“Acceptable” risk levels for carcinogens: their history, current use, and how they affect surface water quality criteria

Policy Forum #3
February 8, 2013
Human Health Criteria and Implementation Tools
Rule-making

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What we’ll cover in this presentation:

Short review of where this process sits in the WQS

Differentiate between non-threshold and threshold effects for HHC chemicals (between carcinogenic and non-carcinogenic HHC) – **Remember: Very simplified discussion**

Why this difference is important in HHC development

What are the risk ranges used in several environmental regulations?

Where did the risk ranges used in HHC come from?

What flexibility does the EPA 2000 HHC guidance on risk ranges contain?

How does changing the risk level change the criteria?

Some of the future policy questions that will need to be answered.

Later today we’ll discuss how the modified criteria could change the permitting requirements in the scenarios

Special thanks to the toxicologists/risk assessors who helped with today’s material on risk. (Any mistakes are not theirs!)

**Abbreviations frequently used in this presentation:**

- **HHC** = Human health-based criteria for surface waters
- **SWQS** = Surface Water Quality Standards (WAC 173-201A)
- **FCR** = Fish consumption rate
- **NTR** = National Toxics Rule (40CFR131)
What are WQS?

WQS are the foundation of state/tribal water quality-based pollution control programs under the Clean Water Act.

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

See 40 CFR 131.2
WQS are composed of three main parts

1. **Designated uses** – include aquatic life, drinking water, recreation, etc...

2. **Criteria** – levels of water quality that fully protect the uses
   - Numeric *
   - Narrative

3. **Antidegradation Policy** - ensures existing and designated uses are maintained and protected, and that waters of a higher quality than the criteria assigned in the standards are not degraded unless necessary and in the overriding public interest (WAC 173-201A-300).

Also: Other policies affecting application and implementation, such as mixing zones, low flows, and variances (40 CFR 131.13).
Where do HHC fit in?

EPA publishes two types of numeric recommended criteria
1. Aquatic life-based
2. Human health-based (HHC)

The two types of EPA recommended HHC:
1. Criteria to protect individuals consuming fish/shellfish and water; and
2. Criteria to protect individuals consuming fish/shellfish only.

HHC Example:
Endrin (EPA 2002)
Water + Organisms = 0.76 µg/L
Organisms only = 0.81 µg/L
What uses do HHC protect?

1. The “fishable/swimmable” goal of the CWA
2. The drinking water designated use

A human health criterion is the highest concentration of a pollutant in surface water that is not expected to pose a significant risk to human health.
EPA’s Recommended Criteria

EPA’s recommended criteria are for states to use as needed. They are developed for nation-wide use.

EPA uses default exposure assumptions that are based on national data in its recommended HHC:

- A drinking water intake of 2 liters per day;
- An average body weight of 70 kg;
- A fish intake rate of 17.5 g/day
Washington’s current HHC are in federal rule

1992 National Toxics Rule
Currently contains criteria for 85 chemicals
Criteria are based on the national default assumptions used in early 1990’s:

<table>
<thead>
<tr>
<th>Assumption</th>
<th>National 1992 value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drinking water intake</td>
<td>2 liters per day (= approx. 2 qts)</td>
</tr>
<tr>
<td>Average body weight</td>
<td>70 kg (= 154 lbs.)</td>
</tr>
<tr>
<td>Fish consumption rate</td>
<td>6.5 g/day (=0.23 oz./day = approx. 5.2 lbs/year)</td>
</tr>
</tbody>
</table>

NTR found at 40 CFR Part 131
Calculating HHC

Each chemical has 2 criteria associated with it

<table>
<thead>
<tr>
<th>Carcinogenic chemicals</th>
<th>Non-carcinogenic chemicals</th>
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<tr>
<td>Example: DDT</td>
<td>Example: Mercury</td>
</tr>
</tbody>
</table>

**Exposure pathway:** fish/shellfish and drinking water

These criteria apply to freshwaters

Carcinogenic chemicals

- Fish and Shellfish ingestion
- Water ingestion
- Cancer effects

Non-carcinogenic chemicals

- Non-cancer effects
- Fish and Shellfish ingestion
- Water ingestion

**Exposure pathway:** fish/shellfish only

These criteria apply to marine waters

Carcinogenic chemicals

- Fish and Shellfish ingestion
- Cancer effects

Non-carcinogenic chemicals

- Non-cancer effects
- Fish and Shellfish ingestion
Carcinogens: chemicals that cause cancer

- These are the chemicals with the “Risk Level” (RL) input in the HHC equations

We are talking specifically about those carcinogens with responses (effects) that are assumed to be linear at low doses.

This includes the chemicals designated as carcinogens in the National Toxics Rule and EPA’s list of recommended human health criteria.

What does “linear responses at low doses” mean?

These chemicals are assumed to have no threshold for effects, and even one molecule of the substance is assumed to confer some increase in the risk of contracting a cancer.

So – when you draw out the observed dose-response curve and then extend the line to ground it at “zero” for “zero effects at zero dose”, you extrapolate a dose-response line that is linear for very low doses.

Why is this important? Because the linear low dose assumption drives the development of the type of incremental “risk level” used for carcinogens.

HHC for a Carcinogen (very simplified equation – “organism only”):

\[
\text{HHC} = \frac{\text{RL} \times \text{BW}}{\text{CSF} \times \text{FCR} \times \text{BCF}}
\]
More about non-threshold responses
Again – These are the chemicals we are focusing on today

All levels of exposure pose some probability of an adverse response

There is an assumed linear response at low doses
The linear approach is used for direct-acting carcinogenic agents, those that cause chemical changes (mutations) to DNA.
The linear approach is the default choice for carcinogens when there are insufficient data to demonstrate that the mode of action of the chemical is nonlinear.

All of the current EPA recommended criteria for carcinogens are linear carcinogens.

EPA targets a risk level of one in one million ($10^{-6}$) when it calculates its national recommended human health criteria for these chemicals.

Notes: 1. We will talk more about the details of carcinogens and non-carcinogens at Policy Forum # 5.
2. The CSF is part of the criteria equations for linear low dose carcinogens.
Chemicals with threshold responses

(These are not the chemicals we are focusing on today)

For purposes of HHC development - these are the **non-carcinogens**

Examples: cyanide, zinc, endrin, mercury

In very simplified terms: These chemicals are assumed to have safe exposure levels up to a certain threshold concentration - below a certain threshold level, no ill effects (responses) are measured.

At this dose the threshold for responses is reached

Dose range with no response

Note: Some carcinogens have a threshold (non-linear) response. EPA’s 2000 Methodology has equations that can be used to calculate HH criteria for both linear and non-linear carcinogens. However, all of the current EPA recommended criteria for carcinogens are linear carcinogens. EPA has not calculated any threshold carcinogen values. Very few threshold carcinogens exist in IRIS and those have not been used by EPA for criteria calculation.

EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000):*

Threshold Responses
These are the non-carcinogens – we are **not** talking about these today

Non-threshold, and, linear response at low doses
These are the carcinogens – we **are** talking about these today

Why the continued reinforcement about today’s focus on carcinogens (and not the non-carcinogens)? One reason is because the risk level we are talking about today applies **only** to the carcinogens – EPA’s list of current recommended HH criteria has approximately **51** criteria for noncarcinogens and **60** criteria for carcinogens.

Criteria calculation for the non-carcinogens has its own details and decisions, related to threshold responses, that are important and **will be discussed at Policy Forum #5**. These include relative source contributions (RSCs) (which were discussed briefly at Policy Forum #3) and the unit of risk associated with non-carcinogens (called the Hazard Quotient).
The language about level of protection in the laws and regulations varies, but encompasses similar concepts.

Examples:

<table>
<thead>
<tr>
<th>Laws and regulation</th>
<th>Levels of Protection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federal Insecticide, Fungicide, and Rodenticide Act</td>
<td>“.. function without unreasonable and adverse effects on human health and the environment”, §3</td>
</tr>
<tr>
<td>National Contingency Plan</td>
<td>“. . . provide the basis for the development of protective exposure levels,” § 300.430(d)</td>
</tr>
<tr>
<td>Clean Water Act</td>
<td>“. . . standards shall be such as to protect the public health or welfare, enhance the quality of water and serve the purposes of this Act.” §303(c)(2)(A) (water quality standards language)</td>
</tr>
<tr>
<td>Clean Air Act</td>
<td>“Emission standards promulgated under this subsection shall provide an ample margin of safety to protect public health.” §112</td>
</tr>
<tr>
<td>Toxic Substances Control Act</td>
<td>“. . . assure chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment,” §2(b)(3)</td>
</tr>
</tbody>
</table>
How do regulatory agencies deal with the different guiding language?

In general, **default** approaches are used for carcinogens:

- For risks calculated to be **linear at low doses**, agencies use acceptable risk levels ranging from $10^{-6}$ to $10^{-4}$
- In some cases the risks from multiple chemicals are addressed, but in many cases only individual risk is calculated (e.g., CWA: EPA’s recommended human health criteria)

**Review:** What do $10^{-6}$ and $10^{-4}$ mean?

$10^{-6}$ means there is a risk of one additional occurrence of cancer, in one million people, at the given exposure assumptions (this is compared to an unexposed population).

For **Washington’s NTR HHC**, the exposure assumptions are:

- **Daily exposure over 70 years**, at a given fish consumption rate (currently **6.5 g/day**), and **2 liters/day** of untreated surface waters for a **154 lb.** person.

<table>
<thead>
<tr>
<th>Numeric</th>
<th>What it means, under specified exposure assumptions</th>
</tr>
</thead>
<tbody>
<tr>
<td>$10^{-6}$</td>
<td>...risk of one additional occurrence of cancer, in one million people...</td>
</tr>
<tr>
<td>$10^{-5}$</td>
<td>...risk of one additional occurrence of cancer, in one hundred thousand people</td>
</tr>
<tr>
<td>$10^{-4}$</td>
<td>...risk of one additional occurrence of cancer, in ten thousand people...</td>
</tr>
</tbody>
</table>
Two important events in the 1970’s:

1. **US Food and Drug Administration**
   

   $10^{-6}$ was considered a screening level of “essentially zero” or *de minimus* risk

   $10^{-6}$ was used for the evaluation of residues in food-producing animals.

   - Diethylstilbestrol (DES) was the chemical at issue, for which no permissible residue was allowed. (DES was used as a growth promoter in cattle)
   - Reaching this *de minimus* risk level could be accomplished by banning use of the chemical.

2. **Consent Decree in NRDC v. Train, 1976**

   USEPA – the 1980 Water Quality Criteria development documents followed the direction given in the Consent Decree

Next two slides show the language from the Consent Decree in NRDC v. Train and from the USEPA 1980 Criteria document for Hexachlorocyclohexane.
NRDC v. Train, 1976 – this consent decree influenced EPA’s published CWA HHC and risk levels

“I. Additional Protection of Public Health

11. Not later than June 30, 1978, after opportunity for public comment, the Administrator shall publish under § 304(a) of the Act water quality criteria accurately reflecting the latest scientific knowledge on the kind and extent of all identifiable effects on aquatic organisms and human health of each of the pollutants listed in Appendix A. Such water quality criteria shall state, inter alia, for each of the pollutants listed in Appendix A, the recommended maximum permissible concentrations (including where appropriate zero) consistent with the protection of aquatic organisms, human health, and recreational activities.”
“Under the Consent Decree in NRDC v. Train, criteria are to state recommended maximum permissible concentrations (including where appropriate, zero) consistent with the protection of aquatic organisms, human health, and recreational activities.” α-HCH, β-HCH, γ-HCH and t-HCH are suspected of being human carcinogens. Because there is no recognized safe concentration for a human carcinogen, the recommended concentration of α-HCH, β-HCH, γ-HCH and t-HCH in water for maximum protection of human health is zero.”

“Because attaining a zero concentration level may be infeasible in some cases and in order to assist the Agency and States in the possible future development of water quality regulations, the concentrations of α-HCH, β-HCH, γ-HCH and t-HCH corresponding to several incremental lifetime cancer risk levels have been estimated. A cancer risk level provides an estimate of the additional incidence of cancer that may be expected in an exposed population...”

“In the Federal Register notice of availability of draft ambient water quality criteria, EPA stated that it is considering setting criteria at an interim target risk level of $10^{-5}$, $10^{-6}$, or $10^{-7}$ as shown...”

How is $10^{-6}$ currently used?

$10^{-6}$ has come into broad usage

$10^{-6}$ is currently part of many state and federal environmental programs, for example:
- CWA – Clean Water Act
- CERCLA – Comprehensive Environmental Response, Compensation, and Liability Act
- CAA – Clean Air Act

$10^{-6}$ is expressed in guidance and regulation as a target for acceptable risk or as part of a range of acceptable risk
- **Guidance examples**: CWA EPA recommended human health criteria
- **Regulation examples**: WA SWQS risk level of $10^{-6}$, Oregon’s water quality standards, CERCLA’s National Contingency Plan, the National Toxics Rule as applied to Washington
- **Law**: Have not found any environmental protection laws that specify a risk level (does not mean they are not there – if you know of an example please let us know)

**General status**: $10^{-6}$ and associated risk ranges are fully embedded in current regulations and guidance, and practiced at sites throughout the nation.

**Main message**: Use of $10^{-4}$ to $10^{-6}$ risk levels is with us now, and is probably with us into the foreseeable future.
<table>
<thead>
<tr>
<th>Federal program</th>
<th>Acceptable Risk Level</th>
<th>Other Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clean Water Act</td>
<td>304(a) criteria are published at a $10^{-6}$ risk level EPA 2000 guidance recommend that States and Tribes set criteria at $10^{-5}$ or $10^{-6}$ Most highly exposed populations should not exceed $10^{-4}$ risk level</td>
<td>EPA 2000 guidance recommends using data for fish/shellfish consumers only (do not include non-consumers).</td>
</tr>
<tr>
<td>CERCLA</td>
<td>Excess upper bound lifetime cancer risk to an individual of between $10^{-4}$ to $10^{-6}$</td>
<td>Decisions made within a risk range for excess cancer of $10^{-4}$ to $10^{-6}$. If cancer risk is greater must take action, and if it is lower no action can be taken.</td>
</tr>
<tr>
<td>Clean Air Act</td>
<td>For Hazardous Air Pollutants (HAPs): Limit <strong>Maximum Individual Risk (MIR)</strong> for cancer to no higher than about $10^{-4}$ <em>(MIR is the person exposed to maximum lifetime HAP concentrations)</em> – Protect the <strong>greatest number of persons to less than $10^{-6}$ lifetime cancer risk</strong></td>
<td>Under the acceptable risk level for the Clean Air Act row, this applies to risk posed by a single facility’s or source category’s emissions. Background sources are not considered when evaluating risks. If risks from hazardous air pollutants are determined to be unacceptable, then EPA may choose to derive a more stringent emission standard for that particular source category.</td>
</tr>
<tr>
<td>Safe Drinking Water Act</td>
<td>No increase in cancer</td>
<td>Non-regulatory level - Maximum contaminant Level Goal (MCLG)</td>
</tr>
<tr>
<td>Safe Drinking Water Act</td>
<td>Risk-based approach overlain by analytical/economic considerations</td>
<td>Regulatory level – Maximum contaminant Level (MCL)</td>
</tr>
<tr>
<td>National Toxics Rule (1992, contains Washington’s current HHC) (40 CFR 131)</td>
<td><strong>$10^{-6}$ for general population.</strong></td>
<td>Paired with the FCR for the general population in the criteria equation, average of consumers and nonconsumers</td>
</tr>
</tbody>
</table>
What about risk levels and current CWA HH criteria?

1992 NTR (Washington’s current HHC):

“In submitting criteria for the protection of human health, States were not limited to a 1 in 1 million risk level ($10^{-6}$). EPA generally regulates pollutants treated as carcinogens in the range of $10^{-6}$ to $10^{-4}$ to protect average exposed individuals and more highly exposed populations.”

• Washington chose $10^{-6}$ and EPA applied their general population FCR

Washington SWQS:

“WAC 173-201A-240(6) Risk-based criteria for carcinogenic substances shall be selected such that the upper-bound excess cancer risk is less than or equal to one-in-one million.”

EPA 2000 guidance on risk levels for HHC:

“EPA believes that both $10^{-6}$ or $10^{-5}$ may be acceptable for the general population and that highly exposed populations should not exceed a $10^{-4}$ risk level.”

(Note: cancer ranges of $10^{-6}$ and $10^{-5}$ have been chosen by states and received CWA approval from EPA)

Also, see full discussion in the EPA 2000 guidance document, pages 2-6 and 2-7 : 2.4 Cancer Risk Range.
How does changing the risk level change the criteria?

Assumed here: FCR (general population) = 6.5 g/day (used here because this is the rate in the NTR)

<table>
<thead>
<tr>
<th>Chemical(s)</th>
<th>Criteria calculated at $10^{-6}$ (Washington’s NTR criteria) (ug/L)</th>
<th>Criteria calculated at $10^{-5}$ (ug/L)</th>
<th>Permit limit compliance assessment level (EPA Sec. 136-approved method) (ug/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Water + Organisms</td>
<td>Organisms only</td>
<td>Water+ Organisms</td>
</tr>
<tr>
<td>Total PCBs (BCF =31,200)</td>
<td>1.71E-04</td>
<td>1.71E-04</td>
<td>1.71E-03</td>
</tr>
<tr>
<td></td>
<td><strong>0.00017</strong></td>
<td><strong>0.00017</strong></td>
<td><strong>0.0017</strong></td>
</tr>
<tr>
<td>DDT (BCF =14,100)</td>
<td>5.88E-04</td>
<td>5.91E-04</td>
<td>5.88E-03</td>
</tr>
<tr>
<td></td>
<td><strong>0.000588</strong></td>
<td><strong>0.000591</strong></td>
<td><strong>0.00588</strong></td>
</tr>
<tr>
<td>Inorganic Arsenic (BCF = 44)</td>
<td>1.75E-02</td>
<td>1.40E-01</td>
<td>1.75E-01</td>
</tr>
<tr>
<td></td>
<td><strong>0.0175</strong></td>
<td><strong>0.14</strong></td>
<td><strong>0.175</strong></td>
</tr>
</tbody>
</table>

**Monitoring for PCBs:** Infrequent permit requirements for EPA Method 1668C (used for monitoring, not compliance assessment):
- QL = 10 pg/L/congener in a fairly clean matrix.
- 10 pg/L = 0.00001 ug/L

1668C is not 40CFR136-approved. 1668C can measure the criteria concentrations as calculated in the table above. Method 608 cannot.

If the HHC for PCBs was calculated using 142 g/day at a $10^{-6}$ risk level, the resulting criteria would be 0.0000079. This value is below the QLs for EPA Methods 608 and 1668.
How do the QLs used for compliance assessment measure up against criteria calculated at a higher FCR and at different risk levels?

FCRs used in this example are:
- 17.5 g/day (the EPA 2000 recommended FCR for the general population)
- 175 g/day (the FCR recently adopted by Oregon for HHC calculation)

<table>
<thead>
<tr>
<th>Chemical(s) and QLs (QLs in ug/L)</th>
<th>Criteria calculated for “Organisms only,” not “Water + Organisms.”</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Criterion at $10^{-6}$ and FCR = 17.5</td>
</tr>
<tr>
<td>PCBs</td>
<td>$6.4 \times 10^{-5}$</td>
</tr>
<tr>
<td></td>
<td>$0.000064$</td>
</tr>
<tr>
<td>Method 608 QL</td>
<td>0.5</td>
</tr>
<tr>
<td>Method 1668 QL (per individual congener)</td>
<td>$0.00001^*$</td>
</tr>
<tr>
<td>DDT</td>
<td>$2.2 \times 10^{-4}$</td>
</tr>
<tr>
<td></td>
<td>$0.0002$</td>
</tr>
<tr>
<td>Method 608 QL</td>
<td>0.05</td>
</tr>
</tbody>
</table>

* Indicates that compliance can be measured by this method.
What levels of protection were the NTR HHC for carcinogens calculated to provide? How does that compare to the EPA 2000 guidance?

EPA 2000 guidance on risk levels for HHC:

“EPA believes that both $10^{-6}$ or $10^{-5}$ may be acceptable for the general population and that highly exposed populations should not exceed a $10^{-4}$ risk level.”

$10^{-6}$ means there is a risk of one additional occurrence of cancer, in one million people, at the given exposure assumptions (this is compared to an unexposed population).

For Washington’s NTR HHC, the exposure assumptions are:

- **70 years** of daily exposure to **6.5 g/day** of fish and shellfish, and **2 liters/day** of untreated surface waters, for a **154 lb.** person.

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<td>...risk of one additional occurrence of cancer, in one hundred thousand people</td>
</tr>
<tr>
<td>$10^{-4}$</td>
<td>...risk of one additional occurrence of cancer, in ten thousand people...</td>
</tr>
</tbody>
</table>

For the “organism-only” criteria: A criterion calculated at $10^{-6}$ risk level and 6.5 g/day fish consumption rate means that individuals who fit the exposure assumptions in the criterion equation and eat 65 g/day are protected at a $10^{-5}$ level, and at 650 g/day are protected a $10^{-4}$ level at that criterion concentration (with all other inputs held constant).
So - what levels of protection are afforded for linear carcinogens under the EPA’s NTR criteria?

The blue box below shows the relationship between the risk level and FCR for the “organisms-only criteria.” This is a direct relationship. The relationship between the risk level and FCR in the “organisms + water” criteria is not so direct: it is complicated by the water exposure and each criteria chemical’s propensity to bioaccumulate. For the “organisms + water” criteria, the fish consumption rate that corresponds to a specific risk level is equal to or higher than the FCR in the “organisms-only” calculation made at the same risk level and with all other criteria calculation inputs held constant.

Levels of Protection for Linear Carcinogens – how the “sliding scale” for each order of magnitude of change works for the “organism only” criteria, (criteria concentrations and all other inputs held constant)

<table>
<thead>
<tr>
<th>Risk Level</th>
<th>Fish Consumption Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>If: $10^{-6}$</td>
<td>And: 6.5 g/day, and if criterion values are held equal,</td>
</tr>
<tr>
<td>Then: $10^{-5}$</td>
<td>Applies to: 65 g/day</td>
</tr>
<tr>
<td>Then: $10^{-4}$</td>
<td>Applies to: 650 g/day</td>
</tr>
</tbody>
</table>

Reality check: Is anyone talking about keeping the current FCR of 6.5 g/day and making the risk level less protective? Not that we have heard. If the risk level were $10^{-5}$ and the FCR were 6.5 g/day, then $10^{-4}$ would apply at 65 g/day. This means that FCR of 65 g/day or less would have to represent the most highly exposed population in WA.

Does this mean that the NTR HHC meet the levels of protection, specified in current EPA guidance, for both the general population and more highly exposed populations in Washington?

We can answer yes for the following situation only:

- carcinogenic chemicals only
  + exposed populations with a FCR of 650 g/day or less
  + meets the other exposure assumptions

We still need to examine that question for the non-threshold chemicals (non-carcinogens). Non-threshold chemicals present a different set of issues that may be more challenging to address in criteria calculation than those associated with carcinogens.
What about non-carcinogens?

There are 51 different non-carcinogens on EPA’s current recommended HHC list.

Non-carcinogens are regulated differently because they exhibit threshold responses.

Because non-carcinogens exhibit threshold responses, effects levels can be observed and “safe“ doses calculated.

Example chemical:

Mercury is a non-carcinogen. The effects of mercury occur over shorter exposure periods (not a 70-year lifetime). The effects last a lifetime. Everyone goes through the developmental period when the effects occur. (We have widespread WDOH fish advisories in WA for mercury in fish.)

The threshold effects exhibited by non-carcinogens will be discussed at PF #5, and at that time we will look at levels of protection for non-carcinogens.
Wrap-up: today’s policy and risk management questions for the linear low dose criteria carcinogens include:

1. Should the risk level for linear low dose chemicals for Washington’s general population stay at $10^{-6}$? This the state’s current risk level and is specified in the WQS and the NTR.
   • Corollary question - Policy Forum #7 – what metric on the fish consumption rate distribution represents the general population?

2. If the policy decision is made to change the risk level, should any changes that are examined be for all the criteria carcinogens, or for a smaller subset? (e.g., the arsenic risk level was changed to $10^{-4}$ in Maine and Oregon).

3. Should $10^{-6}$ risk level for linear low dose chemicals be applied to a population other than the general population? If so, what population?
   • Corollary question - Policy Forum #7 – what metric on the fish consumption rate distribution represents this alternative population?

What will guide how Ecology develops draft alternatives and recommendations on the policy and risk management questions? We will look to EPA guidance to start with...
Risk Management example from EPA (2000):

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

As we pursue development of new HHC for Washington:

Continue to emphasize *Transparency* in science, science policy, and risk management

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


**Also:** we look to state and federal legislation and regulation to set requirements and boundaries...