/client_resources/2009%20nssp%20guide/section%20iv%20chapter%20ii%20.04.pdf
"Action levels and tolerance represent limits at or above which FDA will take legal action to remove adulterated products, including shellfish, from the market. Action levels and tolerances, are established based on the unavoidability of the poisonous or deleterious substance and do not represent permissible levels of contamination where it is avoidable."

# Back to the maps - WQ Assessment Categories

**Only one category, Category 5, represents the 303(d)-listed waters.**

| WQ Assessment Category | Status | Impairment status |
|---|---|---|
| Category 1 | Segment Meets Tested Criteria | Not known to be impaired |
| Category 2 | Segment is a Waters of Concern | |
| Category 3 | Segment Lacks Sufficient Data | |
| Category 4 | Segment Impaired But Does Not Require A TMDL because: | Impaired |
| 4a | Segment Has a TMDL Approved by EPA | |
| 4b | Segment Has a Pollution Control Program | |
| 4c | Segment Impaired by a Non-Pollutant | |
| **Category 5** | **Segment is on 303(d) List** | |

**This map represents <u>all 25 Category 5 Listings for Mercury</u> from the 2012 WQ Assessment, distinctly by medium (red: tissue, blue: water). Category 5 = the 303(d) list.**



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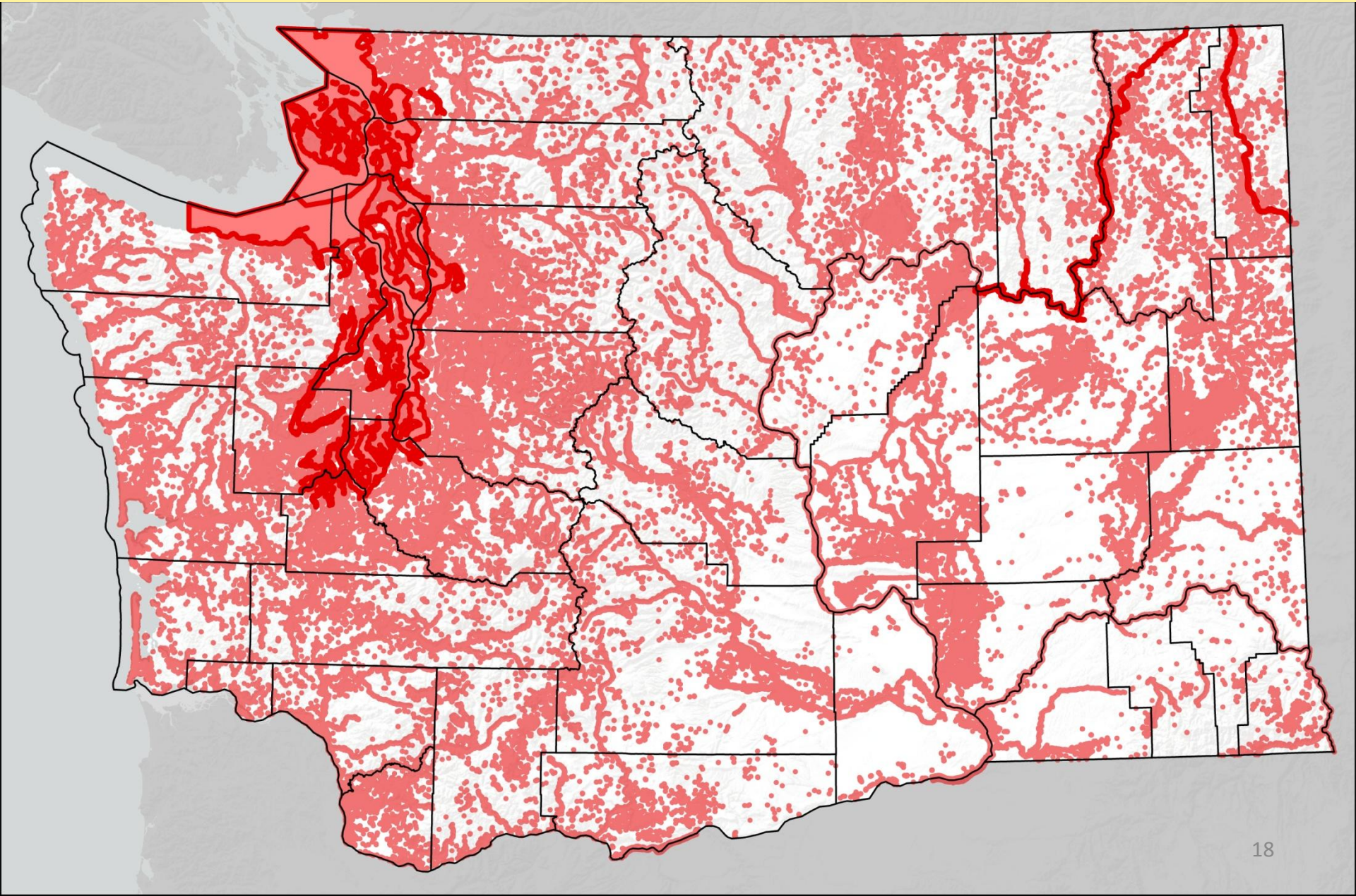


# Review: Waterbody segments listed as impaired under CWA Sec. 303(d)

**How are impairment listings for the "fishable and drinking water" use determined?**

The information needed to make a determination of impairment is specified in:

*Water Quality Policy 1-11: Chapter 1:Assessment of Water Quality for the Clean Water Act Sections 303(d) and 305(b) Integrated Report*

Policy 1-11 and subsequent WQ assessments are developed using a public process.

**Policy 1-11 contains two approaches to make a determination of impairment for HHC:**

1. **Tissue** concentration exceeds FTEC (FTEC = BCF x criterion concentration)

- Resident fin fish (fillet tissue samples (skin on or off)), whole shellfish tissue samples, and/or edible shellfish muscle samples
- At least three single-fish samples or a single composite sample made up of at least three separate fish of the same species

2. **WDOH fish advisory**

- If FA based on less than or equally protective risk assessment assumptions than the tissue approaches above, then segment is listed on Category 5 (303(d) list.)

All listings that are based on numeric criteria must be based on samples collected within the segment.

**Reminder: A listing ≠ a fish advisory**

Policy 1-11 found at: http://www.ecy.wa.gov/programs/wq/303d/policy1-11.html
Information about WA's WQ Assessment is at: http://www.ecy.wa.gov/programs/wq/303d/index.html

# Why such a big difference in the maps?

**1.** The tissue concentrations used in 303(d) listings and in fish advisories are different concentrations (as per prior slides) because of different equation assumptions.

**2.** Ecology lists waterbody **segments.** Segments are **only** listed when samples are available for that segment – entire waterbodies are not listed unless all segments have data that support listings. Fish advisories often cover **broad areas**.

**3.** Approach 2 for listing: If a Fish Advisory is based on less than or equally protective risk assessment assumptions than the tissue approaches above, then segment is listed on Category 5 (303(d) list.)

**What happens in a TMDL for toxics?**

Most frequently Ecology looks at the broader waterbody to identify sources and allocate loads. WA is still in the early stages of carrying out TMDLs for toxics. Many yet to conduct and complete.

**Response to mercury problems?**

Mercury **C**hemical **A**ction **P**lan and subsequent actions (see material from March 28 PF)
Other regulatory actions as required

# The development of a mercury Fish Tissue Residue criterion is new, and adds some complications to permit limit development

## Simplified draft permit limit development diagram for FTR criterion

**Step 1**
Use future FTR criterion (a concentration in tissue)

**Step 2**
Translate the FTR to an equivalent ambient water concentration using a **BAF**

This is the step that adds additional complication

**Step 3**
Use the water concentration to support the "Reasonable Potential Determination." This answers the question: Will the criterion be exceeded at the edge of the mixing zone?

**Step 4**
If **yes** – Calculate NPDES permit limit.

If **no**, no limit is developed

# What happens in Step 2?

**Step 2**
Translate the FTR to an equivalent ambient water concentration using a BAF

BAF

Acceptable ambient water Concentration?

A **Bioaccumulation Factor (BAF)** is used to back calculate from the FTR to a water concentration.

The BAF is different from the Bioconcentration Factor (BCF) that is used for the majority of the HHC. You have seen the BCF input in the criterion equations shown at past Policy Forums.

EPA's 2000 guidance recommends using BAFs over BCFs, but the only EPA recommended criterion developed so far, with a BAF, is the Hg FTR.

The NTR Hg HHC are based on "Practical BCFs" – "PBCFs" are similar to BAFs

Criteria for other chemicals are still based on the older BCFs developed decades ago

1980 EPA Hg criterion doc: Ambient Water Quality Criteria for Mercury, EPA-440/5-80-058, pages C-99 to C-107.

# What is the difference between a BCF and BAF?

## And why is it important?

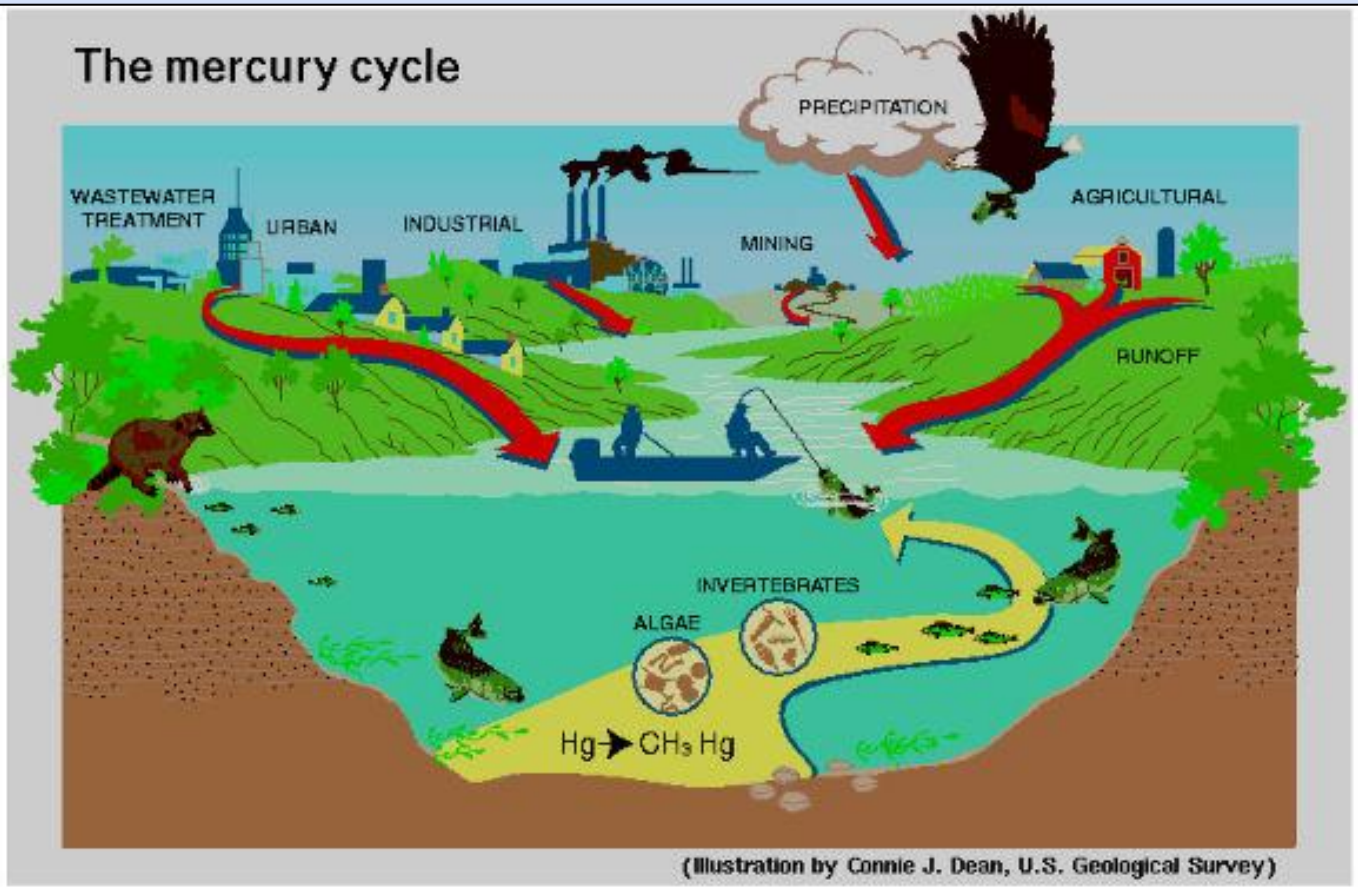
| **BCF – Bioconcentration Factor (this is the default and older input in the equations)** | **BAF – Bioaccumulation Factor (this is the newer equation input)** |
|---|---|
| A **bioconcentration factor (BCF)** represents the ratio of the concentration of a chemical in tissue of an aquatic organism to its concentration in the surrounding water, in situations where **the organism is exposed to water only** and the ratio does not change substantially over time (is near steady-state). | A **bioaccumulation factor (BAF)** represents the ratio of a concentration of a chemical in tissue of an aquatic organism to its concentration in the surrounding water, in situations where **the organism and its food are exposed** and the ratio does not change substantially over time (is near steady-state). |

Fish in water only, no other sources of chemical to fish

BCFs are generally developed in controlled laboratory conditions or modeled.

BCFs are generally developed from modeling or direct site assessments.

Bioaccumulation factors (BAFs) account for all the sources of mercury to fish and shellfish tissue, as shown in the figure below from WDOH.




**Bioaccumulation**

Once released into the environment, mercury eventually ends up in water and settles into sediments. Bacteria in the water converts the inorganic mercury into methylmercury, an organic mercury compound. These bacteria are eaten by plankton and other small creatures, which in turn are eaten by small fish, then larger fish. Mercury does not easily leave the body of an organism, so the amount of mercury builds up in species as they go up the food chain in a process called bioaccumulation. Predatory fish, which sit higher up on the food chain and are long-lived, can accumulate hundreds of thousands to millions of times the concentration of mercury that originally entered the water. As people eat fish with mercury, the mercury is transferred to humans and builds up in the body.

*From: Washington Dept. of Health*

# Why is this important?

The BAFs can be real-world numbers that take into account real-world exposures. Laboratory derived BCFs for highly bioaccumulative chemicals such as DDT, PCBs, and mercury underestimate the accumulation that occurs in natural systems and that are represented by using a model or field-derived BAF.

Using a BAF during calculation means that the equation is taking into account all the exposures an organism has (dermal, respiratory, ingestion, etc…), and all the sources of those exposures: (food chain, sediments, etc..). The CWA NPDES permit system cannot control the sources of chemicals to all those different media.

For highly bioaccumulative chemicals the BAF will be a higher number then the BCF, leading to lower concentrations required in water. However, right now mercury is the only criterion with a BAF included, so this impact on the HHC is small.

# What does the new FTR criterion for mercury mean to NPDES permitting?

BAFs are dependent on a mix of characteristics of a waterbody and its associated biota.

To develop a water concentration for permitting, WA could use site-specific BAFs in the future, or develop default approaches. The approach chosen will have an impact on permit limits.

The good news is that EPA has developed guidance to help the states with this. We will also be looking at the approaches used by other states to see what is working for them.

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Information on the EPA methylmercury criterion and implementation:

EPA web site:
http://water.epa.gov/scitech/swguidance/standards/criteria/aqlife/methylmercury/index.cfm

Implementation: USEPA. 2010. Guidance for Implementing the January 2001 Methylmercury Water Quality Criterion (PDF) (EPA 823-R-10-001)

# EPA implementation guidance is comprehensive, including information on the following:

- Recommended form of a methylmercury criterion
- Criterion adjustments
- Mixing zones
- Variances
- Recommended analytical methods
- Field sampling recommendations
- Assessing non-attainment of fish tissue criterion
- TMDLs
- Permitting procedures

**Policy decision:** As we continue this process toward the draft rule development, WA will have to determine an implementation method applicable to permit limit development in order to develop the economic assessment of the effects of a new mercury criterion on permit limits.

Implementation: USEPA. 2010. Guidance for Implementing the January 2001 Methylmercury Water Quality Criterion (PDF) (EPA 823-R-10-001)

This concludes mercury information

# Questions/Comments/Discussion

# Specific issues associated with Arsenic – Part 1 overview

Policy Forum #5

May 23, 2013

Human Health Criteria and Implementation Tools Rule-makings

Cheryl Niemi

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360-407-6440

# 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 (40CFR131)
**CWA** = Clean Water Act
**As** = Arsenic
**SDWA** = Safe Drinking Water Act
**MCLG** = Maximum Contaminant Level Goal
**MCL** = Maximum Contaminant Level

# Some of the issues surrounding arsenic HHC development and implementation in Washington

**We will discuss summary information on:**

- Natural conditions in WA and other western states
- Human sources
- As HHC Criteria: calculate or use SDWA MCL
- Natural conditions provision in the WQS

# Natural conditions of arsenic in WA

**WA WQS for inorganic arsenic:**

| NTR HHC Organism + Water (ug/L) | NTR HHC Organism Only (ug/L) | WA AQL WQS (WAC 173-201A) Acute Marine (ug/L) | WA AQL WQS (WAC 173-201A) Chronic Marine (ug/L) | WA AQL WQS (WAC 173-201A) Acute Freshwater (ug/L) | WA AQL WQS (WAC 173-201A) Chronic Freshwater (ug/L) |
|---|---|---|---|---|---|
| 0. 018 (inorganic) | 0.14 (inorganic) | 69 (dissolved) | 36 (dissolved) | 360 (dissolved) | 190 (dissolved) |

Inorganic arsenic data set for ambient surface waters is sparse.

Natural conditions of inorganic arsenic exceed criteria in areas

- Freshwater: e.g., Similkameen River

Marine waters:

- Seawater estimates (variety of literature sources) range around 1-2 ppb.

Groundwater data set is rich – U.S. Geological Survey and Washington Dept. of Health

Note: The HHC for As are based on cancer effects.

# Information on natural sources of arsenic

"Most arsenic in the environment exists in rock or soil (ATSDR, 1998). Because arsenic occurs naturally in rock, soil and sediment, these sources are particularly important determinants of regional levels of arsenic in ground water and surface water." (p. 8)

"Arsenic is the twentieth most abundant element in the earth's crust (ATSDR, 1998; NAS, 1977). Concentrations of arsenic in the earth's crust vary, but average concentrations are generally reported to range from 1.5 to 5 mg/kg (ATSDR, 1998; Cullen and Reimer, 1989; NAS,1977). Arsenic is a major constituent of many mineral species in igneous and sedimentary rocks;Table 2-4 presents concentrations of arsenic in igneous and sedimentary rocks. Among igneous rock types, the highest arsenic concentrations are found in basalts. Sedimentary rocks, particularly iron and manganese ores, often contain higher average arsenic concentrations than igneous rocks (Welch *et al., 1988)."* (p. 10)

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From: USEPA. 2000. *ARSENIC OCCURRENCE IN PUBLIC DRINKING WATER SUPPLIES*. EPA-815-R-00-023, December 2000. *www.epa.gov/ogwdw/arsenic/pdfs/occurrence.pdf*

# Freshwater example: Similkameen River TMDL for arsenic

Ecology's 2003 arsenic TMDL for arsenic demonstrated that natural background arsenic levels exceed the NTR HHC (Similkameen R.): Ecology Water Quality Improvement Project**, Similkameen River Area: Arsenic** http://www.ecy.wa.gov/programs/wq/tmdl/SimilkameenRvrTMDL.html

> "It was determined that the Similkameen River naturally exceeds the EPA arsenic criteria upstream of the areas disturbed by mining near Hedley, BC. Under these circumstances, natural conditions constitute the water quality criteria. Because arsenic levels naturally exceed criteria, the loading capacity for the river is set equal to the natural background concentration of arsenic."

> "After responding to public comments, the TMDL report was submitted to EPA for approval. EPA approved the TMDL on February 17, 2004."

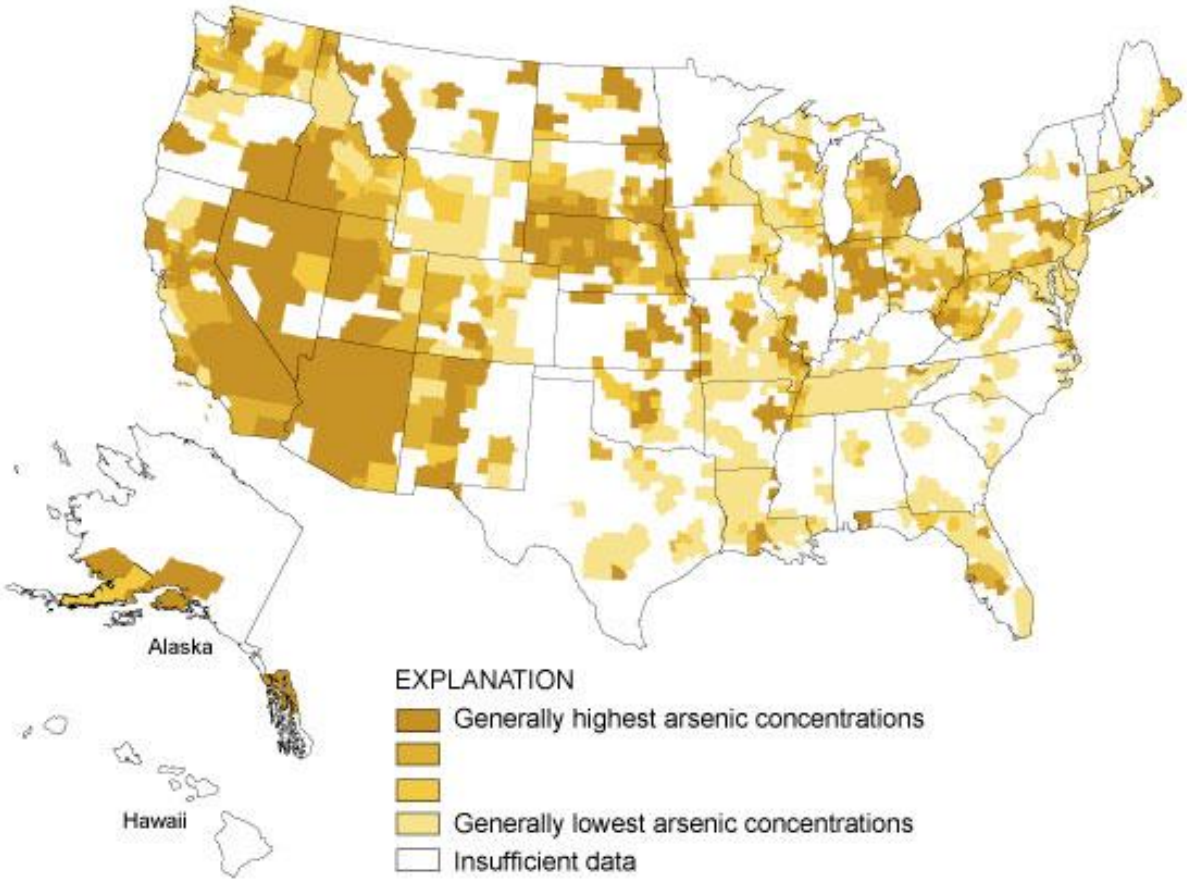



***Figure 3.*** *Counties with arsenic concentrations exceeding possible new MCLs in 10 percent or more of ground-water samples.*

- Counties with arsenic concentrations exceeding 10 μg/L in 10 percent or more of samples.
- Counties with arsenic concentrations exceeding 5 μg/L in 10 percent or more of samples.
- Counties with arsenic concentrations exceeding 3 μg/L in 10 percent or more of samples.
- Counties with fewer than 10 percent of samples exceeding 3 μg/L, representing areas of lowest concentration.
- Counties with insufficient data in the USGS data base to make estimates.

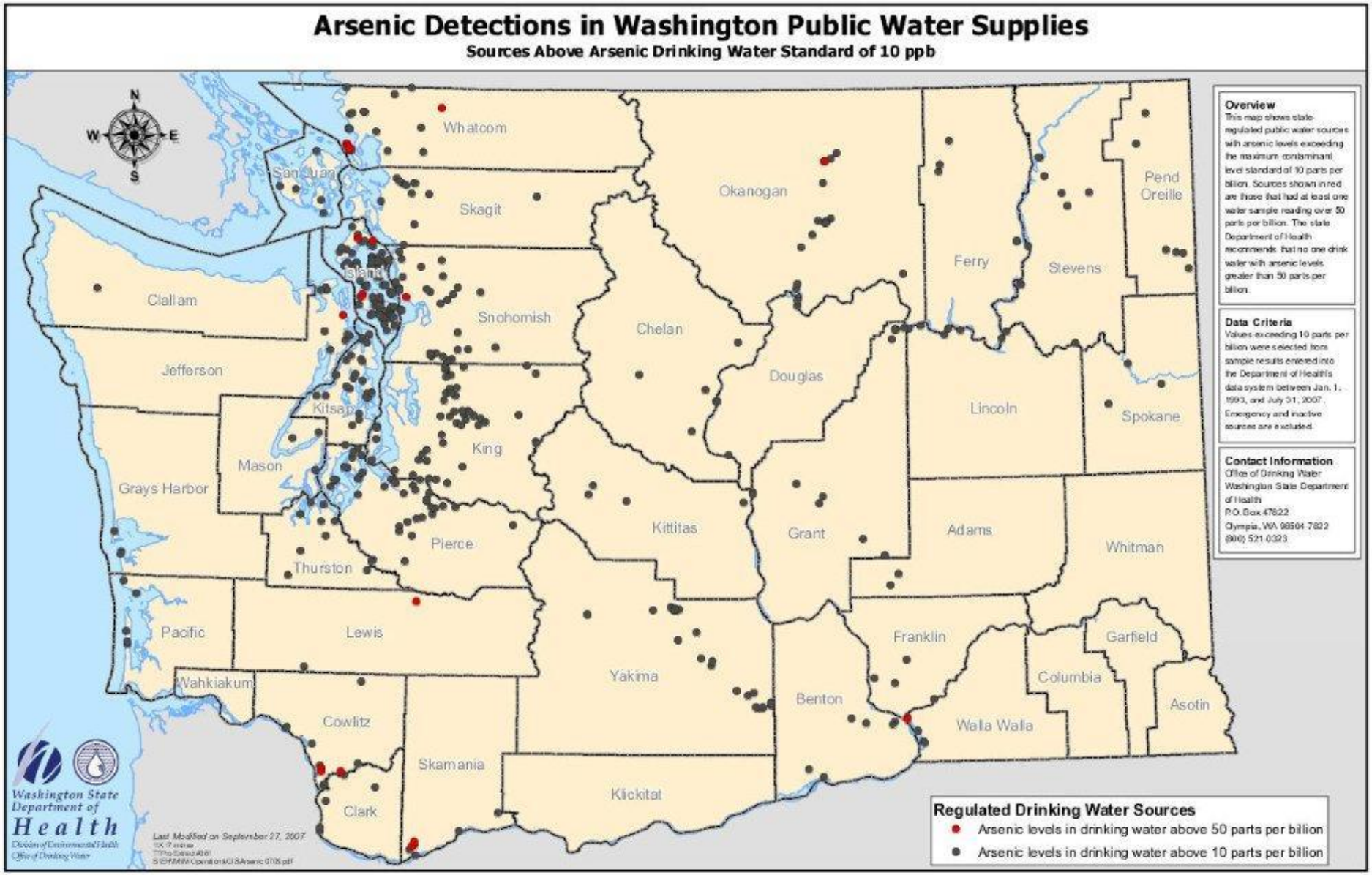
## Groundwater

**U.S. Geological Survey Open-File Report 063-00 Arsenic in Ground-Water Resources of the United States**
**http://pubs.usgs.gov/fs/2000/fs063-00/fs063-00.html#HDR1**

"Arsenic concentrations in ground water generally are highest in the West. Parts of the Midwest and Northeast also have arsenic concentrations that exceed 10 μg/L, the World Health Organization's (WHO) provisional guideline for arsenic in drinking water (World Health Organization, 1999)."

This map was updated in 2001, and the updated version can be found at: http://www.agiweb.org/geotimes/nov01/feature_Asmap.html

# Washington public water supply information from WDOH




http://www.doh.wa.gov/CommunityandEnvironment/DrinkingWater/Contaminants/ArsenicinDrinkingWater.aspx

## Regulatory levels for Clean Water Act (CWA) vs. Safe Drinking Water Act (SDWA) – a possible conundrum for NPDES discharge permits

| NTR HHC Organism + Water (ug/L) | NTR HHC Organism Only (ug/L) | WA AQL WQS (WAC 173-201A) Acute Marine (ug/L) | WA AQL WQS (WAC 173-201A) Chronic Marine (ug/L) | WA AQL WQS (WAC 173-201A) Acute Freshwater (ug/L) | WA AQL WQS (WAC 173-201A) Chronic Freshwater (ug/L) |
|---|---|---|---|---|---|
| 0. 018 (inorganic) | 0.14 (inorganic) | 69 (dissolved) | 36 (dissolved) | 360 (dissolved) | 190 (dissolved) |

| SDWA Maximum contaminant level goal (MCLG) | SDWA maximum contaminant level (MCL) |
|---|---|
| 0 | 10 ug/L |

**Concern:** That water entering municipalities will comply with SDWA MCLs, but will be above the NTR surface water HHC and/or limits developed for those criteria. This could mean that compliance with one federal law and regulatory program (SDWA) could result in non-compliance with another federal law and regulatory program (CWA).

Ecology and WDOH will coordinate closely on this issue as it is addressed.

# Natural conditions in WA WQS

**173-201A-020**
**Definitions. "Natural conditions" or "natural background levels"** means surface water quality that was present before any human-caused pollution. When estimating natural conditions in the headwaters of a disturbed watershed it may be necessary to use the less disturbed conditions of a neighboring or similar watershed as a reference condition.

**WAC 173-201A-260**

**Natural conditions and other water quality criteria and applications.**

**(1) Natural and irreversible human conditions.**

**(a)** It is recognized that portions of many water bodies cannot meet the assigned criteria due to the natural conditions of the water body. When a water body does not meet its assigned criteria due to natural climatic or landscape attributes, the natural conditions constitute the water quality criteria.

https://fortress.wa.gov/ecy/publications/SummaryPages/0610091.html

# EPA's policy on use of the natural conditions approach for HHC

**USEPA , Nov. 5 1997 memorandum from Tudor Davies**
**SUBJECT: Establishing Site Specific Aquatic Life Criteria Equal to Natural Background**

**"**For aquatic life uses, where the natural background concentration for a specific parameter is documented, by definition that concentration is sufficient to support the level of aquatic life expected to occur naturally at the site absent any interference by humans. The State or Tribe should consider refining the designated use for the water body to more precisely define the existing aquatic life use.**"**

**"**This policy does not apply to human health uses. For human health uses, where the natural background concentration is documented, this new information should result in, at a minimum, a re-evaluation of the human health use designation. Where the new background information documents that the natural background concentration does not support a human health use previously believed attained, it may be prudent for the State or Tribe to change the human health use to one the natural background concentration will support (e.g., from drinking water supply to drinking water supply only after treatment).**"**

# Other sources of Arsenic in Washington

- Natural geology – weathering and groundwater
- Atmospheric deposition
- Pesticide use
- Mining and smelting
- Other discharges

**Highlight: Ecology Toxics Clean-up Program's Areawide Soil Contamination Project**

"Area-wide soil contamination is low-to-moderate arsenic and lead soil contamination spread over a large area. The area could range from several hundred acres to many square miles. In Washington State, area-wide contamination comes from three main historical sources:

- Emissions from metal smelters in Everett and Tacoma.
- Use of arsenical pesticides, especially on orchards.
- Combustion of leaded gasoline. "

In the early 2000's, the State of Washington brought together a task force to develop a strategy for dealing with "area-wide" soil contamination. In 2003, the task force put out a report with their recommendations. Ideas included educating the public, protecting children, and cleaning up areas of highest contamination.

Ecology is using many of these ideas for the Tacoma Smelter Plume, the Everett Smelter Plume, and at schools built on former orchard lands"

**(http://www.ecy.wa.gov/programs/tcp/area_wide/area_wide_hp.html)**

# What arsenic HHC do other western states use?

Safe Drinking Water Act for Arsenic = 10 ppb

| State | Inorganic Arsenic criteria (freshwater; water + organisms) |
|---|---|
| Alaska | 10 ppb |
| Idaho | 10 ppb |
| Wyoming | 10 ppb |
| Nevada | 10 ppb |
| Utah | 10 ppb |
| New Mexico | 10 ppb |

| Oregon state-specific HHC for arsenic | |
|---|---|
| ***Human Health Criteria for the Consumption of:*** **Water + Organism (µg/L)** | ***Human Health Criteria for the Consumption of:*** **Water + Organism (µg/L)** |
| **2.1** | **2.1** (freshwater), **1.0** (saltwater) |
| *The arsenic criteria are expressed as total inorganic arsenic. The "organism only" criteria are based on a risk level of approximately of 1.1 x 10-5, and the "water + organism" criterion is based on a risk level of 1 x 10-4* *(From: ODEQ http://www.deq.state.or.us/wq/standards/toxics.htm#Curhttp://www.deq.state.or.us/wq/standards/toxics.htm#Cur* | |

Is using an MCL for a criteria consistent with EPA guidance? Yes.
Is developing state-specific criteria consistent with EPA guidance? Yes.

**Policy question? What approach is right for WA?**

This concludes summary arsenic information, Arsenic: Part 1.

Arsenic: Part 2.

Tentatively scheduled for the next Policy Forum

# Questions/Comments/Discussion

# Next presentation: Lon Kissinger, EPA Region 10.

Lon's material describes EPA's process to develop cancer and non-cancer toxicity factors.

These are important inputs to the HHC equations.

This is important background material to hear prior to the next Policy Forum – where uncertainty and conservatism in HHC development is planned for discussion.

# Estimating Chemical Toxicity and AWQC Development

Lon Kissinger

Office of Environmental Assessment

EPA Region 10

# Presentation Outline

- Review of material from Policy Forum 3.
- Estimating toxicity of chemicals with a non-cancer
- Estimating toxicity of cancer causing chemicals
- The role of EPA's IRIS program in developing toxicity estimates

# Assessing Contaminant Exposure Risk or Hazard

HAZARD IDENTIFICATION

DOSE RESPONSE ASSESSMENT

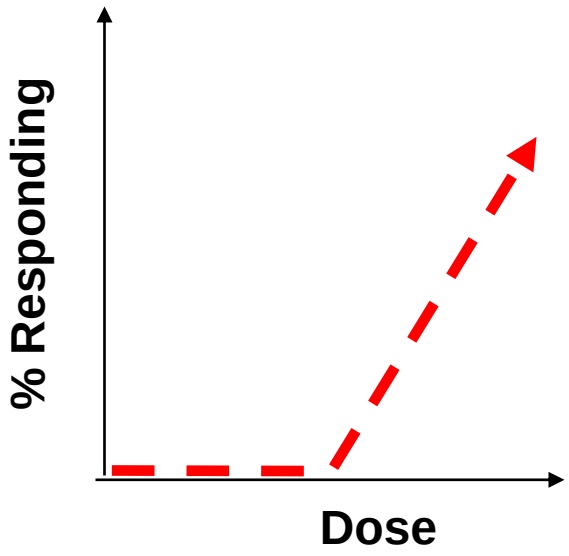
EXPOSURE ASSESSMENT

CHARACTERIZE RISK

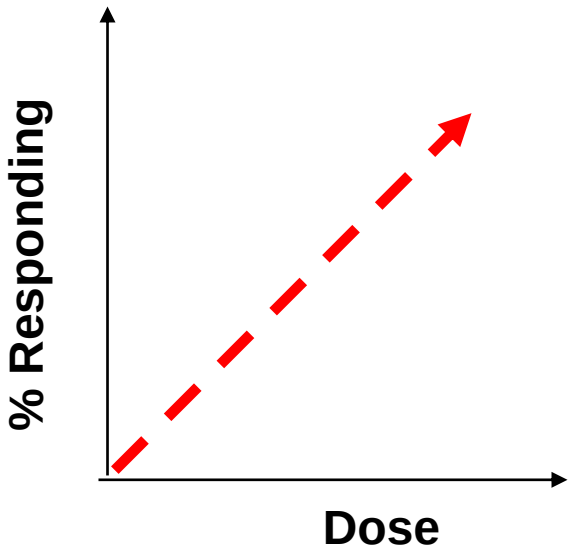
Integrate

HAZARD ID, DOSE-RESPONSE, and EXPOSURE

# Dose Response Relationships




Non-carcinogens
and select carcinogens
(threshold)




Most Carcinogens
(non-threshold)

# Developing Non Cancer Toxicity Estimates

- Identify relevant toxicity studies and effects
- Identify a toxicity threshold or Point of Departure (POD)
- Reduce the POD concentration to account for uncertainty and impart health protectiveness

# Non Carcinogen Toxicity Metric

**EPA Chronic Reference Dose (RfD):** An estimate (with uncertainty spanning perhaps an order of magnitude or greater) of a daily exposure level for the human population, including sensitive subpopulations, that is likely to be without an appreciable risk of deleterious effects during a lifetime.

# Proposed RfD Definition Revision

**Reference Value:** an estimate of an exposure, designated by duration[a] and route, to the human population (including susceptible subgroups)[b] that is likely to be without an appreciable risk of adverse health effects over a lifetime. It is derived from a BMDL, a NOAEL, a LOAEL, or another suitable point of departure, with uncertainty/variability factors applied to reflect limitations of the data used

---

[a] The generalized durations are for acute (#24 hours), short-term (up to 30 days), longer-term (up to 10% of average lifespan), and chronic (up to a lifetime), all considered to be continuous exposures throughout the duration specified.

[b] Susceptible subgroups may refer to life stages, e.g., children or the elderly, or to other segments of the population, e.g., asthmatics or the immune-compromised, but they are likely to be somewhat chemical specific and they may not be consistently defined in all cases.

# The Point of Departure (POD)

- Estimate of toxicity from which the RfD is developed
- Studies for POD development
  - Principal studies
  - Supporting studies
- Study Considerations
  - Animal or human data
  - Route of exposure
  - Length of exposure
  - Quality of study

# Critical Effect and Critical Study

Critical Effect: "The first adverse effect, or its known precursor, that occurs to the most sensitive species as the dose rate of an agent increases" (U.S. EPA, www.iris.gov)

Critical Study: The study defining the critical effect.

# Weight of Evidence

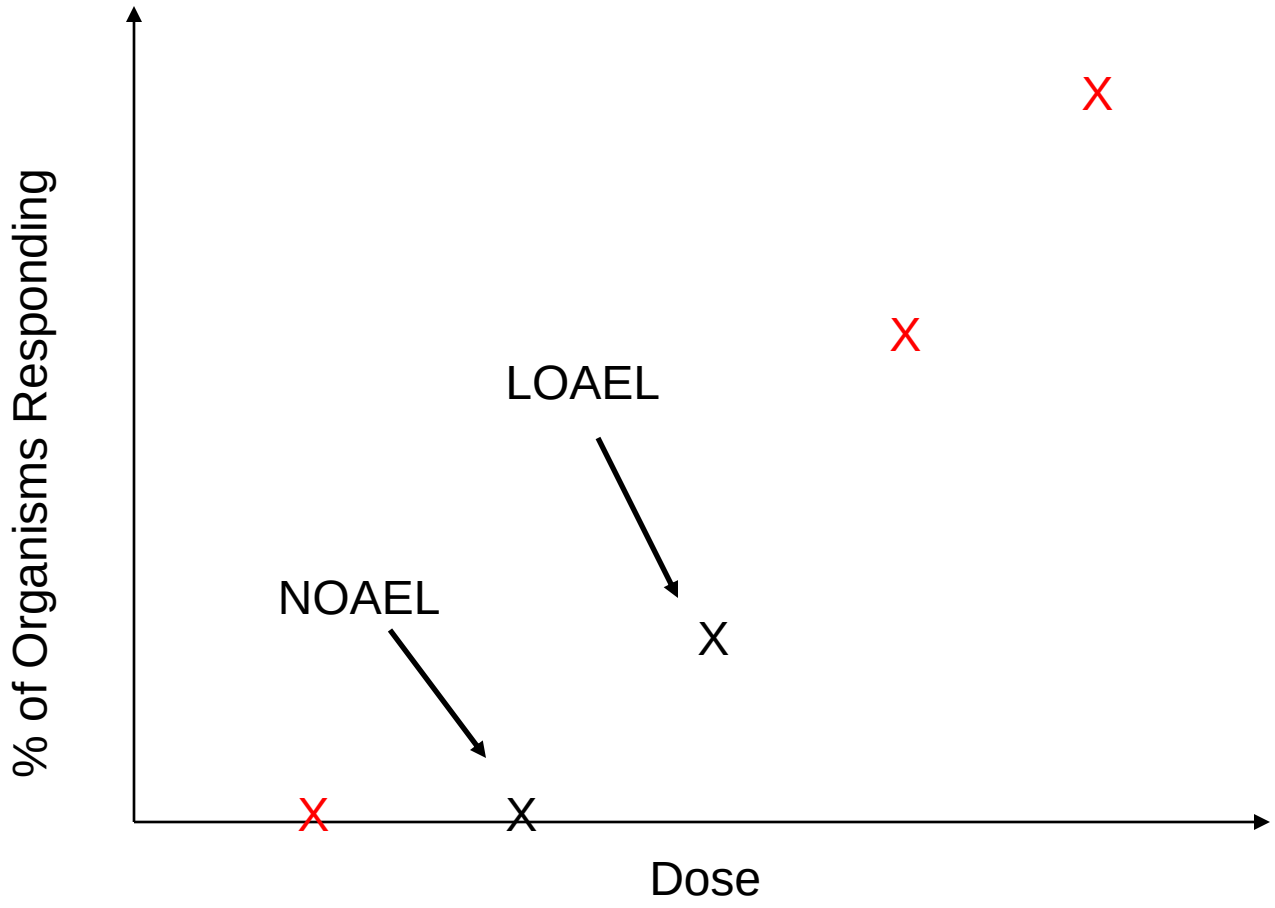
Consideration of all information suggesting that the chemical poses a hazard to humans:

- Animal results replicated by multiple researchers
- Similar effects across sex, strain, species, and route of exposure
- Clear evidence of a dose-response relationship
- Relationship between data on metabolism, postulated mechanism-of-action, and the effect of concern
- Similar toxicity exhibited by structurally related compounds
- Link between the chemical and evidence of the effect of concern in humans.

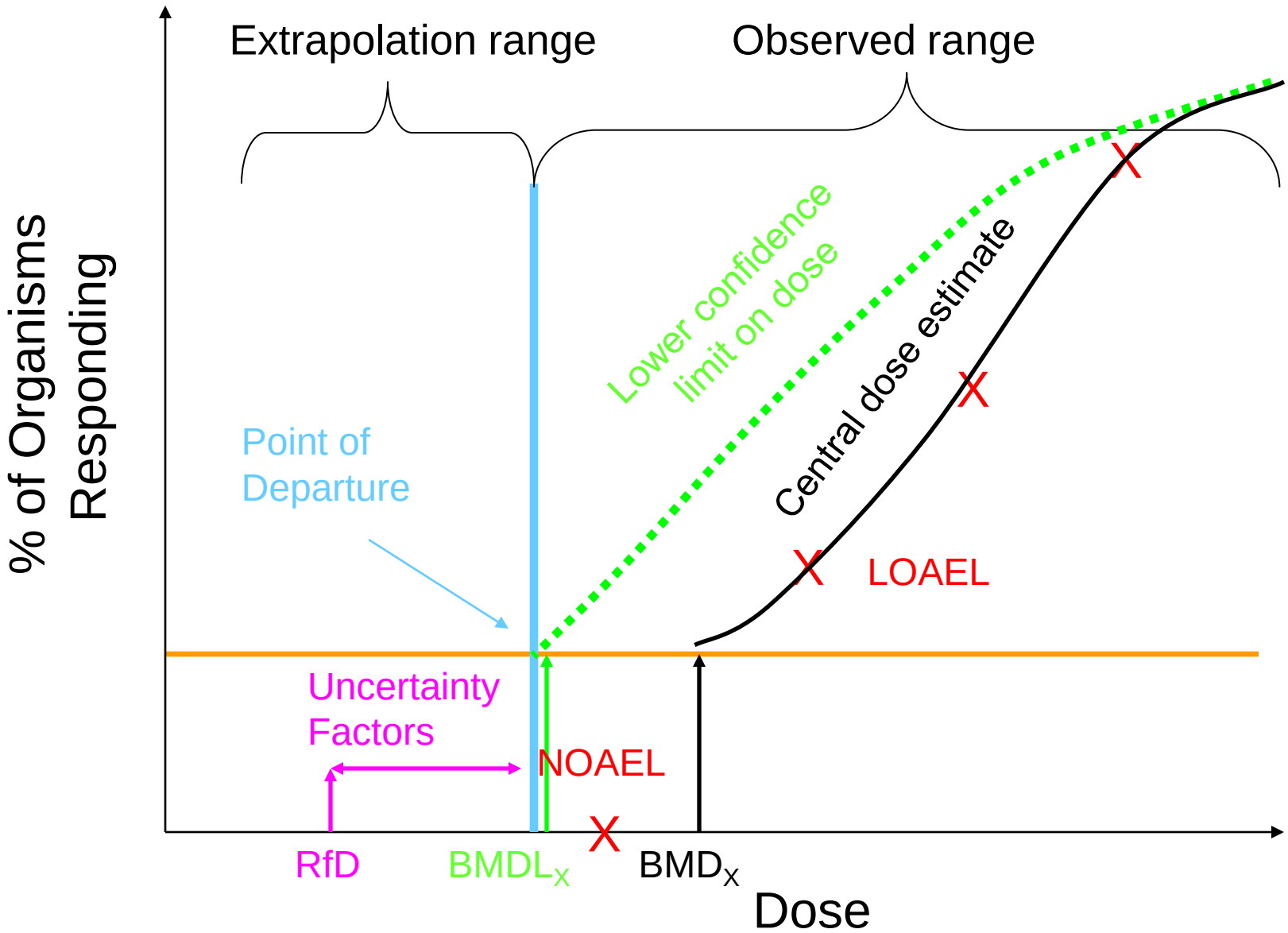
# Derivation of the RfD from the POD

- RfD = Point of Departure divided by Uncertainty Factors (UF)
- Point of Departure Choices
  - No Observed Adverse Effect Level (NOAEL)
  - Lowest Observed Adverse Effect Level (LOAEL)
  - Benchmark Dose (BMD)

# Point Of Departure: NOAEL or LOAEL



# Point Of Departure: Benchmark Dose



# 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 vs. NOAEL ($UF_L$)
  - Uncertainty due an inadequate database ($UF_D$)
- Invoked as integers of 1, 3, 10
  - 3 is a half $\log_{10}$
  - Value selected determined by the data available
  - Total uncertainty factor not be greater than 3,000)
- $U_{Tot} = UF_H \times UF_A \times UF_S \times UF_L \times UF_D$

# Plausibility of Uncertainty Factors $UF_H$, Intraspecies Variability

- 10 reasonable starting from average human response.
- Reducible if data on a sensitive populations are available.
- May be inadequate for populations with a high degree of genetic variation.

# Plausibility of Uncertainty Factors $UF_A$, Interspecies Variability

- Based on differences in
  - Toxicokinetics: movement/metabolism of chemical within an organism
  - Toxicodynamics: degree of effect
- Computer models can adjust animal toxicokinetics to reflect human experience.
- 
- Can’t model toxicodynamics
- Use 10 if modeling is not available, 3 if modeling can reflect human toxicokinetics.

# Plausibility of Uncertainty Factors $UF_S$, Use of a Subchronic Study

- Examined ratios of subchronic to chronic NOAELs or LOAELs.
- Research validates use of 10.

# Plausibility of Uncertainty Factors $UF_L$, Use of LOAEL instead of NOAEL

- 10 used as default.
- Researchers reviewing LOAEL/NOAEL ratios have shown 3 more common.
- Slope of dose response curve important.

# Plausibility of Uncertainty Factors $UF_D$, Database Adequacy

- Are data available for all organ systems and life stages?

- Are prenatal and two generation toxicity data available?
  - $UF_D$ = 3 if one is missing
  - $UF_D$ = 10 if both are missing

# Composite Uncertainty Factors for Major Environmental Contaminants

- Methylmercury: 10, due to intraspecies toxicodynamic/toxicokinetic variability
- Arsenic: 3, due to lack of certainty about reproductive effects and inclusion of all sensitive subpopulations.
- Dioxin (2,3,7,8-TCDD): 30, 3 due to intraspecies variability and 10 due to use of an LOAEL
- PCBs (Aroclor 1254): 300, 10 intraspecies, 3 interspecies (rhesus monkey), 3 LOAEL/effect of mild severity, 3 subchronic to chronic (not 10 because critical effect not dependent on study duration).

# Relation Between Non-cancer Hazard and AWQC Development

A) Hazard Quotient (HQ) (unitless) = Dose received / RfD

B) $1 = C_{H2O} \times ((IR_{water} + \Sigma( IR_{fish} \times BAF)) / BW) / RfD$

C) $AWQC = RfD \times BW / ((IR_{water} + \Sigma( IR_{fish} \times BAF))$

Where:

$C_{H2O}$ = water concentration
IR = ingestion rate
BAF = bioaccumulation factor
BW = body weight

# Developing Cancer Assessments

- Identify available key human studies and cancer bioassays
- Attempt to identify carcinogenic mode(s) of action
- Where data are sufficient, select and apply extrapolation methods to develop Cancer Toxicity Value
- Assign weight of the evidence descriptor of carcinogenic potency

# Mode of Action and Carcinogenicity Assessment

Mode of Action – The mode of action is a sequence of key events and processes, starting with interaction of an agent with a cell, proceeding through operational and anatomical changes, and resulting in cancer formation. Examples of possible modes of carcinogenic action include mutagenicity, mitogenesis, inhibition of cell death, cytotoxicity with reparative cell proliferation, and immune suppression" (U.S.EPA, 2005)

# Use of Mode of Action in Cancer Dose Response Risk Assessment

- Linear extrapolation if linear dose response relationship expected below POD
  - DNA-reactive and direct mutagenic agents, or
  - human exposures near doses associated with key precursor events in the carcinogenic process

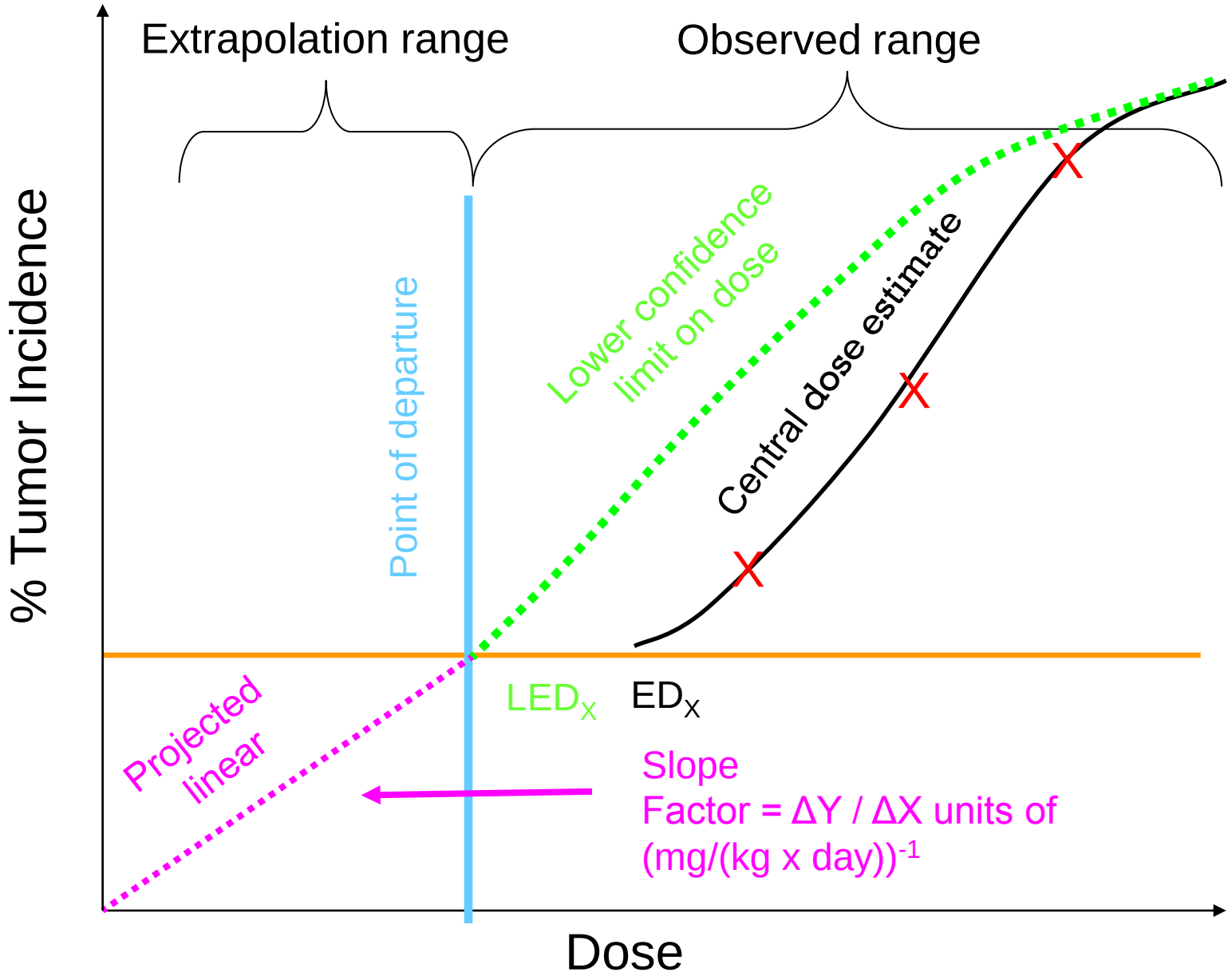
- Nonlinear approach with sufficient data on MOA showing non-linearity at low doses AND agent not mutagenic or other activity consistent with linearity at low doses

- Both linear and nonlinear approaches may be used when there are multiple MOAs. For example, an agent can act predominantly through cytotoxicity at high doses and through mutagenicity at lower doses where cytotoxicity does not occur.

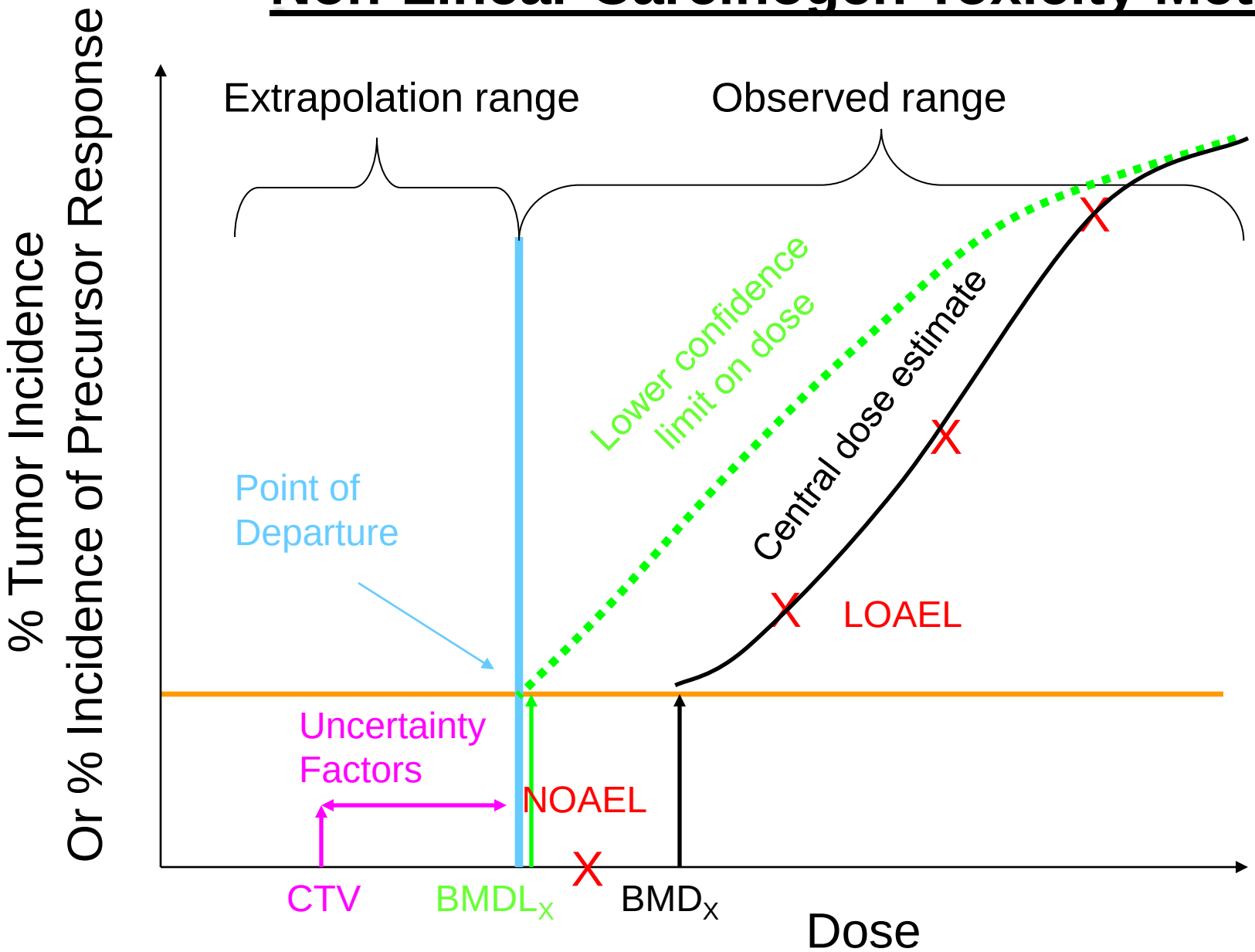
# Linear Carcinogen Toxicity Metric

**Slope factor:** A plausible upper-bound estimate of the probability of a response per unit intake of a chemical over a lifetime. The slope factor is used to estimate an upper-bound probability of an individual developing cancer as a result of a lifetime of exposure to a particular level of a potential carcinogen.

# Derivation of Slope Factor for Linear Carcinogens



# Non-Linear Carcinogen Toxicity Metric



# Carcinogen Classifications

| 1986 Guidelines | 1999 Interim Guidelines | 2005 Guidelines |
|---|---|---|
| A: Human carcinogen | Carcinogenic to humans | Carcinogenic to humans |
| B1: Probable human carcinogen (limited human data) | Likely to be carcinogenic to humans | Likely to be carcinogenic to humans |
| B2: Probable human carcinogen (inadequate or no human data) | Suggestive evidence of carcinogenicity, but not sufficient to assess human carcinogenic potential | Suggestive evidence of carcinogenic potential |
| C: Possible human carcinogen | Data inadequate for assessment of human carcinogenic potential | Inadequate information to assess carcinogenic potential |
| D: Not classifiable | Not likely to be carcinogenic to humans | Not likely to be carcinogenic to humans |

# Relation Between Cancer Risk and AWQC Development for Linear Carcinogens

A) Risk (unitless) = Dose x Slope Factor

B) Target Risk = $C_{H2O}$ x $((IR_{water} + \Sigma( IR_{fish} \times BAF)) / BW)$ x Slope Factor

C) AWQC = Target Risk / Slope Factor x $BW / ((IR_{water} + \Sigma( IR_{fish} \times BAF))$

The term "Target Risk / Slope Factor" is known as the "risk specific dose."

Where:

$C_{H2O}$ = water concentration
IR = ingestion rate
BAF = bioaccumulation factor
BW = body weight

# Integrated Risk Information System (IRIS)

- Develops EPA positions on potential human health effects from exposure to various chemical substances found in the environment
- Follows EPA guidelines for health risk assessment
- Follows IRIS standard operating procedures that are updated yearly
- Fosters consistent risk assessments across EPA Programs and Regions
- Contains over 500 chemical-specific IRIS Summaries, many with Toxicological Review (or similar) background documents available
- Provides qualitative hazard and cancer weight of evidence characterizations
- Provides quantitative toxicity values : Reference Dose, Reference Concentration; cancer slope factor and unit risks

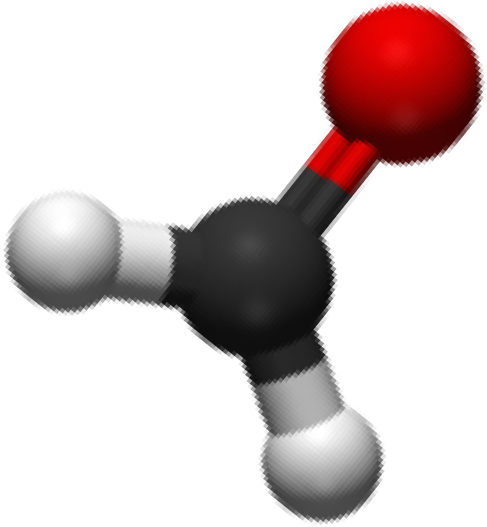
# Who Depends on IRIS?

- EPA program and regional offices
- State and local health agencies
- Other federal agencies
- International health agencies

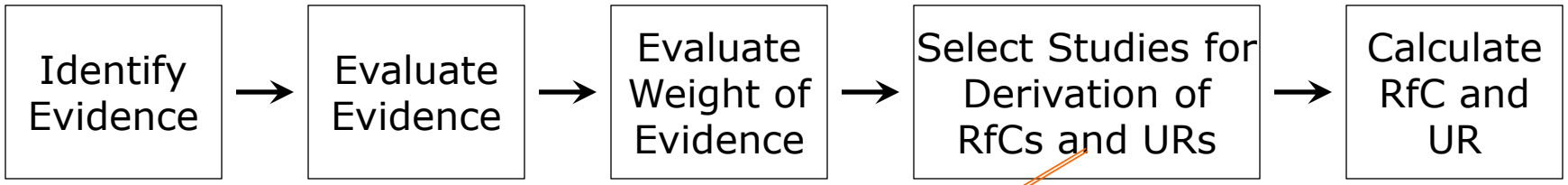
# NRC's Recommendations on Formaldehyde Guide Process for Developing IRIS Assessments

Identify Evidence → Evaluate Evidence → Evaluate Weight of Evidence → Select Studies for Derivation of RfCs and URs → Calculate RfC and UR

Source: NRC (2011) Figure 2-1



# Mapping NRC Recommendations to the IRIS Process




Source: NRC (2011) Figure 2-1

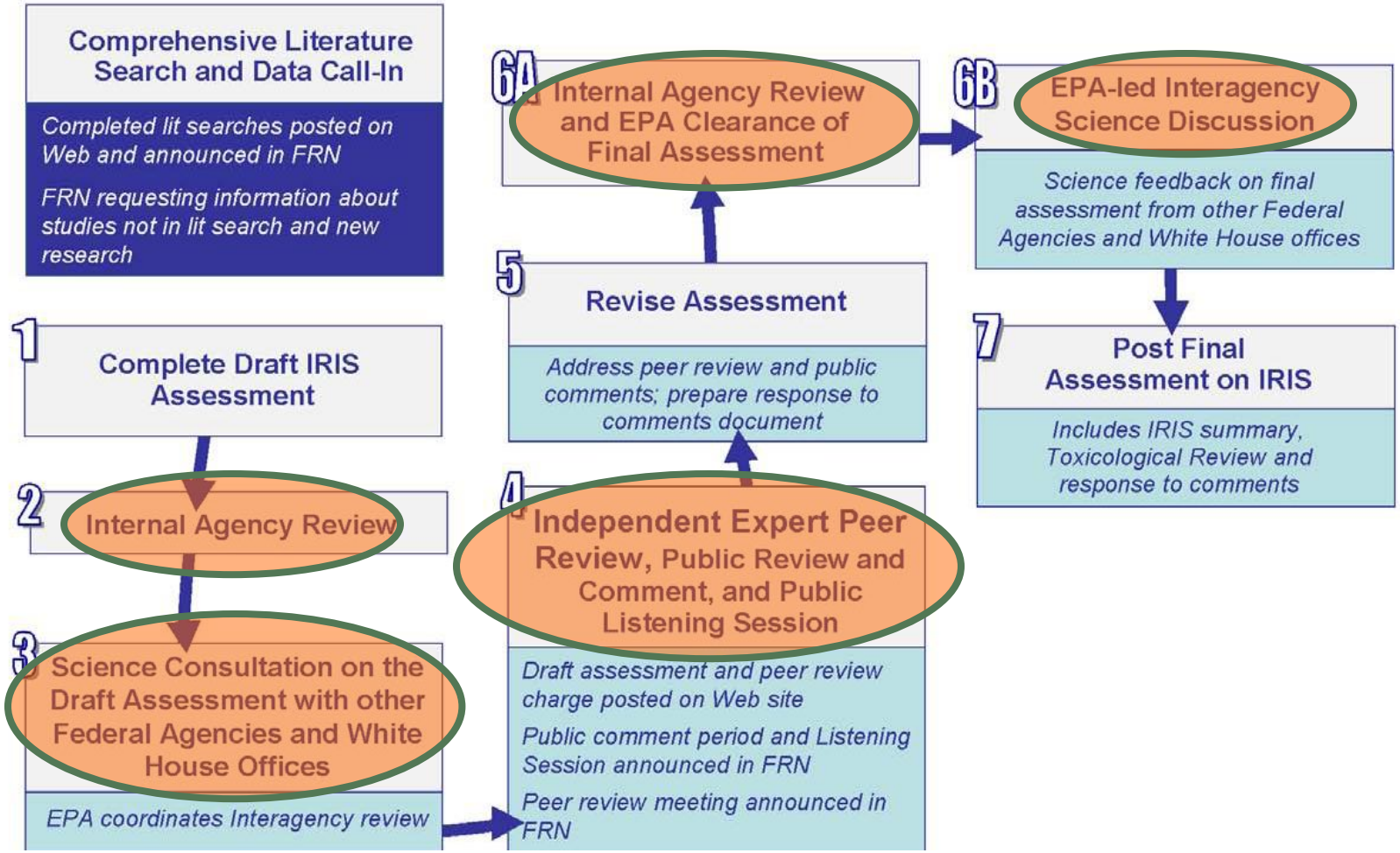
## Preamble to IRIS Toxicological Reviews

1. Scope of the IRIS Program
2. Process for Developing and Peer-Reviewing IRIS Assessments
3. Identifying and Selecting Pertinent Studies
4. Evaluating the Quality of Individual Studies
5. Weighing the Overall Evidence of Each Effect
6. Selecting Studies for Derivation of Toxicity Values
7. Deriving Toxicity Values

# Preamble within IRIS Assessments States a Preference for:

- Epidemiologic studies over animal studies
- Animal models that respond most like humans
- Studies by a route of human environmental exposure
- Studies of longer exposure duration and follow-up
- Studies with multiple exposure levels
- Studies with adequate power to detect effects at lower exposure levels

# The IRIS Process Provides for Multiple Levels of Scientific Review



# Status of Current IRIS Evaluations

See Handout
"IRIS Agenda Chemicals"

# References

http://www.epa.gov/iris/backgrd.html


- U.S. EPA. 2012. Benchmark Dose Technical Guidance
- U.S. EPA. 2005. Guidelines for Carcinogen Risk Assessment
- U.S. EPA. 2002. A Review of the Reference Dose and Reference Concentration Processes

***BREAK FOR LUNCH***

# The Relative Source Contribution – an important input to the criterion equation for non-carcinogens

Policy Forum #5

May 23, 2013

Human Health Criteria and Implementation Tools Rule-makings

Cheryl Niemi

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# 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 (40CFR131)
**CWA** = Clean Water Act
**RfD** = Reference dose
**RSC** = Relative source contribution
**BW** = Body weight
**FCR** = Fish consumption rate
**BCF** = Bioconcentration factor

# Why is the Relative Source Contribution important? The RSC greatly affects the final calculated criterion.

Simplified HHC equation for Non-carcinogens (organism-only exposure):

$$HHC = \frac{RSC \times RfD \times BW}{FCR \times BCF}$$

**Example of RSC effect on final calculated criterion:**
If the RSC is 1.0, then it does not impact the rest of the calculation.
If the RSC is 0.8, then it reduces the criterion by 20%.
If the RSC is 0.5, then it reduces the criterion by 50%.
If the RSC is 0.2, then it reduces the criterion by 80%

More explanation ahead about the RSC and the reason for using a RSC in criteria development.

# Why discuss this now?

EPA's new FAQ (EPA, January 2013, *Human Health Ambient Water Quality Criteria and Fish Consumption Rates: Frequently Asked Questions*, posted at the Policy Forum website along with Ecology comments) makes a recommendation on use of default RSCs that may or may not make sense for HHC development in WA.

Please read the Ecology/IDEQ comments on the FAQ that are posted at the Policy Forum website:
http://www.ecy.wa.gov/programs/wq/swqs/DraftCommentsACWAonEPAHHCFAQdae.pdf

The Washington HHC rule development process needs to fully consider the EPA recommendation on RSCs.

**Policy decision: WA will need to make a policy decision on whether to use EPA's guidance on RSCs, and if not, clearly define how RSCs will be addressed in HHC calculation**.

## Now: on to RSCs….

# What is a Relative Source Contribution?

A Relative Source Contribution is the input to the criterion equation that accounts for exposure from “other” sources of a pollutant.

For purposes of calculating human health-based surface water quality criteria (HHC), the RSC represents the portion of an individual’s daily exposure to a contaminant attributed to the surface water pathway (drinking untreated surface water and eating locally (within-state) caught fish and/or shellfish).

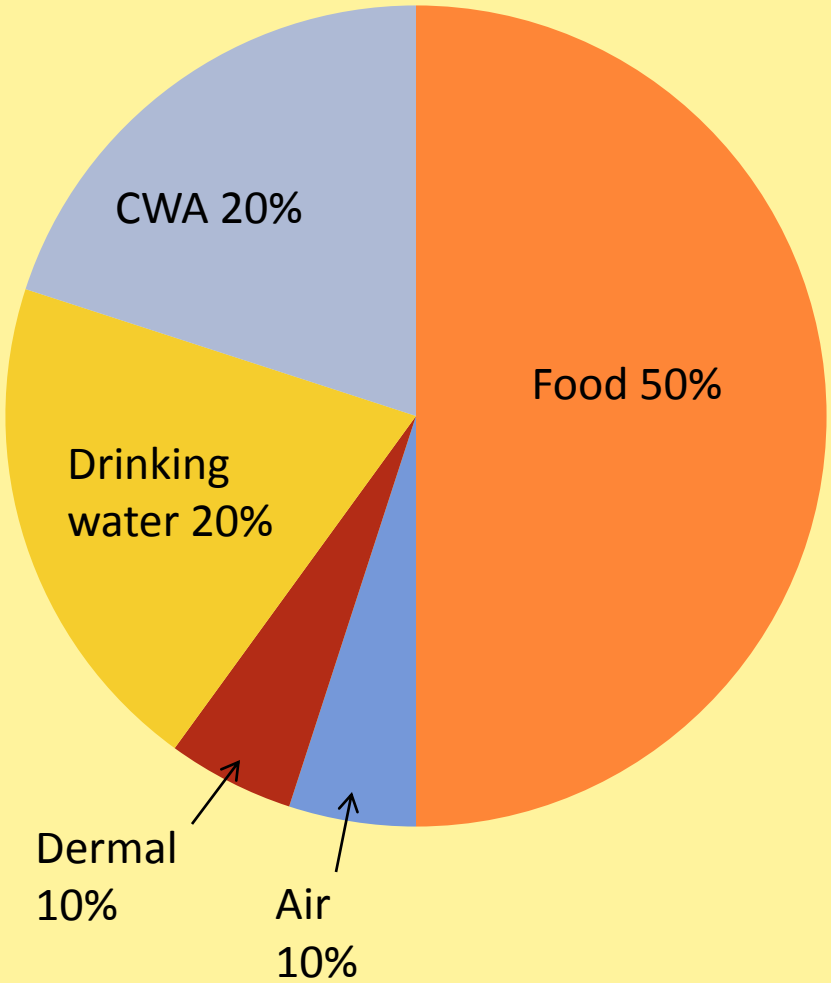
The RSC helps account for exposures to a contaminant from sources other than drinking untreated surface water and eating locally caught fish and shellfish, such as treated drinking water supplies, other foods, or air.

EPA accounts for these other contributions when calculating the HHC by incorporating the RSC into the calculation.  This is part of the EPA 2000 guidance.

RSCs are used in other regulatory programs – not unique to CWA.

How does it work for HHC?  In the simplest language, the calculated criterion is apportioned the amount of allowable exposure that has not used up by other sources.

# Simplistically, this circle represents hypothetical sources of exposure to chemical x, totaling 100% of the allowable "safe" exposure.




Air, treated drinking water, dermal exposures, and food account or 80% of the allowable exposure in this example. Therefore, for this example, the RSC used for the CWA criterion calculation would equal the remaining 20% of allowable exposure.

The RSC would be 0.2 using this example.

This would reduce the calculated criterion by 80% as compared to a RSC of 1.0.

# How have RSCs been addressed in past criteria development?

The 1980 criteria guidance (used to develop the majority of the HHC), did not include a RSC in the equation (see EPA-822-R-02-012). The HHC was given 100% of the allocation of the chemical.

The 2000 EPA guidance does include a RSC in the equation.

Of the 51 non carcinogens that EPA has developed criteria for, 17 have a RSC incorporated in the calculation.

# These are the 17 criteria pollutants that have RSCs included in their EPA recommended national criteria:

| Criteria Pollutant | EPA's RSC Value |
|---|---|
| Antimony | 40% |
| Chlorobenzene | 20% |
| Chlorodibromomethane | 80% |
| Cyanide | 20% |
| Endrin | 20% |
| Ethylbenzene | 20% |
| gamma-BHC (Lindane) | 20% |
| Hexachlorcyclopentadiene | 20% |
| Thallium | 20% |

| Criteria Pollutant | EPA's RSC Value |
|---|---|
| Toluene | 20% |
| 1,1,2-Trichloroethane | 20% |
| 1,1-Dichloroethylene | 20% |
| 1,2,4-Trichlorobenzene | 20% |
| 1,2-Dichlorobenzene(o) | 20% |
| 1,2-trans-Dichloroethylene | 20% |
| 1,4-Dichlorobenzene(p) | 20% |
| Methylmercury | $2.7 \times 10^{-5}$ (subtraction method) |
| Information in this table supplied by USEPA Region 10, current as of 11/2012. | |

**Two approaches to RSC development: default or data-driven.**

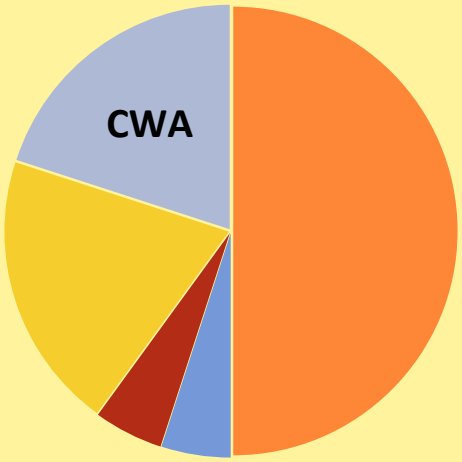
# The two approaches to RSC use in the EPA 2000 guidance:

**Approach 1: 20%80% Default approach**

**EPA Jan. 2013 FCR FAQ:**
"In the absence of scientific data, the application of the EPA's default value of 20 percent RSC in calculating 304(a) criteria or establishing State or Tribal water quality standards under Section 303(c) will ensure that the designated use for a water body is protected. This 20 percent default for RSC can only be replaced where sufficient data are available to develop a scientifically defensible alternative value. If appropriate scientific data demonstrating that other sources and routes of exposure besides water and freshwater/estuarine fish are not anticipated for the pollutant in question, then the RSC may be raised to the appropriate level, based on the data, but not to exceed 80 percent. The 80 percent ceiling accounts for the fact that some sources of exposure may be unknown."

**Approach 2: Data-driven subtraction method.** This method was used for the new mercury criterion and based on extensive data on sources of exposure.

As in the example discussed earlier (figure below), the known exposures are subtracted from the allowable exposures. This is an approach based on known data.



# What are some of the issues associated with using RSCs?

The approach, as developed, leaves the CWA criteria with the "leftover" fraction of the RSC after other exposures have been counted or assumed

An inherent assumption in how the RSC for HHC is developed is that all other sources of the contaminant are required to be considered in the exposure scenario, and the HHC get the remainder of the reference dose or allowable daily exposure.

This results in the odd situation where, as the contribution of a contaminant from water becomes less and less important (a smaller part of the RfD or allowable dose allowed in water), the HHC get more and more stringent – and in effect become a bigger and bigger driver for more restrictive limits and 303(d) listings.

The CWA regulations cannot require changes in regulatory levels of other programs that do not regulate to the risk-based level – such as Superfund, SDWA, MTCA, and others that can act as sources of pollutants to surface waters.

# Issues cont.

The 20%80% RSC default approach used in HHC development is a policy choice by EPA that was intended to help harmonize the CWA with the SDWA. The uses of the default RSCs in the two programs have vastly different regulatory outcomes.

The RSC is used in the SDWA to develop Maximum Contaminant Level Goals (MCLGs). These risk-based MCLGs are not regulatory levels – these values are used as the backdrop to the development of enforceable Maximum Contaminant Levels (MCL), using considerations of cost, benefits and the ability of public water systems to detect and remove contaminants using suitable treatment technologies. The MCLs are the enforceable regulatory levels for pollutants in drinking water.

The risk management/policy decision to use a 20% to 80% RSC in CWA HHC development has direct regulatory outcomes around requirements for HHC to be met in surface waters, the application of the 303(d) program, the requirement for allocation of pollutant loads, subsequent permitting requirements found at 40 CFR 122.4(i), and the Pinto Creek decision. In this context, the HHC themselves are strong regulatory numbers that drive resource intensive programs.

**Pinto Creek decision:** **http://cdn.ca9.uscourts.gov/datastore/opinions/2007/10/03/0570785.pdf**

## Important clarification….

Want to be very clear that you understand that this discussion of SDWA and CWA (earlier with arsenic, and in this talk) is not a criticism of the SDWA.

The SDWA is implemented as required by law and regulation, as is the CWA, and is a critical tool in public health protection.

The incongruity pointed out here is applicable to more than the SDWA and CWA.

Different regulatory programs perform complex and rigorous risk assessments to characterize the risks from sites/exposures, and to underlie the development of enforceable regulatory levels.

The CWA risk assessment equation translates directly to enforceable requirements. This is not the case for all other regulations.

**Examples:**

**Superfund** – site-risk assessments are conducted to characterize the risk from the site, development of clean-up levels includes cost and feasibility.

**MTCA** - site-risk assessments are conducted to characterize the risk from the site, clean-up levels default to analytical quantitation levels or the background level

**SDWA** – risk assessments to characterize risk from pollutants are developed and used to underlie development of the MCLs, which include considerations of cost, benefits and the ability of public water systems to detect and remove contaminants using suitable treatment technologies.

# Summary:

The Washington HHC rule development process needs to fully consider the EPA recommendation on RSCs.

Policy decision:  WA will need to make a policy decision on whether to use EPA's guidance on RSCs, and if not, clearly define how RSCs will be addressed in HHC calculation.

# Questions/Comments/Discussion

# Levels of Protection for Carcinogens and non-carcinogens – additional information

Policy Forum #5

May 23, 2013

Human Health Criteria and Implementation Tools Rule-makings

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**RSC** = Relative source contribution
**FTR** = Fish Tissue Residue
**Hg** = Mercury

## This presentation will provide additional information on how the risks of cancer and non-cancer effects are treated in criteria development.

Very simplified information - pictorial

May be a repeat for many of you – just want to be sure we cover this material so you have a feel for the type of risks we are talking about, and why the risks associated with carcinogens and non-carcinogens are different

# Cancer risk vs. non-cancer hazard

Review

**Cancer**

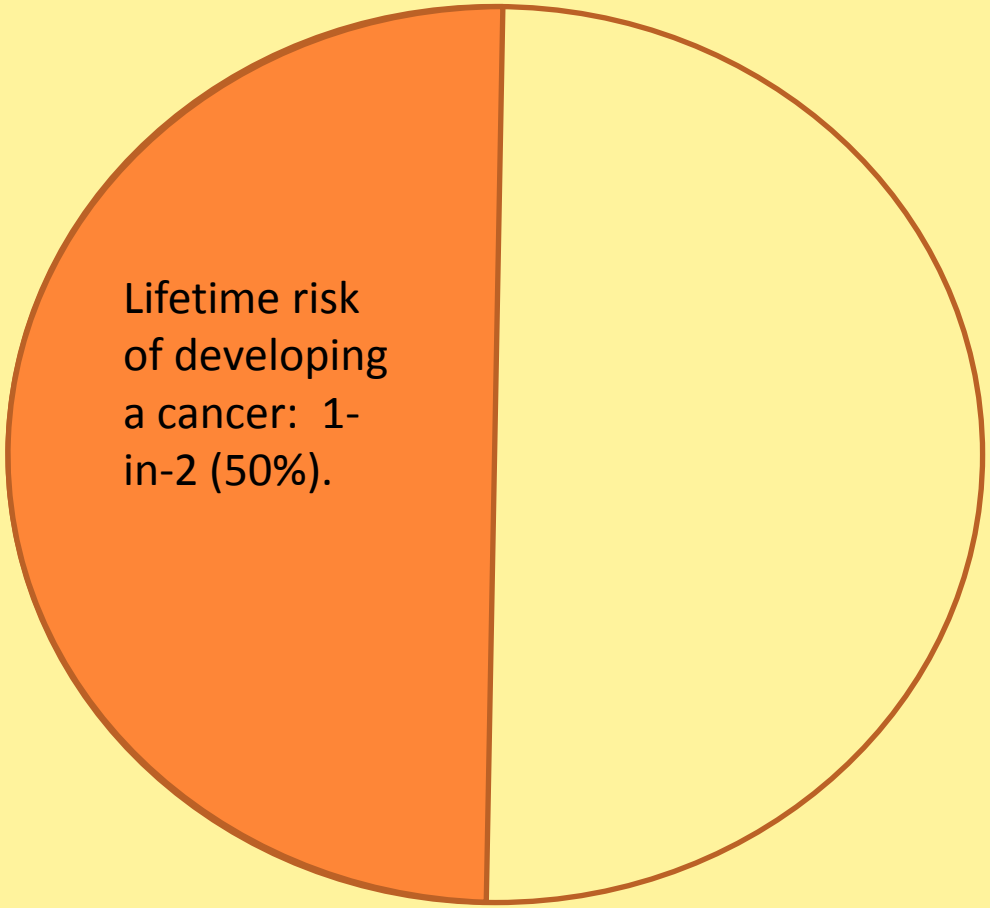
- Based on modeled risk levels with an assumption of non-threshold effects
- Even one molecule of the chemical causes some additional risk of effect

**Non-cancer hazard**

- Based on threshold levels developed from toxicity testing (refer to Lon's talk earlier)
- There are safe levels: below a certain dose no response is detected, above a certain level safety decreases and effects could occur

# Cancer risk levels

- **Lifetime risk of developing a cancer is one-in-three to one-in-two.**
- **This figure illustrates the higher risk level of 1-in-2 (50%).**



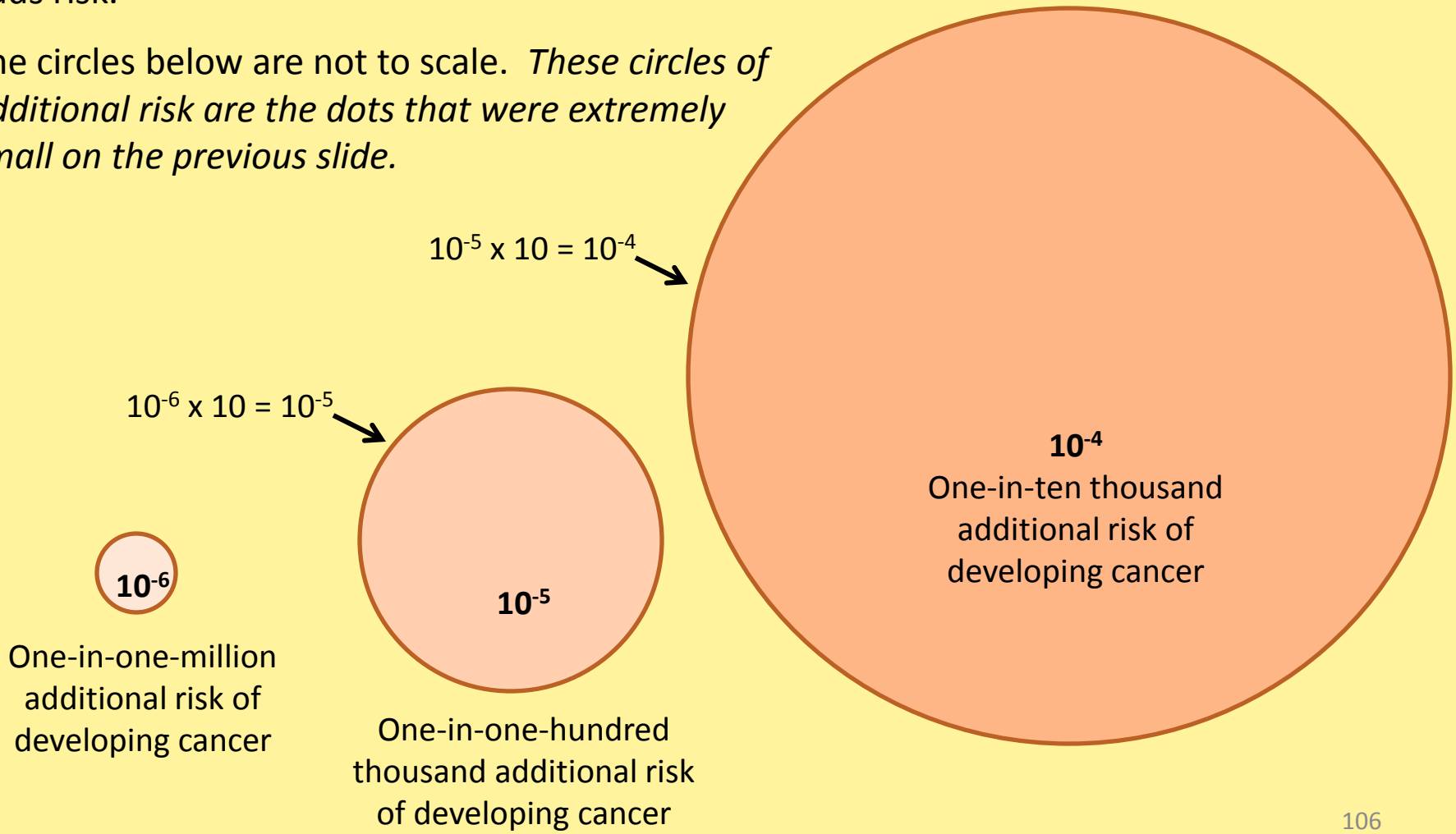

The risk levels we are talking about with HHC are *additional risk* above the risk pictured here. Those additional risk levels range from one-in-one-million ($10^{-6}$) to one-in-ten thousand ($10^{-4}$). That additional risk would be represented by ***extremely small*** *dots* on this circle.

For additional information on lifetime cancer risk see the following useful web sites: http://www.cancer.org/cancer/cancerbasics/lifetime-probability-of-developing-or-dying-from-cancer and http://www.cancerresearchuk.org/cancer-info/cancerstats/incidence/risk/

**This slide and the following slides show simple illustrations of how the different types of risk ("additional" cancer risk level and hazard quotient) can be thought of.**

**Cancer** – within a range of additional risk levels, each larger increment of risk level (**$10^{-6}$**, **$10^{-5}$**, **$10^{-4}$**) adds risk.

The circles below are not to scale. *These circles of additional risk are the dots that were extremely small on the previous slide.*



# Non-cancer effects (threshold)

**The hazard of non-cancer effects is called the "hazard quotient."** HQ is a ratio, which can be used to estimate if risk to harmful effects is likely or not due to the contaminant in question. Lon covered the technical basis of this concept earlier – I am adding pictures.

**EPA definition** (EPA's HQ definition: http://www.epa.gov/nata/gloss1.html)

**"Hazard quotient (HQ):**The ratio of the potential exposure to the substance and the level at which no adverse effects are expected. If the HQ is calculated to be equal to or less than 1, then no adverse health effects are expected as a result of exposure. If the HQ is greater than 1, then adverse health effects are possible.

The HQ cannot be translated to a probability that adverse health effects will occur and it is unlikely to be proportional to risk.

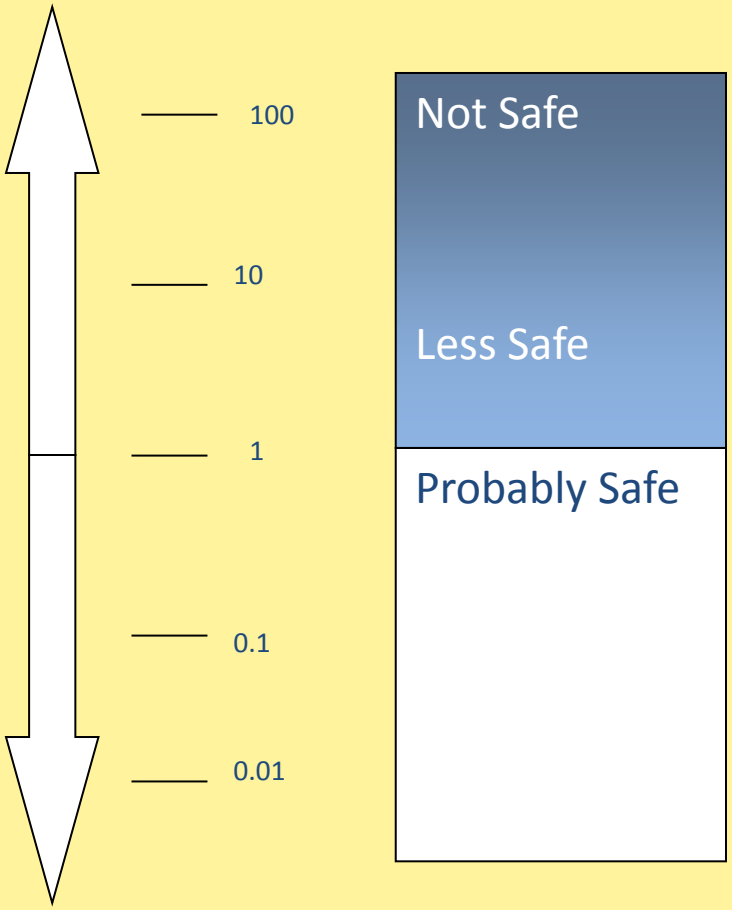
It is especially important to note that an HQ exceeding 1 does not necessarily mean that adverse effects will occur."

**HHC are calculated with a HQ of 1.0. With the non-carcinogens we do not increase the HQ above 1 (although that has been suggested).**

EPA's HQ definition: http://www.epa.gov/nata/gloss1.html
EPA additional information at http://www.epa.gov/R5Super/ecology/erasteps/erastep2.html

# Hazard Quotient illustration

The use of uncertainty factors when deriving RfD's is intended to be protective of public health. Therefore, a HQ greater than one does not mean that adverse health effects will definitely occur. It only indicates an increased potential for adverse effects (i.e., the lower the HQ, the lower the potential for adverse effects).




Graphic by: Gary Palcisko, Ecology Air Quality Program

# Why is this information on HQs and cancer risk levels important?

At a HQ >1, there is an increased potential for adverse effects .

At the acceptable additional lifetime cancer risk levels, the individual additional lifetime risk of developing a cancer is extremely low, even after a lifetime of exposure.

**Policy question**: Because of these differences should the non-carcinogens and carcinogens be treated differently in criteria development?

And - what might that look like?

# Questions/Comments/Discussion

# Preview: the criteria pollutants detected in analytical scans for four POTWs

Policy Forum #5

May 23, 2013

Human Health Criteria and Implementation Tools Rule-makings

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# This is information “in progress”

Only 4 POTWs reviewed so far – more will be reviewed as we progress through the rule-making process..

General description of the four plants:

| POTW | Flow | Total # sampling events | Total years | Chemicals analyzed for |
|---|---|---|---|---|
| A | Large | 33 | 8 | Priority Pollutants |
| B | Large | 9-20 | 5 | Priority Pollutants |
| C | Medium | 2 | 1 | Priority Pollutants |
| D | Small | 1 | 1 | Priority Pollutants |

NTR criteria pollutants detected at 4 POTWs in WA. Green indicates detected concentration.
* indicates quantified level, ▬ indicates an exceedance of a HHC.

| Chemical | Ecology App. A: Effluent Char. for Poll. - EPA methods | NTR HHC Water + Organism (µg/L) | NTR HHC Organism Only (µg/L) | Detection Level (DL) (µg/L) | Quantitation Level (QL) (µg/L) | POTW A | POTW B | POTW C | POTW D |
|---|---|---|---|---|---|---|---|---|---|
| **Antimony** | 200.8 | 14 | 4300 | 0.3 | 1 | 0.67 | 0.95 | ND | ND |
| **Nickel** | 200.8 | 610 | 4600 | 0.1 | 0.5 | 4.45* | 4.23* | ND | ND |
| **Cyanide** | 335.4 | 700 | 220000 | 5 | 10 | 0.028 | ND | ND | ND |
| **Chloroform** | 624 or SM6210B | *5.7* | 470 | 1 | 2 | 2.18* | ▬ 8.21* | ND | ND |
| **Methylene chloride** | 624 | 4.7 | 1600 | 5 | 10 | 7 | ND | ND | ND |
| **Tetrachloro ethylene** | 624 | 0.8 | 8.85 | 1 | 2 | ND | ▬ 1.4 | ND | ND |
| **Toluene** | 624 | 6800 | 200000 | 1 | 2 | 3.86* | ND | ND | ND |
| **Bis(2-Ethylhexyl) Phthalate** | 625 | 1.8 | 5.9 | 0.1 | 0.5 | ND | ▬ 3.03* | ND | ND |
| **1,4-Dichlorobenzene** | 624 | 400 | 2600 | 4.4 | 17.6 | ND | 10.1 | ND | ND |
| **Diethyl Phthalate** | 625 | 23000 | 2900000 | 1.9 | 7.6 | ND | 1.6 | ND | ND |
| **Mercury** | 1631E | 0.14 | 0.15 | 0.0002 | 0.0005 | 0.058* | 0.00825 | ND | ND |

**Summary:**
11 of NTR HHC pollutants were detected at 4 POTWs, 5 NTR HHC pollutants were quantified, 3 pollutants exceeded criteria .

**Comments about the table:**

1. Expect to see more mercury detections over time as method 1631E is used.
2. EPA Method 608 was used for PCBs, and PCBs were not detected. Other POTW monitoring data indicate that if EPA Method 1668C is used in the future, PCBs will commonly be detected.

**11 of the 85** NTR HHC pollutants were detected at 4 of the POTWs,
**5** NTR HHC pollutants were quantified,
**3** pollutants exceeded criteria.

Based on these data it is clear that there would be few, if any, HHC-based effluent limits in these permits.

Effluent limits are most likely to be driven by the 303(d) listing process and subsequent TMDLs. Most common HHC 303(d) listings are for only a few bioaccumulative chemicals, including PCBs and mercury.

**As new HHC are adopted the 303(d) listing policy will be a very important factor.**

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**Policy choices** around 303(d) listings will be important as WA looks at future HHC implementation. Issues will include:

- Should direct tissue measures still be used for listing?
  If so, how?
- What fish would be monitored to represent the chosen FCR?
- Should water measures be used instead? (probably the most common approach)?
- Should the long exposure periods included in the HHC be addressed differently in the future?
- Should critical exposure periods for some specific non-carcinogens drive different listing approaches for those chemicals? (e.g., developmental toxicants)

# Questions/Comments/Discussion

# THANK YOU!