



# Environmental Technology Council

1112 16<sup>th</sup> Street NW • Suite 420 • Washington DC 20036 • (202) 783-0870

---

## Filed electronically

January 22, 2009

Lisa M. Lauer  
U.S. Environmental Protection Agency  
Hazardous Waste Identification Division  
Office of Solid Waste  
1200 Pennsylvania Avenue NW  
Washington, DC 20460

Re: Request for 45-Day Extension of Comment Period on Proposed  
Amendment to Universal Waste Rule: Addition of Pharmaceuticals

Dear Ms. Lauer:

The Environmental Technology Council (ETC) requests a 45-day extension to the comment period on the proposed addition of hazardous pharmaceutical wastes to the Universal Waste Rule (UWR). 73 Fed. Reg. 73520 (Dec. 2, 2008).

The ETC is a trade association that represents the commercial hazardous waste industry, including many companies that are universal waste handlers and disposers. These ETC member firms have well developed commercial programs for the collection, sorting, processing, and disposing of pharmaceutical wastes that are the subject of the proposed rule, and therefore have a great deal of practical experience to inform our comments to the Agency. We strongly agree that hazardous pharmaceutical wastes are one of the most widely mismanaged waste streams under RCRA today.

However, the ETC requires additional time to develop our comments due to delays during the two week holiday period and the difficulty of collecting information and data that are relevant to several key issues in the proposed rule. In particular, one of the critical issues on our view is the extent to which this proposal will also encourage the collection and disposal of non-hazardous pharmaceutical wastes through the UWR program. Like the Agency, we are hopeful that health care facilities will decide to manage both hazardous and non-hazardous pharmaceuticals in the universal waste program, and thus facilitate better management and remove substantially greater volumes of these materials from the municipal waste stream. To address this issue, ETC firms are reviewing waste management information on the nature, percentage and/or volumes of wastes collected from health care facilities that are hazardous vs. non-hazardous and the potential problems during the collection and distribution chain. Many of these facilities are small quantity generators or CESQGs, and obtaining accurate and useful information has proven a challenge.

Likewise, the ETC is attempting to obtain information from members' pharmaceutical take-back programs and household hazardous waste collection programs to gauge the potential for redirecting pharmaceutical wastes into the UWR system. Since these programs are periodic, local, and ancillary to the primary customer base of health care facilities, it is taking longer to collect and review this type of information.

In addition, the ETC considers the coordination of this proposed rule with DEA regulations and programs on controlled substances to be a critical concern. EPA has specifically requested comment on this issue. 73 Fed. Reg. at 73532. Often waste disposal companies face substantial hurdles to collection of pharmaceutical wastes due to the DEA requirements. ETC members have had numerous discussions with DEA representatives regarding this concern, and on January 21, 2009, the DEA issued an advance notice of proposed rulemaking on options for safe and responsible disposal of dispensed controlled substances. 74 Fed. Reg. 3480. We believe it is critical to coordinate these two important regulatory initiatives by EPA and DEA, and require additional time for that purpose.

Another important concern is how the proposed rule would affect state programs that already manage pharmaceuticals as universal wastes, such as Florida and Michigan. ETC companies already have experience with these state programs, and we believe their experience will be very useful in contributing to our comments, but it will take additional time to collect anecdotal and quantitative information from company operations in these states.

The ETC believes that this proposed rule is one of the most important initiatives that EPA has taken related to the universal waste program, and we certainly want this proposal, when finalized, to lead to better management and safer disposal of pharmaceutical wastes. Given the challenges of collecting relevant information and data to prepare useful comments, however, we respectfully request an additional 45 days for the preparation of public comments.

Thank you for your consideration of this request.

Sincerely

A handwritten signature in black ink, appearing to read "David R. Case", followed by a horizontal line.

David R. Case  
Executive Director

cc: Robert Dellinger, EPA OSW