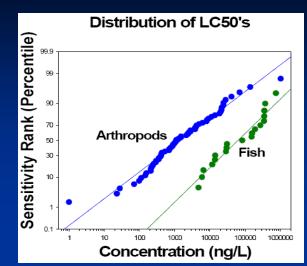
Methods for Developing Community Level Benchmarks For Aquatic Animals

EPA Development Team

Regional Stakeholder Meetings January 11-22, 2010

Outline

- Purpose and Scope
- Potential uses



- **OW and OPP Effects Assessment Approaches**
- Possible approaches for estimating community level benchmarks
- White paper development
 Key research questions/issues
 Evaluation of derivation methods

White Paper Purpose and Scope

- Describe the best integrated use of existing tools for deriving aquatic community-level benchmarks for the protection of aquatic animals.
 - Development of community-level benchmarks with smaller data sets than those currently used to derive AWQC.
- Consider existing approaches used by OW and OPP for characterizing aquatic ecological effects
- Characterize the uncertainty of benchmarks developed for a given approach.

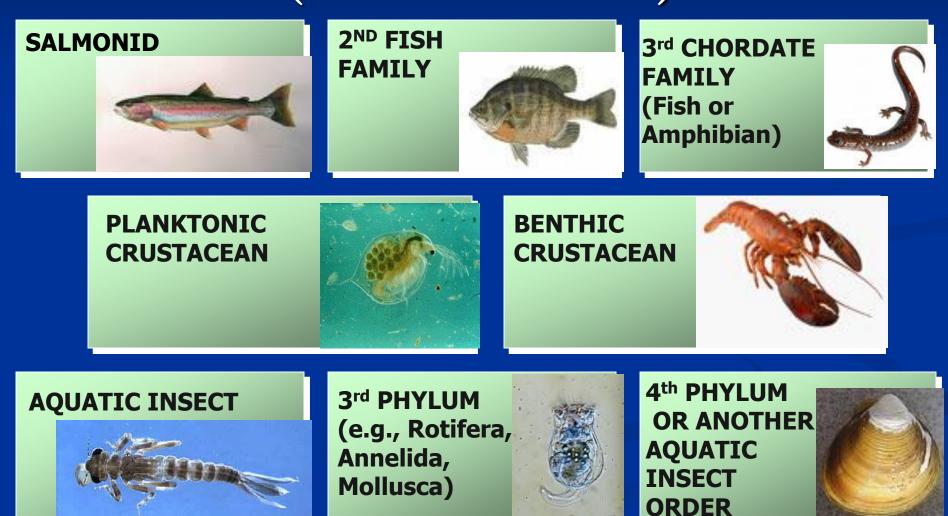
Potential Uses of Community-Level Benchmarks

- **1.** Evaluating water quality monitoring data
- 2. Prioritizing the development of ambient water quality criteria for pesticides
- 3. Informing 305b or 303d assessment and listing decisions
- 4. Developing State/Tribal water quality standards and or NPDES permit limits
- 5. Providing additional characterization of OPP taxaspecific toxicological benchmarks
- 6. Improve the consistency and transparency of ecological effects assessments conducted under FIFRA and the CWA

Developing Aquatic Life Criteria (OW)

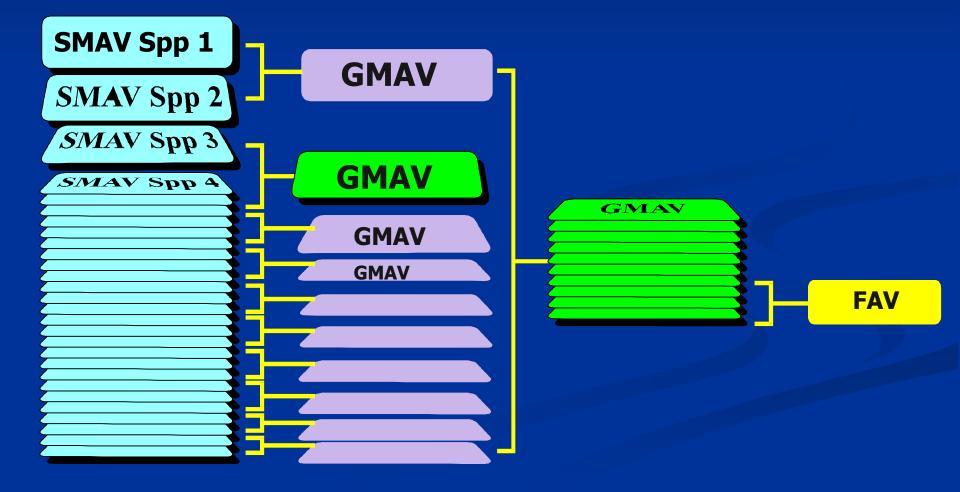
- **1.** Criteria are developed based on national priority
- 2. Addresses acute and chronic effects endpoints: survival, growth, reproduction, development
- 3. Requires a minimum number of data for different animal taxa
 - 8 families (freshwater acute criterion)
 - 3 families (freshwater chronic criterion)
- 4. Specifies toxicity test acceptability and quality criteria
- 5. Designed to be protective of vast majority of aquatic animal species (i.e., 5th percentile of tested aquatic animals).

OW Data Requirements for Aquatic Life Quality Criteria (Freshwater Acute)

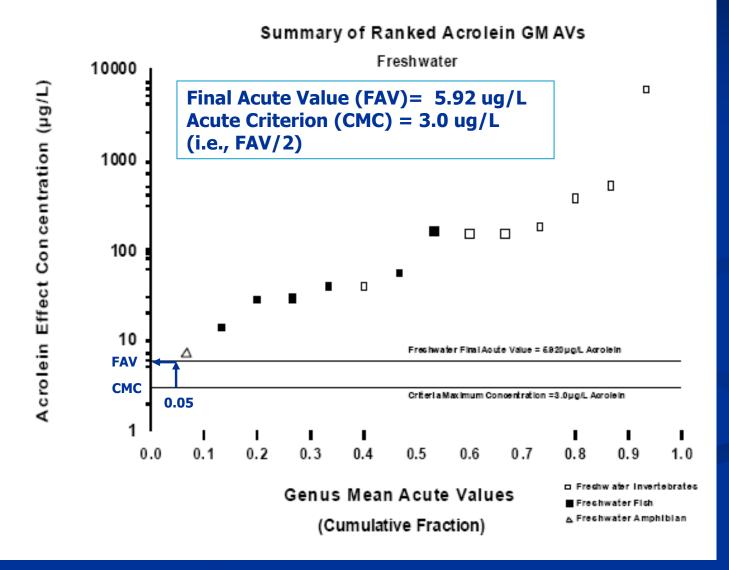


Developing OW Aquatic Life Criteria

SPECIES - LEVEL GENUS-LEVEL



OW Acute Species Sensitivity Distribution: Acrolein (USEPA 2009)



Additional Considerations for Aquatic Life Criteria Development

- Similar saltwater-specific family level taxonomic requirements for derivation of acute saltwater criteria.
- Derivation of chronic criteria (CCC)– relies mostly on estimation through acute to chronic ratios (ACR)
 - Minimum of three families must have fish ACR, invertebrate ACR, and one ACR from acutely sensitive FW taxa
 - For FW chronic derivation 2/3 ACRs can be SW, and vice-versa
- Aquatic plants: at least one acceptable test with algae/vascular plant; if plants are most sensitive, then additional tests on another phylum/division should be available

Developing an Ecological Effects Assessment for Pesticide Registration

- 1. Developed for each registration decision (new pesticide, new use [national or local], re-evaluation of existing use).
- 2. Addresses acute and chronic effects endpoints: survival, growth, reproduction, development
- **3.** Requires data for different taxonomic groups of aquatic animals (fish, invertebrates) depending on use
 - 3 families (freshwater acute animals, outdoor use)
 - 2 families (freshwater chronic animals, outdoor use)
- 4. Specifies toxicity test acceptability and quality criteria
- 5. Designed to be protective of vast majority of aquatic animal species (i.e., most sensitive tested aquatic animal).

FIFRA Data Requirements For Outdoor Use (Freshwater animals)

Acute Toxicity:



Cold-water fish



Warm-water fish



Invertebrate

Chronic Toxicity:



Fish (warm- or coldwater)



Invertebrate

Conditionally Required:

Sediment toxicity, Bioaccumulation, Field studies

FIFRA Ecological Effects Assessment: Additional Considerations

Estuarine/Marine Acute Toxicity:

- Acute: 1 fish and 2 invertebrates are required
- Chronic: 1 fish and 1 invertebrate conditionally required
- Aquatic Plants: Specific nonvascular and vascular plant requirements
 - Green algae; blue-green/cyanobacteria; freshwater and marine diatoms; duckweed
- Acute-Chronic Ratios: commonly used to address lack of chronic data for the most acutely sensitive species
- Other Data: Specific data can be requested to address potential effects of concern, for example:
 - UV light-dependent herbicide toxicity to early life-stage fish
 - Dietary bioavailability/toxicity to fish

FIFRA Aquatic Life Benchmarks (Freshwater)

- Based on the most sensitive toxicity test result within each taxonomic group
 - Fish
 - Invertebrates

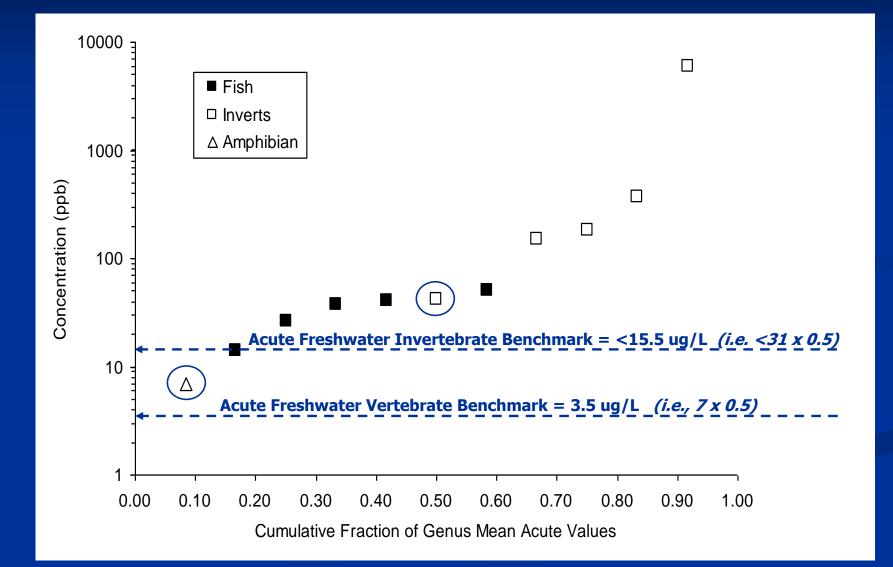
- Nonvascular plants
- Vascular plants
- Toxicity data from public literature are considered

FIFRA Aquatic Life Benchmark Derivation:

- Acute Freshwater Vertebrate and Invertebrate: = most sensitive toxicity value x Level of Concern (e.g., 96-hr LC₅₀ x 0.5)
- Chronic Freshwater Vertebrate and Invertebrate: = most sensitive toxicity value x Level of Concern (e.g., NOAEC x 1.0)

 Aquatic Plants (vascular, nonvascular): = most sensitive toxicity value x level of concern (e.g., EC₅₀ x 1.0) <u>http://www.epa.gov/oppefed1/ecorisk_ders/aquatic_life_benchmark.htm</u> <u>#introduction</u>

OPP Aquatic Animal Sensitivity Distribution For Acrolein (USEPA 2008)



Top 5 similarities in OW and OPP Effects Assessment Methods

- Use all available reliable aquatic toxicity data, including data from public literature
- Peer review data, with transparent data quality standards
- Use same assessment endpoints (survival, growth, reproduction, development)
- Use ACRs to estimate chronic value
- Effects assessment focuses on sensitive aquatic species
 - OW: Using 5th percentile of a species sensitivity distribution
 - OPP: Using most sensitive species in a taxonomic group

Top 5 differences in OW and OPP Effects Assessment Methods

OW	OPP
One toxicity value integrates results from different taxonomic groups	Multiple toxicity values representing different taxonomic groups
Based on 5 th percentile of species- sensitivity distribution	Based on most sensitive species tested within taxonomic groups
Individual toxicity values are averaged within a taxonomic group (e.g. genus)	Lowest toxicity value is used within a taxonomic group (e.g., fish, invert.)
Acute freshwater: 8 animal families	Acute freshwater ^(*) : 3 animal families
Plants: 1 family	Plants ^(*) : 5 families
Effects assessment (Criteria) developed according to national priority	Effects assessment developed for all registration actions

Some Potential Approaches for Developing Community-Level Benchmarks

Extrapolation Factors

- Dependence on data set size (Host et al, 1995 [GLI Tier II])
- With and without consideration of Mode of Action (MOA) (e.g., DeZwart et al 2002; Pennington et al 2003)
- Predictive Methods for Expanding Data Set Sizes
 - Quantitative Structure Activity Relationships (QSAR)
 - Interspecies Correlation Estimations (ICE)
 - Read Across/Data Bridging/Chemical Category & Analogue Approaches
 - Acute to Chronic Ratios (Chronic Only)

Integrative Application of the Above Methods

TenBrook et al. 2009; Intrinsik 2008

General Approach for White Paper Development

- 1. Scoping, literature review, defining key research questions/issues
- 2. Selection and screening of toxicological databases
- **3.** Review and application of available methods
- 4. Evaluation of method performance
- 5. Development and testing of framework for integrated application of methods

Some Key Research Questions

- **1.** How do sensitivity distributions and associated extrapolation factors vary?
 - Across different modes of action
 - For different data set sizes
 - With presence/absence of certain taxa (e.g., *Daphnia*)
 - By type of statistical distribution (e.g. log triangular, lognormal, log-logistic)
- 2. How do extrapolation factors vary with the choice of percentile (e.g., 1st, 5th, 10th) and desired accuracy?
- **3.** How do the benchmarks and their associated uncertainty vary among different derivation methods?
 - Under what circumstances does use of predicted values tend to reduce uncertainty in benchmark derivation?

Additional Considerations for Evaluating Community-Level Benchmark Methods

- Selection of toxicological databases for method development and evaluation will be guided by existing practice within the Agency
- 2. Input from Predictive Tools workgroup for generating predicted values will be crucial
 - Scientific basis
 - **Domain**
 - Performance (uncertainty)
- **3.** Expect strengths and limitations of methods for benchmark derivation to vary depending on available data
- 4. Envision an integrative approach for applying available tools
 - Can strengths of differing tools be combined and leveraged to produce scientifically defensible results?

Summary

- 1. Through this White Paper, the Agency (OW, OPP, ORD) is exploring a variety of methods for making better (and more consistent) use of toxicity data from smaller data sets in the context of effects assessment with aquatic animals.
- 2. It appears that no one method will be best suited to address all situations, and that an integrated framework of methods may be needed.
- 3. Methods developed through this White Paper are expected to supplement existing effects assessment methods for aquatic animals within OW and OPP.

References

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