



Pharmaceuticals and Personal Care Products

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Office of Water

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...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.



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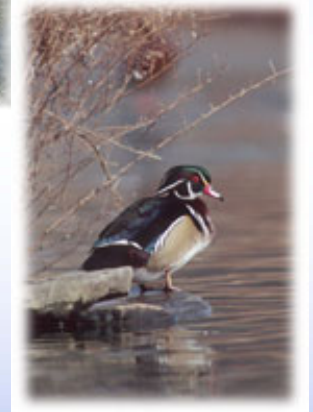
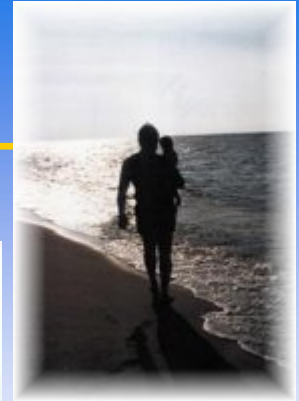
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Overview

- 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

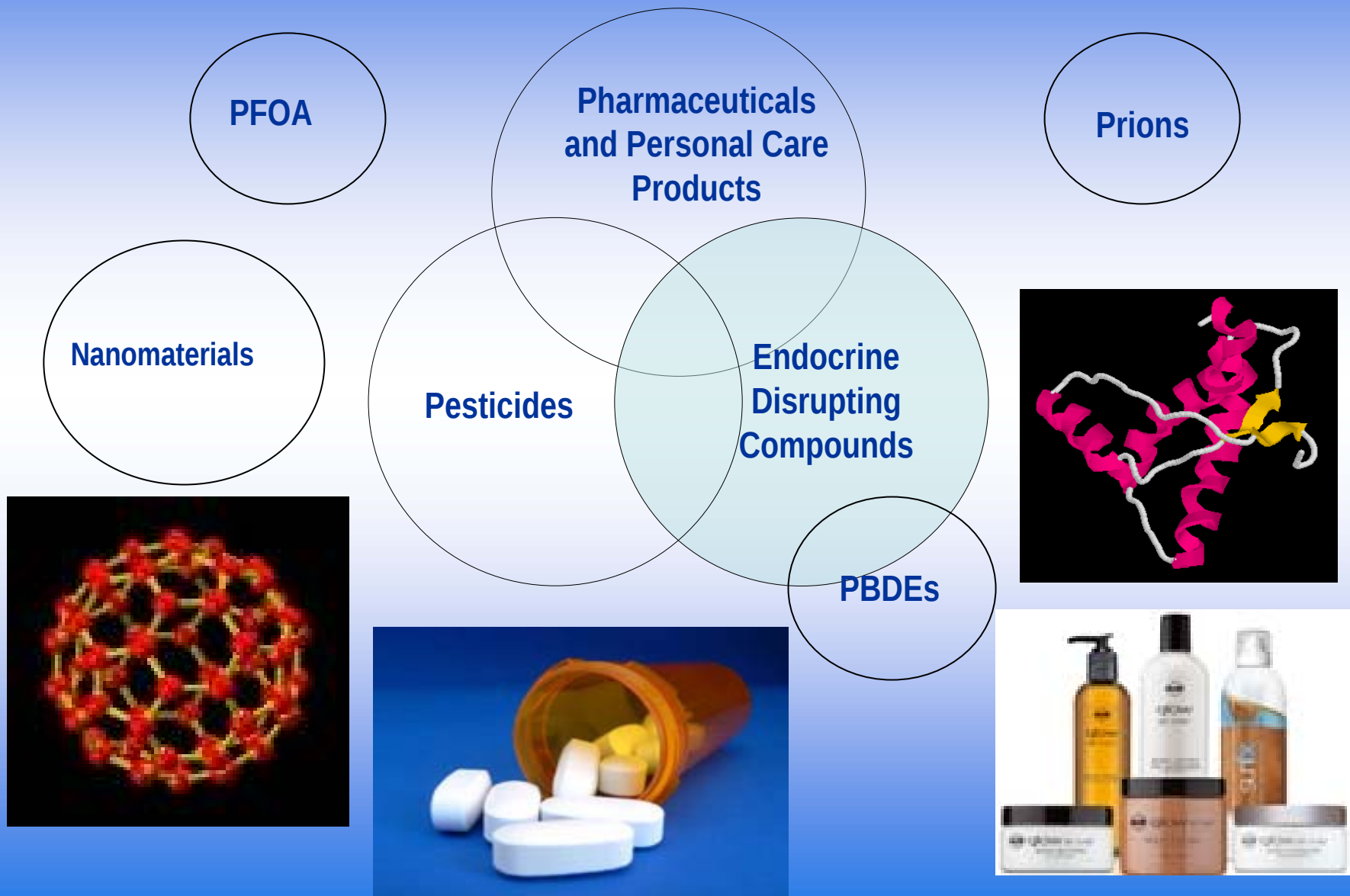


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Why the concern?

- 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*



*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)



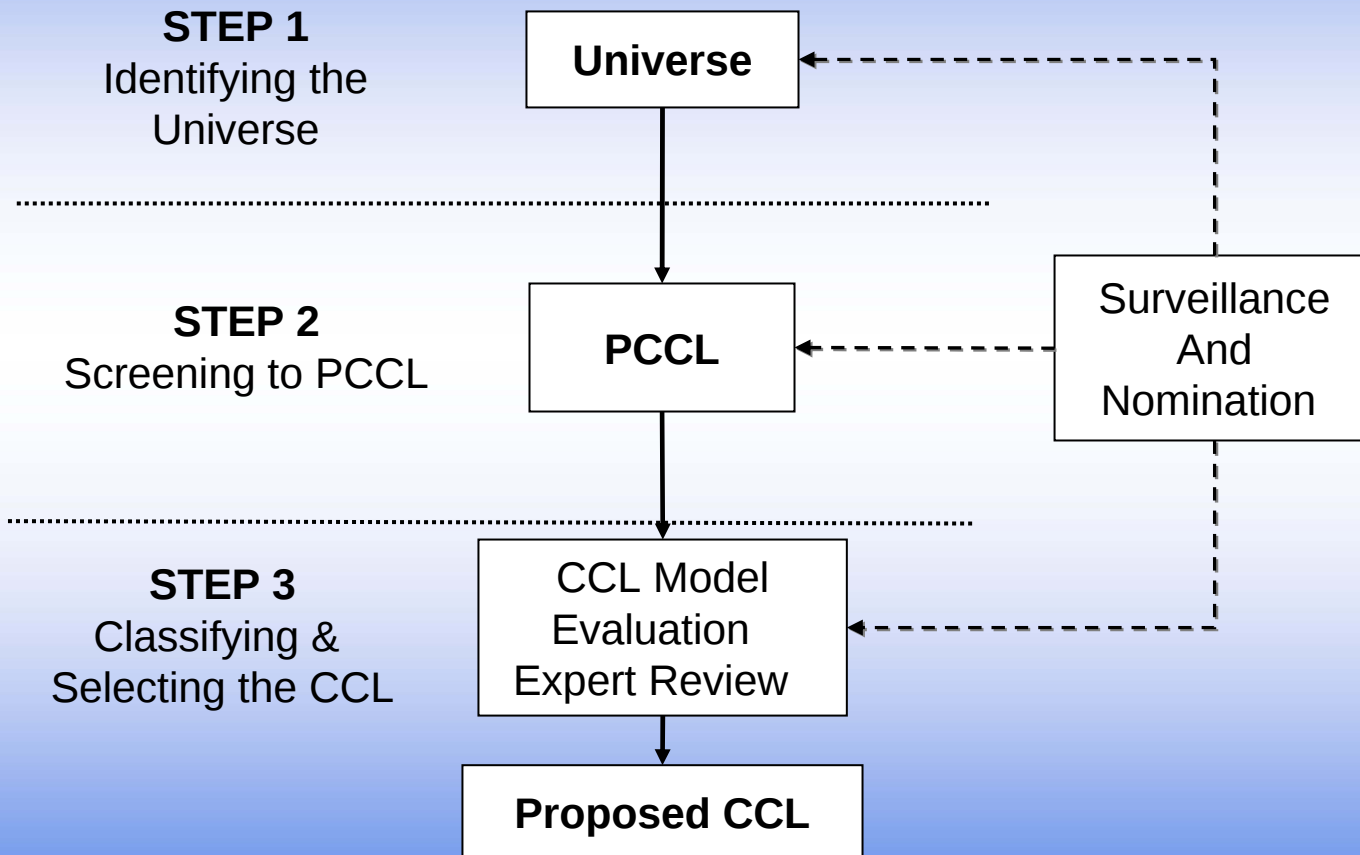
EPA Statutory Framework (Cont'd)

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)

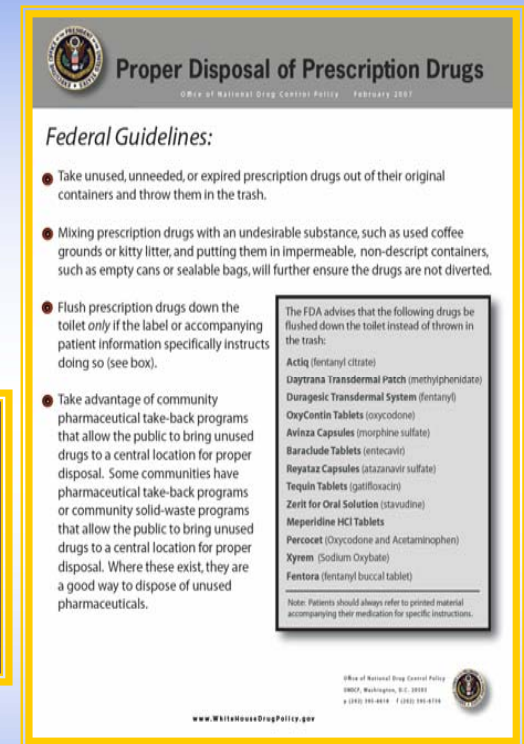
- EPA/ONDACP/DHHS

- Drug Take-Back Pilot Studies

- EPA/OCHP

- Universal Waste Rule

- EPA/OSW



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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

