EPA’s Drinking Water Health Advisories and Recreational Criteria for Cyanotoxins

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*Modified from Lesley V. D'Anglada, Dr.PH, USEPA HQ presentation April 2016
Disclaimer

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Why cyanobacterial HABs are important?

- The prevalence of HABs in freshwater is increasingly reported in the U.S. and worldwide
- Algal blooms can cause:
  - Hypoxia, leading to fish kills
  - Taste and odor problems in treated drinking water
  - Toxins at levels that may be of concern for human health
- HABs may contribute to economic losses to the fishing and recreation industries and increase costs for managing and treating potable water supplies
- Presence in finished drinking water
  - 2014: > 1 µg/L total microcystins detected in finished water in a drinking water system on western Lake Erie
  - City of Toledo, OH (population ~500,000) issued a “do not drink” advisory.
Guidelines and Regulations for Drinking Water

• No federal regulations for cyanobacteria or cyanotoxins in drinking water in the U.S.
• Safe Drinking Water Act Requirements (SDWA Section 1412(b)(1))
  • [Contaminant Candidate List](#)
    • List of unregulated contaminants that are known or anticipated to occur in public water systems and may require a drinking water regulation.
    • EPA publishes the list every five years.
    • Cyanobacteria (CCL 1,2) and cyanotoxins (CCL 1,2, 3 and draft 4)
  • [Proposed Unregulated Contaminant Monitoring Rule (UCMR)](#)
    • Collect data from selected public water systems.
    • EPA included 10 cyanotoxins in UCMR 4 for monitoring from 2018-2021.
  • [Regulatory Determination (RD)](#)
    • Determine whether or not to regulate; EPA publishes determinations every on a five year cycle.
    • RD 1, 2 and 3 – No Regulatory Decision - not sufficient information
Health Effects Assessment: Microcystins

- Most studied and widespread cyanobacterial toxin (microcystin-LR).
- More than 100 congeners exist.
- The toxicological database is almost exclusively limited to data on the -LR congener.

**Noncancer Effects**
- Human data suggest that the liver is the target organ of toxicity
- Studies in laboratory animals have demonstrated toxicity in the liver, kidney, and testes
  - Acute and short term studies, and sub-chronic studies
  - Liver, kidney, reproductive, and developmental effects
- Chronic studies
  - Limited and have not reported significant effects

**Cancer Effects**
- Human epidemiological studies have reported an association between consumption of drinking water with cyanobacteria and microcystins and liver or colon cancer in certain areas of China.
- No chronic cancer bioassays designed to evaluate dose-response for the tumorigenicity of microcystins following lifetime exposures are available.
- Applying the EPA 2005 Guidelines for Carcinogen Risk Assessment, there is *inadequate information to assess the carcinogenic potential* of microcystins.
Health Effects Assessment: Cylindrospermopsin

Noncancer Effects
• Human data on oral toxicity of cylindrospermopsin suggests liver and kidney as the target organs.
• Animal laboratory studies focused on hepatic and renal toxicity
  • Acute, short-term, and subchronic studies demonstrate the liver and kidney as target organs.
  • No chronic studies were identified.

Cancer
• Applying the 2005 EPA Guidelines for Carcinogen Risk Assessment, there is inadequate information to assess the carcinogenic potential of cylindrospermopsin.
  • No human or chronic cancer bioassays in laboratory animals are available
EPA Drinking Water Health Advisories for Cyanotoxins

- Microcystins
- Cylindrospermopsin
Cyanotoxins Health Advisories Development

• 2012 – Joint effort with Health Canada
• 2013 - Literature Review and Health Effects Support Documents (HESD) for microcystin, cylindrospermopsin and anatoxin-a development
  – Comprehensive review of the health effects information.
  – Provides the health effects basis for the development of HAs.
• 2014 -2015 External Peer Reviews HESDs for Anatoxin-a, Cylindrospermopsin and Microcystins
  • Peer reviewers affirmed there is inadequate information to develop an HA for anatoxin-a
  • Peer reviewers confirmed there is adequate information to develop HAs for microcystins and cylindrospermopsin
• 2015 –Development of HA for Microcystins and Cylindrospermopsin
• June 17th, 2015 – HAs Published
Children’s Exposure to Cyanotoxins

- Bottle-fed infants consume large amounts of drinking water compared to their body weight.
- Exposure to children < 12 months is 5 times higher than for adults > 21 years old, on a body-weight basis.
- At 6 years and older, exposure on a body-weight basis is similar to that of an adult.

**Drinking Water Ingestion Rates by Age Group**

![Drinking Water Ingestion Rates](image-url)
### HAs for MCs and CYL by Age Group

<table>
<thead>
<tr>
<th>Toxin</th>
<th>10-day Health Advisory</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Bottle-fed infants and pre-school children</td>
</tr>
<tr>
<td>Microcystins</td>
<td>0.3 µg/L</td>
</tr>
<tr>
<td>Cylindrosporpermopsin</td>
<td>0.7 µg/L</td>
</tr>
</tbody>
</table>

#### HAs for Microcystins

- **Bottle-fed infants up to school-age children** 6.8 µg/L
- **School-age children and adults** 1.6 µg/L

#### HAs for Cylindrosporpermopsin

- **Bottle-fed infants up to school-age children** 0.7 µg/L
- **School-age children and adults** 3 µg/L
Data Gaps Identified

• The toxicity of microcystins to the male reproductive system after sub-acute to chronic oral exposure.
• The toxicity of microcystins to the female reproductive tissues and those of offspring following oral exposure.
• The relative potencies of other microcystin congeners when compared to microcystin-LR.
• The adverse effects of inhalation and/or dermal exposures to cyanotoxins.
• The carcinogenic potential of cyanotoxins.
• Potential health risks from exposure to mixtures of cyanotoxins.
• Bioconcentration and bioaccumulation of cyanotoxins in aquatic food webs.
EPA Recreational Ambient Water Quality Criteria for Cyanotoxins

- Microcystins
- Cylindrospermopsin
Guidelines and Regulations for Recreational Water

- No federal regulations for cyanobacteria or cyanotoxins in recreational water in the U.S.
- World Health Organization (WHO) Guidelines (cyanobacteria cell density):

<table>
<thead>
<tr>
<th>Relative Probability of Acute Health Effects</th>
<th>Cyanobacteria (cells/mL)</th>
<th>Microcystin-LR (µg/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>&lt; 20,000</td>
<td>&lt; 10</td>
</tr>
<tr>
<td>Moderate</td>
<td>20,000-100,000</td>
<td>10-20</td>
</tr>
<tr>
<td>High</td>
<td>100,000-10,000,000</td>
<td>20-2,000</td>
</tr>
<tr>
<td>Very High</td>
<td>&gt; 10,000,000</td>
<td>&gt; 2,000</td>
</tr>
</tbody>
</table>

- Guidance values for recreational water have been adopted by many countries and some states based on WHO guidelines.
## Recreational Water (RW) Guidelines for Cyanotoxins

<table>
<thead>
<tr>
<th>Authority/State</th>
<th>Recreational Water Guidance/Action Level</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>WHO</strong></td>
<td><strong>Relative Probability of Acute Health Effects</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Cyanobacteria (cells/mL)</strong></td>
</tr>
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<tr>
<td>High</td>
<td>100,000-10,000,000</td>
</tr>
<tr>
<td>Very High</td>
<td>&gt; 10,000,000</td>
</tr>
<tr>
<td><strong>California</strong></td>
<td>Microcystin: 0.8 µg/L; Anatoxin-a: 90 µg/L; Cylindrospermopsin: 4 µg/L</td>
</tr>
<tr>
<td><strong>Iowa, Nebraska, Oklahoma, Texas</strong></td>
<td>Microcystin ≥ 20 µg/L</td>
</tr>
<tr>
<td><strong>Illinois</strong></td>
<td>Microcystin-LR concentration results approach or exceed 10 µg/L</td>
</tr>
<tr>
<td><strong>Indiana</strong></td>
<td>Level 1: very low/no risk &lt; 4 µg/L microcystin-LR</td>
</tr>
<tr>
<td></td>
<td>Level 2: low to moderate risk 4 to 20 µg/L microcystin-LR</td>
</tr>
<tr>
<td></td>
<td>Level 3: serious risk &gt; 20 µg/L microcystin-LR</td>
</tr>
<tr>
<td></td>
<td>Warning Level: Cylindrospermopsin: 5 ppb</td>
</tr>
<tr>
<td><strong>Ohio</strong></td>
<td>Microcystin-LR: PHA: 6 µg/L; NCA: 20 µg/L</td>
</tr>
<tr>
<td></td>
<td>Cylindrospermopsin: PHA: 5 µg/L; NCA: 20 µg/L</td>
</tr>
<tr>
<td></td>
<td>Anatoxin-a: PHA: 80 µg/L; NCA: 300 µg/L</td>
</tr>
<tr>
<td></td>
<td>Saxitoxin: PHA: 0.8 µg/L; NCA: 3 µg/L</td>
</tr>
<tr>
<td><strong>Wisconsin</strong></td>
<td>&gt; 100,000 cells/mL or scum layer</td>
</tr>
</tbody>
</table>
EPA’s Ambient Water Quality Criteria (AWQC) Development for Recreational Exposures

- EPA is developing Clean Water Act §304(a) recreational Ambient Water Quality Criteria (AWQC) to ensure safety for recreational exposures to cyanobacteria and the cyanotoxins microcystin and cylindrospermopsin.

- Focus on a recreational scenario where immersion and incidental ingestion of ambient water are likely.

- Consumption of fish and shellfish will **not** be considered in the assessments.
Conceptual Model of Exposure Pathways to Cyanobacteria and Cyanotoxins in Recreational Water

**STRESSORS**
- Cylindropermopsin
- Microcystins
- Cyanobacteria cells

**SOURCES**
- Lakes, ponds, and rivers (freshwater, inland)
- Estuaries, bays, lagoons and oceans (marine, coastal)

**EXPOSURE ROUTES**
- Oral
- Dermal
- Inhalation
  - Incidental ingestion while recreating
  - Dermal contact while recreating
  - Incidental inhalation while recreating

**RECEPTORS**
- General population (adults and children)
- Children

**ENDPOINTS**
- Liver damage
- Kidney damage
- Reproductive effects
- Developmental effects
- Cancer
  - Inflammatory response effects, e.g., GI distress, skin irritation
Next Steps AWQC for Cyanotoxins

• EPA is planning to hold additional webinars in 2016.
  – Engage with stakeholders
  – Communicate our progress
  – Provide a venue for feedback
  – Forum for information/data sharing

• Draft AWQC: Fall 2016
<table>
<thead>
<tr>
<th>1-Entity</th>
<th>2-Primary Contact(s)</th>
<th>3-Website(s)</th>
<th>4-Program Primary Functions</th>
</tr>
</thead>
<tbody>
<tr>
<td>United States Environmental Protection Agency, Region 7 (USEPA Region 7)</td>
<td>Amy Shields <a href="mailto:shields.amy@epa.gov">shields.amy@epa.gov</a> 913-551-7396 Laura Webb (Monitoring) Neftali Hernandez-Santiago (Drinking Water)</td>
<td>Program Page: <a href="https://www.epa.gov/nutrient-policy-data/cyanohabs">https://www.epa.gov/nutrient-policy-data/cyanohabs</a></td>
<td>Urban lakes monitoring Monitoring on tributaries to Mississippi and Missouri Rivers Incident response Lab analysis Tribal support</td>
</tr>
<tr>
<td>5-Spatial Scope</td>
<td>6-Specific Miss/MO River (4-State) Presence</td>
<td>7-Staffing/Field Presence</td>
<td>8-Parameter(s) of Focus</td>
</tr>
<tr>
<td>Region-wide, at select streams and urban lakes</td>
<td>None specific, but can respond to incidents region-wide at request of state or tribe Also, has monitored on tributaries to UMR</td>
<td>Field staff located in Kansas City, KS, but has assets (e.g. boats, sondes, mobile lab) that can be deployed in incident response</td>
<td>Currently, microcystin (for urban lakes monitoring) Expanding in 2016 for cylindrospermopsin and BGA identification</td>
</tr>
<tr>
<td>9-Sampling/Data Collection Methods</td>
<td>10-Sampling/Data Collection Frequency</td>
<td>11-Analytical Methods</td>
<td>12-Laboratories Used</td>
</tr>
<tr>
<td>Field test kits (for laboratory analysis)</td>
<td>In response to reports Urban Lake monitoring monthly during recreational season</td>
<td>ELISA Starting to examine qPCR</td>
<td>USEPA Region 7 lab Mobile lab could also be used</td>
</tr>
<tr>
<td>13-Turnaround Time for Data</td>
<td>14-Data Availability</td>
<td>15-Other Capacities</td>
<td>16-Future Work</td>
</tr>
<tr>
<td>Generally MC results w/in 24 hours</td>
<td>KCWaters.org for urban data, WQX for all data</td>
<td>Mobile lab Emergency response boats Sondes Provide sample kits for DW tribal system sampling triggered by visual/water monitoring results.</td>
<td>Looking to host Region 7 HAB workshop in February 2017.</td>
</tr>
</tbody>
</table>
Contact Information

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EPA’s CyanoHABs Website
www.epa.gov/cyanohabs