

# EPA Office of Water Effort to Address Contaminants of Emerging Concern

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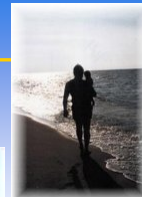
SWiMS 8<sup>th</sup> Annual Meeting  
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*...to protect human health and the environment*

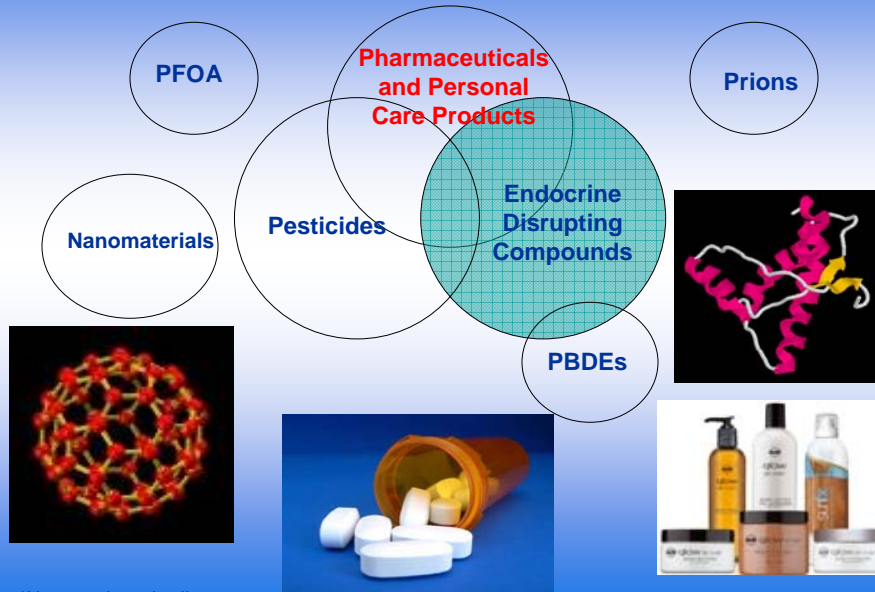
## Overview

- Contaminants of emerging concern
- Reason for concern
- EPA's four-pronged strategy
- Unique challenges ahead



*...to protect human health and the environment*

## *Contaminants of Emerging Concern in Water\**



\*Not an exhaustive list.

## *EPA OW Statutory Framework*

### ❖ Safe Drinking Water Act

- Contaminant Candidate List (CCL)
- Six Year Review
- Health Advisories
- Unregulated Contaminant Monitoring Rule (UCMR)



### ❖ Clean Water Act

- Human Health and Aquatic Life Criteria
- Water Quality Standards
- Effluent Guidelines for point sources
- Concentrated Animal Feeding Operations



## *Why so much concern?*

- Some studies have documented occurrence in low levels in source and finished drinking water.
- Pharmaceuticals are designed to be biologically active at low levels.
- An increase in the use of pharmaceuticals is anticipated as the US population grows older.
- Associated risks to humans and the environment are uncertain. **However, demonstrated presence has generated Congressional and public concern.**



## *Pharmaceuticals of Concern*

- **Pharmaceuticals**
  - Prescription & over-the-counter therapeutic drugs
  - Veterinary medicine
- **Detected in Water**
  - Steroids/Hormones
  - Antibiotics
  - Antidepressants
  - Analgesics
  - Antimicrobials
  - Statins
  - Antiepileptics
  - Antineoplastics



## *EPA's Four-Pronged Strategy*

### 1) **Strengthening our Scientific Knowledge**

- Identifying potential contaminants of concern in surface water and drinking water
- Identifying information gaps and targeting collection of needed effects, dose, concentration, methods, and occurrence information

### 2) **Improving Public Understanding and Risk Communication**

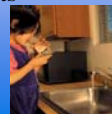
- Providing information to help the public understand the issues and inform policy choices

### 3) **Building Partnerships for Stewardship**

- Working to prevent pharmaceuticals from entering water

### 4) **Using Regulatory Tools**

- Using EPA's regulatory tools when sufficient information exists



## *1. Strengthening our Scientific Knowledge: Methods Development*

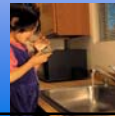
- Analytical methods are lacking for most contaminants of emerging concern
- OST developed and released methods for analysis of ~100 pharmaceuticals, personal care products, steroids, and hormones in water, soil, sediment, and biosolids.
  - Methods 1694, 1698 and 1699 at [www.epa.gov/waterscience/methods/method/other.html](http://www.epa.gov/waterscience/methods/method/other.html)
- Working on drinking water analytical methods



## ***1. Strengthening our Scientific Knowledge: Occurrence***

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- EPA is conducting studies to understand the potential occurrence of pharmaceuticals in wastewater effluent, biosolids, and fish tissue:
  - Publicly Owned Treatment Works (POTW) Study (2009)
  - Pilot Study of PPCPs in Fish Tissue (2008)
  - Expanded Fish Tissue Study (2011)
  - National Targeted Sewage Sludge Survey (2009)
  - Grants (ongoing)
    - Duke University (2008)
    - University of Florida (2010)



## ***1. Strengthening our Scientific Knowledge***

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- SAB review of methodology for Aquatic Life Criteria for Endocrine Disruption (June/July 2008)
- National Academy of Sciences (NAS) workshop to discuss potential risks to human health. (December 2008)



## *Key Observations from NAS Workshop*

- Levels vary from ppt-ppb based on detection limits
- Potency, presence, and persistence identified as key criteria for prioritization
- EPA's risk assessment paradigm adequate w/ "tweaking"
  - Chemical Safety Adjustment Factors for kinetic/dynamic differences
  - Departure from chemical by chemical assessment of risk
  - Identify therapeutic classes of drugs posing greatest risk
  - Explore efficient and effective screening tools
- Lack of data on sensitive populations
- Risk communication essential to build public trust



## *2. Improving Public Understanding and Risk Communication*

- General EPA PPCP website -- focus on research:  
[www.epa.gov/ppcp/](http://www.epa.gov/ppcp/)
- Launched new website -focused on PPCPs in water:  
[www.epa.gov/waterscience/ppcp/](http://www.epa.gov/waterscience/ppcp/)
- Currently coordinating with ONDCP/FDA to revise Federal drug disposal guidelines



## ***2. Improving Public Understanding and Risk Communication***

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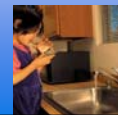
- Priorities identified by major Stakeholder listening sessions:
  - Human Health Effects
  - Risk Communication
  - Take Back Programs
  - Drug Disposal Policy
  - Monitoring programs



## ***3. Building Partnerships for Stewardship***

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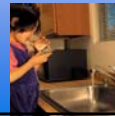
- World Health Organization (WHO) Task Force on PPCPs in Drinking Water
- Pharmaceuticals in the Environment (PiE) Workgroup
- Other stewardship efforts supported by EPA include:
  - Grants to develop pilot take-back programs (OCHPEE)
  - Great Lakes Earth Week Challenge (R5/R2)
  - California Statewide “No Drugs Down the Drain”
- Food and Drug Administration (FDA)
  - Ways to share toxicological data
  - Evaluating approval processes
- United States Geological Survey (USGS)
  - Monitoring efforts



## *4. Using Regulatory Tools*

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- **If sufficient information exists, we will take action**
  - Health Care Industry Study
    - Interim Report on Unused Pharmaceuticals in the Health Care Industry (August 2008)
    - Issued FR on intent to conduct broad survey of health care industry (August 2008)
  - Contaminant Candidate List (CCL3)
  - Universal Waste Rule (ORCR/formerly OSW)
  - Ambient Water Quality Criteria for Human Health and Aquatic Life



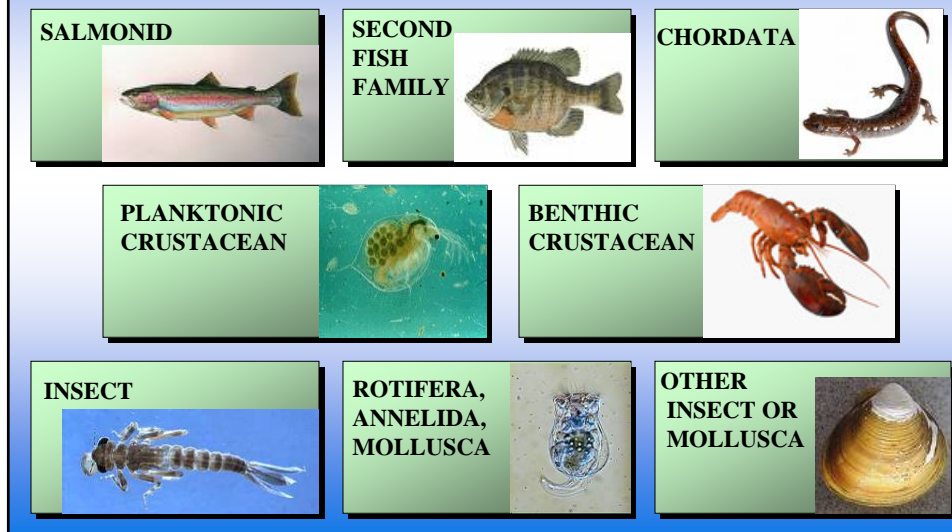
## *Aquatic Life Criteria (ALC)*

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- ALC developed using the “Guidelines” (1985) standardized procedures
- Issued by OW to define limits on chemical exposures which are considered sufficient to preclude unacceptable effects on aquatic communities
- Common element of State water quality standards
- National Pollutant Discharge Elimination System permits
- TMDLs
- Designated use attainment from ambient monitoring data
- Superfund evaluations and remediation goals



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



## *Goals of White Paper*

- Workgroup Recommendations act as a “Supplemental Interpretation” of the 1985 Guidelines for CECs:
  - Recommendations emphasize
    - technical rigor,
    - use of the "good science" clause (which relies on sound scientific evidence),
    - maintaining the level of protection and the amount of uncertainty.
- The white paper shows how criteria can be derived for CECs in a way that is explicitly consistent with the 1985 Guidelines.



## *Developing Aquatic Life Criteria for CEC*

- White Paper: “Aquatic Life Criteria for Contaminants of Emerging Concern: General Challenges and Recommendations”
  - Relevance of Acute Toxicity Effect Levels in Setting ALC
  - Defining Minimum Data Requirements in Terms of Taxonomic Coverage
  - Use of Non-Resident Species in ALC Development
  - Defining Appropriate Chronic Toxicity Data
  - Selection of Effect(s) Endpoints Upon Which to Base ALC
  - Involvement of an Expert Panel



## *Relevance of Acute Toxicity*

- Use existing information including phylogenetic sensitivity, data from closely related chemicals and screening tests (i.e. range finds) to assess the relevance of this information on the need for a CMC.
- the workgroup recommends that aquatic life criteria consist of only a CCC and that no CMC be derived, when sufficient information demonstrates risks of acute lethality are negligible.



## *Defining MDRs in terms of taxonomic coverage*

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- Use lines of evidence regarding :
  - Mode of Action (MOA)
  - taxa physiology
  - other available information from available test data.



## *Non-resident Species*

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- Use species with international acceptance, as well as species that are widely used with standardized test methods.



## *Defining Appropriate Chronic Toxicity Data*

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- Strengthen the Guidelines to require fish life cycle testing
  - require at least one full life-cycle test for a fish
- Potential consideration of tests with different “structures” such as multi-generational studies.



## *Selection of Effects Endpoints upon which to base Criteria*

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- Data should be examined for its potential relevance to criteria derivation, i.e. vtg production in males, testis-ova, etc.
- Endpoints not Historically 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***

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- 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



## ***Expert Panel***

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- Panels should be convened very early in the process for assistance with problem formulation, data ID, and issue scoping.
  - ID big picture issues with major implications on classes of chemicals (i.e. EDCs), not just single compounds
  - Identify data, research and information needs early in the process so that gaps can be filled in a timely manner.



## *Contact Information*

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