

noted above, EPA does not have sufficient data to quantify the amount of COD removed after application of steam stripping with distillation technology and therefore could not determine whether granular activated carbon technology is appropriate to remove remaining COD loads. See Section 16 of the TDD for further discussion of NSPS for all four subcategories.

For reasons set forth above in the discussion of the proposed NSPS for facilities with subcategory A and/or C operations, EPA is proposing NSPS for the pollutant COD best performing advanced biological treatment. EPA is not proposing NSPS for COD based on in-plant steam stripping with distillation technology because it has not been able to date to quantify the removal of COD achievable through that technology. See Section XIV of this preamble, solicitation number 20.

(ii) Conventional Pollutants. EPA today is proposing NSPS for BOD₅ and TSS for facilities with Biological and Natural Extraction and Mixing/Compounding/Formulating subcategories (B and D). As noted above for the proposed NSPS for facilities with subcategory A and/or C operations, EPA is not proposing to change the pH limitations incorporated in the existing NSPS for facilities with subcategory B and D operations. Based upon data available for this subcategory, the technology basis selected for these proposed standards—advanced biological treatment—represents the most stringent demonstrated level of performance (the one best performer) for the control of BOD₅ and TSS in these subcategories.

EPA considered the cost of the proposed technology basis for the proposed NSPS for new plants. EPA concluded that such costs are not so great as to present a barrier to entry, as demonstrated by the fact that one currently operating plant is performing at the NSPS level using this technology. The Agency considered energy requirements and other non-water quality environmental impacts and found no basis for proposing any different standards than those based on the selected NSPS for conventional pollutants.

d. Point of Regulation. For the reasons set forth in Section IX.E.3.d., above in connection with BAT, EPA is proposing to specify an end-of-pipe monitoring location for its proposed NSPS standards for facilities with A, B, C and/or D operations (excluding cyanide, for which EPA proposes in-plant limitations for facilities with subcategory A and/or C operations). EPA seeks comments on all issues

pertaining to this proposal. See Section XIV, solicitation number 15. EPA also proposes to provide in the regulations that the standards set forth in the NSPS tables for subcategories A, B, C and D do not apply for any pollutant for which the permit writer finds it necessary to specify in-plant monitoring requirements under 40 CFR 122.44(i) and 122.45(h). EPA proposes that NSPS for those pollutants would be established on a best professional judgment basis pursuant to 40 CFR 125.3. Permit writers in such cases should use as guidance the standards proposed as PSNS for the particular pollutants (as set forth at §§ 439.17(a)(1), 439.27(a)(1), 439.37(a)(1) and 439.47(a)(1) of the proposed regulation), because those standards are based on the steam stripping with distillation technology that also represents the NSPS technology. See Section XIV, solicitation number 15.7.

5. PSES

Pretreatment Standards for Existing Sources (PSES) are established to prevent passthrough of pollutants from POTWs to waters of the United States, to prevent pollutants from interfering with the operation of POTWs, and to reduce non-water quality environmental impacts (e.g., concerns for worker safety and health, sludge contamination, and air emissions). CWA Section 307(b). The current PSES is based on cyanide destruction, which does not remove volatile organic pollutants. EPA is proposing to establish PSES for this industry to prevent passthrough from POTWs of the same pollutants proposed to be controlled by BAT for the respective subcategories, except polyethylene glycol 600, acetonitrile, and phenol. Standards for existing indirect discharging plants are based upon the best available technologies economically achievable, which may include process changes, in-plant controls, and end-of-pipe treatment technologies. As discussed in section 5.a below, EPA is also proposing to establish no PSES at this time for 33 volatile organic pollutants because there is some doubt that these pollutants actually pass through.

The Agency today is proposing to establish pretreatment standards for existing sources in the pharmaceutical manufacturing point source category. These standards would apply to plants in the four manufacturing subcategories of the industry. Currently, according to the 1990 detailed survey questionnaire responses, 259 plants report discharging to POTWs, 88 of which conduct predominantly A and C subcategory operations and 171 conduct only B and

D operations. In 1993, EPA solicited comments regarding PSES from nine POTWs that treated significant quantities of pharmaceutical wastewater. EPA received responses from six POTWs, each of which report treating significant amounts of pharmaceutical wastewater discharges. The questionnaires asked the respondents to comment on the need for pretreatment standards for the pharmaceutical manufacturing category and other matters relating to discharges from pharmaceutical plants. The six POTWs that responded to the questionnaire and their locations are: The Onondaga County Department of Drainage and Sanitation, Syracuse, NY; the Greenville Utilities Commission, Greenville, NC; the Bergen County Utilities Authority, Little Ferry, NJ; the North Shore Sanitary District, Gurnee, IL; the Passaic Valley Sewerage Commissioners, Newark, NJ; and the Puerto Rico Aqueduct and Sewerage Authority, Barceloneta, Puerto Rico.

Except as provided in 40 CFR 403.7 and 403.13, any existing indirect discharger subject to subparts A, B, C or D would be required to achieve the proposed PSES for the subcategory to which the facility is subject by a date three years from promulgation of the final rule.

a. Pass-Through Analysis. To determine whether pollutants indirectly discharged by plants in this industry pass through POTWs, EPA reviewed pharmaceutical manufacturing industry treatment performance data, responses to the detailed questionnaire, performance data for POTWs, and technical literature. In today's notice, EPA makes two alternative proposals associated with PSES and its pass-through determinations. Under co-proposal (1), for subcategories A and C, EPA concludes that nine priority and 42 nonconventional organic pollutants plus ammonia pass through POTWs. Therefore, for all but five nonconventional pollutants for which EPA has not selected a treatment basis, EPA proposes to establish categorical pretreatment standards to regulate those pollutants for subcategories A and C. Similarly under that co-proposal, for subcategories B and D, EPA proposes to establish categorical pretreatment standards to regulate the same pollutants (minus ammonia and cyanide, which EPA has determined are not present in the wastewater of facilities in those subcategories). Under co-proposal (2), EPA proposes that 33 volatile pollutants do not pass through and therefore does not propose PSES for those pollutants for any subcategory.