MICHIGAN DEPARTMENT OF
ENVIRONMENT, GREAT LAKES, AND ENERGY

Applying Chemicals to Surface Waters: Rule 97

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Presentation Overview

- Rule 97 Introduction
- Bacterial Augmentation Products
- Tracer Dyes
- Individual Rule 97 Applications
- Toxicology Evaluations
  - Rule 57 Overview
  - Environmental Fate Considerations
  - Other Considerations
- Questions and Answers

Rule 97 – Mich. Admin Code R. 323.1097

- All projects involving the application of materials to waters of the state for water resource management purposes require a Rule 97 Certification of Approval from the Michigan Department of Environment, Great Lakes, and Energy (EGLE).

- Rule 97 of the Michigan Water Quality Standards states: "The **application of materials** for **water resources management** projects pursuant to state statutory provisions is not subject to the standards as prescribed by these rules, but **all projects shall be reviewed** and approved by the commision before application."

What is Covered Under Rule 97??

- The definition of Rule 97 is broad, but common applications include:
  - Bacterial Augmentation Products
  - Tracer Dyes
  - Phosphate Binders / Nutrient Reducers
  - Rotenone (invasive species treatment)
  - Others (e.g. Polyacrylamides)

What is not Rule 97?

- Industrial effluent discharges
- Stormwater treatment systems discharges
- Wastewater treatment facility discharges
- Aquatic Nuisance Control (ANC) applications
- Mosquito Control Applications (now under NPDES)
- Situations where materials are not being applied to surface waters of the state

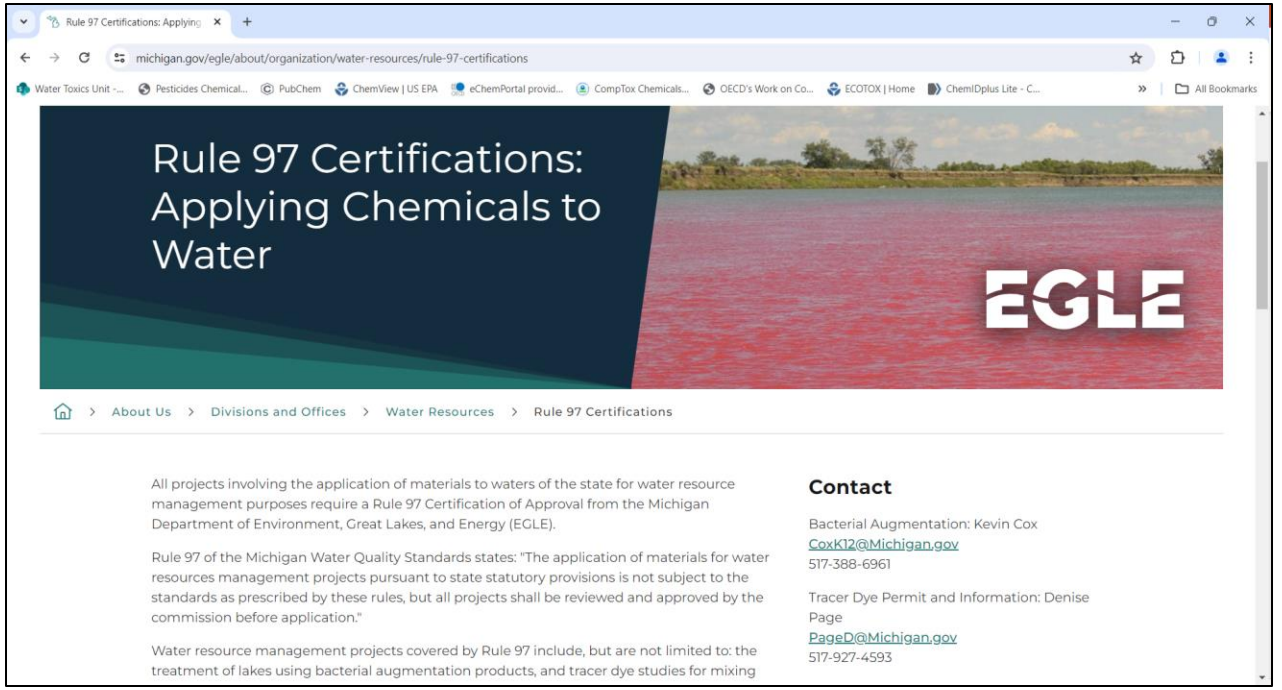
UNCERTAIN IF YOUR PROJECT FALLS UNDER RULE 97??

CALL ME ☺

Actually, I prefer email

Where can I find out more information??

- Visit our Website
  - https://www.michigan.gov/egle/about/organization/water-resources/rule-97-certifications



Bacterial Augmentation Products

- Also known as “Bioaugmentation”
- What is “Bacterial Augmentation”??
  - Application of live bacteria to a water body intended to decrease levels of organic matter, reduce odors, and/or improve water clarity
- Approved Bacterial Augmentation Products are listed on Website

Acceptable Michigan Bacterial Augmentation Products - As of June 7, 2021		
Manufacturer	**Manufacturer's Location**	**Product Name**
Advantis Technologies, Inc.	Alpharetta, GA	AB Nutri-Sorb
Advantis Technologies, Inc.	Alpharetta, GA	Bacti-Klear (Liquid)
Advantis Technologies, Inc.	Alpharetta, GA	Bacti-Klear Pellets
Advantis Technologies, Inc.	Alpharetta, GA	Cygnet BioBlend II WSP
Advantis Technologies, Inc.	Alpharetta, GA	Mukk Busster Pellets
Airmax, Inc.	Armada, MI	MuckAway
Airmax, Inc.	Armada, MI	MuckAway TL
Airmax, Inc.	Armada, MI	MuckAway SMR Pellets
Airmax, Inc.	Armada, MI	Muck Defense
Airmax, Inc.	Armada, MI	Nature's Defense
Airmax, Inc.	Armada, MI	PondClear Liquid
Airmax, Inc.	Armada, MI	PondClear TLC Packets
Airmax, Inc.	Armada, MI	PondClear Water Soluble Packets
Airmax, Inc.	Armada, MI	Seasonal Defense
Alumin-Nu Corporation	Lyndhurst, OH	Nice-n-Easy Pond and Lake Restoration
Alumin-Nu Corporation	Lyndhurst, OH	Pond Clear Liquid Bacteria (Requires Sediment Bacteria, Accelerator, and Nitrifier Bacteria)
Alumin-Nu Corporation	Lyndhurst, OH	Power Accelerator for Ponds and Lakes
Alumin-Nu Corporation	Lyndhurst, OH	Power Nitrification Pond and Lake Treatment
Alumin-Nu Corporation	Cleveland, OH	Power Pond and Lake Restoration
Alumin-Nu Corporation	Lyndhurst, OH	Power Sediment Treatment for Ponds
American Biosystems, Inc.	Roanoke, VA	Accelobac™ 5000 AG
Applied Biochemists	Alpharetta, GA	Aqua-Prep “Enzyme Solution” (maximum allowable dose is 0.124 gallons per acre foot)
Applied Biochemists	Alpharetta, GA	Aqua-Prep “Protein Solution”
Applied Biologicals, Inc.	Wheaton, IL	In-Pipe Bio-25(C)
Aquacide Co.	White Bear Lake, MN	AquaClear Pellets
Aquafix, Inc. / Naturalake Biosciences	Madison, WI	Aquafix Lake Pro Enzyme
Aquafix, Inc. / Naturalake Biosciences	Madison, WI	Aquafix Michigan Enzyme
Aquafix, Inc. / Naturalake Biosciences	Madison, WI	Aquafix PLM Enzyme
Aquafix, Inc. / Naturalake Biosciences	Madison, WI	Aquafix VitaStim 6000
Aquafix, Inc. / Naturalake Biosciences	Madison, WI	Aquafix VitaStim 6000LM
Aquafix, Inc. / Naturalake Biosciences	Madison, WI	Aquafix VitaStim MD Pellets
Aquafix, Inc. / Naturalake Biosciences	Madison, WI	Bio-Maxx Muck Pellets
Aquafix, Inc. / Naturalake Biosciences	Madison, WI	Bio-Maxx Plus
Aquafix, Inc. / Naturalake Biosciences	Madison, WI	Bio-Maxx Plus Arctic
Aquafix, Inc. / Naturalake Biosciences	Madison, WI	Bio-Maxx Plus Liquid
Aquafix, Inc. / Naturalake Biosciences	Madison, WI	Envira3: Bacteria-Enzymes-Biostimulants
Aquafix, Inc. / Naturalake Biosciences	Madison, WI	MD Pellets
Aquafix, Inc. / Naturalake Biosciences	Madison, WI	MuckBiotics
Aquafix, Inc. / Naturalake Biosciences	Madison, WI	Nature's Blend
Aquafix, Inc. / Naturalake Biosciences	Madison, WI	Nature's Liquid Balance
Aquafix, Inc. / Naturalake Biosciences	Madison, WI	Nitrafix
Aquafix, Inc. / Naturalake Biosciences	Madison, WI	PondZilla Michigan
Aquafix, Inc. / Naturalake Biosciences	Madison, WI	Summer Slam

Bacterial Augmentation Products

- Steps to get your project approved
  - Complete the Notice of Intent (NOI)
    - YES, YOU MUST REALLY COMPLETE THE NOTICE OF INTENT… ALL OF IT
  - Send completed NOI by mail or email
  - Is your product on approved list??
  - Please indicate dosing amount and treatment frequency
    - Be sure it matches or is below label rate
    - Do not exceed the maximum dose

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MICHIGAN DEPARTMENT OF ENVIRONMENT, GREAT LAKES, AND ENERGY
Water Resources Division

Notification of Intent to Treat
Certification of Approval Authorizing
Bacterial Augmentation in Surface Waters

R 323.1097, promulgated pursuant to Part 31, Water Resources Protection, of the Natural Resources and Environmental Protection Act, 1994 PA 451, as amended.

R97-24/001

Instructions: Complete (please print or type), sign (electronic signatures are acceptable, and return this notification by email to CoxK12@Michigan.gov or by mail to:

Michigan Department of Environment, Great Lakes, and Energy
Water Resources Division, 3rd Floor South
ATTN: Kevin Cox
P.O. Box 30458
Lansing, Michigan, 48909-7958

All requested information must be provided in order for your application to be processed.

Section 1. Applicant Type

Applicant Type (check all that apply):

☐ A person or entity who owns the property to be treated or who is the bottomland owner of the surface water body.

☐ A lake board established under Part 309, Inland Lake Improvements, of the Natural Resources and Environmental Protection Act, 1994 PA 451, as amended.

☐ A state or local government acting under authority of state law.

☐ A person who has written authorization to act on behalf of the entity checked above.
(If so, please provide site contact information for the property owner below.)

Name: _____

Phone: _____

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Bacterial Augmentation Products

- What if I have multiple sites, must I complete an new NOI for each site?
  - **PLEASE DON'T** – Section 4 of the NOI allows for inputting of multiple locations that may undergo treatment
    - If you have more sites that can fit within the Section 4 Table, an excel sheet with the same columns as the Section 4 Table may be included as an attachment to the NOI
    - If you have different approved products to be used at each site, please make that clear within the application.
  - Please be sure to include identifiable locations for each water body
    - Order of preference: TRS << Address << Lat/Long

Bacterial Augmentation Products

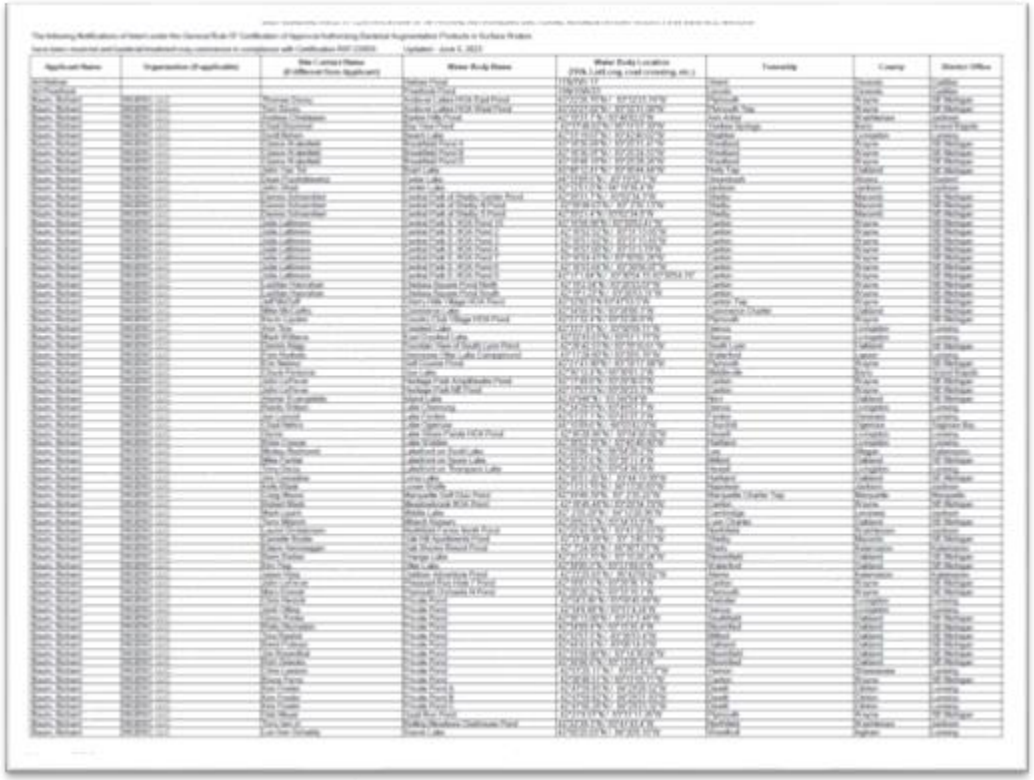
- But what if I have the latest and most awesome new product but it is not on the EGLE approved list??
  - That's great! But you must submit the following information to EGLE for review/approval prior to use:
    1. Product labels that list the application rate and intended uses.
    2. Safety data sheets (SDS) for each product.
    3. A list of **all product constituents** and concentrations/percentages of each
    4. A list of all **strains and species** of microorganisms that are contained within the product.
    5. A statement on company letterhead that the product does not contain any genetically modified organisms (GMOs), does not include added nutrients (e.g. phosphorus)
    6. Any available toxicity data for the products.
    7. (Optional) A description of any monitoring data that will be included as part of the pilot study.

Bacterial Augmentation Products

- Example Incorrect Submission (hypothetical)
  - "We use several different strains, these including: Bacillus subtilis, Bacillus licheniformis, Bacillus amyloliquifaciens, and Bacillus megaterium"
- Example Correct Submissions (hypothetical)
  - "1 Billion CFU/gram Bacillus subtilis **ATCC 6051**"
  - "1 Billion CFU/gram Bacillus licheniformis **ATCC 12713**"

Bacterial Augmentation Products

- Approved project applicants will receive an email notification from EGLE
  - Includes General Rule 97 Certification of Approval pdf (also on website)
  - Terms of General Rule 97 Certification of Approval must be followed
- Additionally, all approved projects will be listed on EGLE website
  - 2024 approved list is currently being developed (likely published in July)
  - 2023 list included several hundred approved projects (on current website)



Tracer Dyes

- Under R 323.1097 of the Michigan Water Quality Standards the Water Resources Division (WRD) is responsible for approving projects where tracer dyes are applied or may be discharged to surface waters of the state.

- Surface waters of the state are defined as the Great Lakes and their connecting waters, inland lakes, rivers, streams, impoundments, open drains, wetlands, and other surface bodies of water within the confines of the state.

Tracer Dyes

- Why are tracer dyes used?
  - Identifying and eliminating illicit discharges and cross connections
  - Identifying pipeline and tank failures during hydrostatic pressure testing
  - Discharge point location studies
  - Mixing zone mapping
  - Time-of-passage studies

CURRENTLY APPROVED TRACER DYES

- Approvals based on chemical/CAS#, not product names
- Applicants will need to check label / SDS /website to determine primary dye chemical

R97-24/002

Michigan Department of Environment, Great Lakes, and Energy

Acceptable Tracer Dye List - 2024

Active Ingredient Name	CAS Number	Alternate Name	Concentration Limit (Final Acute Value)
Blue AZO Liquid	3844-45-9	Acid Sky Blue A Blue 1206 Blue Dye CI Acid Blue 9	12 mg/L**
Eosine Y	17372-87-1	Acid Red 87 Eosine Eosine G Eosine Sodium Eosine YB Eosine YS	7 mg/L
Fluorescein Fluorescein Fluorescein	2321-07-5 518-47-8 6417-85-2	CI Acid Yellow 73 Fluorescein LT Fluorescent FLT Fluro Green 1234 Sodium Florscein Uranine Uranine K	30 mg/L 30 mg/L 30 mg/L
Lissamine Yellow FF	2391-30-2	Brilliant Acid Yellow 8G Brilliant Sulphoflavine FF CI Acid Yellow 7	200 mg/L
Rhodamine WT	37299-86-8	Acid Red 388 FWT Red 200 FWT Red 25* FWT Red 50 KeyAcid Rhodamine WT Liquid*	13 mg/L

*May contain trimellitic acid and have a CAS # of 528-44-9. This is an approved ingredient.
**Milligrams per liter (mg/L).

Tracer Dyes

- Steps to get your project approved
  - Complete the Notice of Intent (NOI)
    - YES, YOU MUST REALLY COMPLETE THE NOTICE OF INTENT… ALL OF IT
  - Send completed NOI by mail or email
  - Is your tracer dye on approved list??
  - Please indicate dosing amount
    - Be sure it matches or is below label rate
    - Do not exceed the maximum dose

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MICHIGAN DEPARTMENT OF ENVIRONMENT, GREAT LAKES, AND ENERGY
WATER RESOURCES DIVISION

Notification of Intent to Treat
General Rule 97 Certification of Approval Authorizing Tracer Dyes in Surface Waters

R97-24/002

Instructions: Complete, sign (electronic or typed signature accepted), and date the form. Submit to Denise Page, Great Lakes Watersheds Assessment, Restoration, and Management Section, Water Resources Division, at PageD@Michigan.gov .

SECTION I. MAILING AND CONTACT INFORMATION

Provide the name, address, telephone number, and e-mail address of the person who will sign this notification (see Section III).

Name: _____
Title (if applicable): _____
Organization (if applicable): _____
Address: _____
City: _____ State: _____ Zip Code: _____
Email: _____ Phone: _____
Contact Name (if different than above): _____
Contact Phone: _____

SECTION II. WATER BODY TYPE, LOCATION, AND CHEMICAL INFORMATION

Identify the water body(ies) that may be affected, location(s), and information regarding the active ingredient(s) to be used.

Water Body Name: _____
Pathway (a discharge rather than direct application): _____
Water Body Location – County: _____ Township: _____
Town: _____ Range: _____ Section: _____
OR Latitude: _____ Longitude: _____
Project Description:

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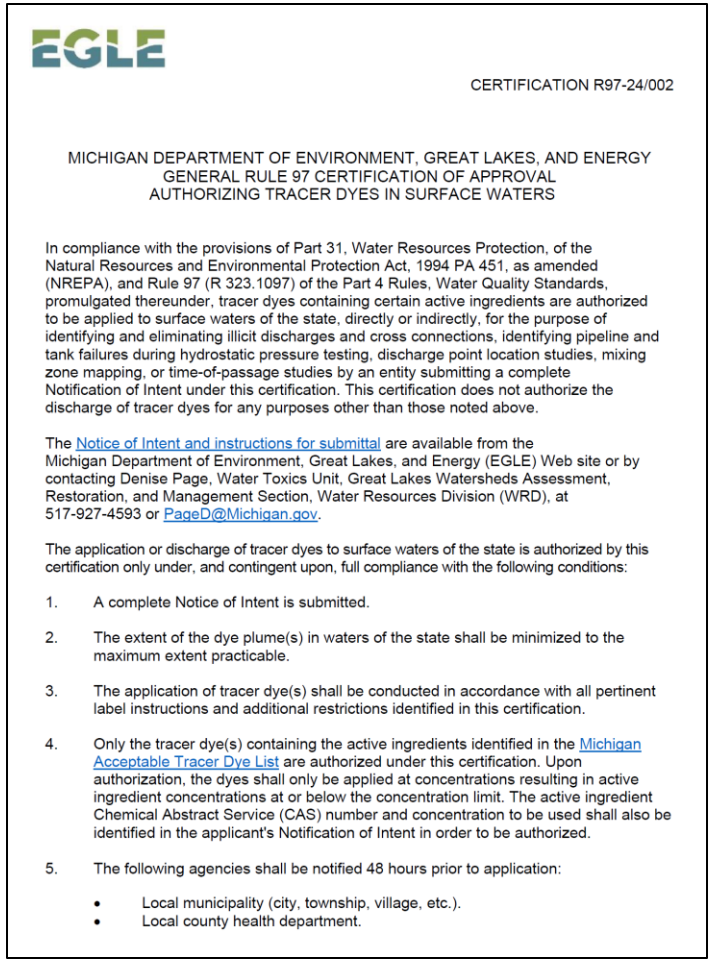
Tracer Dyes

- Approved project applicants will receive an email notification from EGLE
  - Includes General Rule 97 Certification of Approval pdf (also on website)
  - Terms of General Rule 97 Certification of Approval must be followed

- NOTIFICATIONS (IMPORTANT)
  - Must notify 48 hours prior to application
    - Local Municipality
    - Local Health Department
      - (Downstream health departments if affected)
    - Local Area Emergency Coordinator
    - EGLE District Office



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CERTIFICATION R97-24/002

MICHIGAN DEPARTMENT OF ENVIRONMENT, GREAT LAKES, AND ENERGY
GENERAL RULE 97 CERTIFICATION OF APPROVAL
AUTHORIZING TRACER DYES IN SURFACE WATERS

In compliance with the provisions of Part 31, Water Resources Protection, of the Natural Resources and Environmental Protection Act, 1994 PA 451, as amended (NREPA), and Rule 97 (R 323.1097) of the Part 4 Rules, Water Quality Standards, promulgated thereunder, tracer dyes containing certain active ingredients are authorized to be applied to surface waters of the state, directly or indirectly, for the purpose of identifying and eliminating illicit discharges and cross connections, identifying pipeline and tank failures during hydrostatic pressure testing, discharge point location studies, mixing zone mapping, or time-of-passage studies by an entity submitting a complete Notification of Intent under this certification. This certification does not authorize the discharge of tracer dyes for any purposes other than those noted above.

The Notice of Intent and instructions for submittal are available from the Michigan Department of Environment, Great Lakes, and Energy (EGLE) Web site or by contacting Denise Page, Water Toxics Unit, Great Lakes Watersheds Assessment, Restoration, and Management Section, Water Resources Division (WRD), at 517-927-4593 or PageD@Michigan.gov.

The application or discharge of tracer dyes to surface waters of the state is authorized by this certification only under, and contingent upon, full compliance with the following conditions:

1. A complete Notice of Intent is submitted.
2. The extent of the dye plume(s) in waters of the state shall be minimized to the maximum extent practicable.
3. The application of tracer dye(s) shall be conducted in accordance with all pertinent label instructions and additional restrictions identified in this certification.
4. Only the tracer dye(s) containing the active ingredients identified in the Michigan Acceptable Tracer Dye List are authorized under this certification. Upon authorization, the dyes shall only be applied at concentrations resulting in active ingredient concentrations at or below the concentration limit. The active ingredient Chemical Abstract Service (CAS) number and concentration to be used shall also be identified in the applicant's Notification of Intent in order to be authorized.
5. The following agencies shall be notified 48 hours prior to application:
   - Local municipality (city, township, village, etc.).
   - Local county health department.

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Tracer Dyes

- Requests to Use Non-Approved Tracer Dyes?? If you really just cannot live with the currently available color palette:
  - Send request with the following information to EGLE contact listed on website
    1. Product label
    2. Safety data sheets (SDS)
    3. Maximum product dose and use instructions
    4. A list of **all product constituents** and concentrations/percentages of each inclusive of CAS# identifiers
    5. Any available toxicity data for the product

Individual Rule 97 Applications

- Water resource management projects requiring an Individual Rule 97 Certification of Approval include but are not limited to:
  - Application of products to control phosphorus
  - Use of explosives to remove ice dams
  - Application of rotenone for fish removal
    - Yes, but…. (more on this)
  - Use of polyacrylamides to control, flocculate, and settle solids
    - Yes, but…. (more on this)

Individual Rule 97 Applications

- REQUIRED INFORMATION FOR SUBMITTING APPLICATION
  - Applicant name/contact information
  - Description and purpose of the proposed water resource management project
    - A copy of any relevant standard operating procedures should be provided, if available
  - Describe any available water quality data that supports the necessity of the proposed treatment
    - Include whether any water quality parameters will be monitored
    - If so, describe the monitoring regime and parameters to be measured

Individual Rule 97 Applications

- REQUIRED INFORMATION FOR SUBMITTING APPLICATION
  - Geographic location(s) of the specific water body(ies) potentially affected by the proposed project
    - Order of preference: TRS << Address << Lat/Long
  - Name of material(s) to be applied to the water body(ies).
    - A Safety Data Sheet and product manufacturer's label
  - Specific time period when the treatment will occur.
    - It is acceptable for a single request to cover multiple treatment applications scheduled over an extended time period
      - (e.g., ten treatments of water body(ies) planned from April to November with a spacing of three to four weeks between treatments)

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Individual Rule 97 Applications

- REQUIRED INFORMATION FOR SUBMITTING APPLICATION
  - Total load(s) and dosage concentration(s) of the materials to be applied to the water body(ies).
    - If the proposed dosage deviates from dosage recommendations on the manufacturer's label, a brief explanation should be provided.
  - The surface area of the water body(ies) affected by the treatment
  - The name and contact information for the company selling the material to the applicant
  - Lake ownership information, whether public or private. If private, what individual, group, or company has ownership

Individual Rule 97 Applications

- What does EGLE do with all of that required information??
  - Evaluate the both the human health and aquatic toxicity impacts of the proposed project
    - May require reduced dose levels or limitations on surface area of water body that can be treated at one time
  - Determine if additional monitoring is needed based on product type used, any submitted water quality data, and/or water quality data held by EGLE
  - Consider impacts of other or prior Rule 97 applications to targeted water body (if any)

Individual Rule 97 Applications

- Nutrient Reduction
  - Common Products:
    - Phoslock
    - Alum
    - Biochar (new)
    - Eutrosorb G or WC (new)
- Rotenone
  - Invasive species removal
  - However, if application is >80 surface acres, approval is under ANC program

Individual Rule 97 Applications

- Polyacrylamides (PAMS)
  - PAM water treatments are used to flocculate and settle solids before discharge to surface waters.
    - Typical use at construction sites
  - PAM requirements
    - Must contain <0.05 percent acrylamide monomer
    - Must be anionic form
    - No emulsion-based PAMs
  - PAM discharged to surface waters of state (stream, river, drain, lake, etc.) under National Pollutant Discharge Elimination System (NPDES) permit, except Permit-by-Rule: Water Treatment Additive approval is needed
  - PAM discharged or applied to surface water, no NPDES permit in place: Individual Rule 97 Certification of Approval is needed

Toxicology Evaluations

- Whether tracer dye, individual Rule 97 application or bacterial augmentation product, toxicity assessments of chemicals within these products are similar
- Assessment of aquatic toxicity and human health utilizes risk assessment approaches similar to those defined under Rule 57
- Environmental fate of the chemical is also considered (e.g. half-life, partition)
  - Consider what are potential exposures following dosing into surface waters

What are “Rule 57” values?

- Rule 323.1057 of Part 4. Water Quality Standards of the NRPA
  - Water quality values to protect humans, wildlife, and aquatic life
    - These water quality values are applicable to the Great Lakes, the connecting waters, and all other surface waters of the state (unless site-specific values have been derived)

Photo Credit: Mike McCauley winner of the 2022 Water Toxics Unit “Mr. Photogenic” award

What are “Rule 57” values?

Aquatic Life Values

Final Acute Value (FAV)

Final Chronic Value (FCV)

Aquatic Maximum Value (AMV)

Wildlife Values

Wildlife Value (WV)

Human Health Values

Human Noncancer Value (HNV)

-Drinking Water

-Non-drinking Water

Human Cancer Value (HCV)

-Drinking Water

-Non-drinking Water

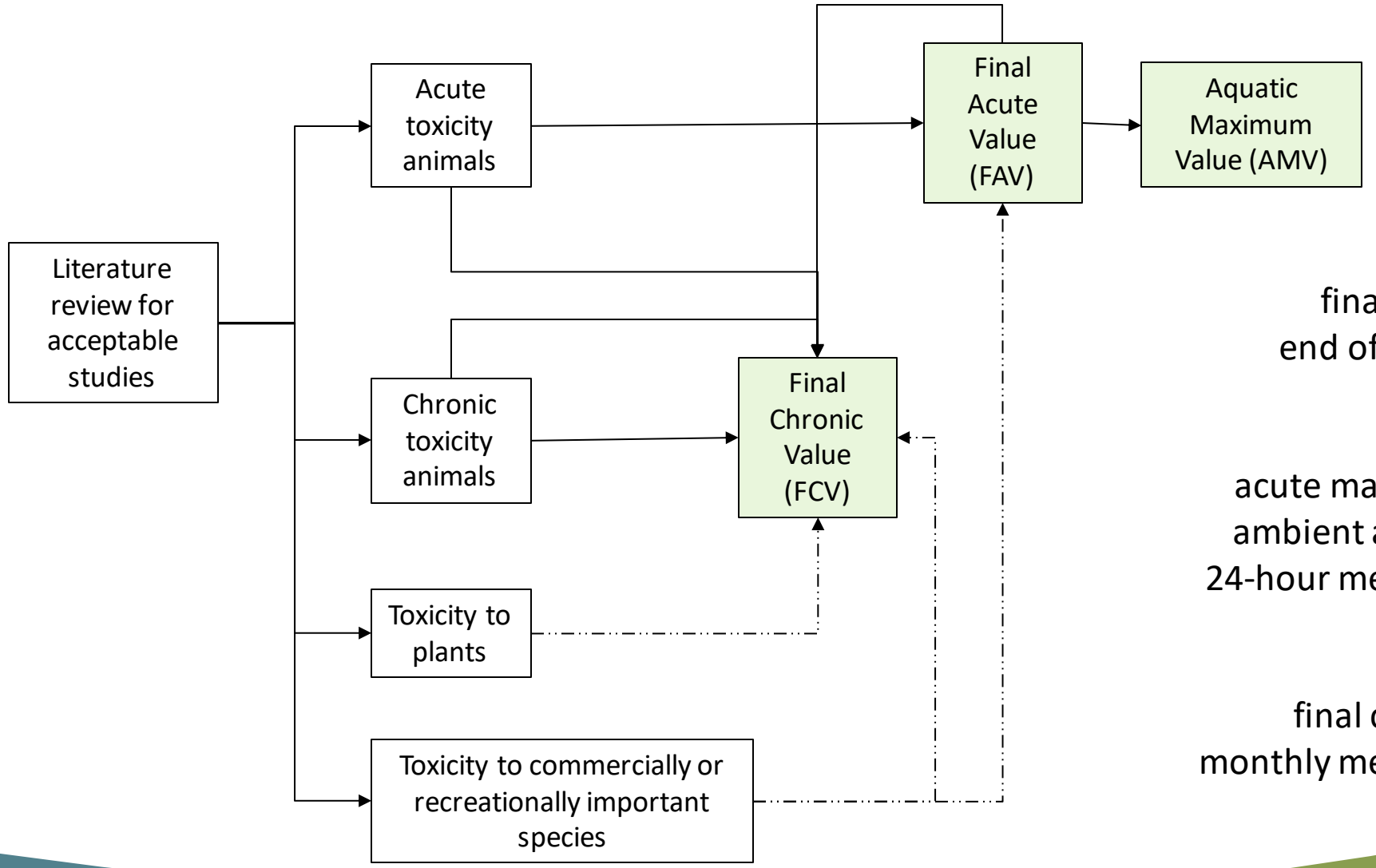
Aquatic Toxicity Values

Final Chronic Value (FCV):
The level of a substance or a mixture of substances that does not allow injurious or debilitating effects in an aquatic organism resulting from repeated long-term exposure to a substance relative to the organism's lifespan

Final Acute Value (FAV):
The level of a chemical or mixture of chemicals that does not allow the mortality or other specified response of aquatic organisms to exceed 50% when exposed for 96 hours, except where a shorter time period is appropriate for certain species.

Aquatic Maximum Value (AMV):
The highest concentration of a material in the ambient water column to which an aquatic community can be exposed briefly without resulting in unacceptable effects. Set equal to one half of the FAV.

Rule 57 Aquatic Life Values Derivation Overview



FAV
final acute value
end of pipe sample

AMV
acute maximum value
ambient acute sample
24-hour mean exposure

FCV
final chronic value
monthly mean exposure

Tier I FAV and AMV

Acceptable acute tests available for each of the following:

i. A Salmonid

ii. Warmwater fish species, class Osteichthyes

iii. A third chordate family

iv. A planktonic crustacean

v. A benthic crustacean

vi. An insect

vii. A family in a phylum other than Arthropoda or Chordata

viii. A family in any order of insect or any phylum not already represented

Tier II FAV and AMV

Acceptable acute tests available for each of the following:

i. Ceriodaphnia sp., daphnia sp., simocephalous sp.

ii. One other species

Example: Tier II FAV Imidacloprid

- Take the most sensitive genus mean acute value (GMAV)
- Assign acute factor based on organism requirements met
- Divide most sensitive GMAV by acute factor
- N. triangulifer
  - Lowest GMAV = 3.11 ug/L
  - Org. req. met = 7
  - Acute factor = 4.3
  - FAV = 3.11 / 4.3 = 0.72 ug/L

Organisms # met	Acute factor
2	13
3	8
4	7
5	6.1
6	5.2
7	4.3

$$Tier\ II\ FAV = \frac{lowest\ GMAV}{acute\ factor}$$

$$Tier\ II\ AMV = \frac{Tier\ II\ FAV}{2}$$

Tier I FCV

Chronic data for each of the 8 organism groups (from previous slide)

OR

Acceptable **acute to chronic ratios (ACR's)** available for each of the following:

i. At least 1 fish

ii. At least 1 invertebrate

iii. At least 1 acutely sensitive freshwater species

Tier II FCV

Tier I FCV requirements not met. Less than three families, use ACR default of 18.

Tier II – Additional data can be submitted which generally increases the water quality value due to less uncertainty

Example: Tier II FCV for Imidacloprid

Species	Endpoint Days	MATC (ug/L)	LC/EC50 (ug/L)	ACR
Midge	Emergence 56	0.13	2.47	2.47/0.13 = **19**
Water flea	Reproduction 21	2164	102000	**47.1**

- Substitute ACR of 18 for missing 3rd study
- Geomean(19, 18, 47.1) = **25.3**
- **Tier II FCV:** FAV/ACR = 0.72/25.3 = **0.029 ug/L**

Human Health Values

Human Noncancer Value (HNV):
The maximum ambient water concentration at which adverse noncancer effects are not likely to occur from lifetime exposure through drinking water, fish, and water-related recreation activities

Human Cancer Value (HCV):
The maximum ambient water concentration at which a lifetime of exposure from either drinking water, fish, and water-related recreation activities will represent an extra risk of contracting cancer of 1 in 100,000

Drinking Water or Non-Drinking Water Values?

"Drinking Water" HNVs and HCVs are relevant for surface waters designated and protected as public water supply sources (The Great Lakes and Connecting Channels and other surface waters within 3000 feet of a point of water intake). Calculated using an assumed water consumption of 2 liters per day.

"Non-Drinking" values are calculated using an assumed incidental ingestion of 0.01 liters per day

Photo Credit: Mike McCauley winner of the 2022 Water Toxics Unit "Mr. Photogenic" award

Human Health Value Development Steps

Need exists for new or updated criteria

Literature Search

Carcinogenicity Assessment

Bioaccumulation Factors
Risk Associated Dose
- Human Equivalent Dose
- Cancer Slope Factor

Human Cancer Value

Human Noncancer Value

Acceptable Daily Exposure
- Uncertainty Factors

Bioaccumulation Factors

Quality Review Tier I/II

Derive Criteria

Photo Credit: Mike McCauley winner of the 2022 Water Toxics Unit "Mr. Photogenic" award

Human Non-Cancer Value vs. Human Cancer Value

$$HNV = \frac{ADE \times BW \times RSC}{WC + [(FC_{TL3} \times BAF_3) + (FC_{TL4} \times BAF_4)]}$$

ADE = acceptable daily exposure (mg/kg-day) from key study

$$HCV = \frac{RAD \times BW}{WC + [(FC_{TL3} \times BAF_3) + (FC_{TL4} \times BAF_4)]}$$

RAD = risk associated dose (mg/kg-day) set at excess cancer risk of 1 in 100,000

HNV or HCV Derivation: Consumption

$$WC + [(FC_{TL3} \times BAF_3) + (FC_{TL4} \times BAF_4)]$$

BAF = Human Health Bioaccumulation Factor for edible portion (L/kg)

- Compound specific information is utilized
- Is the compound lipophilic (compound concentration can be related to the amount of fat in fish)?
- Does the compound bio-magnify (concentrations within fish increase up the food chain)?

Guidance and preferred approaches for BAF development are promulgated within Rule 57

Fish Consumption: bioaccumulation factors

Our rules give us guidance on BAF development:

Most Preferred =	Field measured
	Predicted from a field measured biota-sediment accumulation factor (BSAF)
	Predicted from a laboratory measured bioconcentration factor (BCF) and a food chain multiplier (FCM)
Least Preferred =	Predicted from an octanol-water partition coefficient (Kow) and a FCM

Photo Credit: Mike McCauley winner of the 2022 Water Toxics Unit "Mr. Photogenic" award

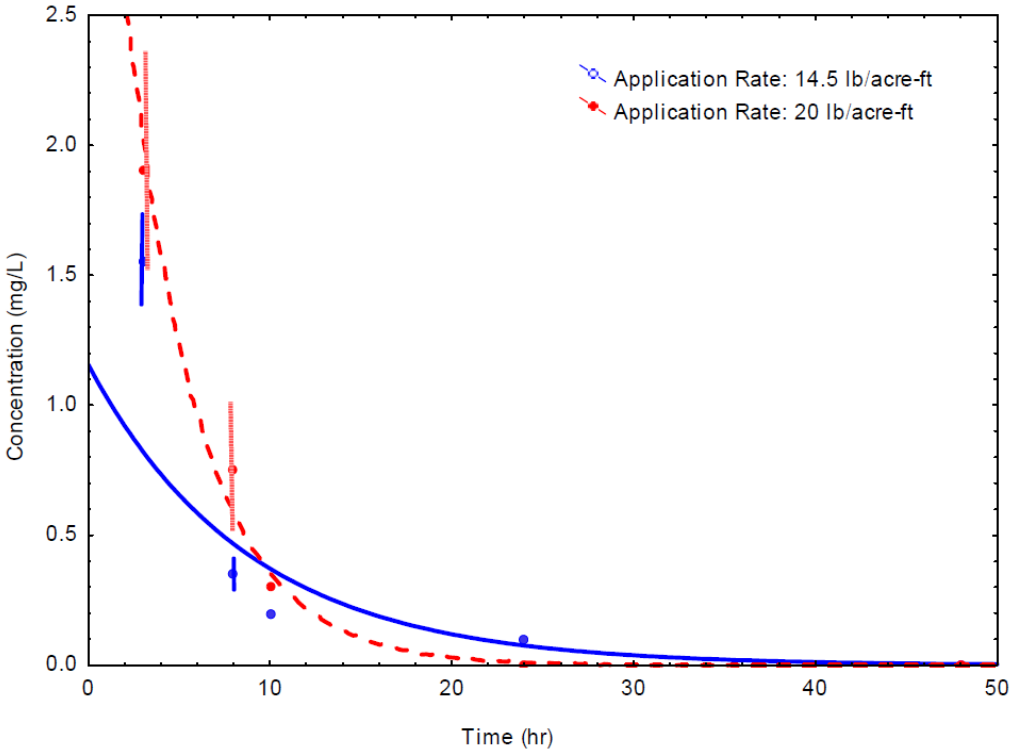
Perfluorohexane Sulfonate (PFHxS)	
Human Health Water Quality Values	**59 ng/L (drinking)** **210 ng/L (non-drinking)**
Key Study	NTP (2019), 28-day gavage study in Sprague Dawley rats administered PFHxSK
Critical Effect	Decreased serum total thyroxine (T_4) in Sprague-Dawley rats with a resulting **$BMDL_{20}$ of 32.4 mg/kg-day**
Toxicokinetic Parameters	Human equivalent dose adjustment based on human elimination half-life (V_d = 0.25, human $T_{1/2}$ = 1935 days) **HED-$BMDL_{20}$ of 0.00292 mg/kg-day**
Uncertainty Factors	**1000x** (3x Interspecies, 10x Intraspecies, 10x Duration, 3x Database)
ADE	**0.0000029 mg/kg-day**
BAF Values	**Trophic 3 = 32 L/kg** **Trophic 4 = 59 L/kg**

EGLE

Environmental Fate

- Three primary factors:
  - Partitioning
    - Based on physical/chemical properties
    - Does it tend to accumulate in water, soil, or volatile?
  - Transport
    - Mobility of the chemical in the environment
  - Half-Life/Transformation
    - How long does it persist?

Time Decay of Hydrogen Peroxide Concentrations Applied to Water. Vertical Lines Represent Range of Reported Values. Fitted Lines are Exponential Decay Curves.



Other Considerations

- Presence of endangered species?
- Water chemistry parameters (when available)
  - May enhance or reduce effect of treatment/toxicity
- Any relevant treatment history

Rule 97 Summary

- Rule 97: “application of materials for water resources management”
  - Broad definition
- Predominant types of Rule 97 projects
  - Bacterial Augmentation Products
  - Tracer Dyes
  - Individual Certifications (nutrient reduction, invasive species, etc)
- Please ensure completeness of applications when submitting
- Evaluation of novel chemicals/products includes, but not limited to, toxicity assessment and environmental fate

Questions?


thank you
danke
謝謝
merci
gracias
obrigado
dziękuję
bedankt
sukriya
kop khun krap
go raibh maith agat
teşekkür ederim
ngiyabonga
спасибо
dank je
tapadh leat
mochchakkeram
terima kasih
dakujem
grazie
arigatô
takk
merci
рахмат
Баярлалаа
faafetai lava
vinaka
спасибі
blagodaram
misaotra
matondo
paldies
grazzi
mahalo
хвала
asante
manana
obrigada
tenki
chokrane
murakoze
mamnun
дякую
djiere dieuf
tau
enkosi
bayarlalaa
grâçie
hvala
mauruuru
köszönöm
akun
dankon
ačiū
nanni
nandri
kiitos
dankie
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sobodi
děkuji
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sagolun
didi madloba
najis tuke
kam sah hamnida
rahmat
তোমাকে ধন্যবাদ
감사합니다
xièxie
ありがとう
tanemirt
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shukriya
merci
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trugarez
chnorakaloutioun
gratias ago
gràcies
sulpáy
taiku
spas
welalin
tack
barka
mersi
kia ora
ευχαριστώ

Toxicology Definitions

Exposure pathway – route by which an organism comes into contact with a hazardous substance [ingestion (soil or water), inhalation, adsorption]

Endpoint – observed and measurable effect (survival, immobility, reproduction, growth, emergence, etc.)

Acute – short-term adverse effects (≤96-hr tox studies; 24-hr for WQS)

Chronic – long-term (≥7 day) adverse effects

LC50 – lethal concentration at which 50% of organisms die

EC50 – effect concentration at which 50% of organisms are immobile or die

Nominal – in toxicity test, chemical concentrations are only measured at the beginning of a test

Geometric mean – average calculated as $\sqrt[n]{x_1 x_2 x_3 .. xn}$

Acceptable Daily Exposure

$$ADE\left(\frac{mg}{kg * day}\right) = \frac{Key\ Study\ NOAEL\ (or\ LOAEL)}{\sum Uncertainty\ Factor\ (UF)}$$

UF_A = Across species (1 to 10)

UF_H = Sensitive humans (1 to 10)

UF_S = Subchronic to chronic (1 to 10)

UF_A = Acute to subchronic (1 to 3)

UF_L = LOAEL to NOAEL (1 to 10)

UF_D = Database (1 to 10)

Risk Associated Dose

$$RAD\left(^{mg}/_{kg}/_{d}\right) = \frac{Risk\ Factor}{Slope\ Factor\ (q1^*)}$$

$$Risk\ Factor = 10^{-5}$$

- 1 person out of 100,000 will develop cancer

$q1^*$= slope factor (mg/kg/d)

- Examines incidences of cancer
- Calculated with a benchmark dose model
- Doses are adjusted with a species scaling factor
- Looks for extra risk of cancer development