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March 3, 2009

RCRA Docket  
Environmental Protection Agency  
Mailcode: 2822T  
1200 Pennsylvania Avenue, NW  
Washington, DC 20460

Re: Docket ID No. EPA-HQ-RCRA-2007-0932  
Comments to the Proposed Rule Issued in Federal Register/ Volume 73, No. 232/  
Tuesday, December 2, 2008 - Amendment to the Universal Waste Rule: Addition of  
Pharmaceuticals

The Retail Industry Leaders Association (“RILA”) and its members are pleased to provide comments on EPA’s Proposed Rule - Amendment to the Universal Waste Rule; Docket ID No. EPA-HQ-RCRA-2007-0932.

RILA is an alliance of the world’s most successful and innovative retailer and supplier companies – the leaders of the retail industry. RILA members represent more than \$1.5 trillion in sales annually and operate more than 100,000 stores, manufacturing facilities and distribution centers nationwide. Its member retailers and suppliers have facilities in all 50 states, as well as internationally, and employ millions of workers domestically and worldwide.

RILA believes that the Proposed Rule - Amendment to the Universal Waste Rule: Addition of Pharmaceuticals offers an excellent alternative to the current practice for managing pharmaceutical wastes that meet the definition of a RCRA hazardous waste. The current Universal Waste Rules for managing lamps, batteries, pesticides and mercury-containing equipment have provided a streamlined process for managing these common waste streams. We believe that generators of pharmaceutical wastes that meet the definition of RCRA hazardous waste will also benefit from the proposed rules while effectively managing these hazardous wastes to protect human health and the environment.

Below are several examples of the benefits of implementing the proposed universal waste rule for RCRA hazardous pharmaceutical wastes identified by RILA.

Benefits Associated with Managing RCRA Hazardous Pharmaceutical Waste as a Universal Waste under 40 CFR, Part 273 include:

Improved management of RCRA pharmaceutical wastes by providing a more streamlined waste management system, ensuring that they are sent to hazardous waste management facilities for final disposal.

Pharmacies generating hazardous pharmaceutical wastes would have two waste management options: (1) continue managing these hazardous wastes under the full subtitle C hazardous waste regulations at 40 CFR, Parts 260 to 268 and 270; or (2) manage the RCRA hazardous pharmaceutical wastes as universal wastes per 40 CFR, Part 273.

The universal waste rule does not distinguish between acutely hazardous P-listed wastes and other hazardous wastes. As a result, handlers of pharmaceutical universal wastes would not be required to separate P-listed wastes from other hazardous wastes for purposes of tracking the volumes generated or accumulation volume limits.

Containers that previously held a pharmaceutical and considered RCRA hazardous waste can be managed as universal waste.

Accumulation containers may be open, covered, or sealed provided the performance standard of preventing a release into the environment is met. Most pharmaceutical universal wastes would likely be unused and in the original packaging. Accumulating these wastes in a larger open container would present a minimal risk of release through spills leaks or emissions into the air.

RCRA pharmaceutical wastes would be managed as a single “universal waste” stream, properly segregated to prevent reaction of incompatible wastes.

Increasing the accumulation amount and storage time limits in comparison with RCRA subtitle C hazardous waste regulations, which would allow facilities to accumulate enough waste to make shipment through a hazardous waste hauler more cost-effective.

Licensed RCRA treatment, storage and disposal facilities (TSDFs) receiving the “universal waste – pharmaceuticals” will be required to have trained and knowledgeable personnel to properly sort, manage and dispose of the waste pharmaceuticals versus requiring that these activities be performed at each pharmacy.

Allowing universal waste handlers to transport universal wastes with a common carrier that abides by the applicable DOT regulations.

Reverse distributors that become “universal waste handlers” under the universal waste rule can accept both pharmaceutical universal waste and unused and “creditable” pharmaceutical products.

In addition, RILA has identified some sensitivities or issues associated with the implementation of the proposed universal waste rule for RCRA hazardous pharmaceutical wastes.

Sensitivities/ Concerns/ Issues/ or Further Explanation Needed Regarding the Proposed Rule include:

RILA does not believe it is necessary or economically practical to manage all pharmaceutical wastes under the proposed universal waste rule. Systems and procedures are already in place to manage non-RCRA pharmaceutical wastes in an environmentally-sound manner. RILA believes that the proposed rule is appropriately focused on RCRA hazardous pharmaceutical waste.

Based on RILA's review of the proposed rule, it appears that spilled pharmaceuticals and materials used to clean-up pharmaceutical spills are potentially NOT covered under the proposed universal waste rule. (See page 73523 of the Federal Register). It states that "*In contrast, this definition [i.e., the definition of a "pharmaceutical"] does not include sharps (e.g., needles from IV bags or syringes), infectious or biohazardous "red-bag" waste, waste chemicals from laboratories, medical devices (e.g., blood pressure cuffs, mercury thermometers, x-ray films and fixers), dental amalgams, personal protective equipment contaminated with hazardous pharmaceuticals (e.g., scrubs, gowns, gloves, etc.) or any materials used to clean up spills of hazardous pharmaceutical wastes.*" For example, if a spill of a RCRA hazardous pharmaceutical waste occurs at a facility, then the resulting spill clean-up materials (e.g., the liquid RCRA hazardous pharmaceutical waste and absorbent used in the clean-up) would be required to be managed as a RCRA hazardous pharmaceutical waste. As a result, the facility could trigger "episodic" hazardous waste management generator requirements under Subtitle C. This scenario would create a burden to the facility to comply with the more stringent hazardous waste management generator requirements, thus defeating the purpose and value of the universal waste system. RILA requests clarification of this issue.

Conclusion

RILA and its members believe that proposed universal waste rule will greatly simplify the management of RCRA hazardous pharmaceutical wastes. However, we believe further clarification/ consideration is needed regarding a streamlined-approach to managing the resulting waste associated with spilled pharmaceuticals.

RILA and its members thank you for the opportunity to respond to EPA's Proposed Rule - Amendment to the Universal Waste Rule; Docket ID No. EPA-HQ-RCRA-2007-0932.

Sincerely,



Katherine Lugar  
Executive Vice President, Public Affairs