Veolia North America - Industrial Business Regulatory Update - February 2019

ENVIRONMENTAL UPDATES

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B. Environmental Protection Agency Action Plan for Per- and Polyfluoroalkyl Substances (PFAS)

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A. EPA Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine

Date Published: 2/22/2019
Source: 40 CFR 261, 262, 264, 265, 266, 268, 270, and 273
Effective Date: Varies - See Effective Dates and State Adoption Table (page 10)
Area: Environmental Protection Agency
Type: Final Rule

On February 22, 2019, the Environmental Protection Agency (EPA) published a final rule (84 FR 5816-5950) in an effort to establish streamlined standards for the management of hazardous waste pharmaceuticals for the healthcare sector while protecting human health and the environment.

Summary

The main goals of the final rule are:

1. Prohibit the disposal of hazardous waste pharmaceuticals down the drain (sewering).
2. Reduce or eliminate the dual regulation of hazardous waste pharmaceuticals and DEA controlled substances.
3. Maintain the Household Hazardous Waste Exemption for hazardous waste pharmaceuticals collected at take-back events.

4. Codify prior EPA policy on non-prescription pharmaceuticals moving through reverse logistics.
5. Amend the P075 listing for Nicotine and Salts by excluding FDA approved over-the-counter Nicotine Replacement Therapies (patches, lozenges, and gums) from the P075 listing.
6. Redefine when containers that held hazardous waste pharmaceuticals are considered "RCRA empty".
7. Establish a policy on the regulatory status of unsold retail items that are not pharmaceuticals and are managed via reverse logistics.

What is NOT included in the final rule:

1. The final rule does NOT expand the universe of pharmaceutical wastes that are considered hazardous wastes. There is no expansion to the waste listings or waste characteristics to include additional pharmaceuticals.

New Definitions

There were several new key definitions included in this final rule. These include:

1. **Evaluated hazardous waste pharmaceutical** means a prescription hazardous waste pharmaceutical that has been evaluated by a reverse distributor in accordance with 40 CFR 266.510(a)(3) and will not be sent to another reverse distributor for further evaluation or verification of manufacture credit.
2. **Hazardous waste pharmaceutical** means a pharmaceutical that is a solid waste, as defined in 40 CFR 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 40 CFR 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 40 CFR 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.
3. **Healthcare facility** means any person that is lawfully authorized to -
    a. 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
    b. 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.
4. **Household waste pharmaceutical** means a pharmaceutical that is a solid waste, as defined in 40 CFR 261.2, but is excluded from being a hazardous waste under 40 CFR 261.4(b)(1).
5. **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 the nursing and skilled nursing care portions of continuing care retirement communities. Not included within the scope of this definition are group homes, independent living communities, assisted living facilities, and the independent and assisted living portions of continuing care retirement communities.

6. **Non-creditable hazardous waste pharmaceutical** means a prescription hazardous waste pharmaceutical that does not have a reasonable expectation to be eligible for manufacturer credit or a nonprescription hazardous waste pharmaceutical that does not have a reasonable expectation to be legitimately used/reused or reclaimed. This includes but is not limited to, investigational drugs, free samples of pharmaceuticals received by healthcare facilities, residues of pharmaceuticals remaining in empty containers, contaminated personal protective equipment, floor sweepings, and clean-up materials from the spills of pharmaceuticals.
7. **Non-hazardous waste pharmaceutical** means a pharmaceutical that is a solid waste, as defined in 40 CFR 261.2, and is not listed in 40 CFR part 261 subpart D, and does not exhibit a characteristic identified in 40 CFR 261 subpart C.
8. **Non-pharmaceutical hazardous waste** means a solid waste, as defined in 40 CFR 261.2, that is listed in 40 CFR part 261 subpart D, or exhibits one or more characteristics identified in 40 CFR part 261 subpart C, but is NOT a pharmaceutical, as defined in the final rule.
9. **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.
10. **Potentially creditable hazardous waste pharmaceutical** means a prescription hazardous waste pharmaceutical that has a reasonable expectation to receive manufacturer credit and is -
    a. In original manufacturer packaging (except pharmaceuticals that were subject to a recall);
    b. Undispensed; and
    c. Unexpired or less than one year past expiration date.

    The term does not include evaluated hazardous waste pharmaceuticals or nonprescription pharmaceuticals including, but not limited to, over-the-counter drugs, homeopathic drugs, and dietary supplements.
11. **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.
12. **Reverse Logistics** refers to the process by which nonprescription pharmaceuticals and other unsold retail items are sent to a reverse logistics center and evaluated for legitimate use/reuse or reclamation. Items sent to a reverse logistics are NOT solid wastes IF there is a reasonable expectation of legitimate use or reclaim.

Amendment of Nicotine Listing

This final rule amends the P075 hazardous waste listing by removing FDA-approved over-the-counter nicotine replacement therapies from the P075 listing because EPA has determined that these wastes do not contain sufficient quantities of nicotine to meet the acute hazardous waste criteria. Over-the-counter nicotine replacement therapies include:

1. Patches
2. Gums
3. Lozenges

These materials are regulated as solid wastes only.

NICOTINE THAT CONTINUES TO BE REGULATED AS P075 ACUTE HAZARDOUS WASTES.

Following are examples of unused formulations containing nicotine as the sole active ingredient that continue to be regulated as P075 acute hazardous wastes:

1. E-Liquids and e-juices in e-cigarettes, cartridges, or vials;
2. Prescription nicotine (e.g., nasal spray or inhaler)
3. “Legacy” pesticides containing nicotine
4. Nicotine used in research and manufacturing

Sewer Prohibition

A prohibition on sewering (disposing of hazardous waste pharmaceuticals down the drain or flushing) is the only regulation included in this final rule that is applicable to all generators of hazardous waste pharmaceuticals. The sewering prohibition applies to all healthcare facilities, including healthcare facilities that are VSQGs, reverse distributors, and DEA controlled substances that are also hazardous wastes. In the final rule EPA strongly discourages the sewering of any pharmaceuticals by any entity.

The sewering prohibition will become effective in ALL states on August 21, 2019.

Summary of 40 CFR 266 Subpart P - Standards for the Management of Specific Hazardous Wastes and Specific Types of Hazardous Waste Management Facilities - Hazardous Waste Pharmaceuticals

A new Subpart P to 40 CFR 266 has been established to regulate the management of hazardous waste pharmaceuticals by healthcare facilities and reverse distributors. Healthcare facilities (for both humans and animals) and reverse distributors will manage their hazardous waste pharmaceuticals under these standards in place of the existing hazardous waste generator regulations. Management of hazardous waste pharmaceuticals under 40 CFR 266 Subpart P is NOT optional.

Subpart P does NOT apply to:

1. Non-pharmaceutical hazardous wastes
2. Hazardous waste pharmaceuticals generated by facilities other than healthcare facilities or reverse distributors

Applicability

The Subpart P regulations apply to:

1. Healthcare facilities managing non-creditable hazardous waste pharmaceuticals, whether they are prescription or not,

2. Healthcare facilities managing prescription potentially creditable hazardous waste pharmaceuticals,
3. Wholesale distributors of hazardous waste pharmaceuticals,
4. Long-Term Care Facilities (LTCFs), although LTCFs with 20 or fewer beds will be presumed to be a VSQG and will be regulated as such.

The following pharmaceuticals are NOT subject to the Subpart P regulations:

1. Pharmaceuticals that are legitimately used, reused, or reclaimed
2. Over-the counter pharmaceuticals, dietary supplements or homeopathic drugs that have a reasonable expectation of being used, reused, or reclaimed
3. Recalled pharmaceuticals
4. Pharmaceuticals under a preservation order or during an investigation or judicial proceeding
5. Investigational new drugs
6. Household waste pharmaceuticals

Generator Regulations under Subpart P

The generator regulations were modeled after EPA's Universal Waste Program in an effort to reduce the regulatory burden for healthcare facilities managing hazardous waste pharmaceuticals.

1. There are no generator categories under Subpart P. All healthcare facilities and reverse distributors are regulated the same regardless of the quantity of hazardous waste pharmaceuticals generated.
2. Facilities do NOT need to track the quantity of hazardous waste pharmaceuticals generated per month.
3. Acute and Non-Acute hazardous waste pharmaceuticals do not need to be segregated.
4. Notification - ALL healthcare facilities must submit a one-time notification that they are operating under Subpart P using the Site ID Form 8700-12.
    a. Facilities that are not required to submit a biennial report must submit the notification 60 days after the rule becomes effective in their state.
    b. Facilities that are required to submit a biennial report may notify on their normal biennial reporting cycle.
5. Training - All personnel managing non-creditable hazardous waste pharmaceuticals must be knowledgeable of the waste handling and emergency procedures relevant to their responsibilities. There are no specific training or recordkeeping requirements.
6. Hazardous Waste Determinations - Healthcare facilities must determine whether a waste pharmaceutical (creditable or non-creditable) is a hazardous waste pharmaceutical. However, if a healthcare facility chooses to manage all of its waste pharmaceuticals as hazardous, individual hazardous waste determinations are not required.
7. Healthcare facilities may accumulate both hazardous and non-hazardous pharmaceuticals in the same container - but they must be managed as hazardous waste pharmaceuticals.
8. Management Standards for Non-Creditable Hazardous Waste Pharmaceuticals
    a. Containers must be marked with the words "Hazardous Waste Pharmaceuticals"
    b. No hazardous waste codes or other labeling requirements
    c. Containers must be structurally sound and compatible with the wastes
    d. Containers must remain closed when not adding wastes
    e. Containers must be secured to prevent unauthorized access to the contents
    f. Hazardous Waste Pharmaceuticals can be accumulated for up to one year

9. Management Standards for Potentially Creditable Hazardous Waste Pharmaceuticals
    a. No labeling requirements
    b. No container standards
    c. No accumulation time limit

Pharmaceutical Hazardous Waste Healthcare Facilities that are VSQGs

Healthcare facilities that are hazardous waste pharmaceutical VSQGs are not subject to Subpart P but can "opt into" Subpart P and comply with all provisions of Subpart P or:

1. Send potentially creditable hazardous waste pharmaceuticals to a reverse distributor
2. Send hazardous waste pharmaceuticals off-site to another healthcare facility provided the facility is:
    a. Operating under subpart P
    b. An LQG operating under 40 CFR Part 262 and meets the requirements for off-site consolidation
3. In all cases, the VSQG MUST comply with the no sewering provisions

Long-Term Care Facilities that are VSQGs

A VSQG LTCF may dispose of hazardous waste pharmaceuticals discarded from the ultimate users in an on-site reception vessel that complies with the DEA regulations. As stated previously a LTCF with 20 or less beds is presumed by EPA to be a VSQG. A LTCF with more than 20 beds can still meet the VSQG requirements.

A VSQG LTCF MUST comply with the no sewering provisions.

Categories of Hazardous Waste Pharmaceuticals

The definition of a hazardous waste pharmaceutical was included previously in the New Definitions section, but in short is a pharmaceutical that is a solid waste that meets one or more of the hazardous waste characteristics or is a listed hazardous waste. This final rule further classifies the pharmaceutical hazardous wastes into three categories:

1. Non-Creditable Hazardous Waste Pharmaceuticals - a prescription hazardous waste pharmaceutical that does not have a reasonable expectation to be eligible for manufacturer credit, or a nonprescription hazardous waste pharmaceutical that does not have a reasonable expectation to be legitimately used, reused, or reclaimed. Examples include:
    a. free samples of pharmaceuticals
    b. investigational drugs
    c. pharmaceuticals that have been removed from the original container
    d. a pharmaceutical that was refused by a patient after an attempt to administer it

SHIPMENTS OF NON-CREDITABLE HAZARDOUS WASTE PHARMACEUTICALS

Shipments of non-creditable hazardous waste pharmaceuticals must comply with the following requirements:

- Must use a hazardous waste manifest
- Must use a licensed hazardous waste transporter

- When shipped by a healthcare facility enter “PHARMS” on the manifest in place of waste codes
- When shipped by a reverse distributor must use applicable waste codes
- Must be sent to a hazardous waste TSDF

2. Potentially Creditable Hazardous Waste Pharmaceuticals - A prescription hazardous waste pharmaceutical that has a reasonable expectation to receive manufacturer credit and is:
    a. in the original manufacturer’s packaging (except pharmaceuticals that are subject to a recall),
    b. undispensed
    c. unexpired or less than one year past the expiration date

    SHIPMENTS OF POTENTIALLY CREDITABLE HW PHARMACEUTICALS

    Shipments of potentially creditable hazardous waste pharmaceuticals must comply with the following requirements:

    - A hazardous waste manifest is not required
    - Use of a licensed hazardous waste transporter is not required
    - May use a common carrier (e.g., FedEx, UPS, USPS)
    - Must receive confirmation of delivery either:
        - from the reverse distributor, or
        - from electronic tracking from a common carrier

3. Evaluated Hazardous Waste Pharmaceuticals is a prescription hazardous waste pharmaceutical that has been evaluated by a reverse distributor and will not be sent to another reverse distributor for further evaluation or verification of manufacturer credit.

    SHIPMENTS OF EVALUATED HAZARDOUS WASTE PHARMACEUTICALS

    Shipments of evaluated hazardous waste pharmaceuticals must comply with the following requirements:

    - Use a hazardous waste manifest
    - Use a licensed hazardous waste transporter
    - Use waste codes on the manifest
    - Must be shipped to a hazardous waste TSDF

Empty Hazardous Waste Pharmaceutical Container Standards

In this final rule EPA is revising the empty container standards for hazardous waste pharmaceuticals to more accurately represent the containers that are utilized in healthcare facilities. EPA has identified four different types of containers typically used in healthcare facilities and has set an empty container standard for each of the types of containers. In the same manner as the existing empty container standards the residues in the empty containers are not regulated as hazardous wastes. The new empty container standards eliminate the requirement to triple rinse these containers if they were used to dispense an acute hazardous waste.

The empty container standards are outlined in the following table.

	Non-Acute RCRA	Acute RCRA Empty

	Empty PHARMS	PHARMS
Stock/Dispensing Bottles (1 liter or 10,000 pills) and unit-dose containers	Remove Contents	Remove Contents
Syringes	Fully Depress Plunger	Fully Depress Plunger
IV Bags	Fully Administer Contents or 40 CFR 261.7(b)(1)	Fully Administer Contents
Other Containers	40 CFR 261.7(b)(1) or (2)	Cannot Be RCRA Empty

Reverse Distributor Standards

A Reverse Distributor can only receive hazardous waste pharmaceuticals that are Potentially Creditable. Prescription pharmaceuticals sent to a reverse distributor are solid wastes when at the healthcare facility. The regulatory standards for a Reverse Distributor are similar to Large Quantity Generators (LQGs). The standards are:

1. No RCRA TSDF storage permit is required.
2. There are NO Generator Categories for Reverse Distributors (e.g., all Reverse Distributors regardless of size are regulated the same).
3. A Reverse Distributor must submit a One-Time Notification using Site ID Form 8700-12.
4. Must maintain an inventory of hazardous waste pharmaceuticals.
5. Must ensure the security of the hazardous waste pharmaceuticals.
6. A Reverse Distributor must inventory and evaluate each potentially creditable hazardous waste pharmaceutical within 30 days of receipt. The evaluation will determine if the waste is creditable and if it needs to be:
    a. Sent to another Reverse Distributor for additional evaluation and is still potentially credicable, or
    b. Sent to a permitted TSDF and is considered an “Evaluated Hazardous Waste Pharmaceutical.”
7. A Reverse Distributor can accumulate hazardous waste pharmaceuticals on-site for up to 180 days.
8. The total time a hazardous waste pharmaceutical can remain at a Reverse Distributor is 210 days (30 days to complete the inventory and evaluate plus 180 days following evaluation).
9. A potentially creditable hazardous waste pharmaceutical can be managed by up to 3 separate Reverse Distributors.

MANAGEMENT STANDARDS FOR POTENTIALLY CREDITABLE HW PHARMACEUTICALS

Reverse distributors managing potentially creditable hazardous waste pharmaceuticals must comply with the following requirements:

1. No specific labeling requirements for containers
2. No specific container standard requirements
3. Not included in biennial report

MANAGEMENT STANDARDS FOR EVALUATED HW PHARMACEUTICALS

Once the manufacturer's credit has been determined/verified, the pharmaceuticals are considered "Evaluated Hazardous Waste Pharmaceuticals" and must be managed by a reverse distributor in accordance with the following requirements:

1. Must Label container as "Hazardous Waste Pharmaceuticals"
2. Containers must be in good condition and managed to prevent leaks
3. Must designate an on-site accumulation area
4. Must conduct weekly inspections of the accumulation area
5. Employees handling Evaluated HW Pharmaceuticals must receive LQG training
6. Hazardous Waste Codes must be applied to the container prior to shipment
7. Must use a hazardous waste manifest and hazardous waste transporter for shipment
8. Must include on the Biennial Report

MANAGEMENT STANDARDS FOR NON-CREDITABLE HW PHARMACEUTICALS

The determination that a hazardous waste pharmaceutical is non-creditable is made by the healthcare facility.

1. During accumulation at the healthcare facility must follow Universal Waste "like" standards
    a. Containers must be structurally sound and compatible with the contents
    b. Containers must be closed
    c. Containers must be secured from unauthorized access
    d. Containers must be marked with the words "Hazardous Waste Pharmaceuticals"
    e. Non-creditable HW pharmaceuticals may be stored on-site for up to one year. The facility can demonstrate one year compliance by:
        i. Marking the accumulation start date on the container
        ii. Maintaining an inventory with accumulation dates
        iii. Storing in a specific area that is identified by the earliest date any non-creditable HW pharmaceuticals were placed in the area
    f. Employees must receive training and be "thoroughly familiar" with proper waste handling and emergency response procedures
    g. Must ship the non-creditable HW pharmaceutical to a permitted TSDF:
        i. Hazardous Waste Manifest
        ii. Hazardous Waste Transporter
        iii. Use Waste Code "PHARMS"

Table Summarizing Subpart P Requirements

	Standards for Healthcare Facilities	**Standards for Reverse Distributors**
	Potentially Creditable	**Potentially Creditable**
On-Site Accumulation	No Standards No Time Limits	Evaluate within 30 Days
Shipping to a Reverse Distributor	Common Carrier Confirmation of Delivery	Common Carrier Confirmation of Delivery
	Non-Creditable	**Evaluated**

On-Site Accumulation	Universal Waste "like" Standards One Year Maximum Timeframe	LQG "like" Standards 180 Days After Evaluation
Shipping to a TSDF	Hazardous Waste Manifest "PHARMS" as Waste Code Hazardous Waste Transporter	Hazardous Waste Manifest Hazardous Waste Codes Hazardous Waste Transporter

DEA Controlled Substances

At this time there are 5 commonly used pharmaceuticals that are both a RCRA hazardous waste that are also DEA controlled substances. In an effort to eliminate the duplication of regulations for these wastes this final rule includes 2 new conditional exemptions for healthcare facilities and reverse distributors for:

1. RCRA hazardous wastes that are also DEA controlled substances; and
2. Household hazardous wastes pharmaceuticals that are collected in DEA authorized collection receptacles.

The above referenced wastes are exempt from the RCRA hazardous waste regulations if they are:

1. Not sewered
2. Managed in compliance with DEA regulations
3. Destroyed using a method that DEA has determined in writing meets the non-retrievable standard
4. Combusted at one of the following facilities that have been determined to meet the non-retrievable standard:
    a. Large or small municipal waste combustor (MWC)
    b. Hospital, medical and infections waste combustor (HMIWI)
    c. Commercial and Industrial Waste Incinerator (CISWI)
    d. Hazardous Waste Combustor

Hazardous Wastes that are also DEA Controlled Substances

Name of Drug	Other Name(s)	RCRA Hazardous Waste Code	DEA Controlled Substance Schedule
Chloral/Chloral Hydrate	Acetaldehyde, trichloro; Aquachloral Noctec, Somnote, Suprettes	U034 Toxic	IV
Fentanyl Sublingual Spray	Subsys	D001 Ignitable	II

Phenobarbital	Bellergal-S Donnatal Luminal	D001 Ignitable	IV
Testosterone Gels/Solutions	Androgel Axiron Fortesta, Testim	D001 Ignitable	III
Valium Injectable/Gel	Diazepam Diastat	D001 Ignitable	IV

Effective Dates and State Adoption

The sewering prohibition is more stringent than current regulations and will become effective in ALL states on August 21, 2019 (6 months after publication of the final rule).

The 40 CFR Subpart P regulations are also more stringent than the current regulations but will not become effective in authorized States until adopted by the States. States that do not require a legislative session to adopt regulations must adopt the Subpart P regulations by July 1, 2021 and States that require a legislative session must adopt the Subpart P regulations by July 1, 2022.

The Nicotine Exemption is less stringent than the current regulations and will only become effective in States that adopt the exemption.

Effective Dates and State Adoption

	Nicotine Exemption (Less Stringent)	**Sewer Ban (More Stringent)**	**Subpart P (More Stringent)**
Non-Authorized States (IA and AK), Territories and Indian Country	August 21, 2019	August 21, 2019	August 21, 2019
Authorized States and Territories where Legislative Session is NOT Required	Effective When State Adopts State Adoption NOT Required	August 21, 2019	Effective When State Adopts State Must Adopt by July 1, 2021
Authorized States and Territories where a Legislative Session IS Required	Effective When State Adopts State Adoption NOT Required	August 21, 2019	Effective When State Adopts State Must Adopt by July 1, 2022

B. Environmental Protection Agency: Information Collection Activities

Agency

Environmental Protection Agency (EPA)

Dates

Published Date: February 8, 2019

Summary

On February 8, 2019, the Environmental Protection Agency (EPA) published Docket EPA-HQ-OLEM-2018-0756 communicating EPA's plan to submit the information collection request (ICR), Requirements for Generators, Transporters, and Waste Management Facilities Under the RCRA Hazardous Waste Manifest System to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (PRA). In addition, EPA is also soliciting public comments on specific aspects of the proposed information collection.

The PRA requires every federal agency to obtain approval from OMB before collecting recordkeeping and reporting information from 10 or more members of the public. Prior to OMB submission, EPA must publish a Federal Register Notice informing the public of the proposed collection of information.

ICR's generally provide a) a description of the information to be collected; b) the reason the information is needed; and c) an estimate of the time and cost for the public to respond to the request. The hazardous waste manifest ICR provides an overview of the recordkeeping and reporting requirements under RCRA and the Hazardous Waste Electronic Manifest Establishment Act, and provides estimates of costs and time for the public to respond.

As part of EPA's ICR effort, the Agency is requesting comment on the following topics:

1. How to improve the precision of waste quantities and units of measure reported on the hazardous waste manifest (both paper and electronic).
    a. EPA is proposing to allow the usage of decimals or fractions in Item 11 of the manifest.
    b. Additionally, EPA is proposing to allow the usage of smaller units of measure, such as ounces, grams, and millimeters, in Item 12 of the manifest.
2. How to enhance the quality of international shipment data reported on the manifest.
    a. EPA is proposing to add separate and distinct fields for export consent numbers for each waste stream.
    b. EPA is proposing to add a new field to capture the exporter EPA ID numbers if not the same as the site initiating the shipment for export.
    c. EPA is proposing to also incorporate new fields on the manifest and whether to consolidate with the movement document.
3. EPA is required by the Hazardous Waste Electronic Manifest Establishment Act to build the e-Manifest system to afford users the ability to report hazardous waste receipt data applicable to the biennial hazardous waste report in e-manifest. To allow for this, EPA is proposing to revise the paper manifest and continuation sheet (EPA 8700-22 and 8700-22A) to include source and form codes and density information.

    EPA will consider the comments received and amend the ICR as appropriate. Once the final ICR package is submitted to OMB for review and approval, EPA will issue another Federal Register notice to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB.

Veolia Impact Statement

Although this is only a request for additional information currently, the future of this rulemaking has the potential to have a significant impact on Veolia operations if changes to the manifest are implemented. Veolia does plan to submit comments to EPA.

Reference/Link

Docket No. EPA-HQ-OLEM-2018-0756; FR Vol. 84, No. 27, 2/8/19, 2854-2858

The link below will allow you to view/print this final rule.
https://www.govinfo.gov/content/pkg/FR-2019-01-29/pdf/2019-00254.pdf

C. Environmental Protection Agency Action Plan for Per- and Polyfluoroalkyl Substances (PFAS)

Agency

Environmental Protection Agency (EPA)

Dates

Released Date: February 14, 2019

Summary

On February 14, 2019, the Environmental Protection Agency released an Action Plan for Per- and Polyfluoroalkyl Substances (PFAS) that includes both short-term solutions and long-term strategies focused on providing states, tribes, and local communities with the tools necessary to provide clean and safe drinking water to their residents and to address PFAS sources.

PFAS belong to a class of thousands of chemicals that have been widely used in a variety of industrial processes and products. Since first being synthesized and introduced in the 1940's, PFAS can be found in aqueous film forming foams (AFFFs) used for fire-fighting and training and in numerous commercial and industrial products. Due to their desired chemical stability of these compounds and their fate and transport, PFAS are now present everywhere in the environment.

EPA is taking a proactive, cross-agency approach to addressing PFAS. The key actions EPA is taking to help provide the necessary tools to assist states, tribes and communities in addressing PFAS are summarized below.

- ***Drinking Water*** - EPA is moving forward with the maximum contaminant level (MCL) process for PFOA and PFOS - two of the most well-known and prevalent PFAS chemicals. The agency is also gathering and evaluating information to determine if regulation is appropriate for a broader class of PFAS.

- **Clean up** - EPA continues strengthening enforcement authorities and clarifying cleanup strategies through actions such as designating PFOA and PFOS as hazardous substances and developing interim groundwater cleanup recommendations. This important work will provide additional tools to help states and communities address existing contamination and enhance the ability to hold responsible parties accountable.

- **Toxics** - EPA is considering the addition of PFAS chemicals to the Toxics Release Inventory and rules to prohibit the uses of certain PFAS chemicals. The Toxics Release Inventory would make information about certain PFAS releases reported by certain industrial sectors and federal facilities available. Additionally, the TSCA new chemicals program will help

manage and, as necessary, reduce risk to human health and the environment from new PFAS.

- **Monitoring** - EPA will propose nationwide drinking water monitoring for PFAS under the next Unregulated Contaminant Monitoring Rule cycle. Monitoring results will improve understanding of the frequency and concentration of PFAS occurrence in drinking water, which can be used to inform regulatory action.

- **Research** - EPA is expanding the scientific foundation for understanding and managing risk from PFAS. Improved detection and measurement methods, additional information about PFAS presence in the environment and drinking water, better understanding of effective treatment and remediation methods, and more information about the potential toxicity of a broader set of PFAS will help EPA, states, and others better manage PFAS risks.

- **Enforcement** - EPA uses enforcement tools, when appropriate, to address PFAS exposure in the environment and assist states in enforcement activities. EPA is seeking to support communities that have PFAS releases by using federal enforcement authorities, where appropriate.

- **Risk Communications** - EPA will work collaboratively to develop a risk communication toolbox that includes multi-media materials and messaging for federal, state, tribal, and local partners to use with the public. This will help ensure clear and consistent messages to the public and will help address concerns related to PFAS

Veolia Impact Statement

This document explains EPA's plan to address PFAS in the environment. As these plans become regulations, they have the potential to significantly impact how Veolia monitors, tests, and treats PFAS.

Reference/Link

EPA publication No. EPA 823R18004

The link below will allow you to view/print this action plan.
https://www.govinfo.gov/content/pkg/FR-2019-01-29/pdf/2019-00254.pdf

D. DOJ/DEA Proposes a new single-sheet format for US Official Order Form for Schedule I and II Controlled Substances (DEA Form 222)

Agency

Department of Justice (DOJ) and Drug Enforcement Agency (DEA)

Dates

Published Date: February 21, 2019
Comments Due Date: April 22, 2019

Summary

On February 21, 2019, the Department of Justice, Drug Enforcement Administration (DEA) published a notice of proposed rulemaking (84 FR 5395-5403) to amend its regulations to implement a new single-sheet format for order forms (DEA Form 222) which are issued by DEA to DEA registrants to allow them to order schedule I and/or II controlled substances. DEA published a notice of proposed rulemaking about this new format in November 2007 but did not finalize it. Due

to the passage time and procedural considerations, DEA is reissuing another notice of proposed rulemaking. This proposal supersedes the November 2007 proposal.

DEA will allow the continued use of existing stocks of the triplicate forms for a two year transition period.

DEA proposes to amend its regulations to reflect that only one original DEA Form 222 will be provided to authorized registrants by DEA. If finalized, registrants that wish to obtain schedule I and II controlled substances (purchasers) would be required to complete and retain a copy of the form and send the original to their supplier for filling. The supplier would be required to record certain information related to the filling on the original and retain such original. The purchaser would be required to record on their copy of the single-sheet form certain information related to the items furnished by the supplier. The purchaser copy is required to be readily retrievable which includes copies that are scanned and stored electronically.

The new single-sheet form will not be produced in "books," which will give DEA and registrants greater flexibility to request a specific number of order forms.

The DEA is also proposing several minor regulatory changes as part of this rulemaking including:

- Clarifying who is authorized to execute a power of attorney.
- Revising the procedure for requisitioning DEA Forms 222 to include any person with an active registration that is authorized to order schedule I and II controlled substances to include obtaining them through a secured network connection.
- Adding procedures for reporting any errors on a DEA Form 222 to the local Diversion Office.
- Adding a computer printer to the list of acceptable methods for filling out a DEA Form 222.

Veolia Impact Statement

This proposed regulation could have a positive impact on Veolia DEA reverse distribution operations by allowing computer completion of DEA form 222 and by increasing the number of entries per form. Veolia will submit comments in favor of this proposed regulation.

Reference/Link

Docket No. DEA-453; 21 CFR Part 1305; FR Vol. 84, No. 35, 2/21/19, 5395-5403

The link below will allow you to view/print this proposed rule.
https://www.govinfo.gov/content/pkg/FR-2019-02-21/pdf/2019-02875.pdf