

2. Wastewater Discharge

Based on the responses to the screener and detailed survey questionnaires and other information, EPA has learned that of the 304 potentially affected facilities, 35 facilities discharge their wastewater directly to surface waters of the United States, 259 discharge to a POTW, three discharge directly to surface water as well as to a POTW, and seven do not discharge to a POTW or to surface waters. EPA estimates that the average daily volume of pharmaceutical process wastewater discharged via a POTW or directly from the manufacturing facility to surface waters of the U.S. is 84 and 20 million gallons, respectively.

3. Wastewater Characterization

The pharmaceutical manufacturing industry generates process wastewaters containing a variety of pollutants. Most of this process wastewater receives some treatment, either in-plant at the process unit prior to commingling with other facility wastewaters or in an end-of-pipe wastewater treatment system. Pharmaceutical manufacturers discharge wastewater containing conventional, priority, and nonconventional pollutants. These pollutants are discussed in Section IX.C below.

a. Conventional Pollutants: BOD₅, TSS, and pH. BOD₅, the quantity of oxygen used in the aerobic stabilization of wastewater streams, is the most widely used measure of general organic pollution in wastewater. BOD₅ discharges from facilities with subcategory A and/or C operations are significantly higher than those discharges from facilities with subcategory B and/or D operations because fermentation and chemical synthesis process operations generate substantially greater concentrations of organic material (on average ten times higher untreated BOD₅ concentrations) than extraction or mixing, compounding, and formulating processes.

TSS is the portion of the total solids that can be filtered out of a solution using a 1-micron filter. (Total solids in wastewater is defined as the residue remaining after evaporation at just above the boiling point.) Discharges of TSS for this industry are generally proportional to the amount of BOD₅ discharged and, as a result, A and/or C subcategory facilities discharge significantly more TSS than do B and/or D facilities.

The pollutant parameter, pH, is a measure of the acidity or alkalinity of an aqueous solution. It is defined as the logarithm of the reciprocal of the hydronium-ion concentration of a

solution. A pH of 7.0 indicates neutrality or a balance between free hydronium and free hydroxyl ions. A pH above 7.0 indicates that a solution is alkaline; a pH below 7.0 indicates that a solution is acidic. Untreated wastewaters from the pharmaceutical manufacturing industry range from being highly alkaline (pH 12 or higher) to highly acidic (pH 2 or lower). The pollutant parameter, pH, is currently controlled within the range of 6.0 to 9.0 by promulgated effluent limitations guidelines and standards for all five subcategories of the pharmaceutical manufacturing industry. EPA does not propose to modify the promulgated pH limitations by this rulemaking. Therefore, pH is not included in the following discussion of pollutant parameters.

b. Priority Pollutants. Questionnaire respondents reported discharging 13 different priority pollutants. The annual mass loading of untreated priority pollutants released to the environment from pharmaceutical wastewater (including pollutants emitted to the air from wastewaters) range from 3.6 million pounds per year to 400 pounds per year. The most significant priority pollutants discharged by the industry are methylene chloride, toluene, chloroform, and chloromethane. EPA sampling data at various direct and indirect discharging facilities indicate over 57 different priority pollutants were detected in pharmaceutical wastewaters at various concentrations. Many of the priority pollutants detected during sampling programs were pesticides unrelated to process operations and priority pollutant metals detected at concentrations incapable of being treated by available technologies.

In general, facilities with subcategory A and/or C operations reported discharging a greater variety of priority pollutants and at greater loads than facilities with Subcategory B and/or D operations. The Subcategory B and/or D direct dischargers reported that they did not discharge any priority pollutant load, while the Subcategory B and/or D indirect dischargers reported discharging some priority pollutant load. See Section 9 of the TDD for a presentation of the current priority pollutant discharge loads by subcategory group.

c. Nonconventional Pollutants. Questionnaire respondents reported discharging 105 different nonconventional pollutants, not including COD. The annual mass loadings of nonconventional pollutants released to the environment from pharmaceutical wastewaters (including air emissions from wastewaters) range

from 15.4 million pounds per year to one pound per year. The most significant nonconventional pollutants discharged by the industry are methanol, ethanol, isopropanol, and acetone. EPA sampling data at various direct and indirect discharging facilities indicate over 59 different volatile and semivolatile organic compounds were detected in pharmaceutical wastewaters at various concentrations.

In general, facilities with subcategory A and/or C operations reported discharging a greater variety of nonconventional pollutants and at greater loads than Subcategory B and/or D operations. In addition, the Subcategory B and/or D direct dischargers reported discharging fewer nonconventional pollutants at lower loads than the Subcategory B and/or D indirect dischargers. See Section 9 of the TDD for a presentation of the current nonconventional pollutant discharge loads by subcategory group.

C. Selection of Pollutant Parameters

1. Pollutants Regulated

a. Introduction. This section lists the pollutants covered by today's proposed rule in groups of conventional, priority, and nonconventional pollutants. For this proposed rule, EPA considered each pollutant identified in questionnaire responses and in EPA's sampling programs. In selecting the pollutants for control, EPA took into account their respective discharge loadings, frequency of occurrence, treatability, and environmental significance. In addition, EPA considered whether appropriate analytical methods were available or could be readily developed to detect and quantify the presence of these pollutants in wastewater. Finally, EPA investigated whether bulk parameters (e.g., COD) could be substituted for groups of individual pollutants. EPA concluded preliminarily that no known bulk parameters could be substituted as indicator pollutants for the individual pollutants to be regulated by these proposed effluent limitations and standards. EPA is soliciting comment on this finding. See section XIV of this preamble at solicitation number 37.0. Table IX.C-1 and Table IX.C-2 list the pollutants to be regulated by the various proposed effluent limitations and standards. A complete discussion of the pollutant selection/exclusion process may be found in section 6 of the TDD.

Conventional Pollutants:

BOD₅ and TSS

Priority Pollutants:

Benzene

Chlorobenzene

Chloroform