

Force. This report, *Reengineering RCRA for Recycling*, presents recommendations of the Task Force to improve the regulation of hazardous waste recycling under RCRA. One of the recommendations of the Task Force was that provision should be made to exempt "clean" waste-derived fuels from the regulatory requirements of RCRA for hazardous wastes. "Clean fuels" are fuels with "*de minimis*" levels of halogens (primarily chlorine in this case) or toxic metals, especially fuels that are characteristically hazardous only because of ignitability. EPA has initiated a rulemaking effort to address the recommendations of the Task Force, including the recommendation on "clean fuels."

In the case of the pharmaceutical manufacturing industry, the volatile organic pollutants that are generated in the largest quantities are non-halogenated volatile organic pollutants, including methanol, ethanol, isopropanol, and acetone. Implementation of in-plant steam stripping or steam stripping with distillation technology affords the opportunity to recover these potentially "clean fuels" for recycle in industrial boilers, such as those on-site at pharmaceutical manufacturing facilities.

Implementation of in-plant steam stripping or steam stripping with distillation technology also affords the opportunity to recover halogenated volatile organic pollutants (e.g., methylene chloride) for recycle in the pharmaceutical manufacturing process. Recovered chlorinated solvents that are not of sufficient quality for reuse in pharmaceutical manufacturing processes may be sold for reuse in other industries.

## 2. Combustion

The Draft Strategy also addresses rigorous controls on hazardous waste combustion facilities using best available technologies to ensure that these facilities do not impose unacceptable risk to human health and the environment. EPA's regulatory activities are scheduled to be directed toward upgrading technical standards for residual wastes and emissions from hazardous waste combustion facilities, including incinerators, cement kilns, light-weight aggregate kilns, and smelter furnaces, as well as boilers and industrial furnaces.

EPA estimates that approximately 115,000 metric tons per year of solvents (halogenated and nonhalogenated) would be recovered from in-plant steam stripping technology at pharmaceutical manufacturing facilities. There is currently adequate capacity at

commercial incinerators to combust the entire mass of solvents (in excess of 1 million metric tons per year) if none was recovered and recycled. However, it is the Agency's policy, as stated in the Draft Waste Minimization and Combustion Strategy, that the most appropriate mode of management for solvents removed from pharmaceutical manufacturing wastewaters by steam stripping is recycle of "clean fuels" in boilers, recycle in the process, or recycle at other facilities.

## XIII. Administrative Requirements

### A. Changes In Format and Name

EPA is not proposing any changes in format to part 439 of the Code of Federal Regulations.

### B. Docket and Public Record

The Record for this rulemaking is available for public review at EPA Headquarters, 401 M Street SW, Washington, DC 20460. The Record supporting the effluent limitations guidelines in part 439 is located in the Office of Water Docket, Room L102 (in the basement of Waterside Mall). The Docket is staffed by an EPA contractor, Labat-Anderson, Inc., and interested parties are encouraged to call for an appointment. The telephone number for the Water Docket is (202) 260-3027.

EPA notes that many documents in the record supporting these proposed rules have been claimed as confidential business information and, therefore, are not included in the record that is available to the public in the Water Docket. To support the rulemaking, EPA is presenting certain information in aggregated form or is masking plant identities to preserve confidentiality claims. Further, the Agency has withheld from disclosure some data not claimed as confidential business information because release of this information could indirectly reveal information claimed to be confidential.

### C. Clean Water Act Procedural Requirements

As required by the Clean Water Act, EPA will conduct a public hearing on the pretreatment standards portion of the proposed rule. The location and time of this public hearing will be announced in a future notice.

### D. Executive Order 12866

Under Executive Order 12866, (58 FR 51735 (October 4, 1993)) requires EPA and other agencies to assess the potential costs and benefits of all significant regulatory actions, and submit these actions to the Office of Management and Budget (OMB). Significant regulatory actions are those

that impose a cost on the economy of \$100 million or more annually or have certain other regulatory, policy, or economic impacts. Today's rule meets the criteria of a significant regulatory action as set forth in section 3(f) of the Executive Order. The regulatory analysis for this proposed rule is presented in "Regulatory Impact Assessment of Proposed Effluent Guidelines for the Pharmaceutical Industry." This analysis (referred to as the RIA) is summarized in section XI.B. Today's proposed rule and the RIA were submitted to the OMB for review.

### E. Regulatory Flexibility Act

The Regulatory Flexibility Act, 5 U.S.C. 601 *et. seq.*, requires EPA and other agencies to prepare an initial regulatory flexibility analysis for regulations that have a significant impact on a substantial number of small entities. EPA projects that today's proposed rule, if promulgated, could affect small businesses. The initial regulatory flexibility analysis for these proposed rules is incorporated into the economic impact analysis and is discussed in section XI.B. Reporting and other compliance requirements are summarized in sections IX.I and detailed in the TDD. While the Agency has not identified any duplicative, overlapping, or conflicting Federal rules, a discussion of other related rulemakings is presented in sections V.B, V.C, V.D, X.A, X.B, XII.A, and XII.B.

### F. Reduction of Unfunded Mandates and Consultation with State, Local, and Tribal Governments

Executive Order No. 12875 supplements Executive Order No. 12866 [Sec. 1(b)(9)], and is intended "to reduce the imposition of unfunded mandates upon State, local, and tribal governments." Facilities in the pharmaceutical manufacturing industry are not associated with tribal governments, and the burden to states and local authorities is expected to be minimal, if not decreased, by the implementation of this rule.

These proposed requirements, when promulgated, will be implemented via the existing regulatory structure and no additional burden is expected beyond that previously estimated by EPA for the NPDES and general pretreatment programs. In the absence of effluent limitations guidelines and pretreatment standards, establishing BAT, BCT, NSPS, PSES, and PSNS permit limitations are to be developed on a case-by-case "Best Professional Judgment" (BPJ) basis. In addition, NPDES permits for all direct dischargers