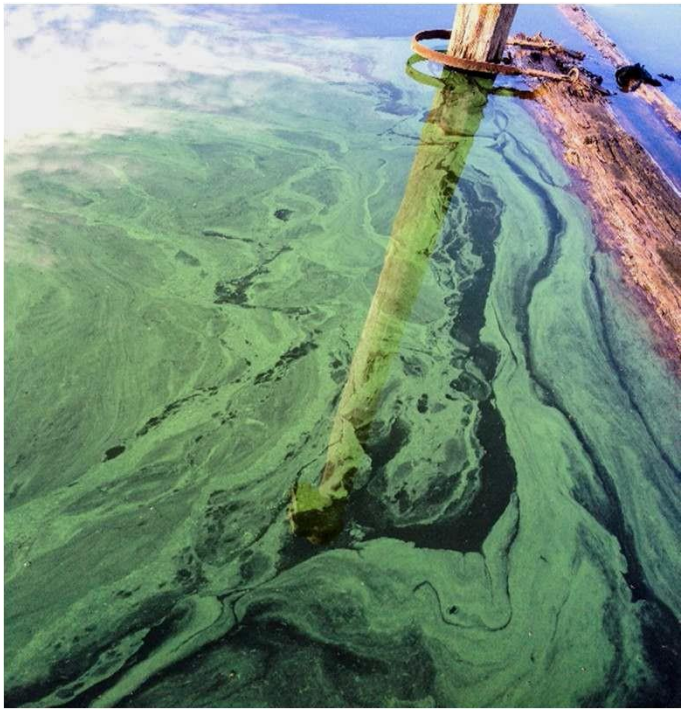
EPA's Drinking Water Health Advisories and Recreational Criteria for Cyanotoxins



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

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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

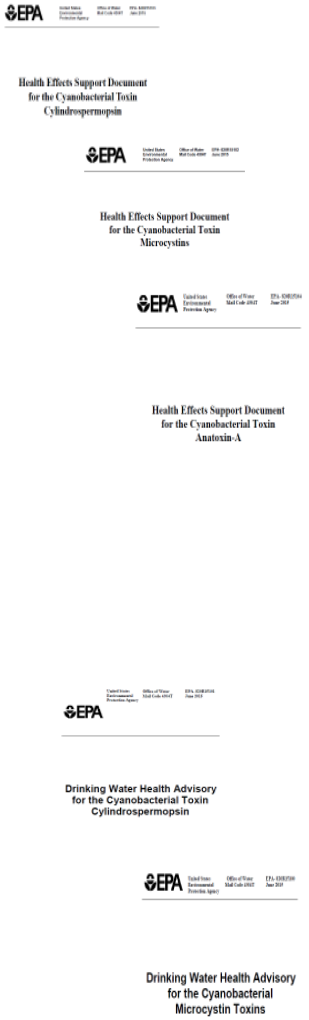
- Applying the 2005 EPA Guidelines for Carcinogen Risk Assessment, there is *inadequate information to assess the carcinogenic potential* of cylindrospermopsin.
  - No human or chronic cancer bioassays in laboratory animals are available

EPA Drinking Water Health Advisories for Cyanotoxins

- Microcystins
- Cylindrospermopsin

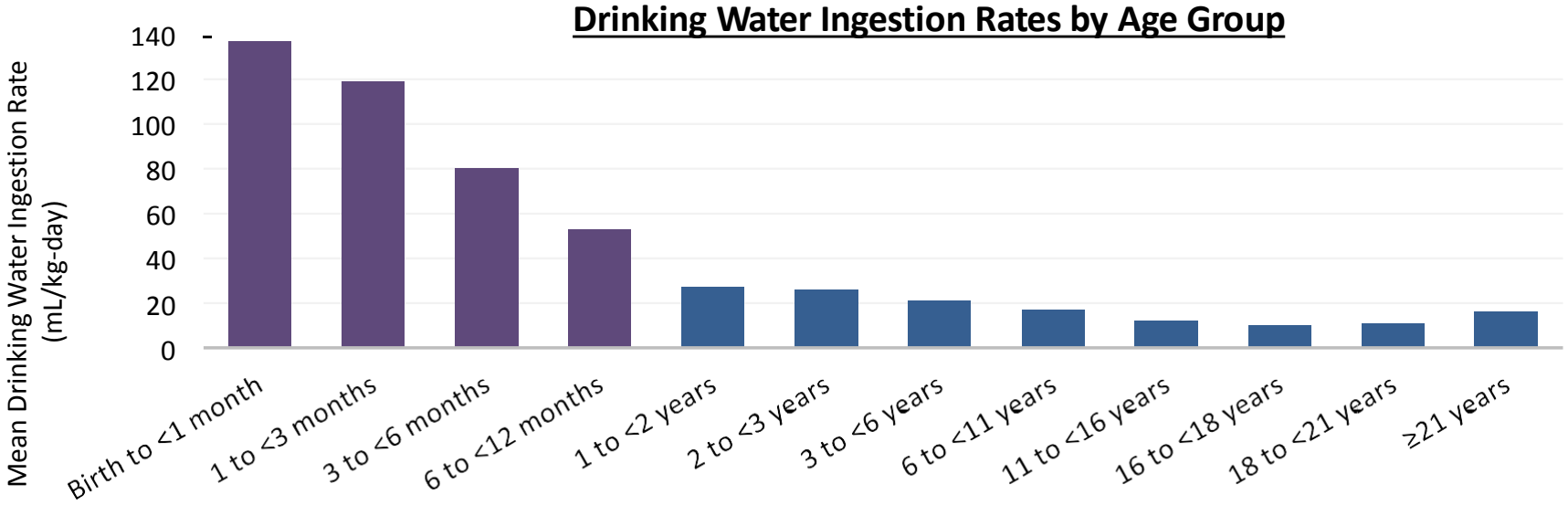
Cyanotoxins Health Advisories Development

- 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

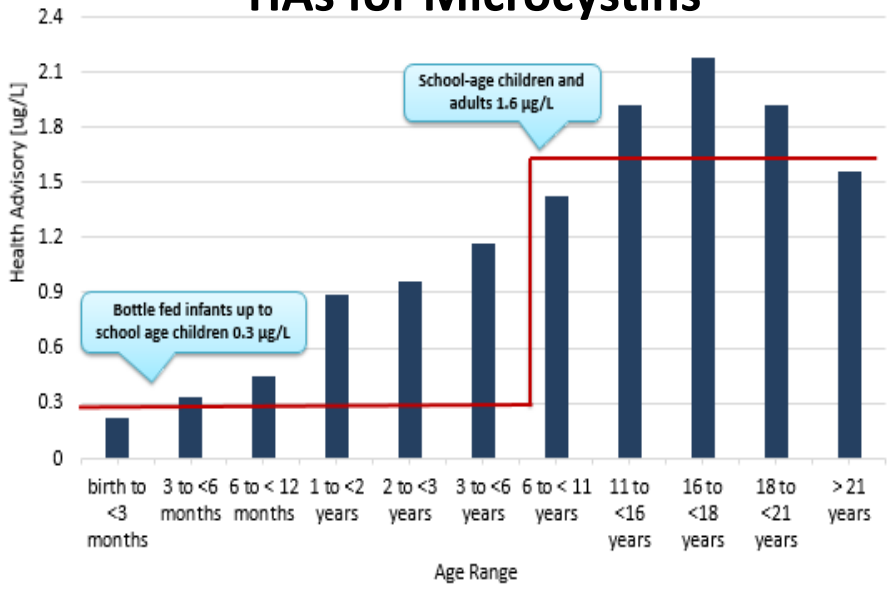
- Bottle-fed infants consume large amounts of drinking water compared to their body weight.
- Exposure to children < 12 months is 5 times higher than for adults > 21 years old, on a body-weight basis.
- At 6 years and older, exposure on a body-weight basis is similar to that of an adult.
- Infant-specific exposure factors are available from U.S. EPA's Exposure Factors Handbook (2011).



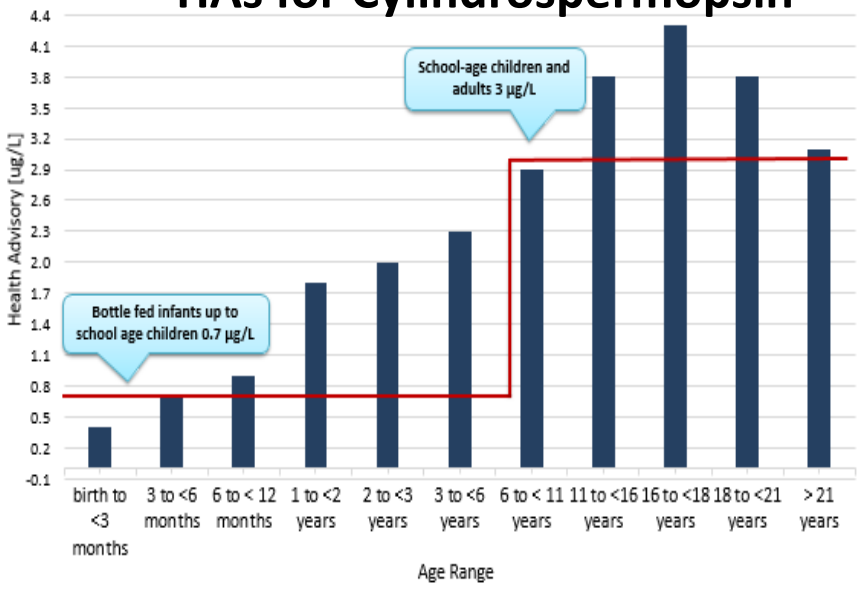
HAs for MCs and CYL by Age Group

Toxin	10-day Health Advisory	
	Bottle-fed infants and pre-school children	School-age children and adults
Microcystins	0.3 µg/L	1.6 µg/L
Cylindrospermopsin	0.7 µg/L	3 µg/L

HAs for Microcystins



HAs for Cylindrospermopsin



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) :

Relative Probability of Acute Health Effects	Cyanobacteria (cells/mL)	Microcystin-LR (µg/L)
Low	< 20,000	<10
Moderate	20,000-100,000	10-20
High	100,000-10,000,000	20-2,000
Very High	> 10,000,000	>2,000

- Guidance values for recreational water have been adopted by many countries and some states based on WHO guidelines.

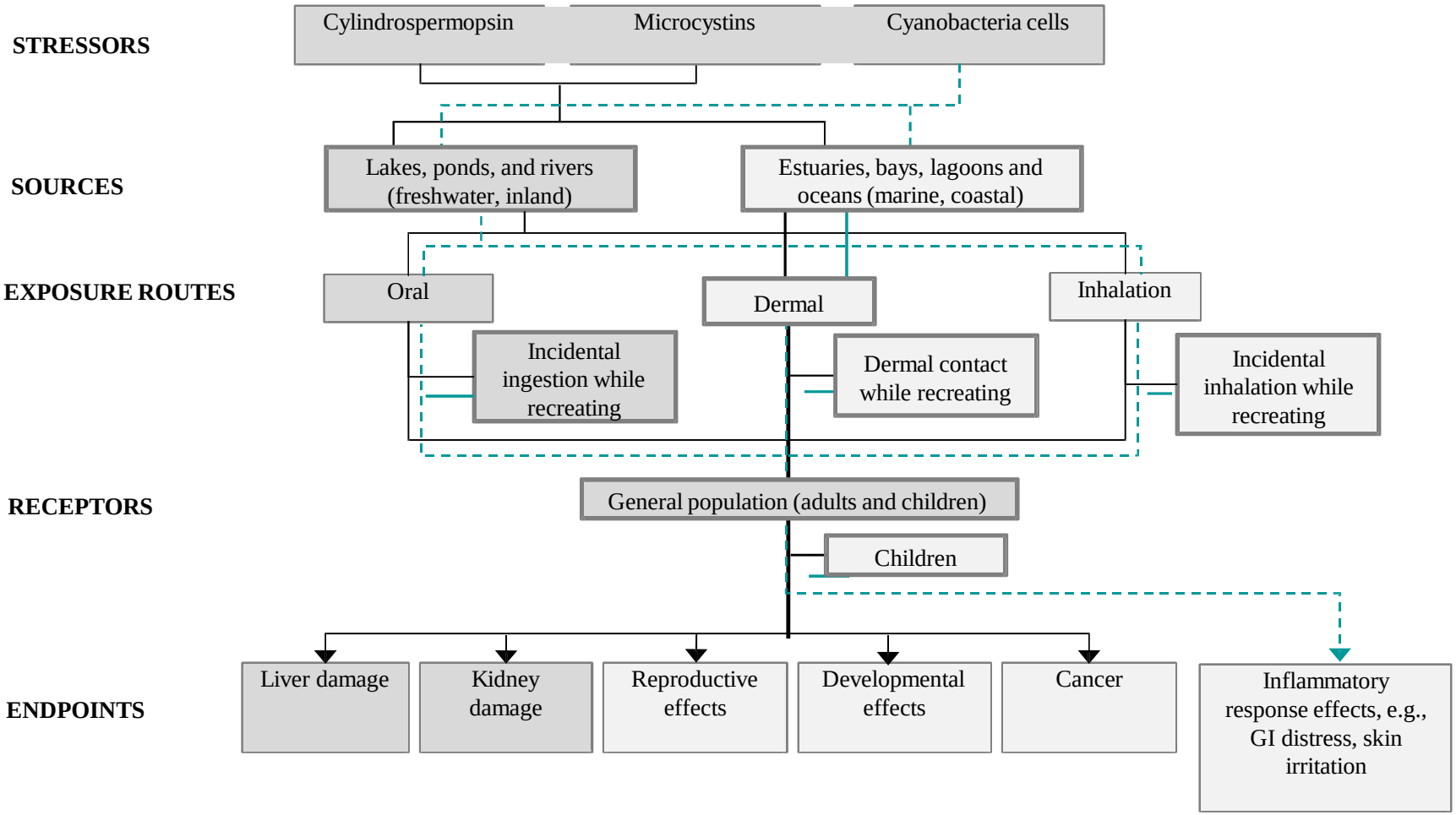
Recreational Water (RW) Guidelines for Cyanotoxins

Authority/State	Recreational Water Guidance/Action Level			
WHO	Relative Probability of Acute Health Effects	Cyanobacteria (cells/mL)	Microcystin-LR (µg/L)	Chlorophyll-a (µg/L)
	Low	< 20,000	<10	<10
	Moderate	20,000-100,000	10-20	10-50
	High	100,000-10,000,000	20-2,000	50-5,000
	Very High	> 10,000,000	>2,000	>5,000
California	Microcystin: 0.8 µg/L; Anatoxin-a: 90 µg/L; Cylindrospermopsin: 4 µg/L			
Iowa, Nebraska, Oklahoma, Texas	Microcystin ≥ 20 µg/L			
Illinois	Microcystin-LR concentration results approach or exceed 10 µg/L			
Indiana	Level 1: very low/no risk < 4 µg/L microcystin-LR Level 2: low to moderate risk 4 to 20 µg/L microcystin-LR Level 3: serious risk > 20 µg/L microcystin-LR Warning Level: Cylindrospermopsin: 5 ppb			
Ohio	Microcystin-LR: PHA: 6 µg/L; NCA: 20 µg/L Cylindrospermopsin: PHA: 5 µg/L; NCA: 20 µg/L Anatoxin-a: PHA: 80 µg/L; NCA: 300 µg/L Saxitoxin: PHA: 0.8 µg/L; NCA: 3 µg/L			
Wisconsin	> 100,000 cells/mL or scum layer			

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



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

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

Compilation of HAB Programs and Capacities for Iowa, Kansas, Missouri, Nebraska and EPA R7

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