



# Water Quality Criteria for Emerging Contaminants

Water Quality Criteria Derivation Issues

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# Outline

- Introduce efforts & process – timeline, players, etc.
- Review of Current WQC Derivation Methodology
- Detailed review of criteria issues
- Ethynylestradiol Case Study (discussion placeholder)
- 2005 SAB Consultation Issues addressed
- Proposed timeline

# Efforts to Date

- October 2006 Congressional Hearing on Potomac River intersex bass sparked efforts in OW.
- Workgroup formed in April 2007 to investigate criteria derivation issues for emerging contaminants.
  - Consists of ORD EDC technical experts, ORD criteria development experts, and OST scientists/policy experts
  - “Streamlined” Guidelines Revision effort due to OW priority
- Workgroup developing “white paper” to inform OST management of issues and assist in decision-making process.

# 1985 Guidelines Methodology Review

# Minimum Dataset for Freshwater Acute Criteria Derivation – 1985 Guidelines Method

**SALMONID**



**SECOND  
FISH  
FAMILY**



**CHORDATA**



**PLANKTONIC  
CRUSTACEAN**



**BENTHIC  
CRUSTACEAN**



**INSECT**



**ROTIFERA,  
ANNELIDA,  
MOLLUSCA**



**OTHER  
INSECT OR  
MOLLUSCA**



# Rationale for Criteria MDR

- 1985 Guidelines assume nothing about the chemical, mechanism of action, or distribution of taxonomic sensitivity across aquatic communities
- The eight taxa in the MDRs represent the minimum sufficient taxonomic “spread”
- When  $\geq 8$  taxa are available, there are no specific taxonomic distribution requirements
- When MDRs are not met, no criterion can be derived
  - addresses consistency in minimum “certainty” and provides reasonable confidence that it is a good estimate

# Acute Criteria Calculation (CMC)

- Step 1. Calculate Species Mean Acute Values (SMAVs)**
  - geometric mean of all acceptable acute values for species
- Step 2. Calculate Genus Mean Acute Values**
  - geometric mean of all SMAVs for genus
- Step 3. Rank Genus Mean Acute Values**
  - from most sensitive (#1) to least sensitive (n)
- Step 4. Calculate Final Acute Value Using 4 Lowest GMAVs**
- Step 5. Divide Final Acute Value by 2 to derive Continuous Maximum Concentration (CMC)**

# Derivation of Chronic Criteria (CCC)

- If  $\geq 8$  chronic tests are available (Rare):
  - Use same methodology (regression analysis) as in acute criteria derivation
- The estimated 5<sup>th</sup> percentile GMCV is the Final Chronic Value (FCV)
- If  $\geq 3 < 8$  chronic tests are available
  - Calculate acute to chronic ratio for each acute-chronic test pair (by species)
  - Divide Final Acute Value (FAV) by ACR to get Final Chronic Value FCV<sub>8</sub>

# Criteria Derivation Issues

- EC Characteristics Identified by the Workgroup (EDCs as an example)
  - Lack of “Environmentally Relevant” Acute Toxicity
  - Disparity in taxa sensitivity to EDC mechanisms of action
  - Diversity of endpoints affected
  - Use of Non-native taxa
- Criteria development procedures (1985 Guidelines) needs to be interpreted and adapted to accommodate these (and potentially others currently unidentified) criteria derivation issues.

# Environmental Concentrations: Lack of Acute Toxicity

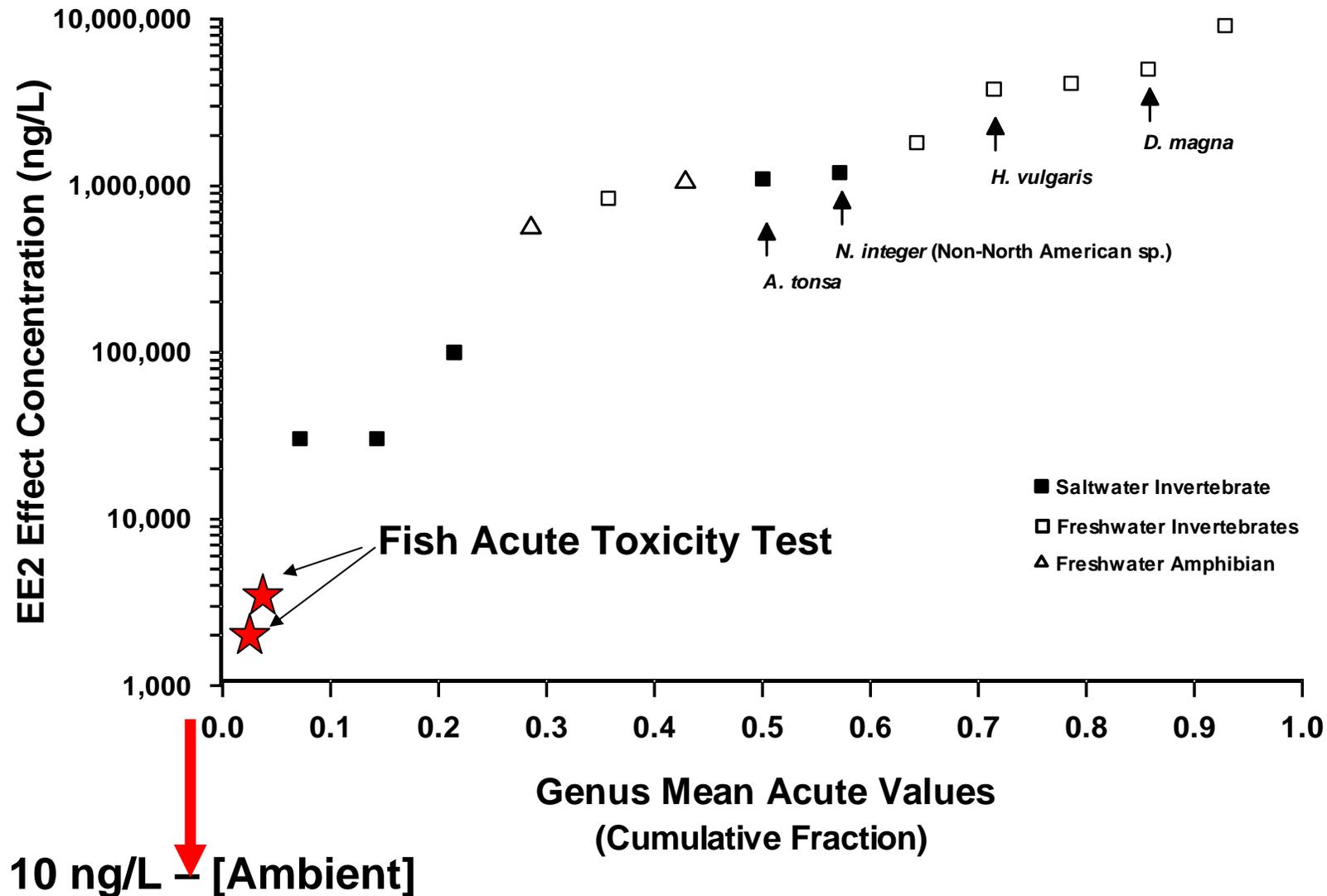
- Many emerging contaminants of current interest are in the class of “PPCPs – pharmaceuticals and personal care products”.
- These compounds (especially most pharmaceuticals) are designed to minimize or eliminate (goal) toxicity to user.
- Compounds have highly specific modes of action, act at receptor site at very low concentrations.
- Most environmental exposure through end user – patient excretion and/or use/disposal.

# Example: 17 $\alpha$ Ethynylestradiol

- Ecologically relevant EE2 concentrations
  - Europe - EE2 has been observed in effluents and surface waters at concentrations between 0.5 and 7 **ng/L** (Desbrow et al. 1998; Larsson et al. 1999; Ternes et al. 1999)
  - A recent study of 139 streams in the United States found that **5.7%** had concentrations > **5 ng/L** (Kolpin et al. 2002a).

# EE2 Effects: Comparison of Acute Toxicity

## Summary of Ranked EE2 GMAVs- All Data



# Acute to Chronic Ratios for Selected Pharmaceuticals

Compound	Animal	Acute LC50 <sup>a</sup> (µg/L)	Chronic NOEC <sup>a</sup> (µg/L)	Chronic LOEC <sup>a</sup> (µg/L)	ACR (LC50/NOEC)	Reference
Diethylstilbestrol	Copepod	>100 (48 h)	10 (21 d)	100 (21 d)	>10	Hutchinson et al. (1999)
	Copepod	290 (96 h)	3 (18 d)	30 (18 d)	97	Breitholz and Bengtsson (2001)
	Daphnid	1200 (48 h)	500 (21 d)	-----	2.4	Baldwin et al. (1995)
	<b>Fish</b>	<b>1400</b> (96 h)	<b>0.01</b> (42 d)	0.032 (42 d)	<b>140 000</b>	Hutchinson et al. (2003b)
Estradiol	Copepod	1600 (96 h)	160 (18 d)	>160 (18 d)	10	Breitholz and Bengtsson (2001)
	<b>Fish</b>	<b>3900</b> (69 h)	<b>0.01</b> (42 d)	0.032 (42 d)	<b>390 000</b>	Hutchinson et al. (2003b)
<b>Ethinylestradiol</b>	Copepod	510 (96 h)	50 (18 d)	>50 (18 d)	10.2	Breitholz and Bengtsson (2001)
	Daphnid	6400 (48 h)	387 (21 d)	>387 (21 d)	16.5	Schweinfurth et al. (1996)
	<b>Fish</b>	<b>1500</b> (96 h)	<b>0.01</b> (42 d)	0.032 (42 d)	<b>150 000</b>	Hutchinson et al. (2003b)
Ibuprofen	Mollusc	17 100 (96 h)	1020 (21 d)	2430 (21 d)	16.8	Pounds et al. (2004)
Propranolol	Amphipod	29 800 (48 h)	500 (27 d)	>500 (27 d)	59.6	Huggett et al. (2002)
	Daphnid	800 (48 h)	1 (7 d)	100 (7 d)	800	Huggett et al. (2002)
	<b>Fish</b>	<b>24 300</b> (48 h)	<0.5 (28 d)	<b>0.5</b> (28 d)	<b>&gt;48 600</b>	Huggett et al. (2002)

# The ACR as an Indicator (Signpost)

- Large ACRs do not make the ACR invalid, but identifies the acute criteria threshold as a moot measurement endpoint.
- It indicates that potential mechanisms of acute and chronic toxicity are different.
  - Existing examples: Se, Hg, TBT
  - Test:  $ACR > 10-100$  consider only chronic data?

**Can we derive “Chronic-Only” WQC?**

# Derivation of Chronic Criteria

- If  $\geq 8$  chronic tests are available (Rare):
  - Use same methodology (regression analysis) as in acute criteria derivation
- The estimated 5<sup>th</sup> percentile GMCV is the Final Chronic Value (FCV)
- If  $\geq 3 < 8$  chronic tests are available
  - Calculate acute to chronic ratio for each acute-chronic test pair (by species)
  - Divide Final Acute Value (FAV) by ACR to get Final Chronic Value FCV

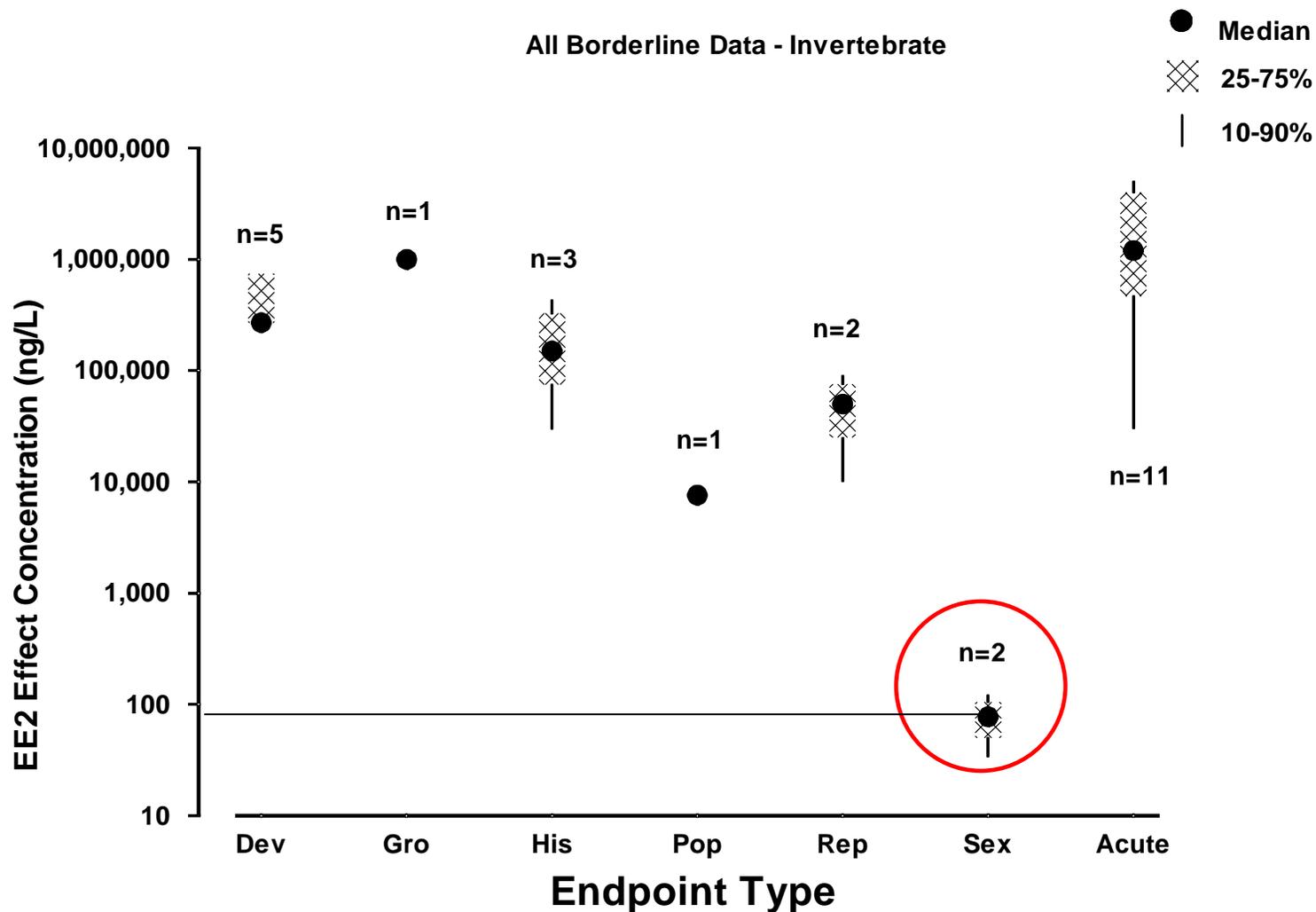
# What are the Options?

- Lack of acute toxicity at environmentally relevant concentrations may obviate the need for WQC to protect against acute effects.
  - If acute criteria are not necessary (as may be the case for many pharmaceuticals), what are the options for a “chronic –only” criteria?
    - If minimum MDRs are met ( $\geq 8$  taxa) for chronic tests, use 1985 Guidelines method – **very rare – EC exception is EE2** - Next Slide
    - If MDRs are not met, chronic criteria cannot be calculated
      - Final Acute Value is not available
      - Acute to Chronic Ratio may not be available for at least 3 taxa
      - Acute to Chronic Ratio not a valid method for calculation of chronic criteria
- If the need for acute criteria is moot; what additional knowledge, data and information is available to allow us to interpret and adapt the 1985 Guidelines to address criteria derivation for emerging contaminants?
  - Chemical potency, mode of action, other characteristics?

# Criteria Derivation Issues

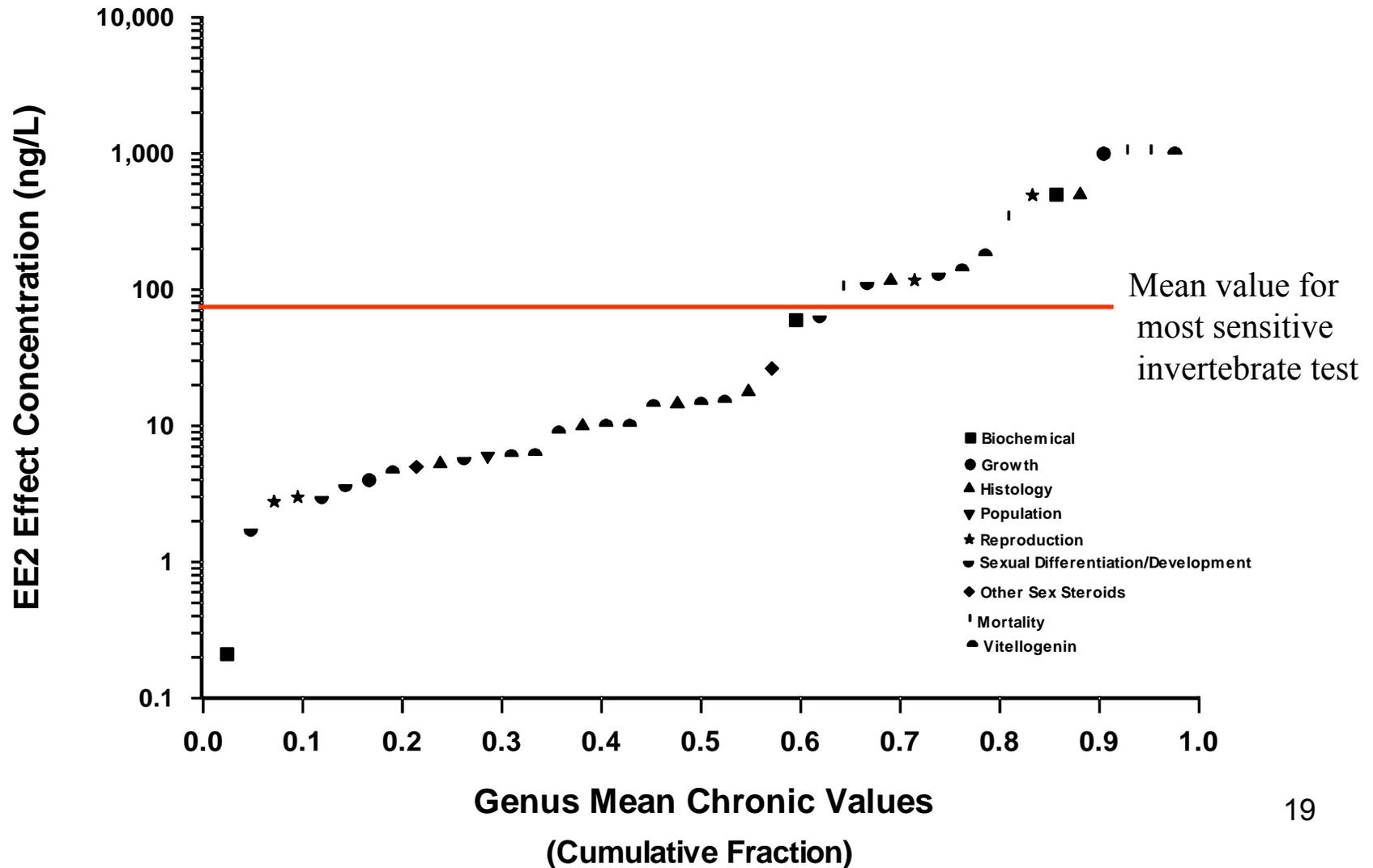
1. Disparity in taxa sensitivity to MOA

# Comparison of EE2 Test Endpoints Using Borderline and Defensible Data for Invertebrates



# Distribution of EE2 Chronic Data by Endpoint: Defensible Data

Cumulative Distribution of EE2 Chronic Effects for Fish  
- Defensible



# Options: Addressing Taxonomic Sensitivity to Mechanism of Action

- If MOA and Potency are well characterized, what level of biological organization is needed to be affected?
  - Test: what organisms can be excluded from concern because of lack of pertinent biological systems?
  - Tools: Can SSD's be used to screen for and exclude insensitive taxa, and would be protected by default? (ie invertebrates and EE2)
  - When plants are most sensitive, how do we proceed with criteria derivation?
    - Final Plant Value?
    - Regression Analysis? Approach similar to 1985 Guidelines, but limited data
    - Plant community response? (ie Atrazine CASM) –"Cadillac" Approach

## 2. Diversity of Endpoints Affected

# Acceptable Chronic Data (Endpoints) (1985 Guidelines - pp 37-39)

## 1. Life Cycle Tests –

- ~48 hrs old → >24 d post F1
- Endpoint data – survival/growth of adults/young, maturation of males and females, eggs spawned per female, embryo viability (salmonids only), hatchability of F1.

## 2. Partial Life Cycle Tests

- immature juveniles > 2 months prior to GD → >24 d post F1
- Same endpoints as above

## 3. Early Life Stage Tests

- Post fertilization → early juvenile development
- Typically used as predictions of outcomes for life-cycle and partial life-cycle tests with the same species.

# Endpoints not traditionally used for WQC: Overview and Possible Roles

- Organizational Events - occur during sexual differentiation/gonad development; usually not reversible
  - Phenotypic sex not aligned with genotypic sex
  - Gonadal (histological) abnormalities (intersex/ovatestis)
- Activational Events - occur later in life (adults) often during active reproduction; can be reversible
  - Morphological changes (SSC)
  - Abnormal gonadal staging (histology)
  - Biochemical alterations (e.g., vtg induction)

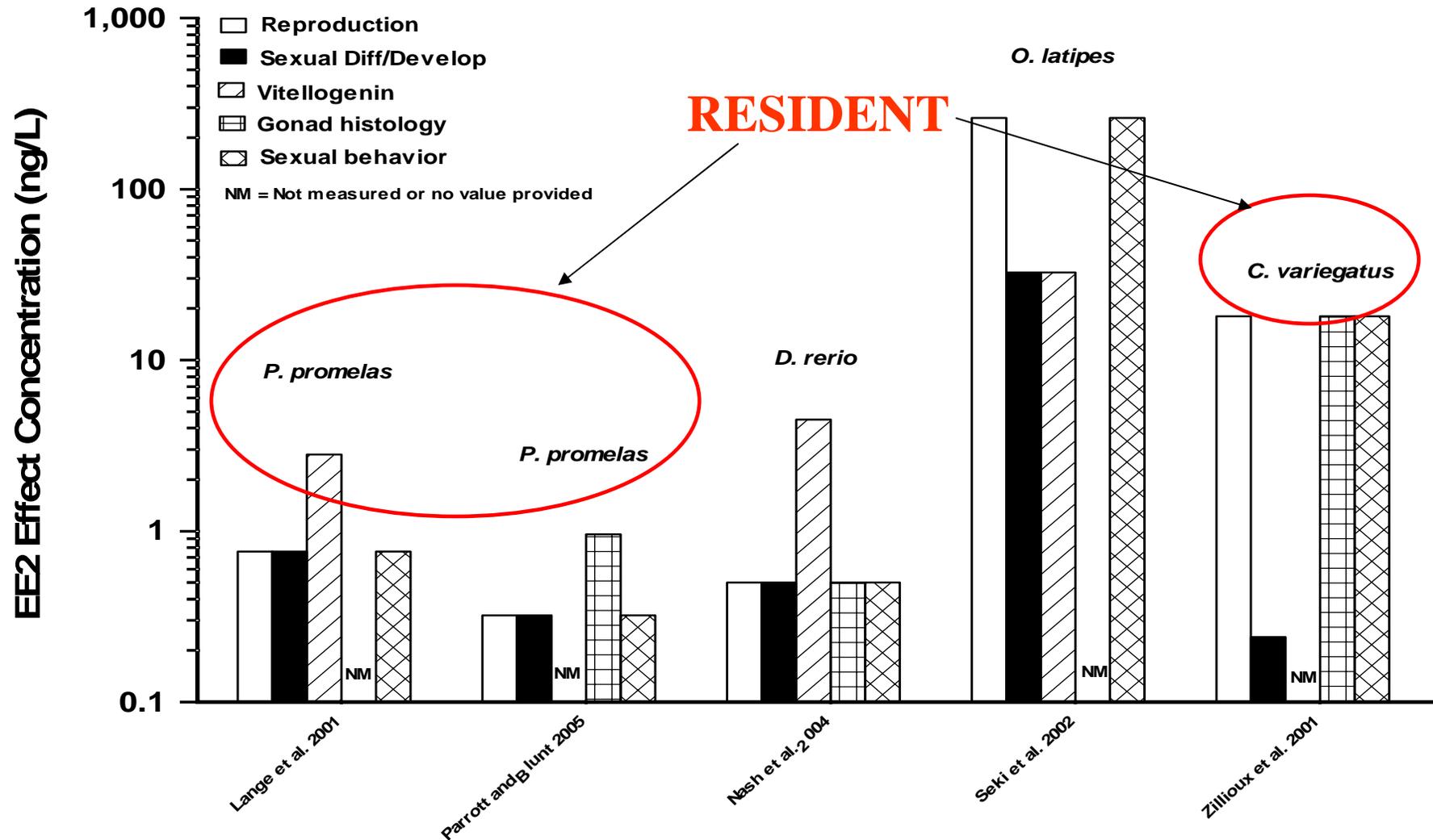
# Roles for Non-Traditional Endpoints

- Screening: as MOA “triggers” to define appropriate tests and endpoints
  - Species sensitivity to chemical’s MOA
  - May help to define windows of sensitivity (e.g., development/reproduction)
- Possibly as a basis for quantitative assessments of risk
  - When the endpoint reflect **both** MOA *and* adverse outcome(s)
  - This requires detailed knowledge of the toxicity pathway of concern

# Use of Non-Resident Species

- The 1985 Guidelines is explicit (page 22) on how data obtained with non-resident species may be used
  - Provide auxiliary information **only**.
  - Policy Decision – not based on scientific understanding
- In this context, nonresident species are not excluded if used in a contextual nature to define important exposure windows, endpoints, relative potency, etc.
- Proposal: Sound science should be used to discriminate when to use nonresident species.
  - Directly include data if
    - there is no reason to believe that native species would not show similar sensitivity
    - have the potential to substantively influence the criterion calculation<sup>25</sup>

# Comparison of Common Test Endpoints between and among Fish Species



# EE2 Case Study

- What is EE2; what is the basis for concern
- Available Data
- Interpretation of key studies
- Use of Data in development of risk-based thresholds

# SAB Concerns Addressed

- Several Key concerns identified in the 2005 Guidelines Revisions Consultation
  - Addressing emerging contaminants
  - Addressing endocrine disrupters
  - Addressing use of sublethal & nontraditional endpoints
  - Problem Formulation
- These efforts may lead to revisions within the context of the Guidelines that address these concerns.

# Schedule Going Forward:

## Timelines, Decision Points and Deliverables

- December 2007
  - White Paper Framework Briefing
  - Management Decision to move forward with further work on derivation methodology for WQC
- January 2008 – May 2008
  - Incremental refinements of white paper & case study
  - SAB Preparation & SAB Briefing
- May 2008 Forward
  - Address SAB comments from consultation/advisory
  - Possible initiation of development & review of draft internal criteria (EE2; trenbolone?) – internal and external review schedules TBD based on strategic planning process
  - Initiate incorporation of white paper framework and EE2 case study into Guidelines Revisions Process

# Contact Information

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