



Pharmaceuticals and Personal Care Products

Octavia Conerly

Office of Water

U.S. Environmental Protection Agency

Washington, DC

Northeast Water Science Forum

August 8, 2007



...to protect human health and the environment

Disclaimer



This presentation is based on the views and opinions of the author and does not necessarily reflect EPA policy.



...to protect human health and the environment

Office of Water

Office of the
Assistant Administrator
Assistant Administrator,
Benjamin Grumbles

Management & Operations
Staff

Water Policy Staff

Resources Management
Staff

Communications Team

American Indian
Environmental Office

Senior Policy Advisor

Office of Ground Water
& Drinking Water

Office of Science & Technology
Director, Ephraim S. King

Office of Wastewater
Management

Office of Wetlands, Oceans
& Watersheds

Water Security Division

Drinking Water Protection
Division

Standards & Risk
Management Division

Engineering & Analysis
Division
Director, Mary T. Smith

Health & Ecological
Criteria Division
Director, Edward Ohanian

Standards & Health
Protection Division
Director, Denise Keehner

Municipal Support Division

Water Permits Division

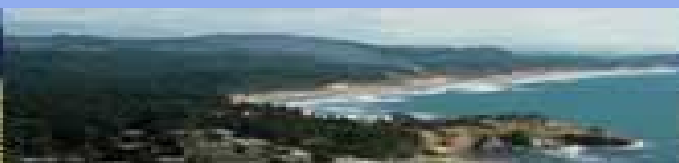
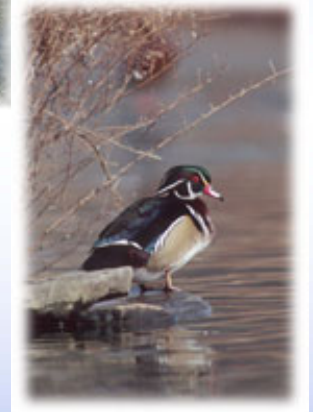
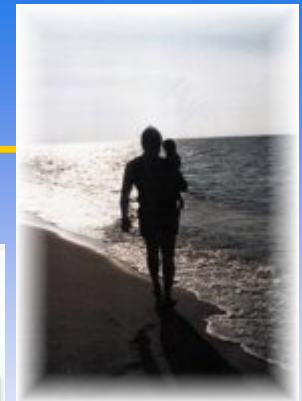
Assessment & Watershed
Protection Division

Oceans & Coastal
Protection Division

Wetlands Division

Overview

- Why the concern?
- Contaminants of interest
- EPA statutory framework related to contaminants
- Office of Water (OW) activities
- Voluntary efforts to reduce emerging contaminants in the environment



...to protect human health and the environment

Why the concern?

- A large number of chemicals are getting into the environment with known and unknown concentrations and effects
- Detection of these chemicals is likely to increase as analytical methods become more sensitive.
- Many of these chemicals are designed to impact the human hormone system
- Numerous reports of intersex fish and other species have triggered Congressional and public interest

Contaminants of Emerging Concern in Water*

PFOA

Pharmaceuticals
and Personal Care
Products

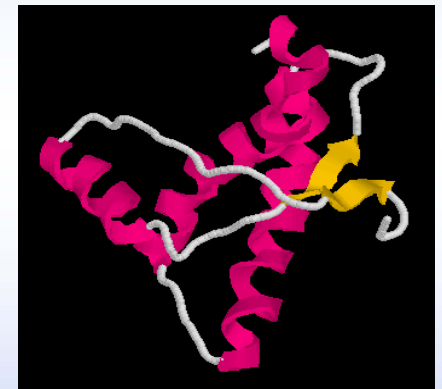
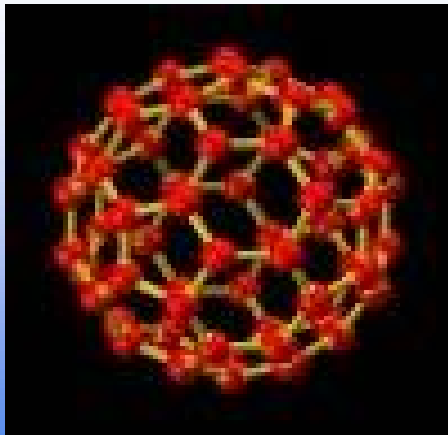
Prions

Nanomaterials

Pesticides

Endocrine
Disrupting
Compounds

PBDEs



*Not an exhaustive list.

EPA Statutory Framework

A. Clean Water Act

- Effluent Guidelines for point sources
 - Pharmaceutical Manufacturing Industry (1998)
 - Aquaculture Rule for large CAAP facilities (2004)
- Concentrated Animal Feeding Operations Rule
 - Rule deals with nutrients – but results in less overall contamination of surface waters
 - Discharge permits required for “large” CAFOs
- Human Health and Aquatic Life Criteria
- Fish Advisory program



Clean Water Act



- **Water Quality Standards**

- States designate use for water
- Water Quality Criteria (conditions supporting designated uses); EPA publishes national criteria (risk assessments)
 - Chemical criteria
 - Biological Criteria (apply to aquatic life designated uses)
- States set standards; EPA approves
- Antidegradation (keeping good-quality waters in good condition)



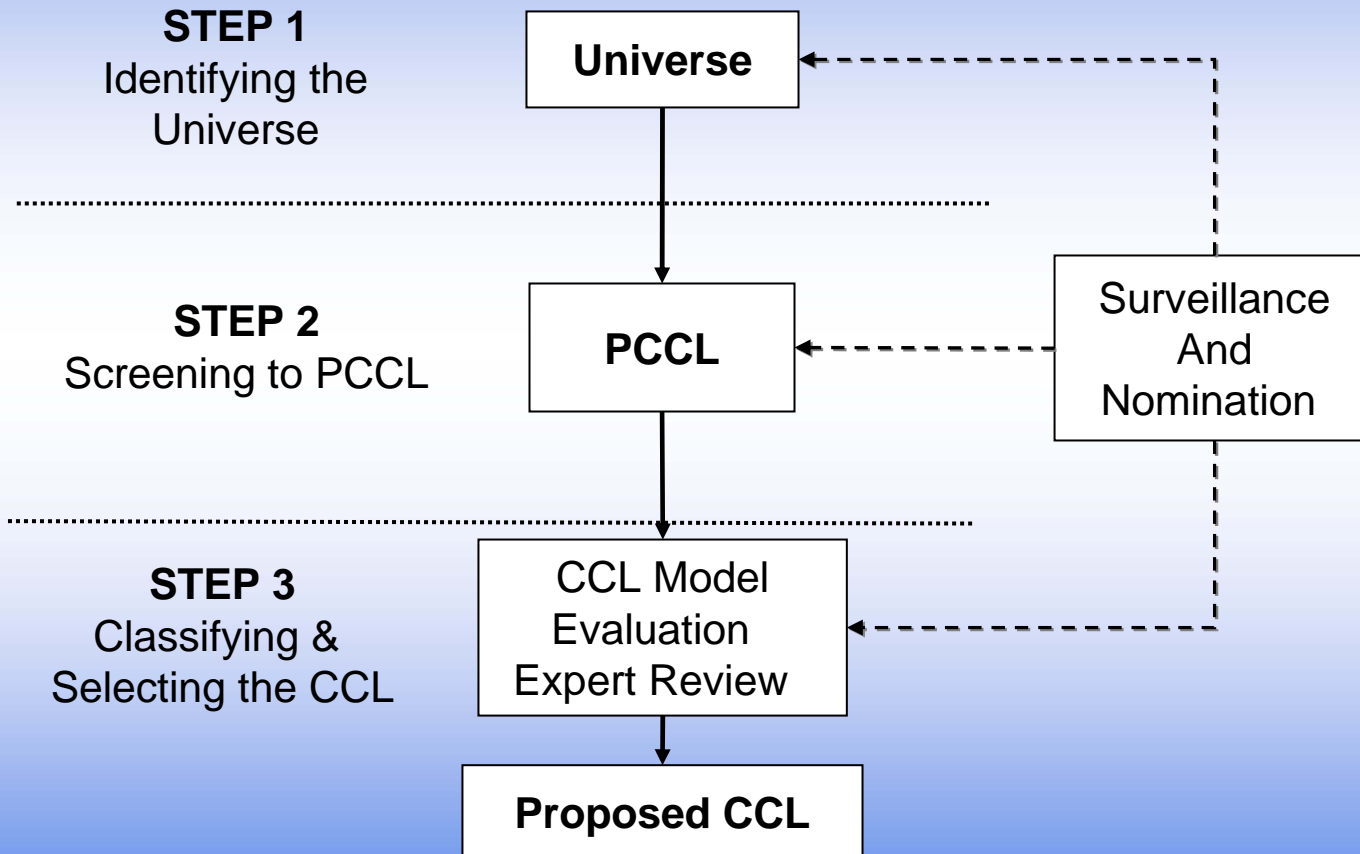
EPA Statutory Framework (Cont'd)

B. Safe Drinking Water Act

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



CCL 3 Process



Regulation under SDWA

Does the contaminant adversely affect public health?

Is the contaminant known or likely to occur in PWSs with a frequency and at levels posing a threat to public health?

Will regulation of the contaminant present a meaningful opportunity for health risk reduction?

**Regulate with
NPDWR**

Ongoing Office of Water Activities

- **National Pilot Study of PPCPs in Fish Tissue**
 - Sampling for 37 PPCPs in fish tissue from effluent-dominated streams at five locations in various parts of the U.S.
 - Analysis expected to be completed by December 2007
- **Publicly Owned Treatment Works Study**
 - Influent, effluent and sludge sampling for over 150 pharmaceuticals, pesticides, and steroids/hormones
 - Study expected to be completed by December 2009
- **National Targeted Biosolids Survey**
 - Sampling for presence and concentration of metals, priority pollutants, PPCPs and flame retardants
 - Draft report expected December 2007



EPA Research and Studies

- **Office of Research and Development**
 - NCER: STAR Grants Program
 - Research targeted at development of new chemical analysis methods, improved waste treatment, aquatic effects and new approaches for prioritizing chemicals for monitoring
 - Endocrine Disruptors Research Program
 - Endocrine Disruptors Screening Program



Various Stewardship Efforts

- **Federal efforts**

- “Do not flush” guidelines (2/07)

- EPA/ONDCP/DHHS

- Drug Take-Back Pilot Studies

- EPA/OCHP

- Universal Waste Rule

- EPA/OSW



Proper Disposal of Prescription Drugs
Office of National Drug Control Policy February 2007

Federal Guidelines:

- Take unused, unneeded, or expired prescription drugs out of their original containers and throw them in the trash.
- Mixing prescription drugs with an undesirable substance, such as used coffee grounds or kitty litter, and putting them in impermeable, non-descript containers, such as empty cans or sealable bags, will further ensure the drugs are not diverted.
- Flush prescription drugs down the toilet only if the label or accompanying patient information specifically instructs doing so (see box).
- Take advantage of community pharmaceutical take-back programs that allow the public to bring unused drugs to a central location for proper disposal. Some communities have pharmaceutical take-back programs or community solid-waste programs that allow the public to bring unused drugs to a central location for proper disposal. Where these exist, they are a good way to dispose of unused pharmaceuticals.

The FDA advises that the following drugs be flushed down the toilet instead of thrown in the trash:

- Actiq (fentanyl citrate)
- Daytrana Transdermal Patch (methylphenidate)
- Duragesic Transdermal System (fentanyl)
- OxyContin Tablets (oxycodone)
- Avinaza Capsules (morphine sulfate)
- Baracade Tablets (entecavir)
- Reyataz Capsules (atazanavir sulfate)
- Tequin Tablets (gatifloxacin)
- Zerit for Oral Solution (stavudine)
- Meperidine HCl Tablets
- Percocet (Oxycodone and Acetaminophen)
- Xyrem (Sodium Oxybate)
- Fentora (fentanyl buccal tablet)

Note: Patients should always refer to printed material accompanying their medication for specific instructions.

Office of National Drug Control Policy
2000 Massachusetts, S.E. 2000
• (202) 343-4414 • (202) 343-4374

www.WhiteHouseDrugPolicy.gov

...to protect human health and the environment

Other Efforts

- OW and Office of Pesticide Programs working to explore the potential impact of antimicrobials on the microbial treatment processes in WWTPs and the environment
- OW is assessing health services industry for potential effluent guideline (304m)
- Identifying potential contaminants of concern in surface water and drinking water
- Evaluating treatment options to reduce discharges of emerging contaminants into the environment, e.g., indicator chemicals & incidental removal in POTWs
- Helping develop White House (CENR) workgroup products

White House Committee on Environment and Natural Resources Interagency Workgroups

- **Pharmaceuticals in the Environment (PiE) Workgroup**
 - **Participating Agencies**
 - EPA/FDA/USGS (Co-leads), CDC, NIEHS, NOAA, USDA, FWS
 - **Goals**
 - Develop 2 strategies delineating data gaps/priorities/areas of collaboration
 - Research strategy for human and veterinary pharmaceuticals in the environment (12/2007)
 - Research strategy for antibiotics in the environment; focusing on the question of antibiotic resistance (12/2008)
- **Endocrine Disruption in the Environment Workgroup**
 - **Participating Agencies**
 - EPA (Lead), NIEHS, DOI, NOAA, FDA, CDC, NSF, ATSDR, NCI, DOE, DOD, USDA, The Smithsonian Institution
 - **Goals**
 - Develop a planning framework for Federal research related to human health and ecological effects of endocrine disrupting compounds
 - Identify research gaps and develop a coordinated plan to address priority research needs

Next Steps

- Collaborate with Federal/non-Federal partners in targeting, research, monitoring and testing to fill data gaps to support criteria development and regulatory actions

