Human Health-based Criteria Development

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Public Workshop

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Presentation will cover :

- Water Quality Standards (**WQS**) and Human Health-based Criteria (**HHC**)
- Current HHC
- How are HHC used in assessment and permitting?
- The criteria calculations
- Some of the technical and policy issues we'll discuss during rule-making

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 (40CFR131.13).

Where do HHC fit in?

EPA publishes two types of **numeric** recommended criteria

1. Aquatic life -based
2. Human health-based (HHC)

HHC Example:
Endrin (EPA 2002)
Water + Organisms = 0.76 µg/L

Organisms-only = 0.81 µg/L

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.

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:

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

NTR found at 40 CFR Part 131

National Toxics Rule

A little over half the 85 chemicals are carcinogens (e.g. DDT and PAHs). The rest are non-carcinogens.

NTR includes a risk level for carcinogens of one-in-one million (Washington's WQS language includes this risk level).

How are current NTR HHC used in regulating sources of pollution?

Identifying impaired waterbodies under CWA Section 303(d)

Targets in Water Clean-up Plans
(Total Maximum Daily Loads)

NPDES permit limits

Calculating HHC

Each chemical has 2 criteria associated with it

	Exposure pathway: fish/shellfish and drinking water **These criteria apply to freshwaters**	**Exposure pathway: fish/shellfish only** **These criteria apply to marine waters**
Carcinogenic chemicals Example: DDT	Fish and Shellfish ingestion Water ingestion Cancer effects	Fish and Shellfish ingestion Cancer effects
Non-carcinogenic chemicals Example: Mercury	Non-cancer effects Fish and Shellfish ingestion Water ingestion	Non-cancer effects Fish and Shellfish ingestion

Organism-only equations (very simplified)

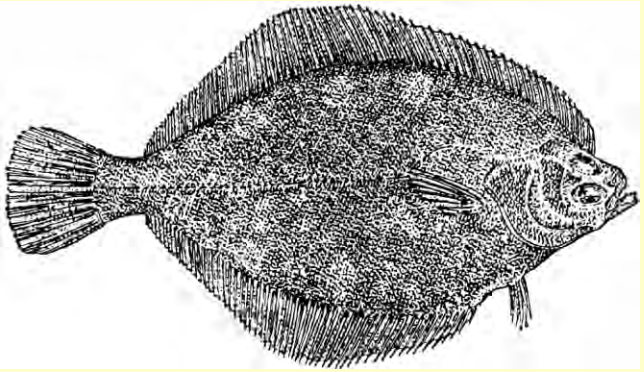
HHC for Carcinogen:

$$HHC = \frac{RL \times \boldsymbol{BW}}{CSF \times \boldsymbol{FCR} \times \boldsymbol{BCF}}$$

This equation will be the subject of many future days of discussion – we will describe the inputs as we go on…

HHC for Non-carcinogen:

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



Blue = Big issue, ***Bold italics*** = common to both equations

Inputs common to both equations

BW = *Human body weight* (adult = 70 kg = 154 lbs)

FCR = *fish consumption rate*. NTR value = 0.0065 kg/day = 0.23 oz./day = approx. 5.2 lbs/year (a new value will be developed for WA)

- This factor has generated and will continue to generate lots of discussion
- More information later in the presentation

BCF = *Bioconcentration factor* (L/kg)

- Chemical-specific
- BCF = $\frac{\text{g/kg in tissue}}{\text{g/L in water}}$ = L/kg

Equation inputs specific to carcinogens

$$HHC = \frac{RL \times \boldsymbol{BW}}{CSF \times \boldsymbol{FCR} \times \boldsymbol{BCF}}$$

RL = *Risk level* (10^{-6} current risk level in NTR and WQS)

- 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.* (more later…)

CSF = Cancer slope factor, values are from EPA's Integrated Risk Information System (IRIS)

- A measure of the potency of the carcinogen – how strong it is

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Remember: Carcinogens make up a little over half of the criteria chemicals

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Blue = Big issue, ***Bold italics*** = common to both equations

Equation inputs specific to non-carcinogens

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

RfD = Reference dose (mg/kg-day), values from IRIS

- The EPA defines an oral reference dose (abbreviated **RfD**) as: An estimate, with uncertainty spanning perhaps an order of magnitude, of a daily oral exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime.

- Used to be called the Allowable Daily Intake (ADI)

Blue = Big issue, ***Bold italics*** = common to both equations

Two other inputs implicit in the equations….

$$\frac{LS}{DE} = 1$$

- Lifespan = 70 years
- Duration of exposure = 70 years (time you are assumed to be eating locally caught fish on a daily basis)

Now – away from the numbers…

Technical and policy issues we'll discuss during rule-making

Transparency in HHC development

Laws and regulations

Specific policy and technical issues

Differentiating between science, science policy, and risk management will be critical in HHC development

Transparency

"…conclusions drawn from the science are identified separately from policy judgements and risk management decisions, and that the use of default values or methods, as well as the use of assumptions in risk assessments, are clearly articulated." (from: USEPA. 2000. *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000)*, EPA-822-B-00-004, page 2-3)

Science, science policy, and risk management

Science example from EPA (2000):

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

Science, ***science policy***, and risk management

Science policy example from EPA (2000):

"The use of an animal study to predict effects in a human in the absence of human data is an inherent science policy decision. The selection of specific UFs when developing an RfD is another example of science policy. In any risk assessment, a number of decision points occur where risk to humans can only be inferred from the available science."

Science, science policy, and ***risk management***

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."

Transparency in science, science policy, and risk management

"…conclusions drawn from the science are identified separately from policy judgements and risk management decisions, and that the use of default values or methods, as well as the use of assumptions in risk assessments, are clearly articulated." (from: USEPA. 2000. *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000)*, EPA-822-B-00-004, page 2-3)

Law, regulation, policy, and guidance

Set requirements and boundaries.

All these can carry different weight when making regulatory decisions.

Will need to clearly articulate the choices and directions guided by these factors, as well as be clear about the policy, science policy, and risk management decisions inherent in HHC development.

Just a few of the big issues we will be addressing

1. Risk level
2. Fish consumption rates
3. Geographic application of the HHC
4. Additional toxics beyond the priority pollutant list
5. New implementation approaches and/or permitting guidance (beyond the current implementation tools rule-making)

Risk level

10^{-6} current risk level in NTR and WQS – this is the current default.

- *"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."*

Risk of one occurrence of cancer, in one million people, at the given exposure assumptions:

- Daily exposure over 70 years, at given fish consumption rate (currently 6.5 g/day), for a 154 lb. person

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Remember: Carcinogens make up a little over half of the criteria chemicals

Fish consumption rates

This input has received more attention than any of the other HHC equation inputs – Oregon process, Ecology draft FCR TSD and SMS rule-making

EPA's uses default fish consumption rate 17.5 g/day in national guidance criteria values. EPA also has a default subsistence fish consumption value of 142.4 g/day.

Default fish consumption rates are not intended to reflect a limit of consumption-instead used to reflect actual consumption rates

The draft Ecology *Fish Consumption Rate TSD* will be used to inform the risk management decision of the appropriate FCR rate to be used in the HHC calculation

Geographic application of the HHC

All surface waters of the state in Washington are protected for fishing.

Waters have different levels of resources. For instance:

- Some small streams might never have supported an abundant fishery
- Certain areas of Puget Sound have, or have potential to have, very large amounts of shellfish

Fishing use varies among waterbodies. For instance:

- Species presence/absence
- Size of the waterbody (e.g., very small stream)

Criteria for additional toxics beyond the priority pollutant list (PPL)

- Federal NTR contains criteria for a subset of the 126 chemicals on the PPL
- EPA has developed recommended criteria for additional PPL chemicals since 1992
- EPA has developed recommended criteria for chemicals not on the PPL
- What about other chemicals of concern where EPA has not yet developed recommended criteria (e.g., flame retardants)?

New implementation regulations and/or permitting guidance

Ongoing implementation tools rule-making is focused on extending time-lines to meet criteria, as well as possible intake credits

Additional discussion will be broader

Likely to include mixing zones, analytical methods, listing policy for impaired waters, and how naturally occurring chemicals (particularly arsenic) are addressed.

What we have ahead

Big and complex process

Address science, science policy, and risk management all within the boundaries and requirements set by law, regulation, policy, and guidance.

Team resources and expertise

- Ecology: WQS and criteria development, CWA and federal regulation, policy, and guidance, toxicology, environmental contaminants, WQ assessment and permitting, chemical analytical methods
- WDOH: toxicology, public health protection
- EPA: WQS and criteria development, CWA and federal regulation, policy, and guidance, toxicology and FCR expertise, nation-wide perspective on HHC development and implementation

Additional resources

1. *Washington's Water Quality Standards for Surface Water of the State of Washington, Chapter 173-201A WAC*. The statement on risk level is at 173-201A-240(6): https://fortress.wa.gov/ecy/publications/summarypages/0610091.html.

2. National Toxics Rule – current version. 40CFR 131.36. This is the federal rule, issued by EPA in 1992 (and since updated for HHC in 1999 for PCBs), that currently applies to Washington. Column D contains the HHC broken down by consumption of (1) water and organisms, and (2) organisms only. In Washington, the "water and organisms" column applies to fresh waters, and the "organisms only" column applies to marine and estuarine waters. These are Washington's current CWA criteria for regulatory purposes: http://edocket.access.gpo.gov/cfr_2010/julqtr/pdf/40cfr131.36.pdf.

3. National Toxics Rule – December 22, 1992 version. This is the version that first established HHC for Washington. The full preamble to the rule – which offers a response to comments on the previous version as well as an explanation of how the criteria were developed - is found in this publication. The preamble of this publication is a good example of the types of technical and policy discussions that can surround development of the HHC: http://water.epa.gov/lawsregs/rulesregs/ntr/ntr.cfm.

4. EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000)*, also known as the "EPA 2000 guidance": http://water.epa.gov/scitech/swguidance/standards/upload/2005_05_06_criteria_humanhealth_method_complete.pdf.

5. EPA's current recommended criteria list. Note that the list contains chemicals that are priority pollutants and chemicals that are non-priority pollutants : http://water.epa.gov/scitech/swguidance/standards/criteria/current/index.cfm.

Questions/comments?