# Department of Energy

Washington, DC
August 23, 2001

RCRA Information Center Docket Clerk (5305W)
U. S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

**Docket Number F-2001-OMPP-FFFFF**

Dear Sir or Madam:

*Re: 66 FR 38396; "Project XL Site-Specific Rulemaking for the Ortho-McNeil Pharmaceutical, Inc. Facility in Spring House, Pennsylvania"; Proposed Rule*

On July 24, 2001, the U.S. Environmental Protection Agency (EPA) published a notice of proposed rulemaking that proposes to implement a pilot project under the Agency's Project XL program. The proposal addresses a Project XL initiative that relates to the management of certain small volumes of low-level mixed wastes (LLMW) generated and treated at a pharmaceutical research and development laboratory – specifically, the Ortho-McNeil Pharmaceutical, Inc (OMP) facility in Spring House, Pennsylvania. Under the proposal, OMP will utilize an innovative bench-scale treatment process (i.e., an electrically heated, high-temperature catalytic oxidation unit) to treat a radioactive/hazardous organic waste mixture. The treatment process oxidizes the LLMW, thereby destroying its hazardous components and capturing the radioactivity as tritiated water or as radioactive carbon dioxide ($CO_2$).

Consistent with the intent of the XL program, the project proposes a "common sense, cost-effective strategy" that is expected to "demonstrate superior environmental performance." The primary objective of this XL project is to assess whether regulatory oversight provided under the authority of the Atomic Energy Act (AEA) is sufficient to ensure protection of human health and the environment, without also applying Resource Conservation and Recovery Act (RCRA) regulatory control (i.e., in the case of this particular subset of LLMW). Depending on the results of the XL project, EPA indicates that it may consider adopting the proposed regulatory approach on a national basis.

To implement this Project XL, EPA proposes to provide a site-specific exclusion in 40 CFR 261.4(b) ("Solid wastes which are not hazardous wastes") for the waste generated and treated at OMP's pharmaceutical research and development (R&D) laboratory. If the proposal is finalized, the waste will be excluded from RCRA Subtitle C hazardous waste regulation at its initial point of generation (66 FR 38401, column 1). EPA is pursuing this site-specific exclusion with the expectation that the project will provide information and data useful in: (a) ascertaining whether this XL project is a success; (b) making determinations "regarding the appropriate regulatory controls for generic mixed waste as well as [other] possible discrete subsets of mixed waste that may be amenable to an alternative regulatory approach;" and (c) discerning whether the proposed

regulatory flexibility should be adopted on a national basis. This pilot project is also expected to provide additional data regarding the performance of the high-temperature catalytic oxidation unit, which EPA plans to consider as part of any future determination regarding the implementation of the regulatory flexibility on a national basis.

The Department commends EPA for continuing to pursue potential options that would provide regulatory flexibility under RCRA relative to the management of certain problematic mixed wastes. Therefore, DOE supports the proposal to implement the OMP XL project which would allow site-specific regulatory flexibility under RCRA (and would assess the appropriateness of concurrent RCRA and AEA regulatory controls) for small volumes of research and development laboratory-generated mixed wastes. DOE also applauds EPA for its willingness to consider potential regulatory options for certain other mixed waste streams, beyond those that qualify for the regulatory flexibility provided under the Agency's recently promulgated Mixed Waste Rule (May16, 2001; 66 FR 27218). Furthermore, DOE supports EPA's intent "to characterize those factors that may determine whether mixed wastes generated and treated in similar circumstances[1] should also be excluded from the regulatory definition of hazardous wastes (and thus, RCRA regulatory control) by providing such regulatory flexibility on a *national basis*" (66 FR 38396, col. 3).

DOE agrees that the case-specific considerations presented (i.e., the very small volumes of wastes being generated and treated, the small size of the treatment unit, the proximity of the treatment unit to the point of generation, the sophisticated level of expertise of the technicians that work in the laboratory, and the protective controls required under AEA authority) provides the exact type of "test" that the Project XL program is intended to facilitate. Also, based on the above considerations, it does not appear that the application of RCRA permitting requirements would offer any additional protection to human health and the environment. Furthermore, as outlined in the Draft Final Project Agreement,[2] the treatment process (located at the same laboratory where the wastes are generated) reduces the risks associated with spills/exposures during handling and transportation, and captures (rather than releases) the radioactive treatment by-products in a form that is amenable to recycling and reuse. As such, the pilot project reflects the core objectives of RCRA ["to promote the protection of health and the environment and conserve valuable material and energy resources" (RCRA 1003)].

Although the Department supports this action, two technical comments are offered for EPA's consideration. First, the Department suggests that EPA revise its proposed regulatory language under 40 CFR 261.4(b)(17) by replacing "mixed waste" with the phrase "low-level waste." As proposed, using the term "mixed waste" may be misleading. Specifically, RCRA as amended by the Federal Facility Compliance Act of 1992, defines the term "mixed waste" as "waste that contains both hazardous waste and source, special nuclear, or by-product material subject to the AEA." However, since EPA proposes to explicitly exclude the OMP radioactive/organic waste

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[1] That is, similar to the small volumes of mixed wastes generated and treated at research and development facilities, and the dual regulatory oversight exerted over such wastes.

[2] See *EPA Project XL Draft Final Project Agreement, Laboratory-Scale High-Temperature Catalytic Oxidation Process to Treat Low-Level Mixed Wastes*, Section 3.1 Anticipated Superior Environmental Performance, p. 7.

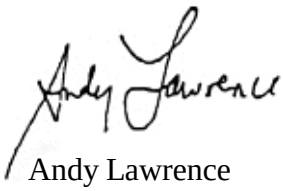
mixture from being hazardous (i.e., the proposed regulatory provision falls under § 261.4(b) which identifies "solid wastes which are not hazardous wastes"), it would not be appropriate to refer to the OMP waste mixture as a "mixed waste."

Second, a discussion in the preamble (at 66 FR 38401, col. 1) states that, because the residuals resulting from the OMP "treatment process will not be derived from hazardous wastes, no "delisting" is required for these residuals (since the original wastestream was not a RCRA "listed" waste)." DOE notes that the above parenthetical statement could be misleading since readers might infer it to mean that delistings ***would*** be necessary for treatment residuals if the original OMP waste meets a listing description (e.g., F001 -F005). DOE points out that, as proposed, each contaminated aqueous mixture will be excluded from RCRA Subtitle C regulation at its point of generation (assuming all the specified conditions are met). Thus, whether the original waste stream would otherwise meet a listing or exhibit a characteristic has no bearing on the RCRA status of its treatment residual, since the residual would be derived from an excluded waste. If this type of discussion is included in the preamble to the final rule, DOE suggests that EPA modify the parenthetical to read as follows [redline font = addition; ~~strikeout~~ font = deletion]:

> . . . no "delisting" is required for these residuals (since the original wastestream ~~was not a~~ is explicitly excluded from RCRA ~~"listed" waste~~ regulation at the point of generation).

DOE recognizes that pilot projects such as the OMP XL project are important in Agency efforts to consider new strategies that reduce regulatory burdens and promote economic growth while achieving better environmental and public health protection. Provided EPA finds this XL pilot project to be a success, the Department encourages the Agency to expedite the implementation of this regulatory flexibility on a nationwide basis. Such relief could alleviate RCRA permitting-related time and resource constraints that currently act as a disincentive to the development of environmentally protective on-site treatment for other small volumes of research and development laboratory-generated mixed wastes.

Sincerely,



Andy Lawrence
Director
Office of Environmental Policy and Guidance

cc: C. Howland, EPA Region III (3OR00)
H. Davis, EPA HQ, Office of Solid Waste (5302W)