

environmentally safe manner whenever feasible; pollution that cannot be prevented or recycled should be treated in an environmentally safe manner whenever feasible; and disposal or other release into the environment should be chosen only as a last resort and should be conducted in an environmentally safe manner. See 42 U.S.C. 13101(b).

Today's proposed rule is consistent with this policy. The technology basis for the proposed NSPS and PSNS for facilities with subcategory A, B, C and/or D operations includes steam stripping with distillation. Today's proposed PSES for facilities with subcategory A, B, C and/or D operations, as well as today's proposed BAT limitations for facilities with subcategory A and/or C operations, are based on steam stripping. Both technologies allow for the recovery from wastewaters and possible reuse of organic solvents. As part of today's proposal, the Agency also investigated whether solvent use could be minimized and/or eliminated through process changes but concluded that such opportunities may be limited to specific process operations at some facilities. The Agency encourages research regarding solvent use reduction and/or elimination procedures for existing as well as future pharmaceutical manufacturing operations. The Agency solicits comment on process change (source reduction) opportunities for pharmaceutical manufacturing and products. See section XIV, solicitation number 12.0.

E. Common Sense Initiative

On August 19, 1994, the Administrator established the Common Sense Initiative (CSI) Council in accordance with the Federal Advisory Committee Act (U.S.C. App. 2, Section 9(c)) requirements. A principal goal of the CSI includes developing recommendations for optimal approaches to multi-media controls for six industrial sectors including Metal Plating and Finishing, Electronics and Computers, Auto Manufacturing, and Iron and Steel Manufacturing. The following are the six overall objectives of the CSI program, as stated in the "Advisory Committee Charter."

1. Regulation. Review existing regulations for opportunities to get better environmental results at less cost. Improve new rules through increased coordination.

2. Pollution Prevention. Actively promote pollution prevention as the standard business practice and a central ethic of environmental protection.

3. Recordkeeping and Reporting. Make it easier to provide, use, and

publicly disseminate relevant pollution and environmental information.

4. Compliance and Enforcement. Find innovative ways to assist companies that seek to comply and exceed legal requirements while consistently enforcing the law for those that do not achieve compliance.

5. Permitting. Improve permitting so that it works more efficiently, encourages innovation, and creates more opportunities for public participation.

6. Environmental Technology. Give industry the incentives and flexibility to develop innovative technologies that meet and exceed environmental standards while cutting costs.

The pharmaceutical manufacturing rulemaking effort was not among those included in the Common Sense Initiative. However, the Agency believes that the CSI objectives already have been incorporated into the pharmaceutical manufacturing industry rulemaking. Nonetheless, given the multimedia considerations affecting this rulemaking, the Agency will continue to pursue these objectives. The Agency particularly will focus on avenues for giving state and local authorities flexibility in implementing this rule, and giving the industry flexibility to develop innovative and cost-effective compliance strategies. In developing this rule, EPA took advantage of several opportunities to gain the involvement of various stakeholders. Section XIII.F of this preamble describes consultations with state, local, and tribal governments and other parties including the industry. EPA has internally coordinated among relevant program offices in developing this rule. Section X of this preamble describes coordination between the Office of Water and the Office of Air and Radiation concerning this proposed water and a related air rule that will be proposed at a later date. Also, Section XII of this preamble describes coordination between the Office of Water and the Office of Solid Waste and Emergency Response regarding the hazardous waste implications of this proposed water rule. See Section XIV of this preamble for pertinent comment and data solicitations. The effluent guideline development process for the pharmaceutical manufacturing industry will continue to implement the principles of the Common Sense Initiative.

VI. Regulatory Development Under the Clean Water Act

This section describes the Agency's approach for developing proposed effluent limitations guidelines and standards applicable to the

pharmaceutical manufacturing industry under the CWA. In developing this rule, EPA first collected information about the industry, next identified potential control and treatment technology bases for the effluent limitations and standards EPA proposes to establish, and then, using methodologies, assumptions, and data described in the economic and regulatory impact analyses (See Section XI of this preamble), estimated and analyzed the total environmental and economic impacts of basing limitations and standards on various combinations of these control technologies. Finally, EPA selected the control technologies upon which it based the proposed effluent limitations and standards.

A. Background

The pharmaceutical manufacturing industry releases significant amounts of pollutants to surface waters, and POTWs, and ambient air. Section V of this notice discusses in greater detail the legal authorities available to EPA to address these pollutant releases.

B. Goals

EPA has several technical and policy goals regarding the development of the proposed effluent limitations guidelines and standards. These goals include: (1) Protecting the public health and the environment by attaining significant reductions in pharmaceutical manufacturing industry pollutant releases to water and other media; (2) minimizing the cost of complying with the rule; (3) promoting and facilitating coordinated compliance planning within the industry; (4) promoting and facilitating pollution prevention; and (5) taking into account the multimedia nature of pollution control.

In light of the multimedia nature of the environmental releases from this industry, the Agency has closely coordinated this effluent guidelines rulemaking with the rulemaking and related activities of the Office of Air and Radiation (OAR) and the Office of Solid Waste and Emergency Response (OSWER).

C. Technical Approach

1. Information Collection

EPA's first step in developing these proposed regulations was to develop a plant-specific database, using information gathered under section 308 of the CWA, of all facilities potentially subject to the limitations and standards. See Section VIII below. Information and data were gathered by EPA from a number of sources, including EPA's wastewater sampling program, the 1989