

organic pollutants covered by this proposed rule. The least stringent control option preliminarily identified in Section X would require all wastewater streams with a flow of 100 liters per minute or greater and a 1,000 ppmw or greater volatile organic HAP concentration to be equipped with controls. Thus, the Agency intends that both rules ultimately will be based on the same control technologies for the same high concentration low volume process wastewater streams that contain the pollutants of concern. In short, EPA expects that the non-water quality environmental benefits that could be achieved by establishing in-plant monitoring requirements in this rulemaking will be realized under the statute that provides the most direct and effective means for controlling the air emissions at issue. By coordinating these rulemakings to the extent that external deadlines allow, EPA hopes to address the multi-media issues associated with the manufacture of pharmaceuticals while using, respectively, the statutory tools best suited to the particular media being protected.

EPA specifically solicits comment on all issues pertaining to the establishment of in-plant limitations on a case-by-case basis, including the burden imposed on permit writers, the recommended limitations, and the reasons EPA considered for setting limitations in-plant on a national basis. See Section XIV, solicitation numbers 7.2, 15.1–15.7. EPA also seeks comment on EPA's policy decision to defer at this time to the Clean Air Act rulemaking. See Section XIV, solicitation number 15.8.

4. NSPS

a. Introduction. The Agency today is proposing New Source Performance Standards (NSPS) for facilities with subcategory A, B, C, and D operations in the pharmaceutical manufacturing industry. New plants have the opportunity to incorporate the best available demonstrated technologies, including process changes, in-plant controls, and end-of-pipe treatment technologies. Current regulations establish NSPS for cyanide based on alkaline chlorination for all four manufacturing subcategories. EPA proposes to revise these standards for facilities with subcategory A and/or C operations and to repeal them for facilities with subcategory B and/or D operations.

b. Definitions of new source. EPA's NPDES regulations define the term "new source" at 40 CFR 122.2 and

122.29. Pursuant to those regulations, to be a "new source" a source must:

- (1) be constructed at a site at which no other source is located;
- (2) totally replace the process or production equipment that causes the discharge of pollutants at an existing source; or
- (3) have processes substantially independent of an existing source at the same site, considering the extent of integration with the existing source and the extent to which the new facility is engaged in the same general type of activity as the existing source. 40 CFR 122.29(b).

Any new source subject to part 439 that was a "new source" as defined under 40 CFR 122.29 prior to the date on which the New Source Performance Standards proposed today are promulgated will continue to be subject to the current NSPS regulations for the subpart to which the source is subject until the expiration of the applicable time period specified in 40 CFR 122.29(d)(1). After that time, the source is no longer considered to be a new source and will be required to achieve the BPT, BCT and BAT effluent limitations proposed in this rulemaking applicable to the source for its subcategory. EPA defines new source for the purpose of NSPS in this rulemaking as a source that commences construction after promulgation of the standards being proposed today, rather than after proposal, because, in accordance with the schedule established in the 304(m) Consent Decree, as modified, EPA does not expect to promulgate final standards within 120 days after proposal. See 40 CFR 122.2 (definition of New Source).

c. NSPS options and selection. (1) Fermentation and chemical synthesis subcategory, subparts A and C. EPA today is proposing NSPS for 58 priority, nonconventional, and conventional pollutants for facilities with operations in the fermentation and chemical synthesis (A and C) subcategories. These proposed standards are based on the best available demonstrated control technology, process, operating method, or other alternative. In developing these proposed standards, the Administrator considered factors including the cost of achieving effluent reductions, non-water quality environmental impacts, and energy requirements.

(i) Priority and nonconventional pollutants. EPA today is proposing New Source Performance Standards for 56 priority and nonconventional pollutants for facilities with subcategory A and/or C operations. In so doing, EPA evaluated two technology options described earlier in section IX.E.3.c.1.

The two options are: (1) In-plant cyanide destruction and steam stripping with distillation plus advanced biological treatment; and (2) option 1 plus Granular Activated Carbon adsorption treatment. EPA did not consider a technology option based primarily on steam stripping without distillation because it is not as effective as distillation in removing pollutants such as methanol, that are difficult to strip. EPA is proposing NSPS based on the technology described in Option 1 for subcategories A and C because EPA has determined that it is the best available demonstrated control technology for treating and removing the pollutants of concern for these subcategories. EPA selected a more stringent NSPS technology than its chosen BAT technology because new sources have the opportunity to segregate their process wastewater in such a way as to minimize the amount of wastewater that will require steam stripping with distillation, thereby reducing the adverse energy impacts that prevented EPA from selecting this technology as BAT.

EPA considered the potential cost of the proposed NSPS technology for new plants, as well as the costs associated with Option 2, which EPA did not select. EPA concluded that costs associated with any option would not be so great as to present a barrier to entry, because EPA anticipated no economic impacts for existing source subcategory A and C plants if they were to implement the proposed NSPS technology. The Agency also considered energy requirements and other non-water quality environmental impacts when comparing the GAC technology (Option 2) with Option 1. EPA concluded that there would be only a slight difference in the energy requirements associated with Options 1 and 2. There are no significant differences in the other non-water quality environmental impacts between the two options considered. EPA did not select Option 2 as the proposed basis for NSPS because, as 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.

EPA is proposing standards to control COD based upon advanced biological treatment, which is the BAT technology. These proposed standards are based on the performance of the "best"