Pharmaceuticals and Personal Care Products

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...to protect human health and the environment
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This presentation is based on the views and opinions of the author and does not necessarily reflect EPA policy.

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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*

- PFOA
- Pharmaceuticals and Personal Care Products
- Endocrine Disrupting Compounds
- PBDEs
- Pesticides
- Nanomaterials
- Prions

*Not an exhaustive list.
A. Clean Water Act

- Effluent Guidelines for point sources
- 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**

**STEP 1**
Identifying the Universe

**STEP 2**
Screening to PCCL

**STEP 3**
Classifying & Selecting the CCL

- Universe
- PCCL
- Proposed CCL
- Surveillance and Nomination
- CCL Model Evaluation
- Expert Review
Regulation under SDWA

1. Does the contaminant adversely affect public health?
2. Is the contaminant known or likely to occur in PWSs with a frequency and at levels posing a threat to public health?
3. 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

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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