

the proposed guidelines and standards. This summary section highlights the technology bases and other key aspects of the proposed rule. The technology descriptions in this section are presented in abbreviated form; more detailed descriptions are included in the TDD.

Today's notice presents the Agency's proposed regulatory approach and several others that EPA considered. The Agency's proposal is based on comments received from interested parties during the development of this proposed rule, and on detailed evaluation of the available data. As indicated below in the discussion of the specifics of the proposal, the Agency welcomes comment on all options, issues, rationale, and proposed decisions and encourages commenters to submit additional data during the comment period (see section XIV of this preamble). In particular, the Agency welcomes comments on the treatment technologies that EPA has selected as the basis for the limitations and standards being proposed today. For example, EPA bases its proposed standards for new sources primarily on steam stripping with distillation technology. For most existing sources, EPA bases the proposed limitations and standards primarily on steam stripping technology, which is less costly and less energy intensive than distillation technology.

EPA expects a variety of human health, environmental, and economic benefits to result from these reductions in effluent loadings and, in some cases, air emissions. In particular, the benefits include: human health and agricultural benefits due to reductions in emissions of ozone precursors (i.e., reductions in VOC emissions); human health benefits due to reductions in excess cancer risk; human health benefits due to reductions in non-carcinogenic risk; ecological and recreational benefits due to improved water quality; and benefits to publicly owned treatment works (POTWs) from reductions in interference, passthrough, and sludge contamination problems and improvements in worker health and safety. EPA monetized the estimated benefits for reductions in air emissions of ozone precursors and cancer risk reductions, but is unable to quantify the dollar magnitude of benefits from the other benefit categories. Therefore, the reported benefit estimate understates the total benefits of the proposed rule. EPA estimates that the annual benefits resulting from the proposed rule will range from \$231,000 to \$7.6 million (\$1994).

EPA has internally coordinated among relevant program offices in

developing this rule. Section X of this preamble describes close coordination between the Office of Water and the Office of Air and Radiation on this proposed water rule and an air rule that will be proposed at a later date for the pharmaceutical manufacturing industry. As explained in detail in Section X, the Agency intends that direct and indirect dischargers will be able to employ a single steam stripper design to achieve the requirements of both final rules. It is also the Agency's intent, upon promulgation, that both rules will apply to essentially the same high concentration, low volume process wastewater streams in which the bulk of the volatile organic pollutants are contained (see Section X for details). The practical effect of this approach will be that only a relatively small portion (i.e., substantially less than half) of all process wastewaters will require control of volatile organic pollutants (e.g., by steam stripping) to achieve compliance with both rules. In the air rule, EPA also will develop air emission standards for other emission points (e.g., process vents, process area fugitive emissions, etc.). 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, including recovering ignitable nonhalogenated organics and reusing them as "clean fuels."

The Agency has worked with the Food and Drug Administration (FDA) to explore pollution prevention opportunities to the maximum extent feasible. EPA shared with FDA information and data gathered from the industry in responses to EPA's detailed Section 308 questionnaire. This was done to assist FDA in evaluating the environmental impacts of revised drug manufacturing processes (as described in "supplement" applications) and of new drug manufacturing processes. These reviews will ensure that opportunities for solvent use minimization/elimination and water-based manufacturing processes (e.g., water-based tablet coating) are considered and adopted within the constraints of maintaining the efficacy of both existing and new pharmaceutical products.

EPA has involved stakeholders and interested parties, including state and local governments, in the process of developing this rule. Since the inception of the project in 1986, there have been periodic meetings with the industry and its trade association, the Pharmaceutical Research and Manufacturers of America (PhRMA), to

discuss progress on the rulemaking. The Agency also has met with the Natural Resources Defense Council (NRDC) to discuss progress on this rulemaking. Because most of the facilities affected by this proposal are indirect dischargers, the Agency conducted an outreach survey in 1990 to a limited number of POTWs substantially affected by one or more pharmaceutical manufacturing facilities to solicit their input on the need for this proposed rule and pertinent technical issues.

The Agency also held a public meeting on May 23, 1994. EPA representatives of the Office of Water and the Office of Air and Radiation outlined the underlying technical basis and options being considered for this proposal, the efforts to coordinate the future air rule and this proposed water rule, and took comments and questions from the audience. The Agency also consulted recently with representatives of selected POTWs regarding underlying technical aspects of this proposal.

The Agency plans to have additional discussions with stakeholders and interested parties during the comment period to minimize the potential for unfunded mandates and to help ensure that the Agency has the views of such parties and the best possible data upon which to base a decision for the final rule. EPA's final rule may be based upon any technologies, rationale or approaches that are a logical outgrowth of this proposal, including any options discussed in this or subsequent **Federal Register** documents.

#### *A. Effluent Limitations Guidelines and Standards*

##### *1. Subcategorization*

EPA is proposing to maintain the subcategorization scheme under the existing effluent limitations guidelines and standards for this industry (in part 439). The rationale for maintaining the existing subcategorization scheme is detailed in section IX.A.

##### *2. Best Practicable Control Technology Currently Available (BPT)*

EPA is proposing to revise the BPT effluent limitations guidelines for biochemical oxygen demand (BOD<sub>5</sub>), COD, and total suspended solids (TSS) for four subcategories of the pharmaceutical manufacturing industry. These proposed revisions are based on the application of advanced biological treatment. EPA also is proposing to revise the BPT effluent limitations guidelines for CN (Total Cyanide) for facilities with subcategory A and/or C operations, based on in-plant cyanide destruction technology. As discussed in