

## **EPA Promulgates New Rule for Hazardous Waste Generators; Fails to Finalize Waste Pharmaceutical Regulations or Issue General Guidance for Retail Sector**

By Daniel Flynn, Esq.

At the beginning of 2016, the U.S. Environmental Protection Agency (EPA) appeared on track to accomplish three tasks intended to address problems faced by the retail sector in complying with hazardous waste regulations under the federal Resource, Conservation and Recovery Act (RCRA). But as a new year and a new presidential administration settle into place, only one of those tasks has actually been finalized.

### **Background**

First promulgated in 1980, the RCRA regulations were admittedly designed with the industrial sector in mind. For the retail sector, they presented a classic “square peg in a round hole” predicament.

EPA’s efforts to address the retail sector problem began back in 2011 with an Executive Order requiring all federal agencies to develop plans to “determine whether any [of their] regulations should be modified, streamlined, expanded, or repealed so as to make the agency’s regulatory program more effective or less burdensome in achieving the regulatory objectives.”

In 2014, EPA collected comments from the public regarding difficulties encountered by the retail sector in complying with RCRA. In August 2015, EPA addressed some of these concerns by proposing two regulatory amendments, the Hazardous Waste Generator Improvements Rule and the Management Standards for Hazardous Waste Pharmaceuticals Rule. The public comment period on the two proposed amendments ended in December 2015, presumably clearing the way for their promulgation in 2016.

In addition, it was expected that EPA would issue a new guidance document explaining, in general, how the retail sector could reasonably work within the amended RCRA program to minimize the problems experienced in the past.

### **Hazardous Waste Generator Improvements Rule**

The final Generator Improvements Rule was published in the Federal Register on November 28, 2016. The regulation is scheduled to become effective on May 30, 2017 in states where EPA directly administers the RCRA program. States with delegated responsibility for RCRA have until July 2018 or July 2019 to adopt the new requirements. The longer grace period is allowed for states in which an amendment of a statute is required.

The final rule is largely the same as the version EPA first proposed in August, with only a handful of minor changes. According to EPA, its “primary intent ... is to foster improved compliance by hazardous waste generators in the identification and management of the hazardous waste they generate and,

as a result, improve protection of human health and the environment.” In reality, the new regulation is a mixed bag that provides a modest increase in flexibility in some areas, but notably increases potential penalty exposure, regulatory burdens, and restrictions in others. All hazardous waste generators should proceed with caution and familiarize themselves with the new compliance requirements.

One flaw perceived by EPA in its regulatory scheme for RCRA was that the requirements relating to generators were not consolidated in one chapter, making it harder for generators to fully grasp the scheme. Accordingly, the main focus of the Generator Improvements Rule is to consolidate the existing regulations applicable to generators into Part 262 of the RCRA regulations. In addition to this ostensibly neutral reorganization, the Generator Improvements Rule provides a mixed bag of substantive changes that modestly increase a generator’s flexibility in some areas, but notably increase potential penalty exposure, regulatory burdens, and restrictions in others.

EPA advises that most of the changes implemented by the Generator Improvements Rule do not affect the substantive meaning of the regulations. However, there are enough wording “improvements,” “clarifications of existing meaning,” and enhancement of existing requirements mixed among the existing regulatory language that the entire reworked regulatory scheme mandates careful consideration by all generators, whether novice or seasoned.

### **An Up-Close Look at the Changes**

Three of EPA’s substantive changes to the generator requirements should provide generators with new flexibility when complying with RCRA:

- Episodic Generation Events – RCRA reduces the regulatory burdens for generators who generate small amounts of hazardous waste per month. For “Small Quantity Generator” status, the monthly maximum is 1,000 kg (2,200 lbs) of nonacute hazardous waste and 1 kg (2.2 lbs) of acute hazardous waste. For “Conditionally Exempt Small Quantity Generator” status, the monthly maximum is reduced to 100 kg (220 lbs) for nonacute hazardous waste and remains at 1 kg (2.2 lbs) for acute hazardous waste. Prior to the effective date of the Generator Improvements Rule, any event that causes a generator to exceed one of these limits renders it ineligible for reduced regulatory burden and leaves the generator out of compliance unless it had anticipated the event and taken necessary precautions to comply with the increased level of regulation triggered when the monthly generation limit is exceeded.

The Generator Improvements Rule allows a generator claiming the status of a “Very Small Quantity Generator” (EPA’s new name for Conditionally Exempt Small Quantity Generator) or a Small Quantity Generator to maintain that status even if it has one event in a year that would otherwise bump the generator into a more stringent regulatory status. The flexibility allowed by this change, however, is tightly conscribed. Only one such event is allowed per year except that a second event may be allowed if a waiver is obtained from EPA. Also, there are new agency-notification and recordkeeping requirements. A Very Small Quantity Generator must obtain an EPA ID number if it wants to take advantage of this provision. Not surprisingly, a generator must become familiar with the regulatory details and plan its waste management activities carefully in order to safely benefit from this new flexibility.

- Consolidation of Wastes at Larger Facility – A Very Small Quantity Generator that also “controls” a facility that is a Large Quantity Generator has the option of consolidating hazardous waste from the Very Small Quantity Generator facility at the Large Quantity Generator facility for waste management purposes. The Large Quantity Generator facility would not be required to obtain a RCRA treatment, storage, and disposal permit. For retailers that have distribution centers or multiple stores in an area, this creates the option of designating one facility as a Large Quantity Generator and consolidating hazardous waste at that facility for management purposes, thereby reducing the overall waste management burden.

This new flexibility is also tightly conscribed. It is not available to small retailers that do not own multiple stores. It is not available to Small Quantity Generators. There are advance notification, recordkeeping, and reporting requirements. When shipped to the Large Quantity Generator, the wastes must be labeled as “Hazardous Waste” with an indication of the hazards presented.

- Waivability of 50’ Buffer Requirement – One of RCRA’s many waste management rules requires Large Quantity Generators to store containers holding ignitable or reactive hazardous waste at least 50’ from the facility’s property line. For some retailers and other facilities having a small footprint, compliance with this buffer requirement may be impracticable, if not physically impossible. The Generator Improvements Rule allows such a generator to contact the local agency responsible for enforcement of the local fire code to obtain a written site-specific waiver of the 50’ buffer requirement.

With the exception of these three potentially beneficial, but tightly conscribed, provisions, the Generator Improvements Rule either increases the degree of burden and restrictiveness imposed on generators or is neutral. The most significant potential adverse impact for generators is the new language that divides all requirements into two categories: “Condition for Exemption” and “Independent Requirement.”

The enforcement consequence of a violation of an Independent Requirement is what is normally expected—a penalty or other enforcement action appropriate for that particular violation. For example, the penalty for an error in a manifest would be limited to that appropriate for a single violation of the manifest requirement. A generator violating a Condition for Exemption, however, is not only subject to penalties for that violation, but also hundreds of theoretical violations that accrue due to an instantaneous forfeiture of the exemption.

The reason offered by EPA for treating violations of a Condition for Exemption differently is that it views the three generator categories to be exemptions from a general requirement to obtain a treatment, storage, and disposal permit allowing the management of hazardous waste onsite. EPA created these exemptions at the very beginning of RCRA because obtaining and maintaining a treatment, storage, and disposal permit is a very significant burden that is inappropriate for generators that only manage waste temporarily onsite pending offsite shipment for disposal.

A significant problem with EPA’s approach is that its definition of Conditions for Exemption is over-inclusive. The main criteria determining eligibility for the three generator categories are the time limits imposed on storage of hazardous waste prior to shipment for offsite disposal and the quantity limits

on the amount of wastes that can be generated per month by Small Quantity Generators and Very Small Quantity Generators. In addition to these, RCRA specifies many requirements that generators in each generator category must undertake in order to maintain compliance. The definition of Conditions for Exemption incorporates not only the eligibility criteria but also all of the requirements that apply once a generator is in a particular category.

As a result, a generator's "exemption" would also be forfeited by any of the following mistakes, even when there is a good faith effort to comply:

- For Very Small Quantity Generators, an error in classifying hazardous waste or shipment to an unauthorized facility for treatment, storage, or disposal; and
- For Small Quantity Generators and Large Quantity Generators, an error in applicable labeling, inspection, preparedness/prevention, container condition, or other requirements applicable to management of containers.

EPA describes the new "condition for exemption" enforcement scheme as a mere "clarification" of the existing law rather than the promulgation of something new. This statement may be true with respect to violations of storage time and monthly generation quantity limits, but runs contrary to the way agencies and industries have routinely enforced other generator-related requirements now deemed to be conditions for exemption. In the preamble, EPA advises that the new language is not intended to "signal a change" in how it enforces the regulations "in the great majority of enforcement efforts," so hopefully the agency will not be pursuing the draconian penalties allowed by the new language for minor infractions.

In addition to the enforcement consequences of the "condition for exemption" change, the Generator Improvements Rule increases the burdens and restrictions imposed on retailers and other generators in a number of ways, including:

- Increased information required to be included on hazardous waste container labels;
- Enhancement of requirements applicable to Large Quantity Generators and Small Quantity Generators for preparedness, prevention, planning and emergency procedures;
- Increased information required to be retained by Small Quantity Generators and Large Quantity Generators relating to a generator's determination that a material is a waste and the generator's classification of that waste;
- A requirement that Large Quantity Generators and Small Quantity Generators renotify EPA as to their generator status every two years (Large Quantity Generators) and four years (small Quantity Generators);
- New closure requirements for central accumulation units (commonly referred to as < 90-day storage areas) by Large Quantity Generators, and
- New biennial reporting requirements for owners and operators that receive hazardous waste from offsite and partially reclaim it into a commodity-like material or recycle hazardous waste without storing it prior to recycling.

### **Pending Developments**

The Management Standards for Hazardous Waste Pharmaceuticals Rule has been stalled as of this writing due to EPA's review of comments. Unlike the Generator Improvements Rule, the Waste

Pharmaceuticals Rule would apply only to a newly defined category of generators, “healthcare facilities,” handling a newly defined category of hazardous waste, “hazardous waste pharmaceuticals.” Having narrowly limited the proposed amendment’s applicability, the proposed Waste Pharmaceuticals Rule is more innovative in deviating from the industrial-oriented regulatory scheme than the Generator Improvements Rule. Once finalized, the amendment has the potential to provide welcome relief to that portion of the retail sector affected by it.

Instead of publishing a RCRA guidance document comprehensively addressing the most significant problems identified by the retail sector, EPA published in September 2016 a “Strategy for Addressing the Retail Sector under RCRA’s Regulatory Framework.” In its strategy document, EPA summarizes the comments received from the retail sector, and suggests that the retail sector has been helped by EPA’s 2015 modification of the RCRA regulations affecting the recycling of waste materials, as well as some aspects of the Generator Improvements Rule. EPA also touts the proposed Waste Pharmaceuticals Rule as part of its ultimate solution for the retail sector.

Beyond these pending and finalized regulatory amendments, EPA is pursuing a more narrow issue-by-issue problem solving strategy. It released guidance letters clarifying when nicotine products are considered hazardous wastes and when pharmaceutical controlled substances can be accepted at Drug Enforcement Agency-authorized collection receptacles. EPA is still working on solutions for retail sector management of waste aerosol cans and consumer goods, including the potential for allowing reverse distribution or management as universal waste.

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