

years other than 1990 (i.e., 1991–1994, or any later period if available).

7.1 Feasibility and Appropriateness of Such Limits

EPA also solicits comment concerning the feasibility and appropriateness of setting BAT limitations on volatile organic pollutants for facilities with subcategory B and/or D operations based on steam stripping or steam stripping with distillation.

7.2 Point of Regulation for BAT Limitations and NSPS Standards Based on In-Plant Technologies

EPA also solicits comment on the point of regulation for any BAT limitations and NSPS standards based on in-plant technologies.

7.3 Limitations if Facilities Change Their Mode of Discharge

EPA also solicits comment on the issue of whether it should promulgate separate BAT limitations, based on in-plant technologies, for facilities with subcategory B and/or D operations that change their mode of discharge from indirect to direct (in view of EPA's proposal today to base PSES on steam stripping for these subcategories).

8.0 Definition of Process Wastewater

The Agency is proposing a definition of process wastewater for the effluent limitations guidelines regulation set out at 40 CFR section 122.2. The definition specifically includes any water which, during manufacturing or processing, comes into direct contact with or results from the production or use of any raw material, intermediate product, finished product, by-product, or waste product. The types of wastewaters considered to be process wastewater are set out in the proposed regulation at § 439.01(m), and discussed in detail in section 5 of the TDD. EPA solicits comment on the wastewaters being defined as process wastewater.

9.0 Prohibited Discharges

The Agency is proposing to prohibit the discharge of certain materials to POTWs or waters of the United States without an NPDES permit or individual control mechanism authorizing such discharge. See proposed regulation at §§ 439.10, 439.20, 439.30 and 439.40. A list of these materials is set forth at § 439.01(m)(1) of the proposed regulation. The Agency believes that discharge and loss of these materials is inappropriate from the standpoint of productivity loss, pollution prevention, adverse impacts on wastewater treatment (i.e., in POTWs) and worker safety and health.

9.1 List of Prohibited Materials

EPA solicits comment on the specific proposed list of materials prohibited for discharge. EPA is separately soliciting comment on whether BMPs are appropriate for application to control the discharge of these materials through leaks, spills, and intentional diversions (see solicitation number 31 in this section of the preamble).

9.2 Non-Process Wastewaters

EPA solicits comment on the following waters and wastewaters proposed to be excluded from the definition of process wastewater: noncontact cooling water, utility wastewaters, general site surface runoff, groundwater (e.g., contaminated groundwaters from on-site or off-site groundwater remediation projects), and other nonprocess water generated on site. EPA also solicits comment on the proposal that the discharge of such waters and wastewaters be regulated separately.

9.3 Costs of Complying With the Prohibitions

EPA solicits comment on the potential costs of complying with the proposed prohibition of the discharge of materials used in or generated by pharmaceutical manufacturing processes.

10.0 TOC Limits as Alternative to COD Limits

EPA is aware of suggestions that, in some instances, the TOC (Total Organic Carbon) test may be an appropriate substitute for the COD test and that, therefore, TOC limits should be promulgated instead of or as an alternative to COD limits. Industrial commenters on analytical methods have indicated that the approved method for determining COD in wastewater does not completely correct for abnormally high chloride (a direct interferent) concentrations found in some wastewaters.

EPA solicits all influent and effluent TOC and COD concentration data points that are descriptive of the same wastewater stream but the Agency is especially interested in those concentration data that are descriptive of wastewaters with high chloride concentrations.

11.0 Wastewaters From Bioengineered Materials

The Agency recognizes that there has been considerable development of bioengineered materials that may be incorporated in pharmaceutical products. The Agency is concerned about the release of these bioengineered materials in pharmaceutical

wastewaters. EPA solicits comment and data that characterize wastewater from the development of bioengineered materials.

12.0 Source Reduction Activities

The Agency solicits information and data on any efforts (ongoing or planned) concerning source reduction activities at pharmaceutical manufacturing facilities, as discussed in Section IX of this preamble.

12.1 Pollution Prevention and Combustion Strategy

EPA solicits comments on the waste minimization and combustion strategy discussed in Section XII.B of this preamble as it may be applied in this industry. See also solicitation number 22 below.

13.0 Water-Based Tablet Coating Processes

EPA is aware that certain facilities engaging in subcategory D operations (compounding/mixing/formulating) have opportunities to make process changes that can result in lower wastewater discharges and air emissions of volatile pollutants. Specifically, facilities may utilize an aqueous-based tablet coating process as opposed to a volatile organic solvent-based tablet coating process. EPA realizes that this substitution is not feasible for all coating processes. Nonetheless, EPA solicits data from plants in the industry on any changes or substitutions made to solvent-based tablet coating processes.

14.0 Concentration Versus Percent Reduction and Mass-Based Limitations

The Agency today is proposing concentration-based effluent limitations and standards as the most appropriate basis for controlling the discharge of conventional, priority, and nonconventional pollutants from the pharmaceutical manufacturing industry. Industry representatives have commented that alternative formats for these limitations and standards controlling volatile pollutants may be appropriate, including percent removal with base concentrations as provided for in the HON.

14.1 Concentration-Based Format

The Agency solicits comment on the concentration-based format for limitations being proposed today.

14.2 Implementation of an Alternative Percent Reduction Limitation

The Agency solicits comment on alternative percent reduction-based limitations, as used for some of the existing effluent limitations and the