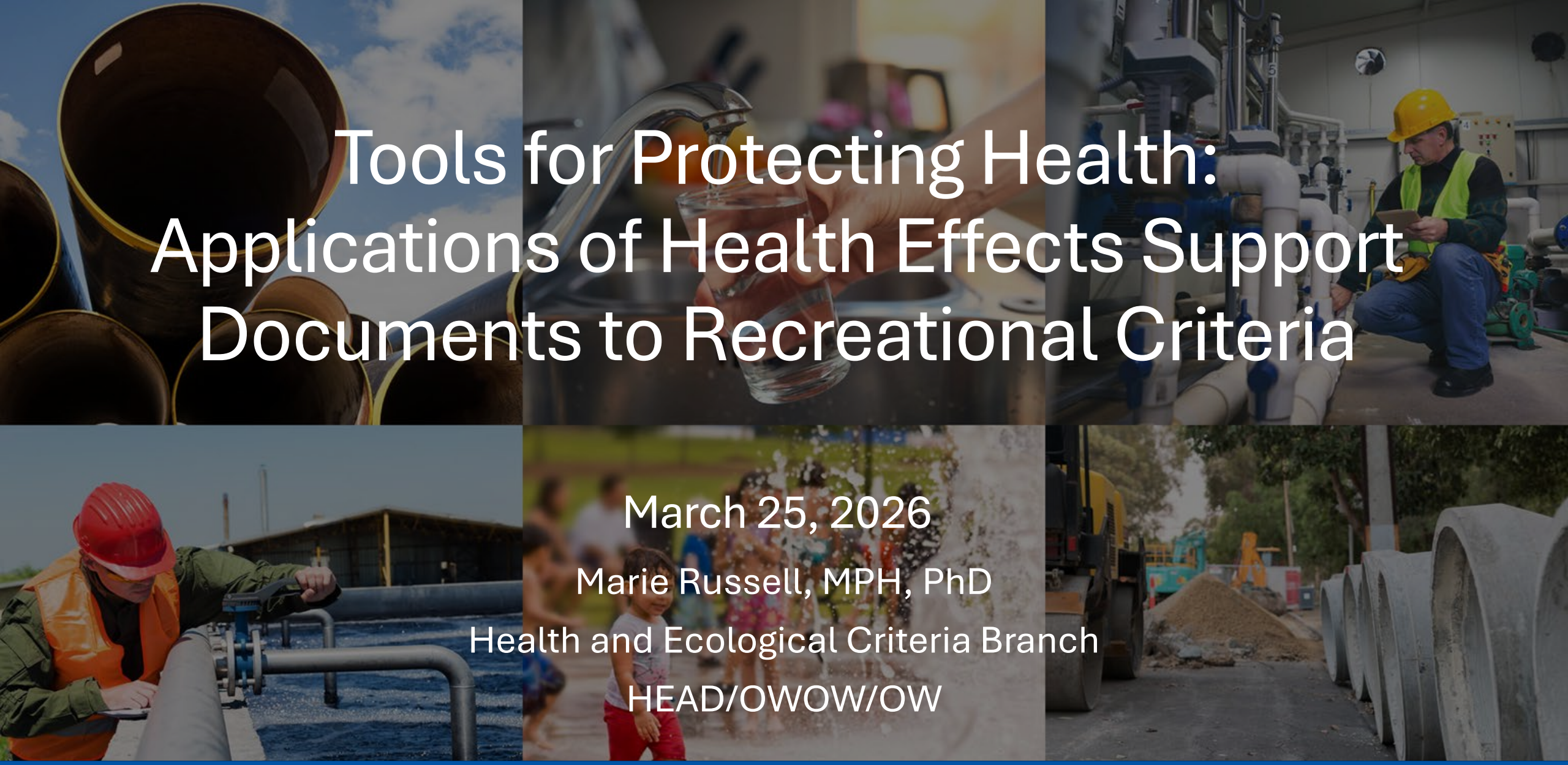

# Tools for Protecting Health: Applications of Health Effects Support Documents to Recreational Criteria

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# Overview

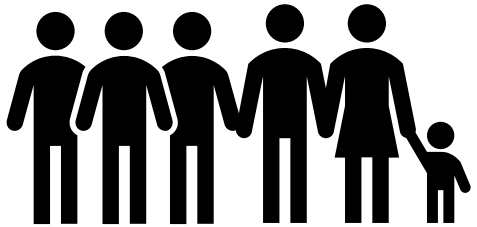
- What are Recreational Water Quality Criteria (RWQC)?
- Developing a Health Effects Support Document (HESD)
- Calculating Recreational Water Quality Criteria (RWQC)
  - Ingestion rate (IR)
  - Reference dose (RfD)
- Using the RfD provided from the HESD to Calculate RWQC or Swimming Advisories
  - Microcystins
  - Cylindrospermopsin
- Developing an HESD for saxitoxins (STXs)

# What are Recreational Water Quality Criteria (RWQC)?

- The 2000 BEACH Act § 304(a)(9)(A) required EPA to publish new or revised criteria for pathogens and pathogen indicators within five years.
- EPA's RWQC are designed to protect people from exposure to illness-causing pathogens during primary contact recreational water body uses.
    - Primary contact uses include swimming, bathing, surfing, and water play by children.
    - Secondary contact uses include sailing, fishing, and kayaking.
- The criteria values are levels in water bodies at or below which human health is expected to be protected.

# Developing an HESD

- An HESD synthesizes information about human health effects after exposure to a contaminant.
    - Background information: chemical and physical properties, environmental fate, and occurrence in water, fish, and shellfish
    - Toxicokinetics information: absorption, distribution, metabolism, and excretion
    - Information about sensitive life stages or susceptible populations
- Hazard identification is conducted based on evidence from both **animal toxicology** and **human epidemiology** studies.

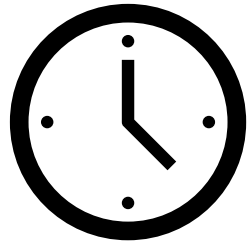


# HESD Terminology

- A **Reference Dose (RfD)** is 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.
    - RfDs are generally used in EPA's noncancer health assessments.
    - Health effects with stronger evidence from the scientific literature are prioritized for RfD derivation.
    - An HESD may conclude that there is not enough data available to derive an RfD.

# HESD Terminology (continued)

- **Uncertainty factors** may be applied to RfD values. There are five areas of uncertainty:
    1.) Intraspecies variation
    2.) Interspecies variation
    3.) Uncertainty due to study exposure duration
    4.) LOAEL to NOAEL extrapolation
        - LOAEL: lowest observed adverse effect level
        - NOAEL: no observed adverse effect level
    5.) Uncertainty due to inadequate database



- Uncertainty factor values of either **1**, **√10** (often averaged to 3), or **10** can be selected. The maximum composite uncertainty factor is 3,000.

# Calculating RWQC

- Under the Clean Water Act, EPA develops recommended RWQC that identify levels of indicator organisms and toxins in water bodies at or below which human health is protected.

$$\text{Recreational value } (\mu g/L) = RfD \; x \; \frac{BW}{IR}$$

RfD is the reference dose (µg/kg/day).
BW is the mean body weight (kg) for the population of interest.
IR is the ingestion rate (L/day).

# Calculating RWQC: Ingestion Rate

- Among the variety of water-related recreational activities**, incidental ingestion during swimming** is the pathway with the greatest potential for cyanotoxin exposure.
- **Children are particularly susceptible** to this route of exposure because they ingest more water and spend more time in the water than adults.
- Most studies estimating incidental ingestion during swimming use units of L/hour. Information on duration of swimming exposure is needed to convert these units to L/day.

# Calculating RWQC: Reference Dose

- The RfD used for cyanotoxins should be based on an oral route of exposure. In animal studies, this exposure route can be described as by feeding, by drinking, or by gavage.
- The HESD will contain the cyanotoxin's oral RfD if the appropriate data are available to derive one.

# Using the RfD provided from the HESD to Calculate RWQC or Swimming Advisories

- The RfDs provided in the HESDs for microcystins and cylindrospermopsin have been used to develop recreational values for these contaminants.
- When the recreational values are used as swimming advisories, they should not be exceeded on a single day.
- When the recreational values are used as water quality criteria, they should not be exceeded in more than three 10-day assessment periods over the course of a recreational season.
  - ➢ The EPA expects states to make explicit risk management decisions regarding the frequency and duration of exceedances that may be allowed in water bodies designated for recreational use.

# Microcystins HESD

- Among approximately 100 different congeners, microcystin-LR is the most widely studied; it is also one of the most toxic and most prevalent congeners.
- There was inadequate evidence to determine the carcinogenicity of microcystins.
- The critical study selected for RfD derivation was an animal tox study that exposed rats to microcystin-LR by drinking water for a subchronic exposure period of 28 days (Heinze, 1999).

HEINZE, R. 1999. Toxicity of the cyanobacterial toxin microcystin-LR to rats after 28 days intake with the drinking water. *Environmental Toxicology,* 14**,** 57-60.

# Microcystins HESD: RfD calculation

- A LOAEL of 50 µg/kg/day was identified based on increased liver weight, altered serum enzyme activities, and histological injuries to the liver (i.e., lesions, including necrosis and hemorrhages).
- The following uncertainty factors were applied:
  - 10 for intraspecies variability
  - 10 for interspecies variability
  - √10 for LOAEL to NOAEL extrapolation
  - √10 for database uncertainties.
- After dividing the LOAEL by a composite uncertainty factor of 1000, the RfD is **0.05 µg/kg/day**.

# Microcystins Recreational Value

$$\text{Recreational value } (\mu g/L) \;=\; RfD \; x \; \frac{BW}{IR}$$

- RfD = 0.05 µg/kg/day
- BW = 31.8 kg (mean body weight of children 6-10 years old)
- IR = 0.21 L/day (90$^{th}$ percentile daily recreational water incidental ingestion rate for children 6-10 years old)

- The recommended recreational value is 8 µg microcystins/L.
- As a swimming advisory, this value should not be exceeded on a single day.
- As a recreational water quality criteria, this value should not be exceeded in more than three 10-day assessment periods over the course of a recreational season.

# Cylindrospermopsin HESD

- There are five analogs of cylindrospermopsin; it is known to inhibit protein synthesis.
- The literature base had inadequate information to assess the carcinogenic potential of cylindrospermopsin.
- The critical study selected for RfD derivation was an animal tox study that exposed mice to cylindrospermopsin by gavage for a subchronic exposure period of 11 weeks (Humpage & Falconer, 2003).

HUMPAGE, A. R. & FALCONER, I. R. 2003. Oral toxicity of the cyanobacterial toxin cylindrospermopsin in male Swiss albino mice: determination of no observed adverse effect level for deriving a drinking water guideline value. *Environ Toxicol,* 18**,** 94-103.

# Cylindrospermopsin HESD: RfD calculation

- A NOAEL of 30 µg/kg/day and a LOAEL of 60 µg/kg/day were identified based on increased kidney weight.
- The following uncertainty factors were applied:
  - 10 for intraspecies variability
  - 10 for interspecies variability
  - √10 for database uncertainties.
- After dividing the NOAEL by a composite uncertainty factor of 300, the RfD is **0.1 µg/kg/day**.

# Cylindrospermopsin Recreational Value

$$\text{Recreational value } (\mu g/L) \;=\; RfD \; x \; \frac{BW}{IR}$$

- RfD = 0.1 µg/kg/day
- BW = 31.8 kg (mean body weight of children 6-10 years old)
- IR = 0.21 L/day (90$^{th}$ percentile daily recreational water incidental ingestion rate for children 6-10 years old)

- The recommended recreational value is 15 µg cylindrospermopsin/L.
- As a swimming advisory, this value should not be exceeded on a single day.
- As a recreational water quality criteria, this value should not be exceeded in more than three 10-day assessment periods over the course of a recreational season.

# Developing an HESD for STXs

green mussel (*Perna viridis*); source: Tan & Lee, 1986

- Human exposure to STXs occurs most commonly through shellfish consumption and is associated with paralytic shellfish poisoning.
- In April of 2021, ORD conducted a literature search for information on six cyanotoxins, including STXs.
- In 2024, OW conducted an update to this literature search using search terms related to STXs, as well as "paralytic shellfish toxins".
  - A second CAS number was also added to the search terms to include the chemical saxitoxin, in addition to saxitoxin dihydrochloride.
  - OW's search was last updated in December of 2025.
- Evaluations of animal tox and human epi studies will be conducted before determining if an RfD can be derived.