

# THE PRETREATMENT PROGRAM AND THE NEW MANAGEMENT STANDARDS FOR HAZARDOUS WASTE PHARMACEUTICALS

Chuck Durham, PG Environmental, Inc.  
Jan Pickrel, US Environmental Protection Agency

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# Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine, 84 FR 5816

- Federal Register: 02/22/2019
- Rule Effective Date: 08/21/2019
- Rulemaking affected the following CFR parts:
  - [40 CFR Part 261, 262, 264-266](#)
  - [40 CFR Part 268](#)
  - [40 CFR Part 270](#)
  - [40 CFR Part 273](#)



■ <https://www.epa.gov/hwgenerators/final-rule-management-standards-hazardous-waste-pharmaceuticals-and-amendment-p075>

[Webinar archived on March 4, 2019](#)

# Regulation Excerpt:

## Management Standards for Hazardous Waste Pharmaceuticals

### 40 CFR 261.4 Exclusions.

(a) *Materials which are not solid wastes.* The following materials are not solid wastes for the purpose of this part:

(1)(i) Domestic sewage; and

(ii) Any mixture of domestic sewage and other wastes that passes through a sewer system to a publicly-owned treatment works for treatment, **except as prohibited by §266.505 and Clean Water Act requirements at 40 CFR 403.5(b).** “Domestic sewage” means untreated sanitary wastes that pass through a sewer system.

### 40 CFR 266.505 Prohibition of sewerage **hazardous waste pharmaceuticals.**

*All **healthcare facilities**—including very small quantity generators operating under § 262.14 in lieu of this subpart— and **reverse distributors** are prohibited from discharging **hazardous waste pharmaceuticals** to a sewer system that passes through to a publicly-owned treatment works. **Healthcare facilities and reverse distributors remain subject to the prohibitions in 40 CFR 403.5(b)(1).***

# Hazardous Waste Pharmaceuticals & the Pretreatment Program

## Discussion Outline

- Background: NPDES, Pretreatment Program & Hazardous Waste
  - *Domestic Sewage Exclusion (RCRA Regulations)*
  - *Pretreatment Program Regulations*
  
- Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine, *February 22, 2019, 84 FR 5816-5950 (135 pgs)*

# Domestic Sewage Exclusion (DSE)

RCRA §1004[27] codified at 40 CFR 261.4(i)

## Part 260 – Hazardous Waste Management System: General

### Subpart B – Definitions

#### 40 CFR 261.4 Exclusions.

- (a) *Materials which are not solid wastes.* The following materials are not solid wastes for the purpose of this part:
  - (1)
  - (i) Domestic sewage; and
  - (ii) Any mixture of domestic sewage and other wastes that passes through a sewer system to a publicly-owned treatment works for treatment, **except as prohibited by §266.505 and Clean Water Act requirements at 40 CFR 403.5(b).** “Domestic sewage” means untreated sanitary wastes that pass through a sewer system.

### Subpart C - Characteristics of Hazardous Waste

#### 40 CFR 261.20 General

- (a) A solid waste, as defined in §261.2 which is not excluded from regulation as a hazardous waste under §261.4(b), is a hazardous waste if it exhibits any of the characteristics identified in this subpart.

Red text above is effective 08/21/2019, 84 FR 5816

# RCRA, NPDES, and the Pretreatment Program

- Domestic Sewage Exclusion (DSE): RCRA §1004[27] *codified at 40 CFR 261.4(a)(1)*
  - *Solid or dissolved material in domestic sewage is not “Solid Waste” [40 CFR 261.2].*
  - *“Not ‘solid waste’” means not hazardous waste.*
- DSE effect on POTWs and Industrial Users
  - *Covers industrial wastes discharged to POTW sewers, even if wastewater would otherwise be hazardous*
  - *IU Wastestream to POTW not subject to RCRA manifest requirements*
  - *IUs still have to comply with other RCRA requirements as hazardous waste generators*
    - Determine whether a waste is hazardous
    - Obtain EPA identification number if wastes are not discharged to POTW sewer
    - RCRA requirements for storing, recordkeeping, reporting, etc.
  - *POTWs receiving such waste via collection system is not RCRA TSD (40 CFR 264)*

# RCRA, NPDES, and the Pretreatment Program

## 1984 Hazardous and Solid Waste Amendments to RCRA

- Created RCRA §3018(a), which required EPA to prepare:
  - *“...a report to the Congress concerning those substances identified or listed under section 3001 which are not regulated under this subtitle by reason of the exclusion for mixtures of domestic sewage and other wastes that pass through a sewer system to a publicly owned treatment works. Such report shall include the **types, size, and number of generators** which dispose of substances in this manner, the **types and quantities disposed of in this manner**, and the **identification of significant generators, wastes, and waste constituents not regulated** under existing Federal law or regulated in a manner sufficient to protect human health and the environment.”*
  
- “Domestic Sewage Study” - Report to Congress on the Discharge of Hazardous Wastes to Publicly Owned Treatment Works (EPA/530-SW-86-004) – February 7, 1986

<https://www.epa.gov/npdes/npdes-pretreatment-program-hazardous-and-solid-waste-amendments-hswa-resource-conservation-and>

# RCRA, NPDES, and the Pretreatment Program

## DSS Conclusion:

“Domestic Sewage Exclusion should be retained at the present time”

- *DSE appropriateness “depends largely on an effective pretreatment program”*

Revise existing regulations and promulgate additional regulations to assure adequate controls to protect human health and the environment: *Rulemaking July 24, 1990, 55 FR 30082*

- *NPDES Regulations:*
  - POTW NPDES Application requirements for Whole Effluent Toxicity Testing
- *Pretreatment Regulations:*
  - General & Specific Prohibitions to improve controls of “characteristic hazardous waste”
  - Notification and Prevention of Spills and Batch (Slug) Discharges
  - Controls on Trucked & Hauled Wastes
  - Notification Requirements – 40 CFR 403.12(p)
  - Individual Control Mechanisms
  - Enforcement (Local limits, Inspections, Definition of SIU, SNC, ERP, SIU reporting, etc.)
  - “Miscellaneous”



# What *is* a Hazardous Waste?

## PART 261—IDENTIFICATION AND LISTING OF HAZARDOUS WASTE (continued)

### Subpart C—Characteristics of Hazardous Waste

§ 261.21 – Characteristic of ignitability

§ 261.22 – Characteristic of corrosivity

§ 261.23 – Characteristic of reactivity

§ 261.24 – Toxicity characteristic

### Pretreatment Standards

§ 403.5(b)(1) - Fire or explosion hazard

§ 403.5(b)(2) - Corrosive structural damage, in no case pH<5

§ 403.5(b)(7) -Pollutants resulting in toxic gases, vapors, or fumes

### 40 CFR 403.5(a) + (c)

#### General Prohibition + Local Limits

- Pass through or interference

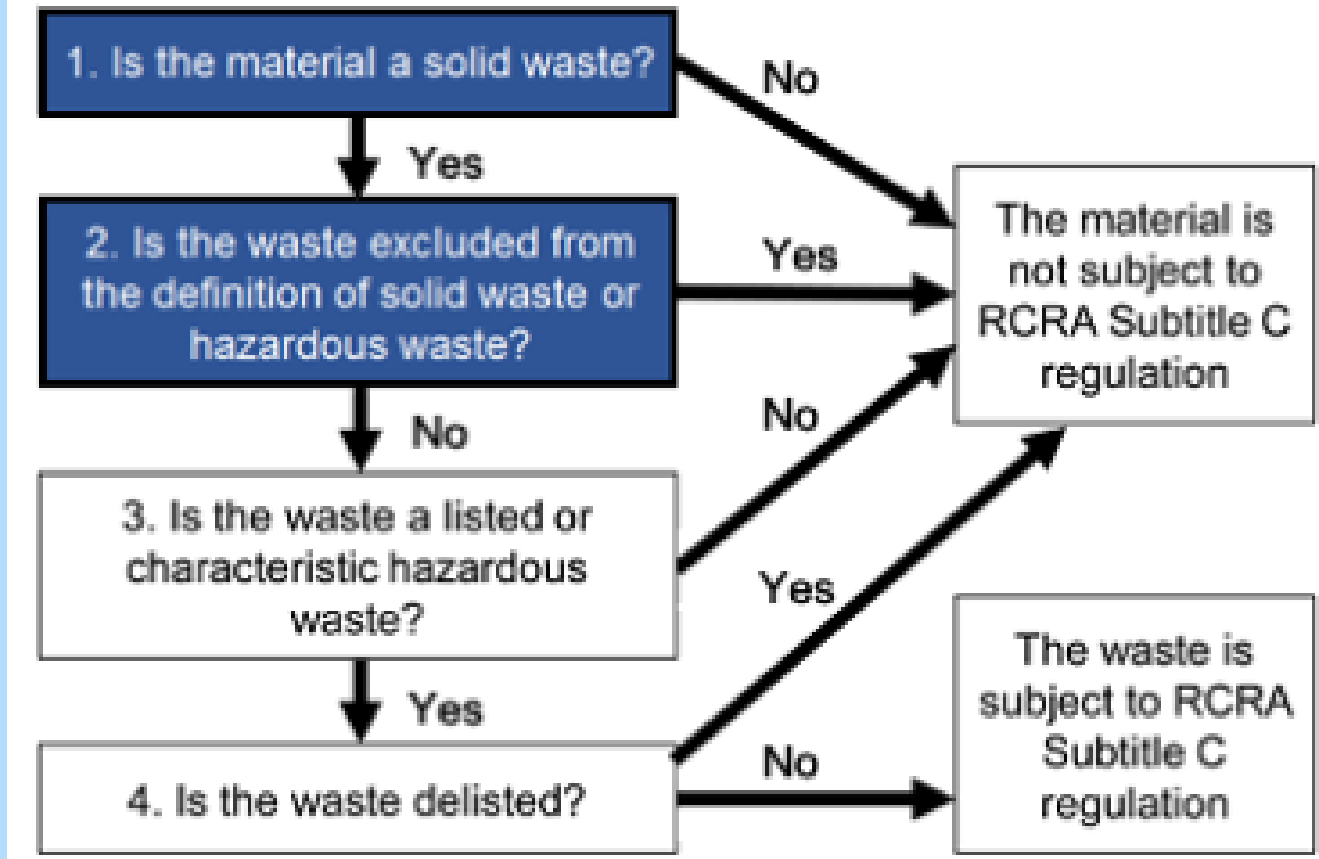
### 40 CFR 122.21(j)

- POTWs must do WET tests

# What is a Hazardous Waste?

## PART 261—IDENTIFICATION AND LISTING OF HAZARDOUS WASTE

### The Hazardous Waste Identification Process



Solid Waste –

“Solid” can be liquid, semi-solid, or contained gaseous material;

“Waste” means discarded, abandoned, ‘inherently waste-like”, “discarded military munition”, recycled in certain ways

40 CFR 261

Subpart A – General

Subpart B – Criteria

Subpart C - Characteristics

Subpart D – Lists

Subpart E – Exclusions/Exemptions

...

Subpart CC

# Subpart D – Lists of Hazardous Wastes

## 40 CFR 261.30 – 261.35

§261.31 Hazardous wastes from non-specific sources = F-Listed Waste

§261.32 Hazardous wastes from specific sources = K-listed Waste

§261.33 Discarded commercial chemical products, off-specification species, container residues, and spill residues thereof = P- & U-listed Waste

§261.35 Deletion of certain hazardous waste codes following equipment cleaning and replacement

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# RCRA/Pretreatment Program Regulation Revisions *within* Management Standards for Hazardous Waste Pharmaceuticals

## 40 CFR 261.4 Exclusions. [Note: this is in the General section of the regulations]

- *(a) Materials which are not solid wastes. The following materials are not solid wastes for the purpose of this part:*
- *(1)(i) Domestic sewage; and*
- *(ii) Any mixture of domestic sewage and other wastes that passes through a sewer system to a publicly-owned treatment works for treatment, except as prohibited by §266.505 and Clean Water Act requirements at 40 CFR 403.5(b). “Domestic sewage” means untreated sanitary wastes that pass through a sewer system.*

## 40 CFR 266.505 Prohibition of sewerage hazardous waste pharmaceuticals.

*All healthcare facilities—including very small quantity generators operating under § 262.14 in lieu of this subpart— and reverse distributors are prohibited from discharging hazardous waste pharmaceuticals to a sewer system that passes through to a publicly-owned treatment works. Healthcare facilities and reverse distributors remain subject to the prohibitions in 40 CFR 403.5(b)(1).*

Red text above is effective 08/21/2019, 84 FR 5816

# RCRA/Pretreatment Program Regulation Revisions Hazardous Waste Pharmaceuticals Sewer Ban - continued

## Definitions:

### § 266.500

- *Pharmaceutical*
- *Hazardous waste pharmaceutical*
- *Healthcare facility*
- *Household waste pharmaceutical*
- *Long-term care facility*
- *Reverse distributor*

# RCRA/Pretreatment Program Regulation Revisions Hazardous Waste Pharmaceuticals Sewer Ban - continued

Definition:

## What is a pharmaceutical?

- Answer: 40 CFR 266.500
- *Pharmaceutical* means any drug or dietary supplement for use by humans or other animals; any electronic nicotine delivery system (e.g., electronic cigarette or vaping pen); or any liquid nicotine (e-liquid) packaged for retail sale for use in electronic nicotine delivery systems (e.g., pre-filled cartridges or vials). This definition includes, but is not limited to, dietary supplements, as defined by the Federal Food, Drug and Cosmetic Act; prescription drugs, as defined by [21 CFR 203.3\(y\)](#); over-the-counter drugs; homeopathic drugs; compounded drugs; investigational new drugs; pharmaceuticals remaining in non-empty containers; personal protective equipment contaminated with pharmaceuticals; and clean-up material from spills of pharmaceuticals.
- This definition does not include dental amalgam or sharps.



# RCRA/Pretreatment Program Regulation Revisions Hazardous Waste Pharmaceuticals Sewer Ban - continued

What is prohibited from being flushed/sewered?

## What is a *Hazardous waste* pharmaceutical?

■ Answer: 40 CFR 266.500

- refers you back to “solid waste, as defined in § 261.2, and exhibits one or more characteristics identified in part 261 subpart C or is listed in part 261 subpart D.”

“*Hazardous waste pharmaceutical* means a pharmaceutical that is a solid waste, as defined in § 261.2, and exhibits one or more characteristics identified in part 261 subpart C or is listed in part 261 subpart D. A pharmaceutical is not a solid waste, as defined in § 261.2, and therefore not a hazardous waste pharmaceutical, if it is legitimately used/reused (e.g., lawfully donated for its intended purpose) or reclaimed. An over-the-counter pharmaceutical, dietary supplement, or homeopathic drug is not a solid waste, as defined in § 261.2, and therefore not a hazardous waste pharmaceutical, if it has a reasonable expectation of being legitimately used/reused (e.g., lawfully redistributed for its intended purpose) or reclaimed.”





# RCRA/Pretreatment Program Regulation Revisions

## Hazardous Waste Pharmaceuticals Sewer Ban - continued

### [40 CFR 266.506](#)

Conditional exemptions for hazardous waste pharmaceuticals that are also **controlled substances** and **household waste pharmaceuticals** collected in a **take-back event or program**.

- (a) *Conditional exemptions*. Provided the conditions of paragraph (b) of this section are met, the following are exempt from [40 CFR parts 262](#) through 273:
  - (1) *Hazardous waste pharmaceuticals that are also listed on a schedule of controlled substances by the Drug Enforcement Administration in [21 CFR part 1308](#), and*
  - (2) *Household waste pharmaceuticals that are collected in a take-back event or program, including those that are collected by an authorized collector (as defined by the Drug Enforcement Administration) registered with the Drug Enforcement Administration that commingles the household waste pharmaceuticals with controlled substances from an ultimate user (as defined by the Drug Enforcement Administration).*
  
- (b) *Conditions for exemption*. The hazardous waste pharmaceuticals must be:
  - (1) **Managed in compliance with the sewer prohibition of § 266.505; and**
  - (2) **Collected, stored, transported, and disposed of in compliance with all applicable Drug Enforcement Administration regulations for controlled substances; and**
  - (3) **Destroyed by a method that Drug Enforcement Administration has publicly deemed in writing to meet their non-retrievable standard of destruction or combusted at one of the following**
  - . . . .

# Examples of HW Pharmaceuticals: “Listed” v. “Characteristic”

## *Characteristic*

### Hazardous Waste

- *Ignitable* (D001):
  - Preparations with >24% alcohol
- *Toxicity* (D004-D043): if present above certain concentrations in the leachate during TCLP test
  - Chromium (multi-vitamins)
  - m-Cresol (preservative in insulin)
  - Mercury (preservative thimerosal)
  - Selenium (multi-vitamins)
  - Silver (burn creams)

## *Listed*

### Hazardous Waste

- *P-Listed* hazardous ACUTE wastes
  - Warfarin (P001)
  - Arsenic Trioxide (P012)
  - Nicotine (P075)
  - Physostigmine salicylate (P188)
  - Physostigmine (P204)
- *U-listed* hazardous wastes
  - Mitomycin C (U010)
  - Chloral hydrate (U034)
  - Cyclophosphamide (U058)
  - Lindane (U129)
  - Selenium sulfide (U205)

# RCRA/Pretreatment Program Regulation Revisions Hazardous Waste Pharmaceuticals Sewer Ban - continued

## Who must comply with the Sewer Ban?

- Answer: 40 CFR 266.505
- *All Healthcare facilities – including very small quantity generators operating under § 262.14 in lieu of this subpart*
- *Long-term care facilities*
- *Reverse distributors*



# RCRA/Pretreatment Program Regulation Revisions

## Hazardous Waste Pharmaceuticals Sewer Ban - continued

Who must comply with the Sewer Ban?

### What is a *Healthcare facility*?

- Answer: 40 CFR 266.500
- **'Healthcare facility'** means any person that is lawfully authorized to—
  - (1) Provide preventative, diagnostic, therapeutic, rehabilitative, maintenance or palliative care, and counseling, service, assessment or procedure with respect to the physical or mental condition, or functional status, of a human or animal or that affects the structure or function of the human or animal body; or
  - (2) Distribute, sell, or dispense pharmaceuticals, including over-the-counter pharmaceuticals, dietary supplements, homeopathic drugs, or prescription pharmaceuticals. This definition includes, but is not limited to, wholesale distributors, third-party logistics providers that serve as forward distributors, military medical logistics facilities, hospitals, psychiatric hospitals, ambulatory surgical centers, health clinics, **physicians' offices, optical and dental providers, chiropractors**, long-term care facilities, ambulance services, **pharmacies**, long-term care pharmacies, mail-order pharmacies, retailers of pharmaceuticals, **veterinary clinics**, and veterinary hospitals. This definition does not include pharmaceutical manufacturers, reverse distributors, or reverse logistics centers..
- **Long-term care facility** means a licensed entity that provides assistance with activities of daily living, including managing and administering pharmaceuticals to one or more individuals at the facility. This definition includes, but is not limited to, **hospice facilities, nursing facilities, skilled nursing facilities, and nursing and skilled nursing care portions of continuing care retirement communities**. Not included within scope of this definition are group homes, independent living communities, assisted living facilities, and independent and assisted living portions of continuing care retirement communities.



# RCRA/Pretreatment Program Regulation Revisions Hazardous Waste Pharmaceuticals Sewer Ban - continued

Who must comply with the Sewer Ban?

## What is a Reverse Distributor?

- Answer: 40 CFR 266.500
- “***Reverse distributor*** means any person that receives and accumulates prescription pharmaceuticals that are potentially creditable hazardous waste pharmaceuticals for the purpose of facilitating or verifying manufacturer credit. Any person, including forward distributors, third-party logistics providers, and pharmaceutical manufacturers, that processes prescription pharmaceuticals for the facilitation or verification of manufacturer credit is considered a reverse distributor.”



# RCRA/Pretreatment Program Regulation Revisions Hazardous Waste Pharmaceuticals Sewer Ban - continued

## As a Pretreatment Control Authority, what am I responsible to do?

- Should the HSWA sewer prohibition for hazardous waste pharmaceuticals be incorporated as another “Specific Prohibition” into local Sewer Use Ordinances (SUOs)?
- Answer: No. The HSWA sewer prohibition for hazardous waste pharmaceuticals is not required to be added to local SUOs. However, a locality may elect to add a new sewer prohibition to its SUO if it has legal authority to do so.
- Note: Pretreatment Control Authority should already have Specific Prohibitions in its SUO that prohibit flushing of characteristic hazardous waste, as well as any waste that could cause toxicity problems. 40 CFR 403.5



# RCRA/Pretreatment Program Regulation Revisions Hazardous Waste Pharmaceuticals Sewer Ban - continued

## As a Pretreatment Control Authority, what am I responsible to do? (continued)

- Then, who will be responsible for enforcing the sewer prohibition?
- Answer: The sewer prohibition of Subpart P will be enforced through RCRA inspections of healthcare facilities and reverse distributors by state or federal officials. The Clean Water Act's NPDES pretreatment program could also potentially apply and result in enforcement of requirements of the sewer prohibition if such requirements are adopted as part of a publicly owned treatment works' approved pretreatment program. Further, elements of the sewer prohibition may be reflected currently in the specific prohibitions on discharge by indirect users of POTWs in EPA's Pretreatment Regulations at 40 CFR Part 403.





# RCRA/Pretreatment Program Regulation Revisions Hazardous Waste Pharmaceuticals Sewer Ban - continued

## As a Pretreatment Control Authority, what am I responsible to do? (continued)

- Does the sewer prohibition apply to pharmaceutical manufacturers?
- Answer: No. The sewer prohibition does not apply to pharmaceutical manufacturers unless those same facilities are also reverse distributors.
- While the sewer prohibition legally applies only to healthcare facilities and reverse distributors with respect to hazardous waste pharmaceuticals, EPA strongly discourages sewerage of any pharmaceutical in any setting.
- EPA's Effluent Guidelines and Standards for Pharmaceutical Manufacturing at 40 CFR 439 address CWA discharges of pollutants associated with the manufacturing industry.





# RCRA/Pretreatment Program Regulation Revisions Hazardous Waste Pharmaceuticals Sewer Ban - continued

## As a Pretreatment Control Authority, what am I responsible to do? (continued)

- Can hazardous waste pharmaceuticals be discharged to septic tanks?
- Answer: No. Section 261.4(a)(1)(ii) allows the discharge of what would otherwise be a hazardous waste to publicly owned treatment works (POTWs), without being considered solid or hazardous waste. The prohibition on discharges of hazardous waste pharmaceuticals that was promulgated as part of the Hazardous Waste Pharmaceuticals final rule reduces the scope of the exclusion in the existing regulations.
- Discharges of hazardous waste to other types of sewage systems, such as septic tanks, privately owned treatment works and federally owned treatment works are not allowed by the exclusion in § 261.4(a)(1)(ii). Therefore, the discharge of hazardous wastes to septic tanks, privately owned treatment works and federally owned treatment works is already prohibited, even though it is not explicitly stated in the sewer prohibition of Subpart P.



# RCRA/Pretreatment Program Regulation Revisions Hazardous Waste Pharmaceuticals Sewer Ban - continued

## As a Pretreatment Control Authority, what am I responsible to do? (continued)

- Can hazardous waste pharmaceuticals be discharged to the sewer from a healthcare facility or reverse distributor that has a pretreatment permit?
- Answer: No. 40 CFR 266.505 prohibits all healthcare facilities and reverse distributors from discharging any *hazardous waste pharmaceuticals* to a sewer system that passes through to a publicly owned treatment works (POTW), regardless of whether the POTW or state has issued a pretreatment permit to the healthcare facility or reverse distributor.



# RCRA/Pretreatment Program Regulation Revisions Hazardous Waste Pharmaceuticals Sewer Ban - continued

## As a Pretreatment Control Authority, what am I responsible to do? (continued)

- Answer: Implement your pretreatment program.

*Note: EPA has not established technology-based standards for discharges from healthcare facilities to POTWs, thus healthcare facilities are not categorical industrial users (CIUs).*

*Healthcare facilities continue to be industrial users (IUs), defined broadly at 40 CFR §403.3(j) as a “Source of Indirect Discharge,” and may be significant industrial users (SIU), defined at 40 CFR §403.3(v).*





*"Now it is well known that when there are many of these flowers together their odor is so powerful that anyone who breathes it falls asleep, and if the sleeper is not carried away from the scent of the flowers, he sleeps on and on forever. But Dorothy did not know this, nor could she get away from the bright red flowers that were everywhere about; so presently her eyes grew heavy and she felt she must sit down to rest and to sleep. . . . "If we leave her here she will die," said the Lion. "The smell of the flowers is killing us all."*

*—Excerpt from *The Wonderful Wizard of Oz* (book, published 1900)*



# CONTACTS

EPA Office of Resource Conservation and Recovery

- *Kristin Fitzgerald, [Fitzgerald.Kristin@epa.gov](mailto:Fitzgerald.Kristin@epa.gov)*
- *Brian Kneiser, [Kneiser.brian@epa.gov](mailto:Kneiser.brian@epa.gov)*

EPA Office of Water, Pretreatment Program

- *Jan Pickrel, [Pickrel.jan@epa.gov](mailto:Pickrel.jan@epa.gov)*
- *Rebecca Christopher, [Christopher.rebecca@epa.gov](mailto:Christopher.rebecca@epa.gov)*

EPA Office of Water, Office of Science & Technology

- *Meghan Hessenauer, [Hessenauer.meghan@epa.gov](mailto:Hessenauer.meghan@epa.gov)*

PG Environmental, Inc. (Contractor to EPA)

- *Chuck Durham, [Chuck.Durham@pgenv.com](mailto:Chuck.Durham@pgenv.com)*

