Federal Register

Monday
September 21, 1998

Part III

Environmental Protection Agency

40 CFR Parts 136 and 439

Pharmaceutical Manufacturing Category Effluent Limitations Guidelines, Pretreatment Standards, and New Source Performance Standards; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 136 and 439

[FRL–6135–7]

RIN 2040–AA13

Pharmaceutical Manufacturing Category Effluent Limitations Guidelines, Pretreatment Standards, and New Source Performance Standards; Final Rule

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: This final regulation limits the discharge of pollutants into navigable waters of the United States and into publicly owned treatment works (POTWs) by existing and new pharmaceutical manufacturing facilities. This regulation revises limitations and standards for four subcategories of the pharmaceutical manufacturing Point Source Category: Subcategory A (Fermentation), Subcategory B (Extraction), Subcategory C (Chemical Synthesis): and Subcategory D (Mixing, Compounding, and Formulating); and reformats and clarifies language without revision to certain specified provisions of these four subcategories and a fifth subcategory: Subcategory E (Research). This regulation establishes effluent limitations guidelines and standards under the Clean Water Act including ''best conventional pollutant control technology (BCT) and ''best available technology economically achievable (BAT)'' for existing direct dischargers, ''new source performance standards (NSPS)'' for new direct dischargers and pretreatment standards for existing and new indirect dischargers (PSES and PSNS). This regulation also amends and clarifies some of the limitations based on ''best practicable control technology (BPT)'' for pharmaceutical manufacturing facilities and establishes analytical methods for certain organic pollutants contained in this regulation. EPA is today also publishing final Maximum Available Control Technology (MACT) standards under the Clean Air Act (CAA) for the pharmaceutical manufacturing industry elsewhere in today's **Federal Register**. The MACT standards final rule will control emissions of hazardous air pollutants (HAPs) from pharmaceutical manufacturing emission sources including wastewater collection and treatment systems. The Offices of Water and Air and Radiation have coordinated the development of these regulations and have used a common technology basis in developing limitations and standards for the volatile organic compounds (VOCs).

The final MACT standards and effluent limitations guidelines and standards rules will benefit the environment by removing a total of 85.4 million pounds per year of conventional, nonconventional and toxic (priority) pollutants from water discharges. The effluent limitations guidelines and standards portion of those removals is 13.9 million pounds per year of nonconventional and 16.0 million pounds per year of organic pollutants including VOCs.

DATES: This regulation shall become effective November 20, 1998. The incorporation by reference of certain publications listed in Part 136 is approved by the Director of the Federal Register as of November 20, 1998.

ADDRESSES: For additional technical information write to Dr. Frank H. Hund, Engineering and Analysis Division (4303), U.S. EPA, East Tower, 401 M Street SW, Washington, D.C. 20460 or send E-mail to: hund.frank@epamail.epa.gov or call at (202) 260-7182. For additional economic information contact Mr. William Anderson at the address above or by calling (202) 260–5131 or send E-mail to: anderson.william@epamail.epa.gov.

The complete record (excluding confidential business information) for this Clean Water Act rulemaking is available for review at EPA's Water Docket, Room EB57; 401 M Street, SW, Washington, DC 20460. For access to Docket materials, call (202) 260–3027 between 9 a.m. and 3:30 p.m. for an appointment. The EPA public information regulation (40 CFR part 2) provides that a reasonable fee may be charged for copying.

The Technical Development Document and Economic Impact Analysis supporting today's final water rule may be obtained by writing to the EPA Office of Water Resource Center (RC–4100), 401 M Street SW., Washington, DC 20460, or calling (202) 260–7786.

FOR FURTHER INFORMATION CONTACT: For additional technical information call Dr. Frank H. Hund at (202) 260–7182. For additional information on the economic impact analyses contact Mr. William Anderson at (202) 260–5131.

SUPPLEMENTARY INFORMATION:

Judicial Review

In accordance with 40 CFR 23.2, the rule will be considered promulgated for purposes of judicial review at 1:00 p.m. Eastern time on October 5, 1998. Under section 509(b)(1) of the Act, judicial review of this regulation can be obtained only by filing a petition for review in the United States Court of Appeals within 120 days after the regulation is considered promulgated for purposes of judicial review. Under section 509 (b)(2) of the Act, the requirements in this regulation may not be challenged later in civil or criminal proceedings brought by EPA to enforce these requirements.

Regulated Entities

Entities potentially regulated by this action include:

Category	Examples of regulated entities
Industry	Facilities that generate process wastewater from the manufacture of pharmaceutical products and/or pharmaceutical intermediates by fermentation, extraction, chemical synthesis and/or mixing, compounding and formulating.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. This table lists the types of entities that EPA is now aware could potentially be regulated by this action. Other types of entities not listed in the table could also be regulated. To determine whether your facility is regulated by this action, you should carefully examine the applicability criteria in §§ 439.1, 439.10, 439.20, 439.30, 439.40 and 439.50 of this final rule. If you have questions regarding the applicability of this action to a particular entity, consult the technical information person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

Compliance Dates

The compliance date for PSES is as soon as possible, but no later than September 21, 2001. The compliance dates for NSPS and PSNS are the dates the new source commences discharging.

Deadlines for compliance with BPT, BCT, and BAT are established in the National Pollutant Discharge Elimination System (NPDES) permits.

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I. Legal Authority

This final regulation establishes effluent limitations guidelines and standards of performance and analytical methods for the pharmaceutical manufacturing point source category under the authorities of sections 301, 304, 306, 307, 308, 402 and 501 of the Clean Water Act (''the Act''), 33 U.S.C. 1311, 1314, 1316, 1317, 1318, 1342 and 1361.

II. Background

A. Clean Water Act

The Federal Water Pollution Control Act Amendments of 1972 established a comprehensive program to ''restore and maintain the chemical, physical, and biological integrity of the Nation's waters,'' (section 101(a)). To implement the Act, EPA is to issue effluent limitations guidelines, pretreatment standards and new source performance standards for industrial dischargers.

These guidelines and standards are summarized briefly below:

1. Best Practicable Control Technology Currently Available (BPT) (Section 304(b)(1) of the Act)

BPT effluent limitations apply to all discharges from existing direct dischargers. BPT effluent limitations guidelines are generally based on the average of the best existing performance by plants of various sizes, ages, and unit processes within the category or subcategory for control of pollutants.

In establishing BPT effluent limitations guidelines, EPA considers the total cost of achieving effluent reductions in relation to the effluent reduction benefits, the age of equipment and facilities involved, the processes employed, process changes required, engineering aspects of the control technologies, non-water quality environmental impacts (including energy requirements) and other factors as the EPA Administrator deems appropriate (Section 304(b)(1)(B) of the Act). The Agency considers the category or subcategory-wide cost of applying the technology in relation to the effluent reduction benefits. Where existing performance is uniformly inadequate within a category or subcategory, BPT may be transferred from a different subcategory or category.

2. Best Available Technology Economically Achievable (BAT) (Section 304(b)(2) of the Act)

In general, BAT effluent limitations represent the best existing economically achievable performance of plants in the industrial subcategory or category, based upon available technology. The Act establishes BAT as the principal national means of controlling the direct discharge of toxic and nonconventional pollutants to navigable waters. The factors considered in assessing BAT include the age of equipment and facilities involved, the process employed, potential process changes, and non-water quality environmental impacts (including energy requirements) (Section 304(b)(2)(B)). The Agency retains considerable discretion in assigning the weight to be accorded these factors. As with BPT, where existing performance is uniformly inadequate within a category or subcategory, BAT may be transferred from a different subcategory or category. BAT may include process changes or internal controls, even when these technologies are not common industry practice.

3. Best Conventional Pollutant Control Technology (BCT) (Section 304(b)(4) of the Act)

The 1977 Amendments to the Act established BCT for discharges of conventional pollutants from existing industrial point sources. Section 304(a)(4) designated the following as conventional pollutants: Biochemical oxygen demanding pollutants (BOD_5), total suspended solids (TSS), fecal coliform, pH, and any additional pollutants defined by the Administrator as conventional. The Administrator designated oil and grease as an additional conventional pollutant on July 30, 1979 (44 FR 44501).

BCT is not an additional limitation, but replaces BAT for the control of conventional pollutants. In addition to other factors specified in Section 304(b)(4)(B), the Act requires that BCT limitations be established in light of a two part ''cost-reasonableness'' test. *American Paper Institute* v. *EPA*, 660 F.2d 954 (4th Cir. 1981). EPA's current methodology for the general development of BCT limitations was issued in 1986 (51 FR 24974; July 9, 1986).

4. New Source Performance Standards (NSPS) (Section 306 of the Act)

NSPS are based on the best available demonstrated control technology. New plants have the opportunity to install the best and most efficient production processes and wastewater treatment technologies. As a result, NSPS should represent the most stringent numerical values attainable through the application of the best available control technology for all pollutants (e.g., conventional, nonconventional, and toxic pollutants). In establishing NSPS, EPA is directed to take into consideration the cost of achieving the effluent reduction and any non-water quality environmental impacts and energy requirements.

5. Pretreatment Standards for Existing Sources (PSES) (Section 307(b) of the Act)

PSES are designed to prevent the discharge of pollutants that pass through, interfere with, or are otherwise incompatible with the operation of publicly owned treatment works (POTWs). The Act authorizes EPA to establish pretreatment standards for pollutants that pass through POTWs or interfere with POTWs' treatment processes or sludge disposal methods. The legislative history of the 1977 Act indicates that pretreatment standards are to be technology-based and analogous to the BAT effluent limitations guidelines for removal of toxic pollutants. For the purpose of determining whether to promulgate national category-wide pretreatment standards, EPA generally determines that there is pass through of a pollutant and thus a need for categorical standards if the nation-wide average percent removal of a pollutant removed by well-operated POTWs achieving secondary treatment is less than the percent removed by the BAT model treatment system.

The General Pretreatment Regulations, which set forth the framework for the implementation of categorical pretreatment standards, are found at 40 CFR Part 403. (Those regulations contain a definition of pass through that addresses localized rather than national instances of pass through and does not use the percent removal comparison test described above. See 52 FR 1586, January 14, 1987.)

6. Pretreatment Standards for New Sources (PSNS) (Section 307(b) of the Act)

Like PSES, PSNS are designed to prevent the discharges of pollutants that pass through, interfere with, or are otherwise incompatible with the operation of POTWs. PSNS are to be issued at the same time as NSPS. New indirect dischargers, like new direct dischargers, have the opportunity to incorporate into their plants the best available demonstrated technologies. The Agency considers the same factors in promulgating PSNS as it considers in promulgating NSPS.

B. Section 304(m) Requirements and the Pollution Prevention Act

Section 304(m) of the Clean Water Act (33 U.S.C. 1314(m)), added by the Water Quality Act of 1987, requires EPA to establish schedules for (i) reviewing and revising existing effluent limitations guidelines and standards (''effluent guidelines''), and (ii) promulgating new effluent guidelines. On January 2, 1990, EPA published an Effluent Guidelines Plan (55 FR 80), in which schedules were established for developing new and revised effluent guidelines for several industry categories. One of the industries for which the Agency established a schedule was the Pharmaceutical Manufacturing Point Source Category.

Natural Resources Defense Council, Inc. (NRDC) and Public Citizen, Inc., challenged the Effluent Guidelines Plan in a suit filed in U.S. District Court for the District of Columbia (*NRDC et al* v. *Reilly*, Civ. No. 89–2980). The plaintiffs charged that EPA's plan did not meet the requirements of sec. 304(m). A Consent Decree in this litigation was entered by the Court on January 31, 1992. The terms of the Consent Decree are reflected in the Effluent Guidelines Plan published on September 8, 1992 (57 FR 41000). This plan, as modified, required, among other things, that EPA propose effluent guidelines for the pharmaceutical manufacturing category by February, 1995 and take final action on these effluent guidelines by April, 1998. Recently EPA filed an unopposed motion requesting an extension of time until July 30, 1998 for the Administrator to sign the final rule.

The Pollution Prevention Act of 1990 (PPA) (42 U.S.C. 13101 *et seq.*, Pub. L. 101–508, November 5, 1990) ''declares it to be the national policy of the United States that pollution should be prevented or reduced whenever feasible; pollution that cannot be prevented should be recycled in an environmentally safe manner, whenever feasible; pollution that cannot be prevented or recycled should be treated in an environmentally safe manner whenever feasible; and disposal or release into the environment should be employed only as a last resort...'' (Sec. 6602; 42 U.S.C. 13101(b). In short, preventing pollution before it is created is preferable to trying to manage, treat or dispose of it after it is created. This effluent guideline was reviewed for its incorporation of pollution prevention as part of this Agency effort.

According to the PPA, source reduction reduces the generation and release of hazardous substances, pollutants, wastes, contaminants or residuals at the source, usually within a process. The term source reduction ''include[s] equipment or technology modifications, process or procedure modifications, reformulation or redesign of products, substitution of raw materials, and improvements in housekeeping, maintenance, training, or inventory control.'' The term ''source reduction'' does not include any practice which alters the physical, chemical, or biological characteristics or the volume of a hazardous substance, pollutant, or contaminant through a process or activity which itself is not integral to or necessary for the production of a product or the providing of a service.'' 42 U.S.C. 13102(5) In effect, source reduction means reducing the amount of a pollutant that enters a waste stream or that is otherwise released into the environment prior to out-of-process recycling, treatment, or disposal.

The PPA directs the Agency to, among other things, ''review regulations of the Agency prior and subsequent to their proposal to determine their effect on

source reduction'' (Sec. 6604; 42 U.S.C. 13103(b)(2). This directive led the Agency to implement a pilot project called the Source Reduction Review Project that would facilitate the integration of source reduction in the Agency's regulations, including the technology-based effluent guidelines and standards.

In the preamble to the proposed regulations, EPA discussed the possible pollution prevention alternatives available in pharmaceutical manufacturing. At that time, EPA indicated that pollution prevention opportunities were limited in the active ingredient manufacturing subcategories (namely, fermentation, natural extraction and chemical synthesis) but the use of water-based coatings in the formulation subcategory operations was a viable pollution prevention approach which eliminates the need for solvents in tablet coating operations. This approach may only be applicable to some and not most tablet coating operations, however. Since the proposal, EPA has received two suggestions for incorporating pollution prevention into the final regulations which were discussed in the August 8, 1997 Notice of Availability at 62 FR 42720. One suggestion presented to the Agency was that Subcategories B and D dischargers that incorporate best management practices (BMPs), which reduce their discharge of any of the regulated pollutants should not have to monitor for the specific regulated pollutants, and possibly only monitor for the conventional pollutants and COD. This pollution prevention approach is similar to the one adopted in the Pesticide Formulators, Packagers and Repackagers (PFPR) final regulation which was published in the **Federal Register** on November 6, 1996 at 61 FR 57518. (It should be noted that PFPR facilities that use the promulgated pollution prevention option have to assess their wastewater and may be required to treat wastewater prior to discharge.) EPA evaluated this suggestion and decided that since EPA is not promulgating BAT limitations for specific organic pollutants, this pollution prevention suggestion was not relevant to compliance by subcategory B and D direct dischargers with final BAT limitations. For PSES, EPA believes the suggestion may be workable for indirect dischargers, since standards for specific organic pollutants are contained in the final rule; however, no information was submitted to identify the pollution prevention practices that would be incorporated into the rule, and EPA has been unable to identify any.

Another pollution prevention approach suggested to EPA was that Subcategories A and C facilities that can demonstrate a reduction in the use of a regulated pollutant and resultant lowered air emissions or water discharges should receive a higher effluent discharge limitation. As suggested, the higher effluent discharge limitation would be directly proportional to the amount of reduction achieved in the use of the regulated pollutant. Along with this suggestion, the commenters provided examples of how this pollution prevention suggestion could work in individual instances.

In evaluating this suggestion including the examples provided, EPA was concerned about the amount and type of process information that would have to be obtained from facilities and the methodology for estimating the pollutant reductions as the result of any pollution prevention practices. Another concern of the Agency had to do with the determination of when, in the new product development phase of work, the practice represents a pollution prevention activity or is just part of normal process development work in bringing a new product process to full scale production. EPA was also concerned that pollutant discharge or emission reductions achieved in the bench scale or pilot scale product development activities may not be realized during full scale production operations. In the period following publication of the NOA, the Agency did not receive sufficient information relative to these concerns to enable it to develop a viable pollution prevention alternative based on this suggestion.

C. Updated Profile of the Industry

The pharmaceutical manufacturing industry covered by this rulemaking is made up of 566 facilities located in 39 states, Puerto Rico and the Virgin Islands. EPA estimates that 304 of these facilities could be affected by today's final rule. The major concentrations of manufacturing facilities are located in the Northeast, the Midwest and Puerto Rico.

The pharmaceutical manufacturing industry is defined by four types of manufacturing operations or processes. These activities result in subcategorization for purposes of this rulemaking. The four subcategories are referred to as:

- Subcategory A: Fermentation
- Subcategory B: Natural Extraction
- Subcategory C: Chemical Synthesis
- Subcategory D: Formulating, Mixing and Compounding

A complete discussion of each subcategory's manufacturing operations and wastewater characteristics may be found in Sections 3 and 5 of the final Technical Development Document (TDD), ''Development Document for Final Effluent Limitations Guidelines and Standards for the Pharmaceutical Manufacturing Point Source Category'' (EPA 821–R–98–005).

A fifth subcategory, Subcategory E: Research, was excluded from regulation beyond the existing BPT regulation promulgated on October 27, 1983 at 48 FR 49808. The Research subcategory is defined by bench-scale activities or operations related to the research on and development of pharmaceutical products. BAT/BCT limitations for this subcategory are determined on a case by case best professional judgment (BPJ) basis. For indirect dischargers, the general prohibition in 40 CFR part 403 apply; in addition POTWs will establish local pretreatment limits on a case by case basis as necessary.

D. Existing and Proposed Rules

EPA promulgated interim final BPT regulations for the pharmaceutical manufacturing point source category on November 17, 1976 (41 FR 50676; 40 CFR Part 439, Subparts A through E). The five subcategories of the pharmaceutical manufacturing industry (40 CFR part 439) were defined at that time as:

- Subpart A—Fermentation Products Subcategory
- Subpart B—Extraction Products Subcategory
- Subpart C—Chemical Synthesis Subcategory
- Subpart D—Mixing, Compounding, and Formulating Subcategory
- Subpart E—Research Subcategory

The 1976 BPT regulations set monthly limitations for biochemical oxygen demand (BOD_5) and chemical oxygen demand (COD) based on percent removal for all subcategories. No daily maximum effluent limitations were established for these parameters. The pH was set within the range of 6.0 to 9.0 standard units. The regulations also set maximum 30 day average concentration-based limitations for total suspended solids (TSS) for subcategories B, D and E. No TSS limitations were established for subcategories A and C. Subpart A was amended (42 FR 6813) on February 4, 1977, to improve the language referring to separable mycelia and solvent recovery. The amendment also allowed the inclusion of spent beers (broths) in the calculation of raw waste loads for Subpart A in those instances where the spent beer is actually treated in the wastewater treatment system.

On October 27, 1983, at 48 FR 49808, EPA revised the subcategory names to those currently applicable and promulgated revised BPT, BAT, PSES and PSNS for Subparts A thru D to cover the toxic pollutant cyanide, conventional pollutants BOD_5, TSS and pH, and the nonconventional pollutant COD. The 1983 regulations kept intact the percent reduction regulations for BOD5 and COD established in 1976 but added floor concentration-based limitations for these parameters applicable to subcategories B, D and E. The revisions for TSS consisted of deriving the limitations by the use of a multiplication factor of 1.7 times each plant's BOD_5 discharge. EPA also promulgated BPT, BAT, PSES and PSNS for pH (6.0–9.0) and BAT concentration-based limitations controlling the discharge of cyanide for subcategory A through D. The Agency also proposed NSPS for BOD_5, TSS and pH in the October 1983 notice, but did not publish final NSPS for these parameters.

On December 16, 1986, at 51 FR 45094, EPA promulgated BCT effluent limitations guidelines for BOD_5, TSS and pH for subcategories A thru D. That final rule set BCT effluent limitations equal to the existing BPT effluent limitations guidelines for BOD_5, TSS, and pH.

1. Clean Water Act Proposal

On May 2, 1995 at 60 FR 21592, EPA proposed revised BPT concentration based limitations for BO_5, COD and TSS based on advanced biological treatment for all subcategories and cyanide limitations based on hydrogen peroxide oxidation technology for the A (Fermentation) and C (Chemical Synthesis) subcategories. For BAT, EPA proposed end-of-pipe limitations for 53 organic pollutants plus ammonia, cyanide and COD for subcategories A and C. For subcategories B (Natural Extraction) and D (Formulating, Mixing and Compounding), EPA proposed BAT limitations for 53 organic pollutants and COD. The technology basis for the volatile organic compounds (VOCs) limitations was steam stripping plus advanced biological treatment for subcategories A and C and advanced biological treatment for subcategories B and D. The technology basis for the non-volatile organics was advanced biological treatment only, and the proposed ammonia limitations were based on nitrification. The proposed BAT cyanide limitations were equivalent to the BPT limitations, and the BCT limitations were also proposed equal to BPT for all manufacturing subcategories.

For NSPS, EPA proposed end-of-pipe standards for 53 organic pollutants plus ammonia, BO_5, TSS, cyanide and COD for subcategories A and C and end-of-pipe standards for 53 organic pollutants plus BO_5, TSS, and COD for subcategories B and D. The BO_5, COD, and TSS standards were based on two sets of performance data from the best performing plants in each of the A or C and B or D subcategories. The end-of-pipe VOC limitations were based on steam stripping with distillation and advanced biological treatment.

For PSES EPA detailed two coproposals (A and B) to control VOCs in all subcategories. Coproposal A had pretreatment standards for 12 highly volatile organic compounds and 33 less volatile organic compounds. To show compliance with the pretreatment standards, monitoring for the 12 highly volatile compounds would have been required in-plant. Coproposal B had only the pretreatment standards for the 12 highly volatile compounds. In addition, EPA proposed cyanide (identical to BPT) and ammonia standards (based on steam stripping) for subcategories A and C. The proposed PSNS differed from PSES in that the standards for all volatile organic compounds were based on steam stripping plus distillation technologies.

Finally, EPA proposed that pilot plant wastewater would not be regulated by Subcategory E (Research) limitations but under appropriate manufacturing subcategory limitations.

2. Clean Air Act Proposal

On April 2, 1997 at 62 FR 15753, EPA proposed National Emission Standards for Hazardous Air Pollutants (NESHAPs) for the Pharmaceuticals Production Source Category. In that proposed rule, the Agency proposed Maximum Available Control Technology (MACT) standards for controlling emissions of hazardous air pollutants (HAPs) from process vents, storage tanks, equipment leaks, wastewater collection and treatment systems and heat exchange systems at pharmaceutical manufacturing facilities that are determined to be major sources of HAPs.

The proposed MACT standards for wastewater emission sources contained two alternative formats for achieving compliance, a percent removal and a reference control technology. Applicability determination, definitions, and control requirements were similar to the Hazardous Organic NESHAPs (HON) MACT standards for wastewater. The proposed standard required facilities to control wastewater streams that exceed the concentration cutoff where the process wastewater stream exits the pharmaceutical process equipment identified as the point of determination (POD). The proposed concentration cutoffs were 1,300 parts per million by weight (ppmw) for partially soluble HAPs and 5,200 ppmw for total HAPs at processes or PODs with annual HAP loads of 1 megagram per year or metric ton per year (Mg/yr).

Also, the proposed standard required all streams having a HAP concentration of 10,000 ppmw to be controlled at facilities with annual HAP loads of 1 Mg/yr or greater.

The proposed standards required that the control of wastewater emissions be accomplished in one of the following manners: (1) Using a design biotreatment system for soluble HAPs; (2) Demonstrating removals achieving 99 percent by weight of partially soluble HAPs and 90 percent by weight of soluble HAPs from treatment systems; or (3) Demonstrating a removal of 95 percent by weight of total organic HAP from the treatment system. The MACT standard proposal also discussed options for CWA controls in light of the CAA MACT standard proposal for controlling emissions from wastewater streams at pharmaceutical facilities being covered by the proposed effluent limitations guidelines and standards. EPA's intent was that the effluent limitations guidelines and standards build on the MACT standards, and the discussion suggested several options to accomplish this.

3. Clean Water Act **Federal Register** Notice of Availability

EPA published a Notice of Availability (NOA) in the **Federal Register** on August 8, 1997 at 62 FR 42720. EPA published this Notice in order to: allow public comment on the data received since the May 2, 1995 CWA proposal, further develop and revise options for the control of the VOCs that were presented in the April 2, 1997 CAA MACT proposal, and suggest responses to some comments on the 1995 CWA proposal.

In section II of the NOA, EPA provided the results of an EPA sampling study designed to provide information concerning the pass through analysis for water soluble organic pollutants such as methanol and discussed the pass through analysis that EPA would be performing with respect to these and other pollutants.

In section III, EPA presented revisions of the pretreatment options which were earlier described in the MACT proposal, and presented options for reducing the discharge loadings of VOCs not controlled by the proposed MACT

standards. One option was compliance with the proposed MACT standards together with additional PSES requirements for all VOCs except alcohols and related compounds based on the performance database used in the 1995 proposal. A second option included coverage of additional pollutants including alcohols and related compounds. EPA also presented costs and loadings for two scenarios involving these two options. One scenario would exclude facilities that discharged less than 10,000 pounds per year of pollutants of concern, while the other scenario would not exclude them.

In section IV, EPA presented the results of analyses with respect to the proposed data base for NSPS requirements for the conventional pollutants, COD and ammonia, pollutant exclusions, use of surrogate pollutants for compliance monitoring, small facility exclusion and changes to engineering costs and loadings removal estimates. In addition, EPA presented data editing criteria and methodologies for deriving BPT and BAT effluent limitations and PSES. On pages 42722–42724 of the NOA, EPA presented BPT, BAT limitations and PSES being considered.

E. Discussion of Final Clean Air Act Rule Published Elsewhere in Today's Federal Register

EPA received a number of comments on the proposed MACT standards for wastewater streams. While certain changes were made (see the final MACT rule published elsewhere in today's **Federal Register**) the controls required by the proposed MACT standards have not changed. As proposed, the final MACT incorporates the HON wastewater standards, thereby clarifying the MACT requirements for off-site treatment of wastewater. Under specified conditions, a source can transfer affected wastewater streams containing soluble HAPs and less than 50 ppmw partially soluble HAPs off-site for treatment. In addition, if the off-site treatment facility is a POTW with uncovered headworks (grit chamber, primary settling tanks, etc.) a demonstration that less than five percent of the total soluble HAPs are emitted is required. For POTWs with completely covered headworks, the final rule does not require a demonstration that less than five percent of the total soluble HAPs are emitted.

F. Relationship Between the MACT and CWA Rules

As noted above, the CAA MACT rule being promulgated today sets emission standards for HAPs from wastewater collection and treatment systems at major source pharmaceutical manufacturing facilities. The CWA final effluent limitations guidelines and standards control the discharge of toxic, conventional and nonconventional pollutants in wastewater discharges from pharmaceutical manufacturing facilities. Some of the water pollutants being controlled by today's effluent guidelines and standards are also HAPs and thus these pollutants are being controlled by both the MACT and CWA final rules. The extent of the coverage of waterborne HAPs by the air and water rules will be discussed in subsequent sections, as will the joint economic analysis and environmental benefits assessment that were conducted for the two rules.

G. Final Clean Water Act Effluent Guidelines Limitations and Standards Rule

Today EPA is promulgating revised BPT limitations only for COD based on advanced biological treatment for all four subcategories.

For subcategories A and C, EPA is promulgating BAT limitations for COD equal to the revised BPT limitations and for 30 organic pollutants, including 28 VOCs (of which 13 are HAPS) based on advanced biological treatment identified as a basis for the revised COD limitations. In addition, for subcategories A and C, EPA is promulgating BAT ammonia limitations based on nitrification technology, and is modifying the BAT compliance monitoring requirements for the existing cyanide limitations.

For subcategories B and D, EPA is adding BAT limitations for COD equal to the revised BPT requirements, and is withdrawing the existing BPT and BAT cyanide limitations since the facilities in these subcategories do not generate cyanide in their wastewaters.

The Agency is promulgating PSES for 23 VOCs (10 of which are HAPs) plus ammonia for subcategories A and C, and is also clarifying the compliance requirements for the existing cyanide pretreatment standards. For subcategories B and D, EPA is promulgating PSES for the 5 VOCs (1 of which is a HAP) and, for the same reason given above, is withdrawing the existing cyanide standards. Subcategories A and C facilities must continue to comply with the cyanide standards, and achieve compliance with the standards for ammonia and the 23 organic pollutants within three years. Subcategories B and D facilities must achieve compliance with the 5 organic pollutant standards within three years. The compliance times of up to three years is being given because of the design and installation of technologies used as a basis for the standards, such as steam stripping and nitrification require sufficient lead times for implementation.

EPA is promulgating NSPS for subcategories A and C equal to the BAT limitations for COD, ammonia and the organic pollutants, including the VOCs, and revised limitations for BOD_5 and TSS based on advanced biological treatment. EPA is also promulgating NSPS for subcategories B and D equal to BAT for COD and revised limitations for BOD_5 and TSS based on advanced biological treatment, and is withdrawing the existing cyanide NSPS for these two subcategories.

For PSNS EPA is promulgating standards equal to PSES for all pollutants and subcategories and is withdrawing the existing cyanide PSNS for subcategories B and D. Finally, EPA is promulgating BCT limitations equal to the existing BPT limitations for BOD_5, TSS and pH.

In today's rule, EPA has republished many parts of the existing guideline in Part 439 to make the changes made today easier to understand, and also reformated the guideline to make it more clear and easier to use. The republication or reformatting of existing requirements is not intended to introduce substantive changes to these regulatory provisions. For that reason, EPA believes prior notice and comment on these provisions is unnecessary.

III. Summary of Most Significant Changes to Water Rules From Proposal

This section describes the most significant changes to the rule since proposal. Many of these changes have resulted from the comments that are discussed below (see section X). This section will discuss the major changes in the rule concerning revisions to the limitations and standards for VOCs, changes in the BAT technology basis and changes in the BPT and BAT limitations for pollutants other than the VOCs. More detailed explanations for changes may be found in the comment response document in the record of the final rule.

A. Limitations and Standards for Volatile Compounds

In today's final rule, EPA is not requiring that the limitations for VOCs be measured in-plant as proposed. For all four subcategories, BAT, NSPS, PSES, and PSNS limitations and standards, except for cyanide limitations and standards in subcategories A and C, this rule does not alter the generally applicable rule

(122.45(h) or 403.6(e)) that limitations generally are measured at the end-of-pipe discharge point. This rule provides clarification of the existing in-plant monitoring for cyanide as discussed in the Implementation Section of this preamble (see section VIII A).

At proposal, EPA proposed PSES for 13 alcohols and related pollutants (compounds) under coproposal B. These pollutants were methanol, ethanol, n-propanol, isopropanol, n-butyl alcohol, tert-butyl alcohol, amyl alcohol, formamide, N,N-dimethylaniline, pyridine, 1,4-dioxane, aniline, and petroleum naphtha. No PSES/PSNS are being promulgated for these pollutants today because EPA determined these pollutants do not pass through POTWs or interfere with the treatment works. (See section IV.E for a discussion of the passthrough analysis for these pollutants).

B. Change in BAT Technology Basis for Organic Pollutants

In the August 8, 1997 NOA, EPA discussed changing the technology basis for BAT organic pollutant limitations for subcategories A and C facilities from in-plant steam stripping and advanced biological treatment to advanced biological treatment only. EPA received comments supporting this change in technology basis. The final MACT standards being promulgated today will control most emissions of VOCs from wastewaters at subcategories A and C direct discharging facilities based on the use of steam stripping technology. Accordingly, EPA believes that it is not necessary or appropriate to include this technology in the BAT technology basis; the CWA limitations and standards are calculated from a data base representing advanced biological treatment only. Thus, EPA is promulgating BAT limitations for all of the 30 organic pollutants for subcategories A and C facilities based on advanced biological treatment only. EPA notes that one facility not covered by the MACT standards would need to install steam stripping technology in order to achieve the effluent limitations following the biological treatment system.

C. BPT and BAT/BCT Limitation Changes

Based on the receipt of new data from commenters, proposed limitations were revised for the nonconventional pollutants COD and ammonia and a number of the organic pollutants. In addition, commenters on the proposed limitations for the conventional pollutants BOD5 and TSS, as well as COD, indicated that EPA should eliminate all non-process wastewater in the calculation of limitations for these parameters. In developing limitations for the proposal, EPA did not back out the estimated non-process wastewater from the total wastewater flow and adjust the concentration accordingly because the non-process flow data provided by facilities in the data sets were only gross estimates and were not based on daily measurements of non-process flow. Despite requesting more precise information (such as daily non-process flow data) from facilities that generated the data sets used to calculate the proposed limitations for BOD5, TSS and COD, EPA did not obtain this information. However, in the NOA, EPA presented revised proposed limitations for BOD5 and TSS and COD that were calculated from the existing plant data sets using the gross estimates of non-process flow, as described below, to adjust the concentrations in addition to several new data sets from plants other than those used for the proposal.

In a previous EPA effluent limitations guidelines and standards rulemaking for the Organic Chemicals, Plastics and Synthetic Fibers (OCPSF) industry (52 FR 42522), only plant data sets that contained less than 25 percent non-process wastewater through treatment were used in calculating limitations. Thus, the 25 percent level of non-process wastewater dilution was determined as a benchmark in order to evaluate biological treatment performance. For the purposes of the NOA, in cases where the non-process flow was estimated to be more than 25 percent of the total flow, the non-process wastewater was backed out of the total flow volume and the parameters corrected for the absence of this non-process wastewater. However, for the final rule, limitations for COD are developed from data sets in which the reported flow volume contains less than 25 percent non-process wastewater and the limitations are calculated without correcting the data sets for the non-process flow dilution. This change is discussed further in section IV.D below. As further discussed below, limitations for BOD5 and some of the remaining TSS are not being revised at this time since the revised COD limits requiring advanced biological treatment will incidentally remove a large portion of the remaining BOD5 and TSS.

Another change to the proposal involved the limitations and standards proposed for cyanide. EPA proposed BPT, BAT, NSPS, PSES and PSNS limitations and standards for cyanide based on the performance of hydrogen peroxide oxidation technology. Following the proposal, EPA received comments indicating that the use of the hydrogen peroxide technology to destroy cyanide could possibly result in equipment explosions with certain types of wastewater. Other commenters indicated that hydrogen peroxide technology may not be an appropriate cyanide destruction technology for all treatment situations. Along with these comments, EPA received additional data on the performance of alkaline chlorination technology in destroying cyanide. Based on these comments and the new performance data, EPA indicated in the NOA that it was considering promulgating two sets of cyanide limitations, one based on the performance of hydrogen peroxide technology and the other based on the performance of alkaline chlorination technology. In the NOA, EPA indicated that only those facilities that could demonstrate that a potential safety hazard could result from their use of hydrogen peroxide technology would be subject to the alkaline chlorination limitations and standards. EPA also solicited information and comments regarding wastestreams with high organic content as evidenced by high COD or total organic carbon (TOC) levels, and at what levels these pollutants would indicate that the wastestream(s) high organic content would present a safety concern and would more appropriately be controlled by limitations based on alkaline chlorination. After consideration of the information provided in response to the solicitation in the NOA, particularly new performance data representing current (post 1990 base year) loadings, EPA has decided not to revise the existing limitations and standards for cyanide based on the small amount of cyanide discharge loadings that would be removed. However, the final rule continues to require compliance with the cyanide limitations be established in-plant, prior to commingling the cyanide bearing wastestreams with non-cyanide wastestreams for those facilities where the cyanide levels would be below the level of detection at the end-of-pipe monitoring location.

Along with comments on its proposed numerical limitations and standards for ammonia and organic pollutants, EPA received data concerning the performance of steam strippers, advanced biological treatment and nitrification in connection with these proposed limitations. EPA evaluated these data, and provided revised numerical limitations and standards in the NOA for ammonia, several organic pollutants controlled by BAT technology (advanced biological treatment) and several VOCs controlled

by steam stripping technology for PSES. As the result of the data received and evaluated, along with comments on the NOA, EPA has changed the numerical BAT limitations for ammonia. In response to comments in the NOA indicating that indirect dischargers should be able to achieve the PSES ammonia limitations using either two-step nitrification technology or steam stripping, EPA has decided to set the PSES ammonia limitations equal to the BAT ammonia limitations, and to provide that indirect discharging subcategories A and C facilities discharging to POTWs with nitrification capability need not comply with the categorical limit for ammonia. EPA has also changed the numerical BAT limitations and PSES for several organic pollutants based on its analysis of data received in response to the proposal.

D. Pollutant Selection

EPA received several comments concerning the reasoning behind the regulation of certain pollutants as well as the overall rationale for selecting pollutants for regulation. In the NOA, EPA indicated that it had reviewed the loadings bases of all the pollutants selected for regulation and had determined that in the case of eight pollutants, insufficient amounts of the pollutants are being discharged to justify national regulation. These pollutants are diethyl ether, cyclohexane, chloromethane, dimethylamine, methylamine, furfural, 2-methylpyridine and trichlorofluoromethane. Since the NOA, EPA has reevaluated its final loadings database and has determined that the exclusion of these pollutants along with an additional 15 pollutants is appropriate. The additional 15 pollutants are excluded from the BAT regulation based on the lack of removals from current discharge or the control of discharges of the pollutant by other regulated pollutant parameters. These pollutants are butanone, formaldehyde, n-butanol, tertiary butanol, n-propanol, ethylene glycol, polyethylene glycol 600, aniline, petroleum naphtha, 1,4-dioxane, formamide and dimethyl formamide, dimethylaniline, dimethylacetamide and pyridine.

EPA proposed PSES for 45 organic pollutants, 37 of which are VOCs, under co-proposal A with compliance for the standards for 12 of the VOCs to be monitored in-plant, and compliance for the standards for the remaining 33 organics to be monitored at the end-of-pipe. In the NOA, EPA presented two revised PSES options, under which EPA would promulgate pretreatment standards for VOCs with end-of-pipe monitoring. The pollutants not regulated under one of these PSES options include water soluble alcohols such as methanol and related compounds. After consideration of comments and evaluating the results of the Barcelonetta POTW study and its implications on the final pass through analysis (see further discussion of pass through analysis in section IV E below) and further evaluation of incidental removals and the amount of or discharge removals for the pollutants, EPA is promulgating PSES and PSNS for 23 VOCs for subcategories A and C and 5 VOCs for subcategories B and D. The PSES and PSNS do not include the alcohols and related compounds, and are based on monitoring at the end-of-pipe unless the POTW determines it to be impractical per 40 CFR 403.6(e).

IV. The Final Clean Water Act Regulation

This section discusses the applicability of the final rule, regulatory options considered and the rationale for the selected options for BPT, BCT, BAT, PSES, PSNS and NSPS.

A. Applicability and Scope of the Final Rule

Today's final effluent limitations guidelines and standards are intended to cover pollutants in process wastewater discharges from existing and new pharmaceutical manufacturing facilities. Based on comments, EPA has revised the proposed scope of the rule. This final rule contains revisions to the effluent limitations guidelines and standards in four subcategories (A thru D) of the pharmaceutical manufacturing point source category, EPA is not revising the scope of the applicability for the fifth subcategory (Subcategory E-Research).

With regard to subcategory E facilities, EPA proposed to revise the description of the research subcategory in the applicability section of the existing subcategory E regulations to exclude pilot or full-scale operations that generate wastewater using fermentation, extraction, chemical synthesis or mixing, compounding and formulating from the scope of subpart E, and these operations were proposed to be covered by the appropriate subcategory A through D. After considering the comments received concerning the regulation of wastewaters from pilot-scale operations, EPA has decided not to change the existing description of the research subcategory in the applicability section. EPA believes that it does not have sufficient information concerning subcategory E generated wastewaters to change the existing description. Subpart E facilities remain subject to the BPT limitations in the existing guidelines. If pilot scale operations occur at either stand alone research facilities or during operations at manufacturing facilities, then BAT and BCT limits for these wastewaters can be determined by permit writers on a best professional judgment (BPJ) basis, or similarly, such wastewater generated at indirect discharging facilities may be addressed by the regulations found at 40 CFR 403.5 and by local limits on a case-by-case basis.

Pharmaceutical manufacturers use many different raw materials and manufacturing processes to create a wide range of products. These products include medicinal and feed grades of all organic chemicals having therapeutic value, whether obtained by chemical synthesis, fermentation, extraction from naturally occurring plant or animal substances, or by refining a technical grade product.

The pharmaceutical products, processes and activities covered by the manufacturing subcategories in this final regulation include, but are not limited to:

a. Biological products covered by the U.S. Department of Commerce, Bureau of the Census Standard Industrial Classification (SIC) Code No. 2836, with the exception of diagnostic substances. (Products covered by SIC Code No. 2836 were formerly covered under the 1977 SIC Code No. 2831.)

b. Medicinal chemicals and botanical products covered by SIC Code No. 2833;

c. Pharmaceutical products covered by SIC Code No. 2834;

d. All fermentation, biological and natural extraction, chemical synthesis and formulation products considered to be pharmaceutically active ingredients by the Food and Drug Administration that are not covered by SIC Code Nos. 2833, 2834, and 2836;

e. Multiple end-use products derived from pharmaceutical manufacturing operations (e.g., components of formulations, intermediates, or final products, provided that the primary use of the product is intended for pharmaceutical purposes);

f. Products not covered by SIC Code Nos. 2833, 2834, and 2836 or other categorical limitations and standards if they are manufactured by a pharmaceutical manufacturer by processes that generate wastewaters that in turn closely correspond to those of pharmaceutical products. (An example of such a product is citric acid.)

g. Cosmetic preparations covered by SIC Code No. 2844 that contain pharmaceutically active ingredients or

ingredients intended for treatment of some skin condition. (This group of preparations does not include products such as lipsticks or perfumes that serve to enhance appearance or to provide a pleasing odor, but do not provide skin care. In general, this also excludes deodorants, manicure preparations, shaving preparations and non-medicated shampoos that do not function primarily as a skin treatment.)

A number of products and/or activities such as surgical and medical manufacturing and medical laboratory activity are not part of the pharmaceutical manufacturing category. A descriptive listing of the products and activities that are specifically excluded from the pharmaceutical manufacturing category are contained in the applicability provision of the final rule and in sections 2 and 3 of the final TDD.

In the NOA, EPA indicated that it was considering excluding from the scope of the regulation organic chemical manufacturers covered by the OCPSF regulation (40 CFR, Part 414) that manufacture pharmaceutical intermediates and active ingredients provided that the pharmaceutical portion of the process wastewater is less than 50 percent of the total process wastewater. EPA received no adverse comments concerning this, and has decided to promulgate this exclusion as described in the NOA. Thus facilities will be covered by the existing OCPSF regulation for both their OCPSF and pharmaceutical manufacturing process wastewaters provided that the pharmaceutical portion of the process wastewater at the facility is less than 50 percent of the total.

B. Options Selection

EPA evaluated final technology options for BPT, BAT, BCT, NSPS, PSES and PSNS limitations and standards for all four subcategories A thru D. The options considered for each level of control are discussed below in sections IV.C thru H.

C. Best Practicable Control Technology Currently Available (BPT)

EPA proposed to revise BPT for the conventional pollutants BOD_5 and TSS, the nonconventional pollutant COD, and the toxic pollutant cyanide for subcategories A and C, and for subcategories B and D, proposed to revise BPT limitations for BOD_5, TSS, and COD and to withdraw the cyanide limitations. In response to this proposal, EPA received comments claiming that EPA lacks the legal authority to revise BPT for the conventional pollutants since the proposed revised BPT limitations did not pass the BCT cost-reasonableness test. EPA also received comments claiming that COD and cyanide should not be regulated at BPT but only at the BAT level.

In today's rulemaking, EPA is revising BPT limitations only as to COD. The current BPT limitations for BOD_5, TSS and cyanide will continue to apply (except for subcategories B and D where EPA is withdrawing the BPT limitations for cyanide). Accordingly, issues raised by commenters regarding EPA's legal authority to revise BPT for BOD_5, TSS, or cyanide do not need to be addressed in this rulemaking. Nonetheless, EPA continues to believe that it has the legal authority to revise BPT limitations as appropriate. EPA further believes it can do so for conventional pollutants without having to apply the BCT cost-reasonableness test. Because EPA's authority to revise BPT limitations for conventional pollutants or cyanide is no longer an issue in this rulemaking, EPA is providing only a general statement of its statutory authority to revise BPT. For example, section 304(b) of the CWA directs EPA to revise all effluent limitation guidelines, including those based on BPT, at least annually if appropriate. Similarly, section 304(m) directs EPA to establish a schedule ''for the annual review and revision of promulgated effluent guidelines, in accordance with subsection (b) of this section.'' EPA does not believe that the addition of the BCT provisions to the CWA supplanted the BPT provisions. When enacting the more recent BCT provisions, Congress did not strip EPA of its explicit authority to revise or update BPT as necessary and appropriate. Moreover, the different purposes of BPT and BCT limitations would support an EPA decision to promulgate best ''practicable'' control technology for conventional pollutant control (represented by BPT), rather than the higher ''best available'' standard (represented by BCT).

Similarly, it is the Agency's position that it is not required to regulate COD or cyanide only at the BAT level. As noted above, section 304(b) of the CWA as well as section 304(m) directs EPA to revise all effluent limitations guidelines, including those based on BPT, at least annually if necessary and appropriate. It is EPA's view that the addition of BAT provisions to the CWA did not supplant the BPT provisions. When enacting the more recent BAT provisions, Congress did not strip EPA of its authority to revise or update BPT as necessary and appropriate. Further, the different purposes of BPT and BAT limitations would support an EPA decision to promulgate revised effluent limitation guidelines for nonconventional or toxic pollutants that reflect simply the next generation of best ''practicable'' control technology (represented by BPT), rather than the higher ''best available'' standard (represented by BAT).

Since EPA is not revising BPT limitations for cyanide (but rather is modifying the compliance monitoring requirements for cyanide for subcategories A and C, and withdrawing the limitations as to subcategories B and D), the issue need not be addressed further in this rulemaking.

EPA believes that the decision of whether or not to revise BPT for nonconventional pollutants should be made based upon consideration of a number of factors, including, but not necessarily limited to, cost, the technology being considered and the relative performance being achieved (best ''practicable'' versus best ''available''), the anticipated pollutant reductions, and implementation burden on permit writers.

In this case, EPA has made a determination that the costs and removals associated with the implementation of advanced biological treatment at a best ''practicable'' level warrant revision of COD at BPT. This is in part due to the relatively high concentrations of COD in the effluent that are allowed under the existing percent removal BPT limitations which are unique to this industry. In other cases, the Agency has decided not to revise BPT (see, for example, Effluent Limitation Guidelines for the Pulp, Paper, and Paperboard Category, subparts B and E, 63 FR 18534, April 15, 1998).

As noted above, EPA proposed to revise BPT for the conventional pollutants BOD_5 and TSS, the nonconventional pollutant COD, and the toxic pollutant cyanide for subcategories A and D, and for subcategories B and D, to revise BPT limitations for BOD_5, TSS, and COD and to withdraw the existing cyanide limitations. The technology basis of the proposed BPT limitations was advanced biological treatment. EPA also determined that the level of performance necessary for a plant to be considered as a best performer at the best ''practicable'' level was full compliance with the existing BPT limitations. Of the plants considered as best performers at proposal, EPA selected five A and C subcategory plants and two B and D subcategory plants. The Agency then calculated long-term average performance concentrations for regulated pollutants from the best performing A and C and B and D plants.

In developing the final BPT limitations, EPA has essentially

followed the proposal methodology except that EPA used only data sets representing less than 25 percent non-process wastewater through treatment and included the additional data sets received since proposal in its final limitations determinations. Except for one facility which adds non-process wastewater after treatment but before the end-of-pipe sample point, the BPT data sets were not corrected for non-process wastewater and the final limitations were calculated using the plant flow that included some non-process wastewater.

EPA did not back out the estimated non-process wastewater in developing the proposed BPT concentration based limitations because non-process flow data available at that time were only gross estimates not identified in sufficient detail and were not based on daily measurements of non-process flow. Regarding the proposed BPT limitations, commenters indicated that EPA should eliminate all non-process wastewater from the calculation of BPT limitations. EPA did not have information such as daily non-process flow data from facilities that generated the data sets used in the calculation of BPT and BAT limitations for BOD_5, TSS and COD to allow adjustment. In the recent NOA, EPA presented BPT limitations for BOD_5 and TSS and BAT COD limitations that were calculated from plant data sets which included the additional data submissions obtained since proposal from which the non-process wastewater had been backed out. In cases where the non-process flow was estimated by EPA to be more than 25 percent of the total flow using the available data, the fraction of the non-process to process flow volume was used to calculate a correction factor and the long-term average concentration values for each of the BPT parameters were adjusted to reflect the parameters absence of this non-process wastewater. No corrections were made to data sets where the non-process flow was estimated to be less than 25 percent of the total flow.

EPA received no adverse comments regarding these adjusted limitations. However, based on further analysis, EPA believes that it is more appropriate to follow the methodology used in developing the final Organic Chemicals, Plastics, and Synthetic Fibers (OCPSF) regulation (52 FR 52522) final BPT limitations. In that rule, only plant data sets that contained less than 25 percent non-process wastewater through treatment were used in the calculation of BPT limits, and the effluent data were not adjusted to take into account plant data sets that contained more than 25 percent non-process wastewater through treatment. EPA selected this approach in calculating the final BPT limitations in this rule for the same two reasons used during development of the OCPSF rule. (See 52 FR 42522). First, using data sets with greater than 25 percent non-process wastewater through treatment introduces considerable uncertainty into the limitation calculations because the flow data that would be used are only in part based on daily flow measurements whereas the concentration-based limitations are calculated from the long term average of daily measurements over long periods of time (12–24 months). Second, the final limitations should represent as much as possible the performance of treatment technology on process wastewater. In determining permit mass limits, permit writers and, where applicable, pretreatment control authorities should identify the amount of non-process wastewater being treated. The flow volume representing 25 percent or less of the total flow should be included in the volume used to calculate allowable mass discharges. Any additional volume would have to be evaluated on a case-by-case basis to determine what, if any, mass allowances are appropriate.

EPA considered four options for the final BPT limitations. Under the first option, EPA would not revise the existing BPT limitations for BOD_5, TSS, COD and cyanide. No costs or removals are associated with this option. Under the second option, EPA would revise the BPT limitations based on advanced biological treatment only for COD, and revise the monitoring requirements for the existing cyanide limitations. Under option three, EPA would revise BPT limitations for BOD_5 and TSS based on advanced biological treatment and revise the monitoring requirements for the existing cyanide limitations. Under the fourth option, EPA would revise BPT limitations for BOD_5, TSS, and COD based on advanced biological treatment, and revise the monitoring requirements for the existing cyanide limitations. The options for all subcategories are the same, except as to cyanide where the option for subcategories B and D contains the option to withdraw the cyanide limitations rather than just modify the monitoring requirements.

The pretax total annualized costs, pollutant removals, and costs per pound removed associated with the options, except the ''no action'' option, are shown below in Table IV.C.1.

TABLE IV.C.1.—BPT PRETAX OPTION COSTS, POLLUTANT REMOVALS AND COST PER POUND REMOVED

Treatment option	Total annualized cost ($ million 1997)	Pollutant removals (lbs)	Cost per pound ($1996/lb)
A/C Subcategory			
Clarify cyanide monitoring, revise COD only	$2.48	14,352,000	$0.17
Clarify cyanide monitoring, revise BOD_5 & TSS	2.61	4,692,000	0.56
Clarify cyanide monitoring, revise BOD_5, TSS, & COD	3.10	15,731,000	0.20
B/D Subcategory			
Withdraw cyanide, revise COD only	$1.38	539,000	$2.56
Withdraw cyanide, revise BOD_5 & TSS	1.89	588,000	3.21
Withdraw cyanide, revise BOD_5, TSS, & COD	2.16	598,000	3.62

In selecting these treatment options, EPA considered the total cost in relation to the effluent reduction benefits, the age of equipment and facilities involved, the processes employed, process changes required, engineering aspects of the control technologies, non-water quality environmental impacts (including energy requirements) and

other factors in accordance with section 304(b)(1)(B) of the CWA.

EPA has determined to revise BPT effluent limitations only for COD. EPA is also clarifying the compliance monitoring requirements for the existing BPT limitations for cyanide for subcategories A and C, and withdrawing the existing cyanide limitations for subcategories B and D. As discussed above, EPA believes that it has the statutory authority to revise BPT and that it has the discretion to determine whether to revise BPT effluent limitations guidelines in particular circumstances. The CWA requires EPA, when setting BPT, to examine the total cost of treatment technologies in relation to the effluent reduction benefits achieved. In addition, in determining whether to set BCT limitations, the Agency needs to consider the reasonableness of the cost of reducing conventional pollutants and compare the cost of removing those pollutants by regulated plants and by POTWs. Accordingly, EPA examined the use of advanced biological treatment as a basis for both BPT and BCT limitations for BOD_5 and TSS. The Agency found that the reductions in these conventional contaminants achieved by this technology were not commensurate with the costs, largely because of the large operational costs associated with the removal of TSS. While it is EPA's view that it can revise BPT limitations for conventional pollutants without passing the BCT cost test (where the BPT effluent reduction ratio is favorable), the Agency is not generally inclined to do so unless the removals achieved by the existing BPT limitations are significantly fewer than would be achieved through revision of BPT. That was not the case here. Revising BPT (and BAT) for COD plants will not only remove large amounts of COD, but also achieve significant incidental removals of BOD_5 and TSS. For this reason, EPA has determined that it is not necessary to separately revise the BPT limits for BOD_5 and TSS in this case.

EPA has determined to revise BPT for COD because the biological treatment technology used as a basis for the limitations really represents BPT technology and is widely used in the industry.

The bulk parameter and nonconventional pollutant COD is an indicator of organic matter in the wastestream that is susceptible to strong oxidation, and as such would also measure organic material susceptible to biochemical oxidation, as well as some that is more difficult to oxidize biochemically. In addition, limited studies and discharge monitoring data have identified toxicity associated with the COD levels contained in effluents from pharmaceutical manufacturing facilities. Further discussion of the toxicity levels measured in the effluents from pharmaceutical manufacturing facilities is contained in Section 6 of the TDD. The revised COD limitations are estimated to remove approximately 14.9 million pounds annually, including incidental removal of 2.7 million pounds of BOD at an annualized cost of $2.48 million ($1997).

The revised COD provisions require the use of either the new effluent concentration limitations or the existing 74 percent reduction requirement, depending upon which method determines the more stringent plant permit limitation. This is being done in order to avoid back-sliding issues for existing plants that because of low influent concentration already meet lower effluent limits for COD.

With regard to cyanide, EPA is retaining the existing BPT limitations for the A and C subcategories. Further revision of the BPT cyanide limitations was not selected since the removals were estimated to be less than 42 pounds per year, thus, determined not to be beneficial in relation to the annualized costs of over $200,000 ($1997).

However, EPA is modifying the requirements for compliance monitoring (for subcategories A and C). The current limitations require compliance monitoring after cyanide treatment and before dilution with other wastestreams, or in the alternative, monitoring after mixing with other wastestreams based on a standard dilution factor. Today's rule does not change the prohibition on dilution to meet the effluent limitations for cyanide. The rule continues to require monitoring for compliance with the existing limitations in-plant, prior to the commingling of cyanide-bearing wastestreams with non-cyanide bearing wastestreams for those facilities where the cyanide levels would be below the level of detection at the end-of-pipe monitoring location. The only change in the monitoring requirements is to eliminate the current dilution standard that applied industry-wide, and to allow individual facilities to demonstrate that end-of-pipe monitoring for cyanide is feasible (i.e., cyanide is detectable); those facilities may continue to monitor at the end of pipe.

The ability of EPA to require in-plant monitoring has recently been questioned in connection with the Great Lakes water quality guidance program. *American Iron and Steel Institute (AISI)* v. *EPA,* 115 F.3d 979 (D.C. Cir. 1997). The Court held that although EPA has the authority to require monitoring of internal wastestreams, *see AISI,* 115 F.3d at 995, the CWA does not authorize EPA to require compliance with water quality based effluent limitations at a point inside the facility and thereby deprive a permittee of the ability to choose its own control system to meet the limitations, see *id.* at 966. EPA does not believe that decision controls here. The *AISI* court did not consider the question whether EPA has authority to regulate internal wastestreams in the context of technology-based controls such as BPT/BAT, PSES and NSPS/PSNS. Unlike water quality-based effluent limitations, which are calculated to ensure that water quality standards for the receiving water are attained, technology-based limitations and standards are derived to measure the performance of specific model technologies that EPA is required by statute to identify. In identifying these technologies, EPA is directed to consider precisely the type of internal controls that are irrelevant to the development of water quality-based effluent limitations, such as the processes employed, process changes, and the engineering aspects of various types of control techniques. EPA's technology-based effluent limitations are intended to reflect, for each industrial category or subcategory, the ''base level'' of technology (including process changes) and to ensure that ''in no case * * * should any plant be allowed to discharge more pollutants per unit of production than is defined by that base level.'' *E.I. du Pont de Nemours & Co.* v. *Train,* 430 U.S. at 129 (1973).

EPA believes that it can require in-plant monitoring to demonstrate compliance with technology-based effluent limitations in accordance with the CWA and its regulations at 40 CFR 122.44(i), 122.45(h), 125.3(e) and 403.6(e). In today's rule, EPA is continuing to require in-plant monitoring for cyanide except where cyanide can be detected in the final effluent. Were EPA to require compliance monitoring of the final effluent without adjustment for the amount of dilution in cyanide-bearing waste streams, there would be no way to determine whether the facility had adequately controlled for cyanide or whether the effluent has simply been diluted below the analytical detection level. Diluting pollutants in this manner rather than preventing their discharge is inconsistent with achieving the removals represented by the technology-based levels of control and hence with

the purposes of the limitations. It is also inconsistent with the goals of the CWA in general.

D. Best Available Technology Economically Achievable

EPA proposed adding new end-of-pipe BAT limitations for 53 organic pollutants plus ammonia, revising the existing cyanide limitations and adding the BPT revised COD limitations for subcategories A and C. For subcategories B and D, EPA proposed adding new end-of-pipe BAT limitations for 53 organics, BPT revised COD limitations and withdrawing the existing cyanide limitations. The technology basis for the limitations for VOCs was steam stripping plus advanced biological treatment for subcategories A and C and advanced biological treatment for subcategories B and D. The technology basis for the ammonia limitations was nitrification. The revised cyanide limitations for the A and C subcategories were the same as the revised BPT proposed limitations. For subcategories B and D cyanide limitations were proposed to be withdrawn since facilities in these subcategories do not use or generate cyanide in their wastewaters.

EPA received a number of comments indicating that steam stripping technology was not appropriate for the treatment of VOCs and that emissions of these pollutants from wastewater should be controlled by CAA regulations. In the preamble to the proposed MACT standards, EPA indicated that, in view of the MACT proposed wastewater standards, that it was considering changing the BAT technology basis for subcategory A and C VOCs limitations to end-of-pipe advanced biological treatment. In the NOA, EPA reiterated this option and provided cost information which compared the original proposal technology basis (steam stripping and advanced biological treatment) to the advanced biological treatment technology basis.

EPA also received comments on its proposed ammonia limitations. Commenters indicated that the ammonia limitations were inadequately supported by nitrification data. In the NOA, EPA indicated that after reevaluating its nitrification data base, it intended to base the BAT ammonia limitations on both one or two stage nitrification technology, presented compliance costs estimates based on two stage nitrification technology and revised limitations based on incorporating additional data, including data representing two stage nitrification, into the data base. In comments on the NOA, commenters indicated that some plants employing the proposed technology basis did not believe that they could achieve consistent compliance with the revised limitations.

In order to respond to these commenters, EPA evaluated additional nitrification data received from facilities after the August 8, 1997 publication of the NOA. As a result of this evaluation, EPA has recalculated the ammonia limitations that were presented in the NOA. In doing so, EPA used only data that showed evidence that nitrification was occurring and compared separate sets of limitations developed using single-stage and two-stage nitrification data sets, respectively. The results of this comparison gave final limitations less stringent than those calculated for the NOA, but reflective of systems that nitrify continuously whether they are one or two stage systems.

EPA considered three regulatory options as the basis for BAT limitations for subcategory A and C facilities. All three options modify the existing BAT regulations to parallel the BPT regulations and to clarify the compliance monitoring point for the existing cyanide limitations. The first option is a no cost revision which incorporates the BPT clarification for cyanide and revised BPT limitations for COD. The second option adds limitations for 30 organic pollutants based on advanced biological treatment and revised limitations for COD equal to the final BPT limitations and clarifies the compliance monitoring point for cyanide. The third option adds limitations for 30 organic pollutants based on advanced biological treatment, ammonia limitations based on one or two stage biological nitrification technology, incorporates the revised COD limitations and clarifies the compliance monitoring point for cyanide. The pretax total annualized compliance costs and pollutant removals associated with the second and third options (only options incurring costs) are shown below in Table IV.D.1 for subcategories A and C:

TABLE IV.D.1—BAT PRETAX OPTIONS COSTS, AND POLLUTANT REMOVALS FOR SUBCATEGORY A AND C DIRECT DISCHARGERS

Regulatory option	Total annualized cost ($ million 1997)	Pollutant removals (million lbs per yr)
Add Organics and COD and clarify cyanide	$2.3	1.4
Add Organics, Ammonia and COD and clarify cyanide	3.6	2.2

EPA evaluated the costs and economic impacts associated with each option and determined that all the options were economically achievable. After considering the pollutant load removals, the costs, as well as the non-water quality environmental impacts associated with the options, EPA selected the third option which adds effluent limitations for 30 organic pollutants, ammonia and COD and modifies the cyanide monitoring requirements. EPA believes that this option is economically achievable and there are no significant adverse non-water quality impacts associated with it. In addition, EPA believes the discharge loadings of ammonia, COD and the organic pollutants are significant from subcategory A and C facilities, and that limitations on these discharges are appropriate. EPA has also evaluated the technology bases of the final BAT limitations in the context of the BAT statutory factors, i.e., the age of equipment and facilities involved, the process(s) employed, potential process changes and non-water quality impacts such as energy requirements. EPA believes the final BAT limitations are appropriate based on its assessment of these factors in relation to A and C subcategory facilities.

For facilities with subcategories B and D operations, EPA has identified only the pollutant COD for control by BAT limitations based on advanced biological treatment (the technology selected as the basis for the BPT limitations). As discussed under BPT, cyanide is not a pollutant of concern for subcategories B and D operations and EPA is withdrawing the current BAT cyanide limitations for facilities with subcategories B and D operations. EPA

also has determined that ammonia is not a pollutant of concern for these subcategories since ammonia is not found in significant amounts in wastewaters from these operations.

Thus, for subcategories B and D, EPA considered two final BAT regulatory options. The first option is a no cost option consisting of the withdrawal of the existing cyanide limitations, the same as the final BPT withdrawal of cyanide control and the addition of the BPT revised COD limitations. The second option includes the withdrawal of the existing cyanide limitations and the addition of the BPT revised COD limitations and limitations based only on advanced biological treatment for 30 of the same organic pollutants selected for regulation at the subcategories A and C facilities.

The total annualized cost and annual pollutant removal associated with the second option are $0.410 million ($1997) and 22,300 pounds per year.

EPA has evaluated the discharge loadings of organic pollutants from subcategories B and D facilities and has determined that 95 percent of the discharge of organic pollutants is from two facilities. Most direct discharging subcategories B and D facilities do not discharge any organic pollutants. EPA believes these organic pollutant discharges are not sufficient to justify national regulations for these subcategories. If permit writers determine the need to further control the organic pollutants from the two facilities, the appropriate limits contained in the subcategories A and C BAT regulations may be used. For this final rule, EPA has selected the first option, which is to only add the BPT revised COD limitations to BAT for subcategories B and D facilities, and to withdraw the existing cyanide limitations.

E. Pretreatment Standards for Existing Sources (PSES)

EPA proposed pretreatment standards for 45 organic pollutants (including 37 VOCs), with in-plant monitoring for 12 VOCs and end-of-pipe monitoring for the remaining 33 organics (25 of which are VOCs) under coproposal A; and in-plant monitoring only for the 12 VOCs under coproposal B. EPA received considerable comment on its proposal pass through analysis which indicated that the 45 organic pollutants passed through POTW treatment works. Thirty-seven of the organic pollutants, including 13 alcohols and related compounds had Henry's Law Constants greater than 10^{-6} atm m^3/gmole, which was the physical property used to consider a pollutant to be too volatile to be treated properly at POTWs. The other eight organic pollutants were determined to pass through based on the BAT technology percent removal exceeding that of well operated activated sludge treatment represented by EPA's 50 POTW data base.

Many commenters objected to the assumption that pollutants with Henry's Law constants greater than 10^{-6} atm m^3/gmole would be considered to pass through based on their volatility. The pollutants commenters identified as being insufficiently volatile and highly biodegradable included: methanol, ethanol and other pollutants with Henry's Law constants lower than 1×10^{-5} atm m^3/gmole. Commenters indicated that many of the alcohols and related compounds were easily biodegraded by POTWs and did not pass through.

EPA also received a number of comments concerning the proposed in-plant monitoring point for the 12 VOCs. Commenters indicated that CAA MACT standards not CWA pretreatment standards should control in-plant emissions of these pollutants from internal wastestreams.

In order to address these and other comments related to controlling the alcohols and related compounds, EPA conducted a sampling study in August 1996 at a POTW in Barceloneta, Puerto Rico. This POTW treats pharmaceutical industry wastewaters containing measurable amounts of the predominant alcohols and related compounds, such as methanol, ethanol and isopropanol. The purpose of the sampling study was to determine the extent to which methanol and other compounds with similar Henry's Law Constants volatilize in the primary treatment works (aerated grit chambers and primary clarifiers) prior to the biodegradation unit process. Amounts volatilized prior to the biodegradation unit are not considered to be treated.

In the NOA, EPA published the preliminary results of the study along with those of a separate bench-scale study of anaerobic degradation in the Barceloneta primary clarifiers conducted by industry. EPA indicated in the NOA that it was considering a finding of no pass through for 13 of the organic pollutants (methanol and other alcohols and related compounds) based on the belief that the volatization of these pollutants in the primary works of POTWs is roughly equivalent to that observed in the primary works of direct discharging BAT level facilities. Thus, the treatment of these pollutants by a well operated POTW is roughly equivalent to that achieved by industrial facilities meeting BAT. As noted earlier in section III.D. EPA proposed PSES for 45 organic pollutants, and subsequently removed eight pollutants based on no pass through at the POTWs, thus making a total of 21 (with the alcohols and related compounds) not passing through POTWs.

In addition to discussing results of its pass through analyses in the NOA, EPA presented two revised pretreatment options for all four subcategories, with end-of-pipe monitoring for all VOCs including the 12 volatile pollutants for which in-plant monitoring for PSES/PSNS had been proposed. In the NOA, EPA indicated that PSES for these 12 pollutants were unnecessary because they would be controlled by the MACT wastewater standards which require an in-plant compliance demonstration for 10 of the 12 VOCs which are HAPs. The remaining 12 VOCs, in addition to the two non-HAPs that are part of the 12 VOCs discussed above, are controlled by end-of-pipe limits based on steam stripping, with removals incidental to controlling HAPs either directly by the MACT standards or separately from the MACT standards at smaller facilities not covered by the MACT rule but controlled by this CWA final rule.

In finalizing the methodology for the pass through analysis discussed above, EPA relied on three criteria that had to be met before a pollutant was deemed to pass through. These criteria included volatility, solubility in water, and the BAT and POTW technologies percent removal comparison. With regard to volatility, EPA raised its Henry's Law Constant threshold for volatility from 1×10^{-6} atm/gmole/m^3 to 1×10^{-5} atm/gmole/m^3 based on comments that the Henry's Law Constant used at proposal was not consistent with what was used for the OCPSF final rule. Pollutants with Henry Law Constants greater than 1×10^{-5} atm/gmole/m^3 were believed to volatilize significantly before reaching treatment at a POTW. In connection with volatility, in order to be consistent with the MACT standards approved for controlling water soluble HAPs, EPA also considered whether a pollutant was water soluble because water soluble compounds are less likely to volatilize than compounds that are partially soluble. Finally, EPA considered differences in removal percentages for organic pollutants obtained by comparing the BAT model treatment system percentage removal to the average pollutant removal percentage achieved by well-operated POTWs achieving secondary treatment performance standards.

In developing BAT pollutant removal percentages, EPA only used pollutant data pairs where the influent

concentrations were greater than ten times the pollutant method detection limits which was the approach used in developing the supporting information for the NOA. In developing the final POTW pollutant removal percentages, EPA utilized the acclimated data from the same sources used to develop these percentages for the NOA. These removal percentages are the POTW removal percentages used in the final comparison. Thus, in order for a pollutant to be deemed to pass through, it had to have a Henry's Law Constant greater than 1×10^{-5} atm/gmole/m^3, be less than totally soluble in water, and have a BAT removal percentage greater than its POTW removal percentage. Based on this analysis, EPA has determined that 23 organic pollutants in subcategories A and C and 5 organic pollutants in subcategories B and D, that pass through POTWs are regulated by pretreatment standards in today's rule. A more detailed description of this analysis may be found in section 17 of the final TDD.

In addition to pretreatment standards for VOCs, EPA proposed ammonia standards based on either steam stripping or two-stage nitrification. In May 1995 EPA proposed ammonia pretreatment standards based only on steam stripping technology. The Agency received a number of comments concerning the proposed ammonia pretreatment standards. Some commenters indicated that steam stripping may not be a reliable treatment technology. Others questioned the need for national ammonia standards because many POTWs have imposed local limits for ammonia and others have nitrification capability. EPA discussed both of these concerns in the NOA. EPA suggested in the NOA that ammonia does not pass through POTWs with nitrification, and requested comments on the preliminary discussion not to set pretreatment standards for industrial users which discharge to POTWs with this technology. Comments from POTW control authorities and industry supported this approach to developing PSES ammonia standards. The final rule contains ammonia pretreatment standards only for subcategories A and C, based on the BAT technology of nitrification and is applicable to those facilities discharging to POTWs without nitrification capability.

EPA determined that cyanide passes through POTWs based on the percent removal comparison with the hydrogen peroxide (BAT) technology. Thus, EPA proposed revised cyanide pretreatment standards based on hydrogen peroxide technology but maintaining that the standards based on in-plant monitoring for the requirements. EPA received comments raising safety concerns using this technology for high organic strength wastes. Based on these comments and additional data submitted by facilities, in the NOA, EPA proposed establishing two sets of cyanide standards. One standard would be identical to the proposed standards based on hydrogen peroxide technology, while the other standard would be based on alkaline chlorination technology and applicable only to those facilities that could demonstrate, due to safety concerns, that hydrogen peroxide technology was not an appropriate technology to use with their wastewater. EPA estimated compliance costs and loadings removals to be the same for both sets of standards because it was assumed that the vast majority of facilities would meet these standards based on the use of the more expensive and efficient hydrogen peroxide technology.

In developing the final PSES for subcategories A and C, EPA considered three options. The first option was not to develop pretreatment standards for ammonia or any of the VOC pollutants, and to modify the monitoring requirements for the existing cyanide standards. The second option would build on compliance with the MACT standard with additional pretreatment standards for 23 VOCS based on steam stripping technology and ammonia based on steam stripping or nitrification and modify the cyanide monitoring requirements. The third option would be the same as the second option, with the addition of revised pretreatment standards for cyanide.

The annualized compliance costs (1997 dollars) and pollutant removals for the second and third options (the only ones incurring costs) are shown below in Table IV.E.1. EPA did not consider additional options involving small facility exclusions because results of the economic analyses for the small facilities using the costs for both options described above showed that both options are economically achievable (see section V of this preamble for more discussion).

TABLE IV.E.1—PSES PRETAX OPTIONS COSTS AND POLLUTANT REMOVALS FOR SUBCATEGORIES A AND C INDIRECT DISCHARGERS

Treatment option	Total annualized cost ($ million 1996)	Pollutant removals (million lbs)
Add organics and ammonia and modify cyanide monitoring requirements	$44.5	10.653
Add organics and ammonia and revise cyanide limits	44.8	10.654

Due to the low pollutant removals achievable by the revised cyanide standards (approximately 1000 lbs per year with 97 percent of the removals coming from one facility) in relation to the compliance costs, EPA has decided not to revise the existing cyanide standards, and has selected the option to add organics and ammonia only and modify the current cyanide monitoring requirements. The selected option adds standards for ammonia and the 23 organic pollutants determined to pass through (see previous discussion in this section), and modifies the monitoring point for the current cyanide pretreatment standards for subcategories A and C.

EPA is setting pretreatment standards for ammonia for subcategories A and C because of the high loads of ammonia currently being discharged by a number of pharmaceutical facilities to POTWs that do not have nitrification capability and receive wastewaters from subcategories A and C facilities. However, EPA is aware that some POTWs treating pharmaceutical wastewaters from these subcategories have nitrification capability, and EPA has made a determination of no passthrough for ammonia at these POTWS. Thus, PSES ammonia limitations will not apply to subcategory A and C facilities discharging to POTWs with nitrification capability. POTWs with nitrification capability oxidize ammonium salts to nitrites (via Nitrosomonas bacteria) and the further oxidize nitrites to nitrates via Nitrobacter bacteria and achieve greater removals of ammonia than POTWs

without nitrification. Nitrification can be accomplished in either a single or two-stage activated sludge system. In addition, POTWs that have wetlands which are developed and maintained for the expressed purpose of removing ammonia with a marsh/pond configuration are also examples of having nitrification capability. Indicators of nitrification capability are: (1) biological monitoring for ammonia oxidizing bacteria (AOB) and nitrite oxidizing bacteria (NOB) to determine if nitrification is occurring, and (2) analysis of the nitrogen balance to determine if nitrifying bacteria reduce the amount of ammonia and increase the amount of nitrite and nitrate.

For subcategories B and D, EPA considered two options. The first option was not to add regulated pollutants to the existing PSES and, since cyanide is not present in wastewaters for these subcategories facilities, to withdraw the existing cyanide standards. Thus, compliance with the MACT standard would be the only requirement for controlling VOC pollutants. The second option was to add pretreatment standards for 5 VOCs (not including the alcohols and related compounds and 19 pollutants determined not to be present in subcategory B and D wastewaters) based on steam stripping in addition to withdrawing the existing cyanide standards. No ammonia standards were considered since facilities in these subcategories do not generate significant levels of ammonia in their wastewaters. The pretax annualized compliance cost for this second option is $8.8 million ($1997) and annual pollutant removals are 3.35 million pounds.

For PSES for subcategories B and D, EPA has selected the second option. EPA is basing this selection on the fact that the 5 pollutants (VOCs) have been determined to passthrough, and the pollutant removals are relatively high with respect to the compliance costs. The costs are economically achievable and the nonwater quality environmental impacts are acceptable.

F. New Source Performance Standards (NSPS)

EPA proposed NSPS for 53 organic pollutants, BOD_5, TSS and COD based on steam stripping or distillation and advanced biological treatment for subcategories A and C. EPA also proposed NSPS for ammonia and cyanide based on nitrification and hydrogen peroxide oxidation technologies, respectively for these two subcategories. EPA received comments indicating that distillation technology was not a demonstrated technology for removing soluble VOCs (such as methanol), and therefore, should not be part of the technology basis of NSPS. EPA has reevaluated its steam stripping and distillation database and has concluded that distillation technology is sufficiently demonstrated to be considered BADT (Best Available Demonstrated Technology). However, after taking into account the high removal of these pollutants achievable by steam stripping and advanced biological treatment, the addition of distillation technology is unnecessary. Consequently EPA did not consider distillation technology as part of final NSPS model technology.

EPA evaluated technology options capable of achieving greater pollutant removal of conventional pollutants (BOD_5 and TSS), COD, Organics, Cyanide and Ammonia than those selected as the basis for existing source limitations (BPT, BCT and BAT). The only option potentially capable of achieving additional removals involves the use of granular activated carbon (GAC) adsorption technology. This technology is capable of reducing the COD from some direct discharging A and C subcategory facilities. However, there is only limited GAC performance data available, from one pilot study.

For subcategories B and D, EPA proposed NSPS for 53 organic pollutants, BOD_5, TSS and COD based on in-plant steam stripping with distillation and end-of-pipe advanced biological treatment. As was the case with the proposed NSPS for subcategories A and C, EPA received comments stating that use of distillation technology as BADT for new sources is inappropriate because its ability to remove methanol and other water soluble organic pollutants has not been demonstrated with respect to representative wastestreams.

For subcategories A and C, EPA is promulgating NSPS equal to the final BAT effluent limitations for 30 organic pollutants, cyanide and ammonia. For subcategories B and D, EPA is promulgating NSPS equal to BAT (including withdrawal of the existing cyanide standards). EPA is also promulgating revised NSPS for BOD_5, COD and TSS for all four subcategories at a level equal to the discharge characteristics of the best performing BPT plants which for COD is also the BAT/BPT level of control. These final standards are based on the best available demonstrated control technologies, which include advanced biological treatment, cyanide destruct and nitrification. In developing these final standards, the Agency considered factors including the cost of achieving effluent reductions, non-water quality environmental impacts, and energy requirements. EPA finds that the final standards represent the best available demonstrated control technologies, are economically achievable and do not present a barrier to entry and have acceptable non-water quality environmental impacts.

G. Pretreatment Standards for New Sources (PSNS)

EPA proposed PSNS for 45 organic pollutants, cyanide and ammonia for subcategories A and C, and the same 45 organic pollutants only, for subcategories B and D. The technology basis for the proposed organic pollutant standards was steam stripping with distillation, and the technology bases for the proposed cyanide and ammonia standards were hydrogen peroxide oxidation and steam stripping technologies, respectively.

The proposed pretreatment standards for new sources were more stringent than the proposed PSES. However, for the final rule, EPA was unable to identify a technology that would achieve greater removal of the pollutants to be controlled by the PSES being promulgated today and is therefore promulgating PSNS equal to PSES for all four subcategories.

H. Best Conventional Pollutant Control Technology (BCT)

EPA proposed BCT equal to BPT for the conventional pollutants BOD_5 and TSS for all four subcategories. The Agency indicated that it had not identified technologies that achieve greater removals of conventional pollutants other than those associated with the proposed revision of BPT limits, and that these technologies did not pass the two-part BCT cost reasonable test. EPA has not received any comments concerning its proposal BCT cost test analysis. The Agency has repeated the cost test with the postproposal data, with the same results. Based on the failure to identify any incremental conventional pollutant removal technology options that pass the BCT cost reasonable test, EPA is promulgating BCT limitations equal to the existing BPT limitations for BOD_5 and TSS for all subcategories.

V. Assessment of Costs and Impacts for the Final Pharmaceutical Regulations

A. Introduction

The economic analysis for the final pharmaceutical effluent limitations guidelines and standards assesses the costs and impacts of these guidelines. The results of this analysis are contained in the record for this final

rule and are summarized in a document entitled Economic Analysis for Final Effluent Guidelines and Standards for the Pharmaceutical Industry (EPA–821–B–98–009). Included in the Economic Analysis (EA) and summarized below are (1) the annualized costs of the rule by subcategory, separately and together with the costs of the MACT standards rule discussed previously; (2) the impacts of the rule both separately and together with the MACT standards on pharmaceutical facilities, both existing and new sources; (3) the impacts of these rules on pharmaceutical firms; (4) the impacts of these rules on employment and communities; and (5) other secondary impacts on trade, inflation, POTWs, environmental justice, and distributional equity. Also included in the EA are a Final Regulatory Flexibility Analysis as required under the Regulatory Flexibility Act and a Cost-Benefit Analysis, as required under the Unfunded Mandates Reform Act (UMRA) and Executive Order 12866, which are summarized in Sections V.E and V.F of this preamble. An additional document, Cost Effectiveness Analysis for Effluent Limitations Guidelines and Standards for the Pharmaceutical Industry (EPA–821–B–98–010), assesses the cost-effectiveness of the rule. The results of this analysis are summarized below in Section V.G.

B. Summary of the Economic Analysis Methodology and Data

EPA determined the annualized costs of compliance in exactly the same way as was done for proposal, with the exception of the choice of discount rate (discussed in V.C). Costs are annualized at seven percent over 16 years (a 1-year installation period a 15-year project life is assumed). The cost annualization also accounts for tax shields on both O&M and depreciation (calculated using the modified accelerated cost recovery system allowed by IRS rules) to develop a posttax estimate of annual costs (see Section 4 of the Economic Analysis for a detailed discussion). For analytical consistency, MACT standards costs are also annualized in the same way, both pretax and posttax. This is slightly different from the way EPA annualized the MACT standards costs in the preamble to the MACT standards rule, where costs are annualized at seven percent over ten years (with no delay for installation) to create a pretax annual cost (i.e., without accounting for tax shields). Additionally, the MACT standards costs presented in the preamble to the MACT standards rule include costs for new sources, which are not included in this preamble. Despite the differences in annualization method, the current cost annualization approach in no way conflicts with the alternative analysis.

To assess impacts on firms and facilities, EPA has set up three baselines in the analysis. Baseline 1 is the usual baseline analyzed in all effluent guidelines. It is a scenario that reflects a baseline condition without additional regulation, that is, no additional effluent limitations guidelines and standards or MACT standards costs are considered. This baseline is taken from the current (i.e., 1990 Survey) financial data. Baseline 2 incorporates certain MACT standards costs pertaining only to wastewater emission controls, and does not include costs for controlling emissions from process vents, equipment leaks and storage tanks. This baseline is presented in the EA, but results of this baseline (which are not appreciably different from those for Baseline 1) are not discussed at length in this preamble. Baseline 3 incorporates costs for all components associated with the MACT standards rule. EPA estimated the capital and operating costs for MACT standards cost components for emission controls on wastewater streams (on which Baseline 2 is based), as well as the capital and operating costs for all MACT components (on which Baseline 3 is based) as a part of the Agency's MACT standards rulemaking process.

To model Baseline 2, EPA used the capital and operating costs associated with the wastewater emission controls for all facilities in the MACT analysis for which costs were developed and matched them to the facilities that are also in the effluent guidelines analysis. However, a number of facilities in the effluent guidelines analysis are not covered by the MACT standards and were not assigned MACT costs.

EPA annualized the costs at seven percent over 16 years in the cost annualization model and also developed a present value of posttax compliance costs over this same time frame. EPA subtracted the present value posttax compliance costs from the Baseline 1 present value posttax facility earnings (derived from the Survey data) to determine Baseline 2 posttax earnings for each facility in the effluent guidelines analysis. EPA used this same approach to derive Baseline 3 posttax earnings (for those facilities without MACT standards costs, earnings are the same in all three baselines).

A facility whose posttax earnings are zero or negative in Baseline 1 is counted as a Baseline 1 closure; a facility whose posttax earnings are zero or negative in Baseline 2 is counted as a Baseline 2 closure; and a facility whose posttax earnings are zero or negative in Baseline 3 is counted as a Baseline 3 closure.

EPA then incorporated the present value posttax costs of the effluent guidelines into each of the baselines in the same way as MACT standards costs were incorporated to calculate postcompliance, posttax earnings. EPA then tallied the closure results (in terms of whether postcompliance, posttax earnings are zero or negative) by counting postcompliance closures incrementally from each baseline. In other words, EPA considered any closures that occurred additional to those occurring in each of the baselines as postcompliance closures under the three baseline scenarios. Any facilities that certified that the effluent guidelines would have no impact on them were assumed not to close under any baseline or in postcompliance. Note that as in the proposal Economic Impact Analysis (EIA), impacts on single-facility firms were assessed at the firm level.

MACT standards costs were also incorporated into firm-level data under the same three baseline scenarios. In the firm-level analysis, however, the key data that could change were assets, liabilities, and earnings before interest and taxes, which were used in an equation called Altman's Z, a multi-discriminant ratio analysis approach to identifying relative firm health. This equation is composed of several common financial ratios that are weighted according to their relative ability to predict bankruptcy based on empirical industry data. The result of this equation is called the Altman's Z-score. Scores below a certain value are considered indicative of poor financial health and a high likelihood of bankruptcy.

For Baseline 1, EPA used the current survey data in the Altman's Z model to determine a Baseline 1 Altman's Z-score. For Baseline 2, EPA took the MACT standards capital costs aggregated at the firm level (since firms often own more than one facility) and adjusted both assets and liabilities to reflect the acquisition of capital equipment through an increase in debt. EPA then adjusted earnings before interest and taxes by subtracting the annualized amount of operating costs plus depreciation computed by the cost annualization model, given the Baseline 2 MACT standards capital and operating costs (also aggregated at the firm level) and then computed a Baseline 2 Altman's Z-score.

EPA used the same approach using the Baseline 3 MACT standards operating and capital costs to create the Baseline 3 Altman's Z-score. If any of

these three baseline scores were below the cutoff point considered a sign of poor financial health, EPA considered the firm a baseline failure.

Compliance costs for the effluent guidelines were then used in the same manner to further adjust the financial data used in the Altman's Z model in each of the baselines. Where the Altman's Z-score changed from one reflecting a healthy firm or one in indeterminate status in any of the baselines to one of poor financial health, EPA considered the firm to be a postcompliance firm failure relative to the baseline under consideration.

EPA's methodology for computing output and employment effects is discussed in detail in Section V.C. These effects are presented as net effects in Section V.D.4. To compute net effects, EPA calculated both losses and gains in output and employment and subtracted losses from gains (or vice versa). Thus EPA calculated net national-level output effects, net national-level employment effects, and net direct employment effects (employment losses in the pharmaceutical industry driven by output losses in the industry). EPA also estimated the employment losses estimated to occur as a result of closures and failures. These types of losses were used to determine whether any community-level impacts are likely.

Trade impacts were assessed in the same way as in the EIA for the proposal, except that a profit margin analysis has been added, as described below in Section V.C. Impacts on inflation were assessed by comparing the cost of the regulation to gross domestic product (GDP). The potential for distributional impacts was assessed by identifying facilities where compliance costs were greater than 10 percent of operating costs and determining what types of products might be most affected if costs are passed through to consumers. The users of these products were then qualitatively identified to determine if these potential users might be disproportionately represented by economically disadvantaged groups. Impacts on environmental justice were also qualitatively addressed.

C. Changes to the Economic Analysis Since Proposal

The most significant change in the EA since proposal is associated with the change in costs. The costs of the effluent limitations guidelines and standards for the pharmaceutical industry point source category are now substantially lower than those estimated at proposal because the costs of controlling air emissions are now a part of EPA's MACT standards. Impacts from the final rule do not change measurably from proposal, however, mostly because impacts both now and at proposal were estimated to be very small.

Costs for control of air pollutants, previously assigned to the effluent guidelines at proposal, are now assigned to the MACT standards requirements. The economic analyses show the impacts of the effluent guidelines against three separate regulatory baselines: no MACT standards requirements in place, wastewater emissions control and treatment system requirements in place, and all MACT standards requirements in place (see Section II.E. of this preamble for a description of MACT standards requirements). In this way, EPA can present impacts from the effluent guidelines alone and in combination with impacts from the MACT standards requirements. The methods EPA used to assess the impact of MACT standards on the baselines against which the effluent guidelines are measured were discussed in Section V.B.

EPA is now using a seven percent discount rate in all of its analyses. Previously, the Agency used the seven percent rate only in determining the pretax cost of the regulation. EPA has chosen to use a seven percent social discount rate (in real terms) in this analysis, rather than the 11.4 percent discount rate used in the proposal, for two reasons. First, the seven percent discount rate is strongly recommended by the Office of Management and Budget for use in economic analyses (see the EA for more details). Second, the cost of capital has generally declined since 1990. This change in discount rate, however, has little effect on the analysis. A comparison of estimated impacts in the proposal to impacts as estimated here show that the analyses are not sensitive to assumptions about discount rates in the ranges used.

In terms of content, the economic analyses are now presented as a more comprehensive report, in which the EIA and Regulatory Impact Analysis (RIA) have been combined into one report (the EA). The cost-benefit portion of the RIA is now contained in Section 10 of the EA report.

EPA has also made a few methodological changes in its firm and facility analyses. In the EIA for the proposal, EPA included salvage value in the calculations for the facility closure analysis for projection of baseline closures (i.e., before compliance costs are considered) and postcompliance closures. EPA recognized some potential difficulties with the salvage value calculations and, in the proposal EIA, investigated the effects of assuming salvage value does not play a role in determining facility viability. EPA found that the facility closure projections were not sensitive to the alternate salvage value assumption. Furthermore, industry also commented that using salvage value overstated baseline closures. Thus EPA believes that its current analysis, which does not consider salvage value but rather uses negative posttax earnings as the indicator of closure, is the best methodology to use, given the uncertainty of salvage value data.

An additional difference in the closure analysis addresses the issue of non-self-supporting facilities (baseline facility closures). In the current analysis, EPA investigates all baseline closures at the firm level to determine if a multi-facility firm could install and operate pollution control equipment at all of its affected facilities, including those estimated as baseline closures. If the firms can continue to support a baseline closure facility without risk of failure, EPA determines that impacts to the firm and its affected facilities are minimal. EPA performed this analysis under the assumption that if the facility was not expected to support itself in the baseline, the firm level is the appropriate level at which to assess impacts.

EPA also modified the methodology for determining impacts on firms. In response to comments that baseline firm failures were overstated because the Agency used benchmarks that identified lowest quartile firms as baseline failures, EPA reassessed the methodology and turned to a more sophisticated method for determining firm financial health. EPA used a multi-discriminant analysis approach for evaluating the financial health of firms. This analysis, developed by Edward Altman, is known as Altman's Z-score analysis. This approach allows the simultaneous analysis of several common financial ratios and answers the question of how to determine financial health when some ratios appear strong and some appear weak. The equation developed by Altman assigns relative weights to the various ratios on the basis of how well they predict bankruptcy (determined using actual firm data and information on whether the firms did in fact go bankrupt). This approach reduced the proportion of firms considered baseline failures from 28 percent in the EIA for the proposal to about 10 percent (see Section V.D.3), thus allowing for substantially more firms to be evaluated at the firm level in the postcompliance

analysis. The Altman's Z analysis is also described in Section V.B above and is fully described in Section 6 of the EA Report.

The Agency has added an analysis of national-level output and employment effects to the EA for the final rule. Output is measured in terms of revenues, and under the assumption that industry cannot pass through compliance costs to consumers, the worst-case output loss to the pharmaceutical industry is equal to the pretax costs of compliance. The output losses occurring in the pharmaceutical industry (direct effects) affect input industries, which are industries that provide inputs (e.g., raw chemicals) to the pharmaceutical industry. These effects are known as indirect effects. The direct output losses also affect consumption, as workers lose jobs or work fewer hours and their households reduce purchases of goods and services. These effects are called induced effects. Thus a dollar of output lost in the pharmaceutical industry can also result in additional dollars lost in the U.S. economy as a whole through indirect and induced effects. EPA calculates these additional losses at the national level using input-output analysis. The relevant multipliers used in the analysis were developed by the U.S. Department of Commerce's Bureau of Economic Analysis (BEA).

In addition to output losses, EPA calculates national-level output gains based on output gains in pollution control industries. These industries receive revenues from the pharmaceutical industry for pollution control equipment and operations. Using BEA multipliers, the Agency calculates the subsequent effect of these gains on the pollution control industries' input industries and consumption (i.e., indirect and induced effects). By comparing national-level output losses and gains, EPA develops a net national-level output loss or gain.

In the EA, EPA no longer relies exclusively on employment losses from closures and failures to calculate employment losses in the pharmaceutical industry or national-level employment losses. Because output effects and employment are linked in input-output analysis, EPA calculates employment losses based on output effects using BEA's final demand and direct effect multipliers. EPA uses final demand employment multipliers to compute the total number of jobs lost (including direct, indirect, and induced job losses) given the total loss of output in millions of dollars in the pharmaceutical industry and uses direct effect multipliers to compute the total number of job losses occurring just in the pharmaceutical industry (direct losses), given the total jobs lost nationwide (which include direct, indirect, and induced losses).

Output-based employment losses can be thought of as longer-term losses associated with longer-term market equilibrium, whereas losses associated with closures and failures can be considered the more immediate impact of the rule before market equilibrium is achieved. Thus output-based employment losses may be greater than or less than the losses estimated on the basis of closures and failures, which means that nonclosing facilities might gain or lose production and employment depending on how many facilities close. If no facilities close, nonclosing facilities might lose some production and employment. If many facilities close, nonclosing facilities might actually gain production and employment if closure losses ''overshoot'' the expected losses at market equilibrium. Note, however, that both the output-based employment effects and the closure/failure employment effects derived here are worst-case impacts within the pharmaceutical industry since EPA assumes the industry cannot pass through the costs of compliance to consumers.

EPA also computes employment gains on the basis of output gains in pollution control industries in much the same way as was done for the EIA for the proposal. The approach has been changed slightly to accommodate labor costs estimated as a part of the engineering cost analysis rather than relying on assumed labor shares. EPA compares the employment losses and gains to estimate a net gain or loss in employment both at the national level and in the pharmaceutical industry alone (some gains will occur in the pharmaceutical industry since labor to operate pollution control equipment is required).

EPA now performs an assessment of impacts on profit margins to address commenter concerns that pharmaceutical firms will locate (or relocate) facilities outside of the U.S. because of environmental regulatory requirements. EPA assumes that those firms most likely to consider relocating facilities are those with measurable differences in profitability with sufficient means to effect a relocation. EPA also addresses comments that reductions in loadings to POTWs will result in substantial impacts on POTWs.

All other methodologies used and analyses undertaken in the EA remain substantively the same as those in the EIA for the proposal.

D. Estimated Economic Impacts

1. Costs of Compliance

Table V.D.1 presents a summary of compliance costs for the effluent limitations guidelines and standards and for the MACT standards. EPA estimated annualized compliance costs on both a pre-tax and post-tax basis; both sets of costs are shown in Table V.D.1. Post-tax costs reflect tax savings accruing to the industry from the installation and operation of pollution control equipment; the post-tax costs are used in the economic analysis to assess impacts to facilities and firms in the industry. Pre-tax costs are a component of the total social cost of the regulatory action (see Section V.F).

EPA describes the cost annualization procedure in Section V.B and in the EA. The annualized costs in Table V.D.1 for both the effluent limitations guidelines and standards and the MACT standards rule incorporate the same annualization period assumptions. The annualized costs reported in the preamble to the MACT standards rule are based on another annualization period and thus, do not correspond exactly to Table V.D.1. As noted in Section V.B, costs are annualized over 16 years (with an 1-year installation period and a 15-year project life), while in the preamble to the MACT standards rule, costs are annualized over 10 years (with no delay for installation). As an illustration, Table V.D.1 reports pre-tax annualized costs for the MACT standards rule for all facilities (referred to as ''existing sources'' in the MACT standards rule) at $58.4 million. In the preamble to the MACT standards rule, the corresponding annualized costs are reported at $64.8 million.

The annualized post-tax compliance costs for effluent guidelines for the selected options are $39.4 million. The annualized post-tax compliance costs of the MACT standards for the subset of facilities also subject to effluent guidelines are $32.4 million. The total annualized costs for facilities covered by both the effluent guidelines and MACT standards are $71.8 million, and the total annualized costs for all facilities (i.e., including those facilities covered by MACT standards only) are $77.5 million.

TABLE V.D.1—ANNUALIZED COSTS OF COMPLIANCE FOR EFFLUENT GUIDELINES AND MACT REQUIREMENTS

Subcategory	Option	Posttax annualized cost of compliance (million 1997$)	Pretax annualized cost of compliance (million 1997$)
A/C Direct	BPT=Revise COD and modify cyanide	$1.6	$2.5
	BAT=Add organics, ammonia and COD and modify cyanide.	2.3	3.6
B/D Direct	Revise BPT COD and withdraw cyanide	0.9	1.4
A/C Indirect	PSES=Add organics and ammonia and modify cyanide.	28.8	44.5
B/D Indirect	PSES=Add organics and withdraw cyanide	5.8	8.8
Total Annualized Cost of Effluent Guidelines for all Selected Options.		39.4	60.8
Cost of MACT Standards	Effluent Guidelines Facilities	32.4	49.6
	All Facilities	38.1	58.4
Total Annualized Cost of Effluent Guidelines and MACT Standards for Effluent Guidelines Facilities.		71.8	110.4
Total Annualized Costs of Effluent Guidelines and MACT Standards for All Facilities.		77.5	119.2

2. Economic Impacts on Facilities

EPA determined on the basis of zero or negative posttax earnings that 18 facilities, or 9 percent of all facilities in the analysis, would be likely to close even without the effect of the effluent guidelines or MACT standards requirements. The impacts to the firms of installing and operating pollution control equipment at these facilities are, however, assessed at the firm level to determine if the firms can continue to support these facilities postcompliance (see below under results of the firm analysis). When all MACT standards costs are incorporated into the initial baseline financial conditions (Baseline 3), no additional facilities close.

When the costs of compliance for this final effluent guidelines rule are incorporated into the financial conditions of facilities in the analysis (the postcompliance analysis), only one additional facility closes (an A/C indirect). Even though this facility does not close when faced with costs of meeting this effluent guidelines rule alone, EPA conservatively attributes this closure to the effluent guidelines. In general, however, neither MACT standards costs nor effluent guidelines costs singly or together have major impacts on pharmaceutical facilities operated by multifacility firms.

3. Economic Impacts on Firms

EPA projected that 18 firms would be likely to fail even without the effect of the effluent guidelines or MACT standards requirements (Baseline 1). Two additional firms are projected to fail before effluent guidelines costs are considered when all MACT standards costs are included in the initial baseline financial conditions (Baseline 3).

In the postcompliance analysis, EPA estimated that four firms would fail under the Baseline 1 scenario and two firms would fail under the Baseline 3 scenario. (There are two fewer postcompliance firm failures under the Baseline 3 scenario because these failures were estimated to be precompliance failures when all MACT standards costs were included.) Thus at most, regardless of baseline, four firms fail postcompliance. To be conservative in the EA, EPA attributes these failures to the Pharmaceutical Effluent Guidelines alone. Out of the four firm failures projected to occur, EPA estimates only one will result in both a firm failure and a facility closure (because earnings become negative at the only facility owned by the firm). The other three firms will incur substantial impacts, up to and including firm failure, but own financially viable facilities. Because the facilities are self-supporting, they are likely to be attractive for acquisition by financially stronger firms. Therefore, the three failing firms with viable facilities might not fail, but instead might be forced to sell their facilities.

As discussed in Section V.D.2, EPA evaluated all facilities projected to close in the baseline analysis at the firm level, under the assumption that perhaps these facilities are not expected to be self-supporting and thus might not close in the baseline. If this is so, the appropriate level of analysis is the firm. EPA determined that all facilities projected to close in the baseline facility closure analysis can continue to be supported by their firms postcompliance without significant impact on these firms.

TABLE V.D.3 FIRM FAILURE ANALYSIS RESULTS (BASELINE 1)

Type of discharger	Failures only			
	Number Failures with closures	Percentage of total firms in subcategory	Number	Percentage of total firms in subcategory
A/C Direct	0	0	0	0
B/D Direct	0	0	0	0
A/C Indirect	2	3.2	1	1.6
B/D Indirect	1	1.2	0	0

TABLE V.D.3 FIRM FAILURE ANALYSIS RESULTS (BASELINE 1)—Continued

Type of discharger	Failures only			
	Number Failures with closures	Percentage of total firms in subcategory	Number	Percentage of total firms in subcategory
Total All Firms	3	1.8	1	0.6

4. Impacts on Output and Employment

EPA estimates that at the national level, output gains will exceed output losses. EPA determines a net output gain of about $21.7 million (1996$) as a result of the effluent guidelines. Net output gains for the combined rulemakings (including MACT standards for facilities in the effluent guidelines analysis only) will total $40.1 million (1996$). EPA also determines that employment gains will exceed employment losses at the national level. The net gain in national-level employment as a result of the effluent guidelines alone will total 218 full-time equivalents (a full-time equivalent, or FTE, equals 2,080 hours per year of labor), and net employment gains for the combined rulemakings (including MACT standards for facilities in the effluent guidelines analysis only) will total 407 FTEs.

Despite net employment gains at the national level, EPA calculates that losses will exceed gains in the pharmaceutical industry. Direct losses in the pharmaceutical industry are composed of two types of losses—output-based losses and closure/failure type losses. As noted in Section V.C., closure/failure employment losses might be less than the output-based employment losses that are driven by the contraction in the pharmaceutical industry as it responds to the compliance costs and a new market equilibrium is achieved. Closure/failure employment losses can also be greater than these output-based losses if they ''overshoot'' the expected market equilibrium result. In this case, the direct losses computed on the basis of output losses (and net of gains in employment in the industry due to the need to operate the pollution control equipment) are slightly greater than the closure/failure losses (which are estimated to total 139 FTEs). Output-based losses total 138 FTEs, or 0.1 percent of pharmaceutical employment in the analysis. With MACT standards costs for facilities included in the effluent guidelines analysis, net direct employment losses will total 254 FTEs, or 0.1 percent of employment.

Because output-based employment losses are greater than closure/failure employment losses, nonclosing facilities might experience some small reductions in labor hours and production over time that are additional to the losses of labor hours and production associated with facilities that close or fail (assuming a worst-case scenario where no costs can be passed through to consumers).

The losses in employment due to closures/failures will have a negligible impact on individual communities. No community is expected to experience a change in its unemployment rate exceeding 0.4 percent.

5. Other Secondary Impacts

No trade losses or major changes in the balance of payments are associated with closures/failures of firms or facilities, as these firms and facilities indicate no foreign shipments. Thus EPA finds that neither rule, together or separately, will have a substantial impact on trade or the balance of payments.

An analysis of profit margin shows only a few firms will experience impacts on profit margin as a result of the effluent guidelines. A total of 8 firms (6 percent of the firms analyzed) have a greater than 10 percent change (e.g., go from a 5 percent profit margin to a 4.5 percent profit margin) in their profit margin. Most of these firms are considered the least likely to relocate their facilities to foreign countries. These firms tend to be small, and generally, they are unlikely to have experience in international locations. The transaction costs of learning how to operate in foreign countries, along with the expense of relocating, are likely to be prohibitively expensive for these firms. With the MACT standards costs included for the facilities analyzed as part of this effluent guidelines final rule, one additional firm shows a greater than 10 percent change in profit margin. Thus EPA has determined that even under the combined effect of the two rules, firms are unlikely to relocate to foreign countries to escape the impacts on profitability induced by the two rules.

The rules, together or separately, will have no major impact on inflation, as the costs of the two rules are at most only 0.001 percent of gross domestic product (GDP).

Although the Agency received comments on the proposal arguing otherwise, EPA expects that impacts on POTWS will be minimal. EPA is promulgating pretreatment standards for 24 VOCs for all four subcategories and ammonia for subcategories A and C. The Agency expects that the reduction in the BOD discharged to POTWs as the result of compliance with PSES for these pollutants will be minimal. As a result, EPA believes that any reduction in revenue to POTWs that charge industrial users subject to the PSES will be insignificant. Since many of these pollutants are highly volatile and are volatilized in the POTWs primary units before they can be biodegraded, EPA believes that the final PSES should not have any substantial effect on the variable operating costs of POTWs as well. In summary, EPA believes that compliance with the final PSES by pharmaceutical facilities should not have any significant effect on the POTW revenues. Furthermore, EPA believes that the benefits associated with reduced discharges of VOCs and ammonia to POTWs by pharmaceutical industrial users will outweigh any revenue losses.

Based on the analysis in the proposal EIA and further investigation in the EA for this final rule, the MACT standards and effluent guidelines, together or separately, will have no major distributional impacts. Compliance costs are generally a very small percentage of baseline operating costs, thus any cost increases are likely to be very small and are not likely to have any major effect on any one group of consumers.

Impacts on environmental justice also should be minimal. As noted above, any price increases on drugs will be very small and impacts on disadvantaged groups such as the poor and certain minority groups will be minimal. Furthermore, many of these groups will benefit from the effluent guidelines final rule. A large portion of the affected facilities are located in urban areas where poor or minority populations tend to be high. Although everyone benefits, it is these populations that will

likely benefit the most from the cleaner water resulting from both rules.

6. Impacts on New Sources

The selected options for new sources are equivalent to the selected options for existing sources. Because the costs for designing in pollution control technologies are generally no more expensive than and are usually less expensive than retrofitting pollution control technologies, costs for new facilities will be no more expensive than costs for existing facilities. Because EPA has shown that the requirements for existing sources are economically achievable, they should be economically achievable for new sources. Furthermore, since the requirements for new sources will not be more expensive than those for existing sources, the rule will not pose a barrier to entry for new sources. In response to proposal comments, EPA also investigated whether impacts from the effluent guidelines rule (with and without MACT standards) might contribute to firms locating new facilities in foreign countries. EPA found the median percentage of capital costs of compliance to total costs to build a new facility to be negligible (0.21 percent, on average including MACT standards costs among surveyed newer facilities). Thus compliance costs are unlikely to be a major impetus to locating new facilities outside the U.S.

E. Regulatory Flexibility Analysis

There are no major changes to EPA's Regulatory Flexibility Analysis (RFA), except that the Agency has undertaken a revenue test in addition to the closure analysis to better assess the potential impact on small firms. The revenue test measures impact on the basis of annual compliance costs as a percentage of annual revenues. The analysis indicates that out of 145 firms considered small (i.e., firms with fewer than 750 employees), only four firms will experience annual compliance costs that are greater than one percent of annual revenues (six with MACT costs included). No firms will experience annual compliance costs exceeding 3 percent. When MACT standards costs are included only one small firm will experience annual compliance costs that exceed three percent of annual revenues, but this firm is not estimated to incur any effluent guideline costs.

The RFA further also considered impacts to small firms in terms of firm failures or facility closures. Five small firms are significantly affected by the rule. The regulatory action is found to be economically achievable for all dischargers, including small entities as detailed in Section V.D. Further, the analysis indicates no disproportionate effect on small entities, compared to large entities. Based on these findings, EPA certifies that this final rule does not have a significant impact on a substantial number of small entities.

F. Cost-Benefit Analysis

Because the combined costs of the rules are at the level that defines a major rule both under Executive Order 12866 and UMRA (although neither rule considered separately would be near this level), EPA has undertaken a cost-benefit analysis. As in the proposal, pretax costs for all facilities are used as a proxy for social cost. The major portion of the social cost of the effluent guidelines is the total pretax annual cost, which is $60.8 million (1997$). Adding in the cost of administering the rule and providing administrative services to the unemployed (the only other significant cost categories), the total social cost of the rule is $61.0 million (1997$). Combined with the costs of the MACT standards rule for facilities in the effluent guidelines analysis, the two rules together have annual social cost of $110.7 million (1997$). (Costs of both rules including MACT standards costs to facilities that will not be affected by the effluent guidelines are $119.5 million (1997$)).

Benefits include the benefits of water removals and benefits of air removals. Types of benefits analyzed include human health risk, recreational use benefits, benefits to POTWs, and benefits of reductions in VOCs (other than human health). The benefits to POTWs, however, could not be monetized (see Section VI.E. of this preamble for more details). Total monetizable benefits of the effluent guidelines alone total $0.93 to $14.0 million (1997$), while the combined benefits of the two rules total $4.06 to $81.1 million (1997$).

TABLE V.F.1

Costs ($ millions)	
Total Social Cost of Effluent Guidelines.	$61.0
Total Social Cost of MACT (ELG facilities only).	49.7
Total Social Cost of MACT (all facilities).	58.4
Social Cost of Combined Rules (ELG facilities only).	110.7
Social Cost of Combined Rules (all facilities).	119.5
Benefits ($ millions)	
Effluent Guidelines	0.9 to 14.0
MACT Standards	3.9 to 67.2
Total	4.8 to 81.1

G. Cost-Effectiveness Analysis

Cost-effectiveness evaluates the relative efficiency of options in removing toxic pollutants. Costs evaluated include direct compliance costs, such as capital expenditures and operation and maintenance costs.

Cost-effectiveness results are expressed in terms of the incremental and average costs per pound-equivalent removed. A pound equivalent is a measure that addresses differences in the toxicity of pollutants removed. Total pound-equivalents are derived by taking the number of pounds of a pollutant removed and multiplying this number by a toxic weighting factor. EPA calculates the toxic weighting factor using ambient water quality criteria and toxicity values. The toxic weighting factors are then standardized by relating them to a particular pollutant, in this case copper. EPA's standard procedure is to rank the options considered for each subcategory in order of increasing pounds-equivalent (PE) removed. The Agency calculates incremental cost-effectiveness as the ratio of the incremental annual costs to the incremental pounds-equivalent removed under each option, compared to the previous (less effective) option. Average cost-effectiveness is calculated for each option as a ratio of total costs to total pounds-equivalent removed. EPA reports annual costs for all cost-effectiveness analyses in 1981 dollars to enable limited comparisons of the cost-effectiveness among regulated industries.

Table V.G.1 presents the results of the cost-effectiveness analysis for all subcategories. As the table shows, the average and incremental cost-effectiveness of the selected BAT option for subcategories A and C is $224/lb. eq., the average and incremental cost-effectiveness of the selected PSES option for subcategories A and C is $96/lb. eq. and the average and incremental cost-effectiveness of the selected PSES option for subcategories B and D is $66/lb. eq. The selected BAT option for the subcategories B and D directs is the no additional action alternative, so no cost-effectiveness results are calculated.

The cost-effectiveness determined for this rule does not represent an estimate of the removal of the toxic pounds resulting from the removal of COD. As discussed previously in section IV.C., discharges from pharmaceutical manufacturing facilities exhibit toxicity as measured by the whole effluent

toxicity test and reported as part of the routine NPDES discharge monitoring reports (DMRs). One study conducted by EPA at a pharmaceutical manufacturing facility showed a significant decrease in toxicity with a corresponding decrease in COD level for the tested effluent sample from the facility and a sample effluent of a pilot scale biological treatment plant study. Because of the limited amount of data, and the inability to identify the different mix of specific organic compounds represented by the COD measurement, the total amount of toxic pound-equivalent represented by the nonconventional pollutant parameter of COD could not be determined.

Based on the lack of pound-equivalents associated with COD removals the cost-effectiveness analysis results understates the true cost-effectiveness of this rule. EPA therefore considers these options to be cost-effective.

TABLE V.G.1—COST/EFFECTIVENESS ANALYSIS RESULTS

Option	Total Annual		Incremental		Average C-E ($/lb.eq.)	Incremental C-E ($/lb. eq.)
	Lb. eq. removed	Cost (1981$)	Lb. eq. removed	Cost (1981$)		
A/C Direct						
MACT Only	0	$0	0	$0	NA	NA
Advanced Bio	9,780	2,186,106	9,780	2,186,106	$224	$224
A/C Indirect						
MACT Only	0	0	0	0	NA	NA
Steam Stripping no alcohols	282,614	26,990,998	282,614	26,990,998	96	96
B/D Indirect						
MACT Only	0	0	0	0	NA	NA
Steam Stripping no alcohols	80,807	5,353,790	80,807	5,353,790	66	66

VI. Environmental Benefits

In addition to costs and impacts, EPA also estimated the environmental and human health benefits of implementing CWA requirements. Benefits identified as a result of this final rule are associated with improvements in both water quality and air quality, since many of the regulated and incidentally controlled pollutants are prone to volatilization from the effluent waste streams. Section IV of this preamble and Section IX of the TDD describe the estimated reductions in effluent discharges, and those reductions and the estimates of incremental environmental improvements noted in Section IV are derived compared to a baseline consisting of current discharges. Because current discharges are a function of current technology, this is the same baseline that is used to establish the costs of complying with this rule.

EPA is confident that its estimation of compliance costs is a full and accurate account of such costs; however, EPA is less confident that the estimation of benefits is similarly complete. EPA is not currently able to quantitatively evaluate all human health and ecosystem benefits associated with air and water quality improvements. EPA is even more limited in its ability to assign monetary values to these benefits. A comparison of costs to only the limited monetized subset compromises the validity of the cost-benefit analysis. The economic benefit values described below and in Section 10.4 of the EA should be considered a limited subset of the total benefits of this rule and should be evaluated along with descriptive assessments of benefits and the acknowledgment that even these may fall short of the real-world benefits that may result from this rule. For example, the analyses consider the impacts of toxic pollutants, but do not evaluate the impacts of other pollutants (such as BOD_5, COD, and TSS) which can produce significant adverse environmental impacts.

Within these limitations, EPA analyzes the effects of current air and water emissions and assesses the benefits of reductions in these emissions resulting from this final regulation. EPA expects a variety of human health, environmental, and economic benefits to result from these reductions in effluent loadings and air emissions (See *Environmental Assessment of the Final Effluent Guidelines for the Pharmaceutical Manufacturing Industry*, (July 1998, EPA–821–B–98–008). In particular, the benefits assessment addresses the following benefit categories: 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 hazard (systemic); ecological and recreational benefits due to improved water quality with respect to toxic pollutants, including intrinsic benefits; and benefits to publicly owned treatment works (POTWs) from reductions in interference, pass through, and sludge contamination problems, improvements in worker health and safety, and elimination of some of the efforts associated with establishing local pretreatment limits. EPA monetizes the estimated benefits for reductions in air emissions of ozone precursors, cancer risk reductions, improvements in recreational fishing opportunities, and improvements in intrinsic value, but is unable to quantify the dollar magnitude of benefits from the other benefit categories. Air benefits due to reductions in emissions of ozone precursors, are estimated using the methods and data summarized in the November 5, 1997 OAQPS memorandum titled ''Benefits-Transfer Analysis for Pulp and Paper''. This methodology is based on the recently published benefits analyses provided in the *Regulatory Impact Analyses for the Particulate Matter and Ozone National Ambient Air Quality Standards and Proposed Regional Haze Rule.* The methodology and data used in the estimate of all benefits are described in detail in the Environmental Assessment.

a. Reduced Emissions of Ozone Precursors

These final effluent guidelines are expected to result in reductions in ambient ozone concentrations due to reductions in VOC emissions. Controlling VOC emissions is beneficial because some VOCs are precursors to ozone, which negatively affects human health and plant life.

EPA estimates that the annual monetized benefits resulting from reductions in VOC emissions due to this final rule range from $755,000 to $9.8 million ($1997). The benefits are monetized using a benefits-transfer-based approach. Specifically, the estimated reductions in VOC emissions in nonattainment areas alone, and in both nonattainment and attainment areas (1,254 Mg to 3,608 Mg, respectively) are multiplied by an existing estimate of the range of the value of a unit reduction in VOC emissions ($602/Mg to $2,723/Mg, $1997). This range is based on the ozone National Ambient Air Quality Standard (NAAQS) benefits analysis, which used new scientific studies to quantify the association between ozone exposure and premature mortality. The $602/Mg estimate does not include mortality effects associated with ozone exposure, while the $2,723/Mg estimate includes mortality effects.

The overall benefit estimate for ozone precursor reduction also includes an estimate of the potential adverse effects which may result from increased emissions of particulate matter (PM) and sulfur dioxide (SO_2) related to steam stripping of the VOCs. Emissions of PM and SO_2 arise from the use of fossil fuels as an energy source for the steam stripping technology basis. The quantity of these emissions is based on the type of fossil fuel (natural gas or fuel oil) used.

Particulate matter is associated with adverse human health and welfare effects. EPA estimates that the annual monetized adverse environmental impact resulting from increases in PM emissions due to this final rule is $266,000 ($1997). This value was obtained by using an estimated increase in PM emissions of 20 Mg multiplied by an estimate of the value of a unit reduction in PM emissions of $13,325 per Mg ($1997). This value is based on the PM NAAQS benefits analysis.

Sulfur dioxide is associated with the adverse human health effects and environmental impacts, including ''acid rain.'' EPA estimates that the annual monetized adverse environmental impact resulting from increases in SO_2 emissions range from $311,000 to $688,000 ($1997). This value was obtained using an estimated increase in SO_2 emissions of 52.1 Mg (51.8 Mg eastern U.S. and 0.3 Mg western U.S.) multiplied by an estimate of the value of a unit reduction in SO_2 emissions of $5,984 to $13,251 per Mg ($1997) for the eastern U.S. and $4,329 to $5,164 per Mg ($1997) for the western U.S. These ranges are based on the PM NAAQS benefits analysis and assumes emission reductions of SO_2 are proportional to emission reductions of PM. The lower values include a measure of premature mortality due to short-term exposure, and the higher values use a measure of premature mortality due to long-term exposure.

The benefits transfer method is utilized to value the pollutants discussed above (VOCs, PM, and SO_2). This method relies on previous benefit studies that have been conducted for the same pollutants that are identified in this rulemaking. These studies provide useful data that can be transferred across contexts in order to approximate the benefits of the pharmaceuticals industry's emission reductions.

The impacts and benefits associated with the different emission components are aggregated by adding the lower values separately from the higher values to give a maximum total range. Using this method of analysis, the total monetized air benefits from reduction of ozone precursors, including associated PM and SO_2 increases, range from an adverse environmental impact of $0.20 million ($1997) to a benefit of $9.2 million ($1997).

b. Reduced Human Health Cancer Risk

The benefits from the final rule include human health benefits from reductions in excess cancer risk. EPA expects the final rule to reduce loadings of toxic substances that otherwise would volatilize and pose a cancer risk to humans, resulting in reductions in excess cancer risk in exposed populations from inhalation of VOCs. In addition, EPA expects that reduced loadings to surface waters will improve water quality and thus reduce cancer risk to the exposed populations from consumption of contaminated drinking water and fish tissue. Based on the cancer risk assessment conducted for fugitive air emissions, EPA estimates that the final guidelines will result in 0.15 excess cancer cases avoided per year nationwide due to reduced exposure to four identified pollutants (benzene, chloroform, 1,2-dichloroethane, and methylene chloride). The estimated monetized value of the human health benefits from these cancer risk reductions ranges from $350,000 to $1.9 million ($1997) annually. EPA developed these benefit estimates by applying an existing estimate of the value of a statistical life to the estimated number of excess cancer cases avoided. The estimated range of the value of a statistical life used in this analysis is $2.3 million to 12.6 million ($1997). This estimated range is based on EPA's Office of Policy, Planning and Evaluation (OPPE) review of willingness-to-pay studies for valuing an avoided event of premature mortality or a statistical life saved.

c. Reduced Noncarcinogenic Human Health Hazard

Exposure to toxic substances poses risk of systemic and other effects to humans, including effects on the circulatory, respiratory or digestive systems and neurological and developmental effects. This final rule is expected to generate human health benefits by reducing exposure to these substances, thus reducing the hazards of these associated effects.

As in the case of the cancer risk assessment, systemic hazards from exposure to fugitive air emissions and consumption of contaminated fish tissue and drinking water are evaluated. Based on this analysis, reductions in fugitive air emissions are expected to result in reduced systemic hazard to 32,300 individuals due to reduced exposure to four identified toxic pollutants (ammonia, chlorobenzene, methyl cellosolve, and triethylamine). No systemic hazards reductions are expected to result from reduced exposure to contaminated fish tissue or drinking water. Sufficient data to quantify these benefits further are not available.

d. Improved Ecological Conditions and Recreational Activity

EPA expects this final rule to generate environmental benefits by improving water quality. There are a wide range of benefits associated with the maintenance and improvement of water quality. These benefits include use values (e.g., recreational fishing), ecological values (e.g., preservation of habitat), and passive use (intrinsic) values (e.g., aesthetics). For example, water pollution might affect the quality of the fish and wildlife habitat provided by water resources, thus affecting the species using these resources. This in turn might affect the quality and value of recreational experiences of users, such as anglers fishing in the affected streams. EPA considers the value of the recreational fishing benefits and intrinsic benefits resulting from this final rule, but does not evaluate the

other types of ecological and environmental benefits (e.g., increased assimilative capacity of the receiving stream, protection of terrestrial wildlife and birds that consume aquatic organisms, and improvements to other recreational activities, such as swimming, boating, water skiing, and wildlife observation) due to data limitations.

To estimate some of the benefits from the improvements in water quality expected to result from this rule, instream concentration estimates are modeled and then compared to both aquatic life and human health ambient water quality criteria (AWQC) or toxic effect levels to evaluate whether these discharges pose risk to aquatic organisms or to human health. The projected reductions in toxic loadings to surface waters and POTWs are significant. Modeled end-of-pipe pollutant loadings are estimated to decline by 71 percent, from 11.2 million pounds per year under current conditions to 3.3 million pounds per year under this final rule.[1] The analysis comparing instream concentration levels to AWQC estimates that current discharge loadings result in excursions of AWQC at five locations. The analysis also indicates that no excursions are expected to occur at these five sites under this final rule.

EPA estimates that the annual monetized recreational benefits to anglers associated with the expected changes in water quality range from $520,000 to $1.8 million ($1997).[2] EPA evaluates these recreational benefits, applying a model that considers the increase in value of a ''contaminant-free fishery'' to recreational anglers resulting from the elimination of pollutant concentrations in excess of AWQC at these five sites. The monetized value of impaired recreational fishing opportunity is estimated by first calculating the baseline value of the receiving stream using a value per person day of recreational fishing, and the number of person-days fished on the receiving stream. The value of improving water quality in this fishery, based on the increase in value to anglers of achieving contaminant-free fishing, is then calculated.

In addition, EPA estimates that the annual monetized intrinsic benefits to the general public, as a result of the same improvements in water quality, range from at least $260,000 to $920,000 ($1997).[3] These intrinsic benefits are estimated as half of the recreational benefits and may be significantly underestimated.

e. Improved POTW Operations/ Conditions

EPA considers three potential sources of benefits to POTWs from this final regulation: (1) reductions in the likelihood of interference, pass through, and sewage sludge contamination problems; (2) reductions in health and safety risks to POTW workers; and (3) reductions in costs potentially incurred by POTWs in analyzing toxic pollutants and determining whether to, and the appropriate level at which to, set local limits. Although the benefits from reducing these effects at POTWs might be substantial, the EPA does not quantify all of these benefits due to data limitations.

First, regarding potential interference, pass through and sewage sludge contamination problems, this final rule is expected to help reduce these problems by reducing toxic loadings in the industry's effluent and reducing shock releases. Anecdotal evidence from POTW responses to an EPA survey and sampling results indicate that such effects can occur. In addition, based on an analysis comparing POTW influent levels to available data on inhibition levels, inhibition problems are projected to occur at three POTWs for five pollutants (acetonitrile, diethylamine, N,N-dimethylacetamide, N,N-dimethylformamide, and triethylamine) under current conditions. Inhibition problems are projected to remain at the same three POTWs for three of these pollutants (acetonitrile, N,N-dimethylacetamide, and N,N-dimethylformamide) after this final rule.[4] While this rule is not expected to completely eliminate inhibition problems, the reduction in pollutant loadings is expected to reduce the severity of the impact. Sufficient data are not available to further quantify this benefit category.

Furthermore, toxic substances, particularly the VOCs, in effluent discharges to POTWs pose health risks to POTW workers. This final rule is expected to reduce these risks, thus generating human health benefits. Based on the assessment of the risk posed to POTW workers from exposure to the toxic pollutants (primarily acetonitrile, benzene, chloroform, diethylamine, n-heptane, n-hexane, methylene chloride, toluene, and triethylamine), this final rule is estimated to reduce occupational risk at nine POTWs.[5] Data are not available to monetize this benefit category.

Finally, reducing the pollutant load to local POTWs may eliminate some of the efforts associated with establishing local pollutant limits. Local limits are sometimes required to protect against pass-through and interference, and to protect worker health and safety. Establishing local limits involves labor and analytical costs to determine the relative contribution of each industrial discharger and to set limits which will be protective of the treatment works, the workers, and the receiving environment. Several POTWs contacted in EPA's survey indicated that establishment of more effective national pretreatment standards would help them avoid these significant costs. In addition, they indicated that where local limits are still required, stricter national pretreatment standards will bolster the validity of the limits they set.

Furthermore, reducing the discharge of toxic pollutants reduces the likelihood that the POTW effluents will exhibit excessive toxicity. When POTW effluent exhibits excessive toxicity, the POTW must enact a rigorous, costly analytical program to identify and reduce the source of toxicity.

f. Other Unquantified Benefits

The above benefit analyses focus mainly on identified compounds with quantifiable toxic or carcinogenic effects. This leads to a potentially large underestimation of benefits, since some significant pollutant characterizations are not considered. For example, the analyses do not include the benefits associated with reducing the particulate load (measured as TSS), or the oxygen demand (measured as BOD and COD) of the effluents. TSS loads can degrade ecological habitat by reducing light penetration and primary productivity, and from accumulation of solid particles that alter benthic spawning grounds and feeding habitats. BOD and COD loads can deplete oxygen levels, which can produce mortality or other adverse effects in fish, as well as reduce biological diversity.

The benefits of COD reduction extend beyond reducing oxygen depletion, since COD also represents the presence of organic chemicals in a waste stream. Due to a lack of analytical methods, not all of the compounds represented by COD are identified. In this benefits

[1] [2] [3] These benefits are a result of the CAA MACT Rule and/or the CWA Rule. Monetized benefits of $290,000 to $1.0 million ($1997) of the total recreational benefit to anglers can be solely attributed to the CWA Rule. Monetized benefits of $140,000 to $510,000 ($1997) of the total intrinsic benefit can be solely attributed to the CWA Rule.

[4] This benefit is a result of the CAA MACT Rule and/or the CWA Rule.

[5] This benefit is a result of the CAA MACT Rule and/or the CWA Rule. Reduction of occupational risk at five POTWs can be solely attributed to the CWA Rule.

assessment, specifically identified compounds represent only 2.2 million pounds of the 11.5 million pounds of COD projected to be removed. This limits the estimate of benefits, since the analysis relies on comparing instream concentrations to established criteria, and there are obviously no established criteria for unidentified compounds. However, there is inherent value in reducing pollutant loads, despite (or perhaps due to) the lack of quantifiable effects.

The benefits analyses are further limited because they concentrate on projected excursions from established minimum standards, and do not account for protection of higher quality conditions. Likewise, they do not account for prevention of future impacts which could occur due to increased effluent loadings.

g. Summary of Benefits from Effluent Limitations Guideline Final Rule

EPA estimates that the annual monetized benefits resulting from this final effluent guidelines rule will range from $0.93 million to $14 million ($1997). This range includes $0.34 to $1.2 million that cannot be differentiated between the effluent guidelines rule and the wastewater portion of the MACT standard. Table XI.B.9.g summarizes these benefits, by category. The range reflects the uncertainty in evaluating the effects of this final rule and in placing a dollar value on these effects. As indicated in the table, these monetized benefits ranges do not reflect many of the benefit categories expected to result under this final rule, including reduced noncarcinogenic human health hazards; improved ecological conditions from improvements in water quality; improved POTW operations; and improved worker health and safety at POTWs. Therefore the reported benefit estimate understates the total benefits of this final rule.

h. Benefits of the MACT Rule

The CAA MACT Rule will regulate an estimated 101 facilities. The Rule is expected to produce environmental and human health benefits due to reductions in fugitive air emissions from four planks: wastewater, process vents, storage tanks, and equipment leaks. EPA conducted analyses on the 23 facilities covered under the wastewater plank, based on site-specific raw loadings data from the 1990 Pharmaceuticals Section 308 Questionnaire. These analyses were conducted using the same methodologies, within the same limitations, as those conducted to evaluate the CWA Rule as discussed in the previous Sections. Data on emission reductions from the other planks were obtained by OAQPS, however, a detailed benefit analysis of these planks was not conducted due to data limitations (specifically, the lack of site-specific data).

Within these limitations, the estimated benefits are as follows:

Reduced Emissions of Ozone Precursors

EPA estimates that the final MACT Rule will produce benefits due to reductions in fugitive VOC emissions from wastewater, process vents, storage tanks, and equipment leaks at pharmaceutical manufacturing facilities. Considering the wastewater plank only, EPA estimates that the annual monetized benefits range from $1.2 million to $45 million ($1997). These benefits are based on estimated emission reductions in VOC emissions in nonattainment areas alone, and in both nonattainment and attainment areas (2,057 Mg to 16,619 Mg, respectively).

The annual monetized adverse environmental impacts for these 23 facilities due to increases in PM emissions is estimated by EPA at $56,000 ($1997). This value is based on an estimated increase in PM emissions of 4.2 Mg. EPA also estimates that the annual monetized adverse environmental impacts for these 23 facilities due to increases in SO_2 emissions due to the final MACT Rule range from $65,000 to $143,000 based on an estimated increase in SO_2 emissions of 11.0 Mg (10.6 Mg eastern U.S., and 0.4 Mg western U.S.).

The total monetized air benefits from reductions of ozone precursors from wastewater, after correction for PM and SO_2 increases, range from $1.0 million to $45 million ($1997).

In addition, based on the analysis of the 101 pharmaceutical manufacturing facilities covered by the MACT rule, EPA estimates that the reductions in fugitive VOC emissions from process vents, storage tanks, and equipment leaks would result in a range of annual monetized air benefits of $0.77 million to $11 million ($1997). These benefits are based on estimated reductions in VOC emissions in nonattainment areas alone, and in both nonattainment and attainment areas (1,278 Mg to 4,027 Mg, respectively). Adverse impacts due to increased energy consumption from control of these planks are not quantified due to data limitations. The total monetized benefits from reductions in VOC emissions from all four planks are estimated to be $1.8 million to $56 million ($1997).

Reduced Human Health Cancer Risk

The estimated monetized value of the human health benefits from cancer risk reductions due to reductions in fugitive air emissions from wastewater ranges from $2.1 million to $11 million ($1997) annually. This is based on EPA estimates that the MACT Rule will result in 0.88 cancer cases avoided per year nationwide, considering an inhalation exposure route. EPA also expects that reduced loadings to surface waters will improve water quality and thus reduce cancer risk to the exposed populations from consumption of contaminated drinking water and fish tissues.

EPA estimates that cancer risk will be further reduced due to reductions in fugitive air emissions from process vents, storage tanks, and equipment leaks. However, these reductions were not quantified due to lack of site-specific data.

Reduced Noncarcinogenic Human Health Hazard

EPA estimates that reductions in fugitive air emissions from wastewater are expected to result in reduced systemic hazard to 370,000 individuals due to reduced exposure to four identified toxic pollutants. EPA also expects that reductions in fugitive air emissions from process vents, storage tanks, and equipment leaks will result in reduced systemic hazard. However, EPA does not quantify these benefits due to data limitations. No systemic hazard reductions are expected to result from reduced exposure to contaminated fish tissue or drinking water.

Improved Ecological Conditions and Recreational Activity

EPA estimates that the annual monetized recreational benefits to anglers associated with the expected changes in water quality at two locations range from $230,000 to $820,000 ($1997). The annual monetized intrinsic benefits to the general public range from at least $115,000 to $410,000 ($1997). These benefits are a result of the CAA MACT Rule and/or the CWA Rule. These monetized benefits cannot be solely attributed to the MACT Rule.

Improved POTW Operations

Inhibition problems are projected by EPA to occur at three POTWs for five pollutants under current conditions. Inhibition problems are projected to remain at the same three POTWs for three of these pollutants. The benefits cannot be solely attributed to the MACT Rule.

Additionally, the MACT Rule is expected to reduce health risks to POTW workers. This rule is estimated to reduce occupational risks at four POTWs. However, these benefits cannot be solely attributed to the MACT Rule.

Summary of Benefits From MACT Final Rule

EPA estimates that the annual monetized benefits resulting from the MACT final rule will range from at least $3.9 million to $67 million ($1997). Additional annual monetized benefits that cannot be solely attributed to the CAA portion of this final rule will range from $0.34 million to $1.2 million ($1997). Table VI.B.9.h summarizes these benefits, by category. As explained previously in Section g, the expected benefit estimate understates the total benefits of the MACT rule. The estimate is further constrained by data limitations.

TABLE VI.B.9.G.—POTENTIAL ECONOMIC BENEFITS FROM FINAL EFFLUENT LIMITATIONS GUIDELINES FOR THE PHARMACEUTICAL INDUSTRY

Benefit category	Millions of 1997 dollars per year
Reduced Emissions of Ozone Precursors	−$0.20 to $9.2.
Reduced Cancer Risk	$0.35 to $1.9.
Reduced Noncarcinogenic Hazard	Unquantified.
Improved Ecological Conditions	Unquantified.
Improved Recreational Activity	$0.52 to $1.8.
Improved Intrinsic Value	$0.26 to $0.92.
Improved POTW Operations (Inhibition and Sludge Contamination)	Unquantified.
Improved Occupational Conditions at POTWs	Unquantified.
Total Monetized Benefits	$0.93 to $14.0.

Note: These benefits include a portion of recreational and intrinsic monetized benefits attributed to the CAA Rule. Specifically, two facilities included in the modeling were required to have MACT strippers and were also costed for additional strippers to meet the CWA effluent guidelines. Overall removals due to these strippers cannot be differentiated between MACT and CWA requirements. These two facilities represent a total of $0.34 to $1.2 million based on improved recreational activity and improved intrinsic value.

TABLE VI.B.9.H.—POTENTIAL ECONOMIC BENEFITS FROM CAA MACT RULE FOR THE PHARMACEUTICAL INDUSTRY

Benefit category	Millions of 1997 dollars per year		
	Wastewater	Other fugitive emissions[1]	Total benefits
Reduced Emissions of Ozone Precursors	$1.0 to $45	$0.77 to 11	$1.8 to $56.
Reduced Cancer Risk	$2.1 to $11	Unquantified	$2.1 to $11.
Reduced Noncarcinogenic Hazard	Unquantified	Unquantified	Unquantified.
Improved Ecological Conditions	Unquantified	Unquantified	Unquantified.
Improved POTW Operations (Inhibition and Sludge Contamination)	Unquantified	Unquantified	Unquantified.
Improved Occupational Conditions at POTWs	Unquantified	Unquantified	Unquantified.
Total Monetized Benefits	$3.1 to $56	$0.77 to $11	$3.9 to $67.

[1] Includes process vents, storage tanks, and equipment leaks.

Notes: These benefits exclude a portion of the recreational and intrinsic monetized benefits attributed to the CAA Rule. Specifically, two facilities included in the modeling were required to have MACT strippers and were also costed for additional strippers to meet the CWA effluent guidelines. Overall removals due to these strippers cannot be differentiated between MACT and CWA requirements. These two facilities represent a total of $0.34 to $1.2 million dollars, based on improved recreational activity and improved intrinsic value.

The benefits analysis for the MACT Rule is particularly limited due to data constraints.

VII. Non-Water Quality Environmental Impacts

The elimination or reduction of one form of pollution may create or aggravate other environmental problems. Therefore, Sections 304(b) and 306 of the Act call for EPA to consider the non-water quality environmental impacts of effluent limitations guidelines and standards. Accordingly, EPA has considered the effect of these regulations on air pollution, solid waste generation, and energy consumption.

A. Air Pollution

EPA estimated the impacts of the selected technology options for the existing source BAT and PSES regulations and the technology basis for the MACT standard on air emissions. EPA considered emissions of HAPs and non-HAPs as well as criteria air pollutants (CO, No_X, SO_2 and particulate matter) in its analysis. EPA estimates that the MACT standards steam strippers will reduce air emissions of HAPs and non-HAPs at direct and indirect subcategory A and C facilities by 14.1 and 41.4 million lbs. per year, respectively. No emission reductions have been estimated for B and D subcategory direct and indirect dischargers as the result of the MACT standard because these facilities are not ''major sources'' of hazardous air pollutants (HAPs) (defined as facilities with total annual emissions of HAPs greater than 25,000 metric tons). EPA has estimated the reduction in air emissions of HAPs and non-HAPs as the result of steam strippers that may be installed to comply with PSES for VOC pollutants for A and C and B and D subcategory facilities to be 10.7 and 3.3 million lbs. per year, respectively. With

respect to criteria pollutants, EPA estimates that as a result of steam generation requirements for PSES steam strippers, emissions of criteria pollutants will increase by 616,000 pounds per year.

B. Solid Waste

EPA has estimated the increases in solid waste generation as from the use of advanced biological treatment (the basis for BPT/BCT limitations), and steam stripping technology (the basis for PSES). EPA also estimated an increase in waste hydrogen chloride due to scrubber liquor generated by facilities with wastewater containing ammonia.

EPA estimates that compliance with the BPT/BCT limitations will increase the mass of wastewater treatment sludge by subcategories A and C and B and D direct dischargers by 343 and 194 tons per year, respectively. Compliance with BAT ammonia and organic limitations by A and C subcategory plants is expected to increase wastewater sludge generation by 308 tons per year. No increase in sludge generation is expected as the result of the subcategories B and D BAT COD limitations because these limitations are equivalent to the BPT COD limitations and there are no BAT organic compound limitations for these subcategories. EPA does expect that indirect discharging A and C facilities will generate an increase in waste aqueous hydrogen chloride resulting from the use of wet hydrogen chloride scrubbers to control air emissions from steam strippers used to remove ammonia from wastewater. EPA estimates that waste aqueous hydrogen chloride generation will increase by 283 tons per year.

Compliance with PSES subcategory A and C and subcategory B and D facilities is expected to increase the amount of waste solvents generated. This increase in waste solvent generation is due to the waste solvents recovered from the in-plant steam stripping operations at these facilities. EPA anticipates that 10,600 and 3,310 tons/yr of waste solvents will be generated at subcategory A and C and B and D facilities, respectively.

Ten of the pollutants being regulated by BAT limitations and pretreatment standards are solvents listed as hazardous waste constituents (F0002, F0003, and F0005) under 40 CFR 261.31. These pollutants are acetone, 4-methyl-2-pentanone (MIBK), ethyl acetate, methanol, benzene, toluene, xylenes, methylene chloride, chlorobenzene, and o-dichlorobenzene. EPA is promulgating PSES for nine of these pollutants and has included costs for disposal of all overheads from steam stripping as hazardous wastes in its steam stripping cost estimates. As noted above, EPA has estimated increased sludge generation as a result of compliance with BAT limitations for 29 pollutants including the 10 pollutants listed above. EPA has assumed that this sludge will be incinerated in developing its final BAT cost estimates, but does not believe that the increased sludge generated will be considered as hazardous.

C. Energy Requirements

EPA has estimated the energy impacts on the pharmaceutical manufacturing industry associated with compliance with the final BPT, BAT and PSES regulations. The Agency estimates that electrical usage would increase for subcategory A and C and subcategory B and D facilities by 5.9×10^6 and 1.07×10^6 kilowatt hours (kWh) as the result of the final BPT and BAT regulations. This increase is equivalent to a 0.1 percent increase above current electrical usage by the industry. EPA also estimated the increase in electrical usage as the result of increased steam generation. The increased steam generation is required to operate the steam strippers that EPA anticipates will be installed to comply with the pretreatment standards for VOCs. (The impacts of the BPT and BAT regulations on electrical usage for steam generation are negligible). EPA estimates that electrical usage for steam generation will increase for subcategories A and C and subcategories B and D indirect dischargers by 454×10^6 and 58.8×10^6 kWh, respectively. The total of these two increases in electrical usage is equivalent to an eight percent overall increase in electrical usage above current levels.

VIII. Regulatory Implementation

The purpose of this section is to provide assistance and direction to permit writers and control authorities to aid in their implementation of this regulation and its unique compliance alternative. This section also discusses the relationship of upset and bypass provisions, variances and modifications, and analytical methods to the final limitations and standards.

A. Implementation of the Limitations and Standards

Upon the promulgation of these regulations, the effluent limitations for the appropriate subcategory must be applied in all Federal and State NPDES permits issued to direct dischargers in the pharmaceutical manufacturing industry. In addition, the pretreatment standards are directly applicable to indirect dischargers.

Permit writers and pretreatment authorities need to be aware of special circumstances involving compliance with the cyanide limitations and standards, ammonia pretreatment standards, pH monitoring and the portion of nonprocess wastewater in the final effluent. In the case of the cyanide limitations and standards, EPA determined that the monitoring point for purposes of compliance with the cyanide will generally be in-plant at a point before the cyanide-bearing wastewaters are commingled with noncyanide-bearing waste streams in accordance EPA permit and pretreatment program regulations at 40 CFR 122.44(i)(1)(iii) for direct dischargers and § 403.6(e) for indirect dischargers. These regulations allow permit writers and pretreatment control authorities to establish in-plant monitoring points for regulated pollutants in cases where it is impractical or infeasible to monitor at the normal end-of-pipe monitoring point e.g., because the regulated pollutant is not detectable at the end-of-pipe. This, in turn, is the result of the wastewater stream bearing the regulated pollutant being commingled with significantly higher volume streams not bearing the regulated pollutant. EPA's analysis of waste stream flow data, from subcategories A and C facilities containing cyanide in their wastewaters, indicate that the volume of cyanide-bearing wastewaters is, on average, less than 2.1 percent of the total process wastewater flow and that all but two of the facilities required to monitor for cyanide do so at an in-plant monitoring point. Facilities that can demonstrate that it is not impractical or infeasible to monitor for cyanide at the normal end-of-pipe point, i.e., cyanide can be detected at the end-of-pipe point, may do so.

In connection with the ammonia pretreatment standards being promulgated for subcategories A and C, EPA has determined that the pollutant ammonia does not passthrough POTWs that possess nitrification capability. As a result, ammonia pretreatment standards would not apply to subcategories A and C industrial users that discharge to these POTWs. In order to provide guidance to pretreatment authorities, EPA describes the treatment system requirements under which nitrification is considered to occur in section 17 of the final TDD and defines the basis for considering a POTW to have acceptable nitrification capability in § 439.1 of the final rule. POTWs that nitrify should impose local limits for

ammonia if they believe that the ammonia load from the pharmaceutical industrial user(s) will nevertheless pass through their facilities (see 40 CFR 403.5).

During the post-proposal period, EPA has received comments from industry commenters that complying with the pH requirements 100 percent of the time when using continuous monitoring is not practical for many facilities. Direct discharging pharmaceutical facilities are required by today's final regulation to maintain effluent pH in the 6.0–9.0 range. The general pretreatment regulations specifically in 40 CFR 403.5(b)(2), set a pH minimum of 5.0, except in certain design conditions, but do not set an upper boundary. EPA has addressed the problem of random excursions at 40 CFR 401.17 for direct discharging facilities. This regulation recognizes that random excursions from the pH range (6.0–9.0) may occur in the process of continuous monitoring and these random excursions should not be treated as violations. EPA is developing a proposal for a similar provision for indirect dischargers and expects to propose this provision by the end of this year.

In implementing the final limitations and standards, permit writers need to account for the facility's nonprocess wastewater contained in the effluent being discharged in developing either mass or concentration based permit limits. As discussed previously, in section IV of this preamble, the final limitations and standards are developed from data sets from plants which had less than 25 percent nonprocess wastewater in the total plant discharge. The flow basis of the final limitations and standards is discussed in section 13 of the TDD. In addition, examples of BPT and BAT permit limit calculations involving different plant flow configurations are provided in Appendix A to the TDD. In addition, permitting authorities have requested clarification on whether certain operations performed at pharmaceutical facilities would cause those facilities to be regulated under additional effluent guidelines. Specifically, guidance has been requested in cases where pharmaceutical facilities, during routine maintenance and cleaning periods, use acid containing solutions on or in stainless steel processing equipment. Some permitting authorities have inquired whether these operations are considered passivation operations which would place the wastewater generated during such cleaning operations under the limitations set forth by 40 CFR Part 433, the Metal Finishing Point Source Category. The Food and Drug Administration requires that pharmaceutical products must be of high purity and cannot be contaminated with dirt, biological organisms, or corrosion products. The pharmaceutical production equipment includes many interconnected pipes, storage vessels, and reactors. Most of the piping system and tanks are fabricated from austenitic stainless steel similar to AISI 304. The Agency is aware of several pharmaceutical facilities which clean production equipment with a mild alkaline ''soap'' followed by a flush with an acid containing solution. Some of these acid solutions contain nitric acid. The alkaline cleaner/acid-rinse operation is usually performed during plant shut-downs or routine preventative maintenance. Because much of the plant piping is fabricated from austenitic stainless steel, and such stainless steels are known to be ''passivated'' using nitric acid solutions, it has been asked if the nitric-acid-based process used by the pharmaceutical facilities would be considered ''passivation'' or ''cleaning'' for the purpose of regulation under the 40 CFR Part 433 Metal Finishing regulation.

The ''Development Document for Effluent Limitations Guidelines, New Source Performance Standards for the Metal Finishing Point Source Category'' describes the ''coating'' unit operation, which includes ''passivation'', as one of the six key ''trigger'' processes, while the ''cleaning'' operation description includes a discussion of acid cleaning as an operation that is not one of the six ''trigger'' processes. For a process wastestream to be regulated under 40 CFR Part 433, a facility must perform one of the six ''trigger'' operations. To determine the status of the alkaline ''soap''/acid-based operations performed at pharmaceutical facilities, key provisions of the ''passivation'' and ''cleaning'' definitions were reviewed. From the definitions provided in the Development Document ''passivation'' is a process in which iron particles are removed from a surface, while a protective coating is formed. ''Cleaning'' is a process in which acid can be used in combination with detergent to remove soil from metal surfaces. Based on these definitions from the Metal Finishing Development Document, the process conducted at pharmaceutical facilities should be considered cleaning for the following three reasons:

1. The processes in question use both acid and detergent.

2. The processes in question are not used to remove imbedded iron particles.

3. The processes in question are not used to form a coating on stainless steel piping. (This conclusion can be reached based on the inherent vulnerability of non-passivated stainless to corrosion. If the pipes in this system were not already passivated, they would corrode during the production operations and contaminate the pharmaceutical products.)

For the reasons listed above, the pharmaceutical production operations performed at these facilities should be considered ''acid cleaning'' and non ''passivation'' with respect to 40 CFR Part 433 Metal Finishing. Because the facilities only perform ''acid cleaning'' and not ''passivation'' there is no metal finishing ''trigger'' process performed at the facility and therefore the facility would not be regulated using 40 CFR Part 433.

B. Upset and Bypass Provisions

A recurring issue is whether industry limitations and standards should include provisions authorizing noncompliance with effluent limitations during periods of ''upset'' or ''bypass''. An upset, sometimes called an ''excursion,'' is an unintentional and temporary noncompliance with technology based effluent limitations occurring for reasons beyond the reasonable control of the permittee. EPA believes that upset provisions are necessary to recognize an affirmative defense for an exceptional incident. Because technology-based limitations can require only what properly designed, maintained and operated technology can achieve, it is claimed that liability for such situations is improper.

While an upset is an unintentional episode during which effluent limitations are exceeded, a bypass is an act of intentional noncompliance during which wastewater treatment facilities are circumvented in emergency situations.

EPA has both upset and bypass provisions in NPDES permits, and has promulgated NPDES and pretreatment regulations which include upset and bypass provisions. (40 CFR 122.41(m), 122.41(n) and 40 CFR 403.16 and 403.17.) The upset provision establishes an upset as an affirmative defense to prosecution for violation of technology-based effluent limitations. The bypass provision provides that EPA may enforce against facilities that bypass except where necessary to prevent loss of life, personal injury, or severe property damage; there were no feasible alternatives; or permittee submitted notices as required under 122.41(n)(3).

C. Variances and Modifications

Upon the promulgation of these regulations, the effluent limitations for

the appropriate subcategory must be applied in all Federal and State NPDES permits issued to direct dischargers in the pharmaceutical manufacturing industry. In addition, the pretreatment standards are directly applicable to indirect dischargers.

1. Fundamentally Different Factors Variances

For the BPT effluent limitations, the only exception to the binding limitations is EPA's ''fundamentally different factors'' (''FDF'') variance (40 CFR Part 125 Subpart D). This variance recognizes factors concerning a particular discharger which are fundamentally different from the factors considered in this rulemaking. Although this variance clause was set forth in EPA's 1973–1976 effluent guidelines, it is now included in the NPDES regulations and not the specific industry regulations. (See 44 FR 32854, 32893 [June 7, 1979] for an explanation of the ''fundamentally different factors'' variance). The procedures for application for a BPT FDF variance are set forth at 40 CFR 122.21(m)(1)(I)(A).

Dischargers subject to the BAT limitations and PSES in these final regulations may also apply for an FDF variance, under the provisions of sec. 301(n) of the Act, which regulates BAT, BCT, and PSES for existing sources pretreatment FDFs. (See 40 CFR 122.21 and 40 CFR 403.13, respectively) In addition, BAT limitations for nonconventional pollutants may be modified under sec. 301(c) (for economic reasons) and 301(g) (for water quality reasons) of the Act. Under sec. 301(l) of the Act, these latter two statutory modifications are not applicable to ''toxic'' or conventional pollutants.

2. Removal Credits

Congress, in enacting Section 307(b) of the CWA, recognized that, in certain instances, POTWs could provide some or all of the treatment of an industrial user's wastestream that would be required pursuant to the pretreatment standard. Consequently, Congress established a discretionary program for POTWs to grant ''removal credits'' to their indirect dischargers. The credit, in the form of a less stringent pretreatment standard, allows an increased amount of pollutants to flow from the indirect discharger's facility to the POTW.

Section 307(b) of the CWA establishes a three-part test for obtaining removal credit authority for a given pollutant. Removal credits may be authorized only if (1) the POTW ''removes all or any part of such toxic pollutant,'' (2) the POTW's ultimate discharge would ''not violate that effluent limitation, or standard which would be applicable to that toxic pollutant if it were discharged'' directly rather than through a POTW and (3) the POTW's discharge would ''not prevent sludge use and disposal by such [POTW] in accordance with section [405]. . . .'' Section 307(b).

EPA has promulgated removal credit regulations in 40 CFR 403.7. The United States Court of Appeals for the Third Circuit has interpreted the statute to require EPA to promulgate comprehensive sewage sludge regulations before any removal credits could be authorized. *NRDC* v. *EPA*, 790 F.2d 289, 292 (3rd Cir. 1986) *cert. denied*. 479 U.S. 1084 (1987). Congress made this explicit in the Water Quality Act of 1987 which provided that EPA could not authorize any removal credits until it issued the sewage sludge use and disposal regulations required by section 405(d)(2)(a)(ii).

Section 405 of the CWA requires EPA to promulgate regulations which establish standards for sewage sludge when used or disposed for various purposes. These standards must include sewage sludge management standards as well as numerical limits for pollutants which may be present in sewage sludge in concentrations which may adversely affect public health and the environment. Section 405 requires EPA to develop these standards in two phases. On February 19, 1993, EPA published the Round One sewage sludge regulations establishing standards, including numerical pollutant limits, for the use and disposal of sewage sludge. 58 FR 9248. EPA established pollutant limits for ten metals when sewage sludge is applied to land, for three metals when it is disposed of at surface disposal sites and for seven metals and total hydrocarbons, a surrogate for organic pollutant emissions, when sewage sludge is incinerated. These requirements are codified at 40 CFR Part 503.

At the same time EPA promulgated the Round One regulations, EPA also amended its pretreatment regulations to provide that removal credits would be available for certain pollutants regulated in the sewage sludge regulations. *See* 58 FR at 9386. The amendments to Part 403 provide that removal credits may be made potentially available for the following pollutants:

(1) If a POTW applies its sewage sludge to the land for beneficial uses, disposes of it on surface disposal sites or incinerates it, removal credits may be available, depending on which use or disposal method is selected (so long as the POTW complies with the requirements in Part 503). When sewage sludge is applied to land, removal credits may be available for ten metals. When sewage sludge is disposed of on a surface disposal site, removal credits may be available for three metals. When the sewage sludge is incinerated, removal credits may be available for seven metals and for 57 organic pollutants. *See* 40 CFR 403.7(a)(3)(iv)(A).

(2) In addition, when sewage sludge is used on land or disposed of on a surface disposal site or incinerated, removal credits may also be available for additional pollutants so long as the concentration of the pollutant in sludge does not exceed a concentration level established in Part 403. When sewage sludge is applied to land, removal credits may be available for two additional metals and 14 organic pollutants. When the sewage sludge is disposed of on a surface disposal site, removal credits may be available for seven additional metals and 13 organic pollutants. When the sewage sludge is incinerated, removal credits may be available for three other metals. *See* 40 CFR 403.7(a)(3)(iv)(B).

(3) When a POTW disposes of its sewage sludge in a municipal solid waste landfill that meets the criteria of 40 CFR Part 258 (MSWLF), removal credits may be available for any pollutant in sewage sludge. *See* 40 CFR 403.7(a)(3)(iv)(C).

Thus, given compliance with the requirements of EPA's removal credit regulations, following promulgation of the pretreatment standards in today's rule, removal credits may be authorized for any pollutant subject to pretreatment standards if the applying POTW disposes of its sewage sludge in a MSWLF that meets the requirements of 40 CFR Part 258. Currently there are two pretreatment programs authorized to issue removal credits. EPA is not promulgating pretreatment standards for metals, thus removal credits for metals are not applicable. Given compliance with § 403.7, removal credits may be available for the following organic pollutants (depending on the method of use or disposal) if the POTW uses or disposes of its sewage sludge: benzene, chloroform, 1,2-dichloroethane, methylene chloride and toluene.

D. Analytical Methods

Section 304(h) of the Act directs EPA to promulgate guidelines establishing test methods for the analysis of pollutants. These methods are used to determine the presence and concentration of pollutants in wastewater, and are used for compliance monitoring and for filing applications for the NPDES program

under 40 CFR 122.21, 122.41, 122.44 and 123.25, and for the implementation of the pretreatment standards under 40 CFR 403.10 and 403.12. To date, EPA has promulgated methods for conventional pollutants, toxic pollutants, and for some nonconventional pollutants. The five conventional pollutants are defined at 40 CFR 401.16. Table I–B at 40 CFR Part 136 lists the analytical methods approved for these pollutants. The 65 toxic metals and organic pollutants and classes of pollutants are defined at 40 CFR 401.15. From the list of 65 classes of toxic pollutants EPA identified a list of 126 ''Priority Pollutants.'' This list of Priority Pollutants is shown, for example, at 40 CFR Part 423, Appendix A. The list includes non-pesticide organic pollutants, metal pollutants, cyanide, asbestos, and pesticide pollutants. Currently approved methods for metals and cyanide are included in the table of approved inorganic test procedures at 40 CFR 136.3, Table I–B. Table I–C at 40 CFR 136.3 lists approved methods for measurement of non-pesticide organic pollutants, and Table I–D lists approved methods for the toxic pesticide pollutants and for other pesticide pollutants. Dischargers must use the test methods promulgated at 40 CFR 136.3 or incorporated by reference in the tables, when available, to monitor pollutant discharges from the pharmaceutical manufacturing industry, unless specified otherwise by the permitting authority.

As a part of today's final rule, EPA is promulgating additional test methods for the additional pollutants to be regulated under Part 439 by adding a new Table IF at 40 CFR 136.3 listing test methods for the pharmaceutical pollutants. To support the Part 439 regulations at the time of proposal, EPA published test methods developed specifically for the pharmaceutical industry in a compendium entitled, ''Analytical Methods for the Determination of Pollutants in Pharmaceutical Manufacturing Industry Wastewater,'' EPA–821–B–94–001. These proposed test methods were discussed in the proposed rule. The proposed test methods have been revised in response to public comment and the revised test methods are available for monitoring some pollutants covered by today's final rule. The revised test methods have been published in a revised compendium (the ''Pharmaceutical Methods Compendium, Revision A''; EPA–821–B–98–016 [A, July 1998] with the same title as the proposed compendium. EPA does not anticipate that any dischargers from industrial categories other than the pharmaceutical manufacturing industry will ever need to monitor for the additional pollutants (with methods listed in Table 1F).

In addition, EPA is allowing use of applicable drinking water methods that have been promulgated at 40 CFR part 141 and use of ASTM Methods D3371, D3695, and D4763, for monitoring of the pollutants included in this rulemaking. The final rule allows for use of these additional test methods for several reasons: (1) it allows greater flexibility in monitoring as requested by some commenters; (2) it conforms use of methods in EPA's drinking water and wastewater programs, (3) it moves toward a performance-based measurement system, and (4) it allows use of technical standards as contemplated by the National Technology Transfer and Advancement Act of 1995 (NTTAA; see Section IX.G.).

For pollutants to be monitored under today's final rule, EPA has included a new table of methods in § 136.3(a). The methods in this table are in addition to other methods approved at 40 CFR 136.3. The listed methods are incorporated by reference into this rule.

With the allowed use the methods included in the new Table IF at 40 CFR 136.3, in addition to those already approved in other Tables at 40 CFR 136.3, EPA believes that dischargers in the pharmaceutical manufacturing point source category will have great flexibility in selection of a method for monitoring the pollutants being regulated in today's final rule.

On October 6, 1997, EPA published a Notice of the Agency's intent to implement a Performance Based Measurement System (PBMS) in all of its programs to the extent feasible (62 FR 52098). The Agency is currently determining the specifics steps necessary to implement PBMS in its programs and preparing an implementation plan. Final decisions have not yet been made concerning the implementation of PBMS in water programs. However, EPA is currently evaluating what relevant performance characteristics should be specified for monitoring methods used in the water programs under a PBMS approach to ensure adequate data quality. EPA would then specify performance requirements in its regulations to ensure that any method used for determination of a regulated analyte is at least equivalent to the performance achieved by other currently approved methods. EPA expects to publish its PBMS implementation strategy for water programs in the **Federal Register** by the end of calendar year 1998.

Once EPA has made its final determinations regarding implementation of PBMS in programs under the Clean Water Act, EPA would incorporate specific provisions of PBMS into its regulations, which may include specification of the performance characteristics for measurement of the regulated pollutants in today's final rule.

IX. Regulatory Assessment Requirements

A. Executive Order 12866

Under Executive Order 12866, (58 FR 51735 (October 4, 1993)) the Agency must determine whether the regulatory action is ''significant'' and therefore subject to Office of Management and Budget (OMB) review and the requirements of this Executive Order. The Order defines ''significant regulatory action'' as one that is likely to result in a rule that may: (1) have an annual effect of the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

Pursuant to the terms of the Executive Order, it has been determined that this rule is a ''significant regulatory action'' As such, this action was submitted to OMB for review. Changes made in response to suggestions or recommendations are documented in the public record.

B. Regulatory Flexibility Act and the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA)

Under the Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq.*, as amended by SBREFA, EPA generally is required to conduct a regulatory flexibility analysis describing the impact of the regulatory action on small entities as part of the rulemaking. However, under section 605 (b) of the RFA, EPA is not required to prepare the regulatory flexibility analysis if EPA certifies that the rule will not have a significant economic impact on a substantial number of small entities.

Pursuant to section 605(b) of the RFA, the Administrator certifies that this rule will not have a significant impact on a substantial number of small entities. Nevertheless, the Agency prepared a small business analysis, which is presented in the Economic Analysis for Final Effluent Guidelines and Standards for the Pharmaceutical Industry and summarized in Section V.E. of this document. Briefly, EPA estimates that 145 small businesses will incur costs to comply with this rule (based on a small business definition of 750 or fewer employees as recommended by the U.S. Small Business Administration). EPA evaluated the compliance costs of the regulatory action relative to the company's annual revenue. When considering the effluent limitations guidelines and standards costs only, four small firms are estimated to incur annualized compliance costs exceeding one percent of revenue and no firms are estimated to incur annualized compliance costs exceeding three percent of revenue. When considering the aggregate costs of the effluent limitations guidelines and standards and the MACT standards, six small firms are estimated to incur annualized compliance costs exceeding one percent of revenue and one firm is estimated to incur annualized compliance costs exceeding three percent of revenue. No firms are expected to incur annualized compliance costs in excess of four percent of revenue.

Further, EPA's economic achievability analysis considers the potential for facility closure and corporate bankruptcy. The analysis indicates no disproportionate effects for small businesses compared to large businesses. The regulatory action is found to be economically achievable for all dischargers, including small businesses.

C. Submission to Congress and the General Accounting Office

Under 5 U.S.C. 801(a)(1)(A) as added by the Small Business Regulatory Enforcement Fairness Act of 1996, EPA submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the General Accounting Office prior to publication of the rule in today's **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

D. Paperwork Reduction Act

This rule contains no new information collection activities requiring an information collection request, and therefore, no information collection request was submitted to OMB for review under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* OMB has approved information collection requirements for existing regulations (40 CFR Part 439) and assigned OMB Control No. 2040–0110 in connection with NPDES related information collection requirements and No. 2040–0009 in connection with pretreatment information collection requirements. The information collection requirements resulting from the regulations being promulgated today are covered by these OMB control numbers.

E. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), P.L. 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and Tribal governments, and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures to State, local, and Tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost effective or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

EPA has determined that this CWA rule does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local or tribal governments, in the aggregate, or the private sector in any one year. EPA estimates that the annual compliance costs to the private sector are $61.0 million ($1996). Thus, this rule is not subject to the requirements of sections 202 and 205 of UMRA. EPA has also determined that this rule contains no regulatory requirements that might significantly or uniquely affect small governments and thus, this rule is not subject to the requirements of section 203 of UMRA. Nevertheless, EPA has consulted with state and local governments pertaining to implementation issues. EPA's evaluation of their comments is reflected in the final rules.

F. Executive Order 12875 Enhancing Intergovernmental Partnership

To reduce the burden of Federal regulations on States and small governments, the President issued Executive Order 12875, entitled Enhancing the Intergovernmental Partnership, on October 28, 1993 (58 FR 58093). Under Executive Order 12875, EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or Tribal government unless the Federal government provides the necessary funds to pay the direct costs incurred by the State, local or Tribal government or EPA provides to the Office of Management and Budget a description of the extent of the Agency's prior consultation and written communications with elected officials and other representatives of affected State, local and Tribal governments, the nature of their concerns, and an Agency statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local and Tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.'' As discussed above in paragraph IX.E, this regulation would not result in expenditures to state, local and tribal governments of $100 million or more in any one year. The discussion of the Unfunded Mandates Reform Act of 1995 that precedes this paragraph applies to Executive Order 12875 as well and is incorporated here by reference. Since this rule does not impose a significant unfunded mandate on governments subject to this Executive Order, the provisions of the Order do not apply. Nonetheless, EPA did consult with State and local

governments during development of this rule. In particular, EPA has had numerous discussions with representatives of the North Shore Sanitary District regarding PSES for pharmaceutical plants. In addition, EPA also consulted with the Puerto Rico Aqueducts and Sewer Authority (PRASA) regarding discharges of VOCs by pharmaceutical industrial users. In addition, prior to the proposal, EPA sent a questionnaire concerning pharmaceutical discharges to a number of POTWs receiving significant amounts of these discharges. The meeting summaries and questionnaire responses may be found in the record of this rule.

G. National Technology Transfer and Advancement Act

Under Section 12(d) of the National Technology Transfer and Advancement Act (NTTAA), the Agency is required to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, business practices, etc.) that are developed or adopted by voluntary consensus standards bodies. Where available and potentially applicable voluntary consensus standards are not used by EPA, the Act requires the Agency to provide Congress, through the Office of Management and Budget (OMB), an explanation of the reasons for not using such standards.

EPA performed a search of the technical literature to identify any applicable analytical test methods from industry, academia, voluntary consensus standard bodies, and other parties that could measure the analytes in this rule. EPA's search revealed that there are consensus standards for many of the analytes specified in the tables at 40 CFR 136.3. Even prior to enactment of the NTTAA, EPA has traditionally included any applicable consensus test methods in its regulations. Consistent with the requirements of the CWA, those applicable consensus test methods are incorporated by reference in the tables at 40 CFR 136.3. The consensus test methods in these tables include American Society for Testing Materials (ASTM) and Standard Methods.

Today's rule requires dischargers to monitor for 31 organic pollutants, ammonia nitrogen and COD. Examples of pollutants with consensus methods promulgated by reference in today's rule include various volatile organics such as benzene, chlorobenzene, chloroform, chloromethane, methylene chloride, and toluene. In addition, EPA developed several test methods for certain nonconventional pollutants not included in the tables at 40 CFR 136.3 in support of the pharmaceutical rule and these methods were discussed in the proposal. Examples of the pollutants for which methods were developed are acetone, cyclohexane, diethylamine, ethanol and methylamine. The test methods being promulgated for those pollutants without test methods listed at 40 CFR 136.3 are EPA Methods 1665, 1666, 1667, 1671 and 1673 which are found in a Methods Compendium, and EPA Method 8015. EPA notes that no applicable consensus methods were found for those pollutants.

H. Executive Order 13045 and Protecting Children's Health

The Executive Order ''Protection of Children From Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997) applies to any rule that EPA determines (1) ''economically significant'' as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children; and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

EPA interprets the E.O. 13045 as encompassing only those regulatory actions that are risk based or health based, such that the analysis required under section 5–501 of the E.O. has the potential to influence the regulation. This rule is not subject to E.O. 13045 because it does not involve decisions regarding environmental health or safety risks.

X. Summary of Public Participation

The following section describes the major comments on the proposed rule and the NOA, and EPA's responses. The full comment summary and response document can be found in the public record for this rulemaking.

A. Summary of Proposal Comments and Response Summary

Sixty six different commenters provided detailed comments on all aspects of the May 2, 1995 proposal. In all, the comments dealt with 27 separate aspects of the proposal. In this comment and response summary, only major comments and responses will be summarized. Responses to all comments are contained in the Comment Response Document in the record for this final rule. In selecting comments and responses for summary in this section, the Agency has selected those major and controversial issues that received considerable numbers and types of comments. Alternatively, comments and responses on other less controversial issues and issues where EPA essentially agrees with the commenters are not included in the comment and response summaries below.

Comment: EPA's decision to set in-plant limits is primarily based on controlling air emissions. The appropriate statutory authority for regulating air emissions from wastewater is under the MACT rule, therefore, in-plant wastewater limits should not be used for the purpose of controlling air emissions. The intention of the Clean Water Act is to set limits at the end-of-pipe to protect surface water quality and POTW's from pass through and interference. Application of end-of-pipe standards and limitations will fulfill this intent.

Response: EPA agrees that the intention of the Clean Water Act is to set limits to protect surface water quality and POTWs from pass through and interference. EPA is promulgating effluent limitations guidelines and standards for which compliance will generally be monitored end-of-pipe, except for cyanide. EPA has the authority to control any pollutants found in wastewater. Although in-plant air emissions will be regulated under the MACT standards rule, organic pollutants in wastewater will be controlled by this effluent guidelines rule using limits monitored at end-of-pipe except in cases where end-of-pipe monitoring is impractical as authorized in § 122.45 or § 403.6(e).

Comment: Oxygenated organic solvents such as methanol, ethanol, acetone, and isopropanol should not be regulated by pretreatment standards because they do not volatilize in appreciable amounts and do not typically pass through the POTW or interfere with POTW operations.

Response: EPA agrees that oxygenated organic solvents such as methanol, ethanol, acetone and isopropanol with Henry's Law Constants less than 1.0×10^{-5} atm/gmole/m^3 will not volatilize in appreciable amounts in POTWs and sewers, and will biodegrade in POTW biological treatment units to a large extent. EPA has made this determination based on information submitted by PhRMA which estimated sewer losses of VOCs and EPA and PhRMA empirical sampling and modeling data from the Barceloneta POTW sampling episode. Based on an evaluation of this data, EPA agrees that

the oxygenated (alcohols and related) compounds under normal conditions will not pass through or interfere with POTW operations. Therefore, EPA is not promulgating categorical pretreatment standards for these pollutants for the pharmaceutical industry. However, local control authorities can set local limits for these compounds to take care of any site specific pass through or interference problems that may occur (§ 403.5.b.2).

Comment: Steam stripping with distillation is not a demonstrated treatment technology for the pharmaceutical industry since the Agency has not demonstrated the performance of this technology for any pollutant other than methanol and the data set used for proposing limits and standards was generated during treatment of a clean process wastewater which is not representative of typical industry process wastewaters.

Response: EPA agrees that the distillation data set used at proposal for setting limitations and standards based on steam stripping with distillation for alcohols were generated during treatment of a wastewater for a process which generated mostly methanol in the wastewater. EPA has not used these performance data in the calculation of final BAT limitations for the alcohols. Since the alcohols are not being regulated at PSES or PSNS because they do not pass through or interfere with the POTW operation, use of steam stripping with distillation technology is not an issue.

Comment: Solgar is a small business with process wastewater flow of approximately 100 gallons per day. They manufacture vitamins of natural origin and are not under the jurisdiction of the FDA. The definition of Subcategory D includes products and processes covered by SIC No. 2833 (Medical and Botanical Products). Being a regulated facility creates an adverse economic effect because of the operating costs related to permitting, sampling, analysis and reporting. EPA should consider exempting such facilities from the definition of pharmaceutical manufacturing.

Response: EPA has estimated compliance costs for all of the pharmaceutical manufacturing facilities which discharge pollutants for which effluent limitations and standards have been developed. If a facility does not discharge regulated pollutants, the compliance costs connected with sampling and analysis will be minimal. Permitting costs were not included in the cost estimates because these costs would be incurred by all dischargers regardless of category and are not specific to this regulation. EPA does not believe that small facilities such as the one described in the comment will incur significant costs in complying with the final rule. In a part of the economic analysis for this rule, special emphasis was placed on small businesses as required by the Regulatory Flexibility Act. Results of this analysis showed that there are no significant adverse impacts on small facilities or firms. (See the Economic Analysis Report)

Comment: Facilities should not be required to monitor for constituents that they do not use. In lieu of annual testing, facilities could submit annual (or on other frequencies) certifications regarding the constituent used or expected in the wastewater based on a review of all raw materials used and an assessment of all chemical processes used, considering resulting products and by-products. This would avoid incorrect data created by inflow of contaminated groundwater in facility sewers. Most commenters supported the certification approach.

Response: EPA agrees that facilities should not be required to monitor for constituents that they do not use. EPA disagrees that in lieu of annual testing, facilities could submit annual certifications regarding the constituents used or expected in the wastewater based on a review of all raw materials used and an assessment of all chemical processes used. Facilities will not have permit limits or be required to monitor regularly for constituents not used in their pharmaceutical processes, and EPA agrees that most commenters support the certification approach. In cases where groundwater may be contaminated by regulated pollutants which are not used in manufacturing operations at a facility, the facility should submit groundwater sampling data along with the other certification information to avoid regular monitoring for these regulated pollutants.

Comment: Provisions d and f of the applicability section of the Preamble, Section IV.B, would have the effect of extending the applicability of the proposed regulations to many diagnostic products listed in SIC Code 2835. The processes used in, and the wastewater produced from the manufacture of many of these products is substantially different from products listed in SIC code no. 2833, 2834, and 2836. EPA should define applicability by SIC code, without the exceptions contained in provisions d and f, and excluding SIC code no. 2835. Provisions d and f will be difficult to administer because they are based on subjective determinations.

Response: Defining applicability strictly by SIC code could result in considerable amounts of wastewater at some facilities not being covered by any categorical limitations and standards and therefore the Agency has not adopted this approach in the final regulation. The Agency agrees that regulatory decisions based on applicability section IV.B.f. may require a subjective judgement by the permit writer or pretreatment authority with regard to the nature of the wastewater generated by the manufacture of the products in question. In order to remove any ambiguity that may be associated with this applicability section, EPA has revised the applicability provision of the final rule in 439.1.

B. Summary of Notice of Availability Comments and Responses

EPA received comments on the August 8, 1997 Notice of Availability from 25 commenters regarding seven major topics and 35 subtopics. A summary of the major comments and EPA responses is provided below. Responses to all of the comments are contained in the Comment Response Document in the record for this final rule.

Comment: The commenters support Option 1 for PSES and PSNS that provided for compliance with the MACT standards plus some regular monitoring. Option 1 will reduce redundant regulation, needless cost, confusion, and potentially contradictory rulemakings.

Response: EPA disagrees with the commenters. EPA is promulgating PSES/PSNS limitations based on Option 2 because this option controls VOC wastewater discharges from pharmaceutical wastewaters that are not controlled by the final MACT standard for the pharmaceutical industry. Therefore, EPA does not believe that selecting Option 2 will result in a redundant, confusing, and potentially contradictory regulation. EPA is directed to control pollutants found in wastewater that pass through or interferes with POTWs. EPA has taken into account the effects of the MACT rule in estimating the compliance costs for the industry to meet the final effluent guidelines and standards.

Comment: The commenters believe EPA should also exclude benzene and o-dichlorobenzene from coverage under this regulation because they are each discharged by only one plant. The fact that a pollutant is a priority pollutant is not justification for regulating it when it is found at a small number of sources within an industrial point source category. EPA excluded 20 priority

pollutants from regulation by the Organic Chemicals, Plastics, and Synthetic Fibers (OCPSF) effluent guidelines under the authority of Paragraph 8(a)(iii) of the then applicable consent decree (Table VI–3, OCPSF Development Document, EPA 440/1–87/009). Another reason for excluding benzene is that the one plant that currently discharges this chemical has permanently shut down the process generating this pollutant.

Response: Benzene and o-dichlorobenzene were reported in the 1990 Questionnaire as discharged from one facility; however, EPA sampling data found they were present at more than one facility. Using industry supplied data, EPA has determined that benzene and o-dichlorobenzene were discharged in 1990 at quantities of approximately 120,200 and 21,500 lbs per year, respectively, well above the 3,000 lbs/year small discharge limit and there are estimated removals in excess of 1000 lbs/year. Both criteria that are used to determine which pollutants are excluded from this regulation. In addition, given the variable nature of the pharmaceutical industry, EPA has not excluded pollutants from regulation that may be present at more that one facility. Benzene is a good case in point, since even though only one facility identified it as discharged in 1990, it was found to be present in 10 of the samples taken by EPA in August 1996 at the Barceloneta Regional Wastewater Treatment Plant, which is a POTW that receives predominately pharmaceutical wastewaters.

Comment: Several commenters will be requesting fundamentally different factor (FDF) variances for ammonia production because EPA has not properly developed nitrification-based BAT ammonia limits. (1) EPA did not properly identify facilities that may have to treat ammonia, (2) it excluded data from the biological nitrification database for plants that had influent ammonia concentrations of greater than 100 mg/L, (3) it assumed ammonia in process wastewaters are all ammonium hydroxide and not ammonium nitrate or ammonium phosphate, (4) and it did not consider the effects of high organic nitrogen loading present with high ammonia nitrogen loading. Because of the incorrect chemistry and engineering assumptions, EPA has overestimated the feasibility to meet the proposed BAT limits on ammonia-nitrogen. Therefore, commenters would request that EPA handle wastewater discharges of ammonia-nitrogen from certain facilities in a fundamentally different manner.

Response: In response to point one, EPA has identified all facilities that may have to treat ammonia from information provided in the 1990 questionnaire responses and data submissions provided in response to the proposal. With regard to point two, the five plant data sets used to develop the final limits included numerous influent ammonia concentration points greater than 100 mg/L. With regard to point three, EPA has converted all ammonium salt and hydroxide loadings to NH3 nitrogen loadings. In response to point four, EPA did consider the effect of the presence of high organic ammonia along with high ammonia nitrogen with respect to achieving compliance with the final ammonia limitations. EPA has concluded that ability of nitrification systems to nitrify ammonia is not affected by large loadings of organic amines because these compounds are biodegraded to ammonia in the advanced biological treatment along with other carbonaceous waste. The ammonia thus generated is then nitrified in the nitrification system. In certain cases, where organic amine levels are sufficiently high, two-stage nitrification will be necessary. The limitations and standards for ammonia in the final rule were determined using all of the data (one and two stage), after comparing the single stage and two stage performance data, and then setting the limits at the levels that were reflected by the data bases being examined separately. In conclusion, EPA costed compliance with the limits by two-stage nitrification, and believes the final BAT limits based on two stage nitrification technology are appropriate.

Appendix A to the Preamble—Lists of Abbreviations, Acronyms, Defintions and Other Terms Used in This Document

I. Definitions, Acronyms, and Abbreviations

1990 Detailed Questionnaire—The 1990 Pharmaceutical Manufacturing Survey. A questionnaire sent by EPA to certain facilities in the pharmaceutical manufacturing industry in September 1991 to gather technical and financial information. The questionnaire was sent to those facilities likely to be affected by promulgation of revised effluent limitations guidelines, pretreatment standards, and new source performance standards for this industry.

Administrator—The Administrator of the U.S. Environmental Protection Agency.

Agency—The U.S. Environmental Protection Agency. Mass loading at the relevant point of measurement).

Average monthly discharge limitation—The highest allowable average of ''daily discharges'' over a calendar month, calculated as the sum of all ''daily discharges'' measured during a calendar month divided by the number of ''daily discharges'' measured during that month.

BAT—The best available technology economically achievable, as described in Section 304(b)(2) of the Clean Water Act.

Bench-scale operation—Laboratory testing of materials, methods, or processes on a small scale, such as on a laboratory worktable.

BCT—The best conventional pollutant control technology, as described in section 304(b)(4) of the Clean Water Act.

BID—Background Information Document, which presents the technical basis for air pollution controls under the Clean Air Act.

Biological and Natural Extraction—The chemical and physical extraction of pharmaceutically active ingredients from natural sources such as plant roots and leaves, animal glands, and parasitic fungi. The process operations involving biological and natural extraction define subcategory B (40 CFR Part 439, subpart B).

BMP or BMPs—Best management practices, as described in section 304(e) of the Clean Water Act.

BOD_5—Five-Day Biochemical Oxygen Demand. A measure of biochemical decomposition of organic matter in a water sample. It is determined by measuring the dissolved oxygen consumed by microorganisms to oxidize the organic contaminants in a water sample under standard laboratory conditions of five days and 20°C. BOD_5 is not related to the oxygen requirements in chemical combustion.

BPT—The best practicable control technology currently available, as described in section 304(b)(1) of the Clean Water Act.

CAA—Clean Air Act. The Air Pollution Prevention and Control Act (42 U.S.C. 7401 *et seq.*), as amended, *inter alia*, by the Clean Air Act Amendments of 1990 (Pub. L. 101–549, 104 Stat. 2399).

Chemical Synthesis—The process(es) of using a chemical reaction or a series of chemical reactions to manufacture pharmaceutically active ingredients. The chemical synthesis process operations define subcategory C (40 CFR Part 439, subpart C).

Clarifier—A treatment unit designed to remove suspended materials from wastewater, typically by sedimentation.

CN—Abbreviation for total cyanide.

COD—Chemical oxygen demand (COD)—A nonconventional bulk parameter that measures the total oxygen-consuming capacity of wastewater. This parameter is a measure of materials in water or wastewater that are biodegradable and materials that are resistant (refractory) to biodegradation. Refractory compounds slowly exert demand on downstream receiving water resources. Certain of the compounds measured by this parameter have been found to have carcinogenic, mutagenic, and similar adverse effects, either singly or in combination. It is expressed as the amount of oxygen consumed by a chemical oxidant in a specific test.

Condensate—Any material that has condensed from a gaseous phase into a liquid phase.

Controlled-release discharge—A discharge that occurs at a rate that is intentionally varied to accommodate fluctuations in receiving stream assimilative capacity or for other reasons.

Conventional pollutants—The pollutants identified in section 304(a)(4) of the Clean

Water Act and the regulations thereunder (i.e., biochemical oxygen demand (BOD_5), total suspended solids (TSS), oil and grease, fecal coliform and pH).

CWA—Clean Water Act. The Federal Water Pollution Control Act Amendments of 1972 (33 U.S.C. 1251 *et seq.*), as amended, *inter alia,* by the Clean Water Act of 1977 (Pub. L. 95–217) and the Water Quality Act of 1987 (Pub. L. 100–4).

Daily discharge—The discharge of a pollutant measured during any calendar day or any 24-hour period that reasonably represents a calendar day for purposes of sampling. For pollutants with limitations expressed in units of mass, the daily discharge is calculated as the total mass of the pollutant discharged over the day. For pollutants with limitations expressed in other units of measurement, the daily discharge is calculated as the average measurement of the pollutant over the day.

Direct discharger—A facility that discharges or may discharge treated or untreated process wastewaters, non-contact cooling waters, or non-process wastewaters (including stormwater runoff) into waters of the United States.

Effluent—Wastewater discharges.

Effluent limitation—Any restriction, including schedules of compliance, established by a State or the Administrator on quantities, rates, and concentrations of chemical, physical, biological, and other constituents which are discharged from point sources into waters of the United States, the waters of the contiguous zone, or the ocean.

Emission—Passage of air pollutants into the atmosphere via a gas stream or other means.

EOP effluent—Final plant effluent discharged to waters of the United States or to a POTW.

EOP treatment—End-of-pipe treatment facilities or systems used to treat process wastewaters, non-process wastewaters (including stormwater runoff) after the wastewaters have left the process area of the facility and prior to discharge. End-of-pipe treatment generally does not include facilities or systems where products or by-products are separated from process wastewaters and returned to the process or directed to air emission control devices.

EPA—The U.S. Environmental Protection Agency.

General Provisions—General Provisions for national emission standards for hazardous air pollutants and other regulatory requirements pursuant to section 112 of the Clean Air Act, as amended November 15, 1990. The General Provisions, located in subpart A of part 63 of title 40 of the Code of Federal Regulations, codify procedures and criteria to implement emission standards for stationary sources that emit (or have the potential to emit) one or more of the 189 chemicals listed as hazardous air pollutants in section 112(b) of the Clean Air Act as amended in 1990. EPA published the NESHAP General Provisions in the **Federal Register** on March 16, 1993 (59 FR 12408). The term General Provisions also refers to the General Provisions for the effluent limitations guidelines and standards proposed today, to be located at 40 CFR part 439.

Fermentation—A chemical change induced by a living organism or enzyme, specifically bacteria or the microorganisms occurring in unicellular plants such as yeast, molds, or fungi. Process operations that utilize fermentation to manufacture pharmaceutically active ingredients define subcategory A (40 CFR Part 439, subpart A).

HAP—Hazardous Air Pollutant. Any of the 189 chemicals listed under section 112(b) of the Clean Air Act.

HON—Hazardous Organic NESHAP. As used in this document, it refers to the standard published by EPA for the Synthetic Organic Chemical Manufacturing Industry (SOCMI) on April 22, 1994 (59 FR 19402).

Incinerator—An enclosed combustion device that is used for destroying organic compounds. Auxiliary fuel may be used to heat waste gas to combustion temperatures. Any energy recovery section present is not physically formed into one manufactured or assembled unit with the combustion section; rather, the energy recovery section is a separate section following the combustion section and the two are joined by ducts or connections carrying flue gas.

Indirect discharger—A facility that discharges or may discharge wastewaters into a publicly owned treatment works.

In-plant Control Technologies—These include controls or measures applied within the manufacturing process to reduce or eliminate pollutant and hydraulic loadings; these also include technologies, such as steam stripping and cyanide destruction, applied directly to wastewater generated by manufacturing processes.

IU—Industrial User. Synonym for ''Indirect Discharger.''

Junction box—A manhole access point to a wastewater sewer system or a lift station.

LTA—Long-term average. For purposes of proposed effluent limitations guidelines and standards, average pollutant levels achieved over a period of time by a plant, subcategory, or technology option. LTAs were used in developing the limitations and standards in today's proposed regulation.

MACT—Maximum Achievable Control Technology. Technology basis for the national emission standards for hazardous air pollutants.

Major source—As defined in section 112(a) of the Clean Air Act, major source is any stationary source or group of stationary sources located within a contiguous area and under common control that emits or has the potential to emit, considering controls, in the aggregate 10 tons per year or more of any hazardous air pollutant or 25 tons per year or more of any combination of hazardous air pollutants.

Maximum daily discharge limitation—The highest allowable daily discharge of a pollutant measured during a calendar day or any 24 hour period that reasonably represents a calendar day for purposes of sampling.

Mg—Megagram. One million (10^6) grams, or one metric ton.

Metric ton—One thousand (10^3) kilograms (abbreviated as kkg), or one megagram. A metric ton is equal to 2,204.5 pounds.

Minimum level—The level at which an analytical system gives recognizable signals and an acceptable calibration point.

Mixing/Compounding/Formulating—Processes through which pharmaceutically active ingredients are put in dosage forms. Processes involving mixing/compounding/formulating define subcategory D (40 CFR part 439, subpart D).

NESHAP—National Emission Standard for Hazardous Air Pollutants. Emission standard promulgated that has been or will be promulgated under section 112(d) of the Clean Air Act for hazardous air pollutants listed in section 112(b) of the Clean Air Act.

New Source—As defined in 40 CFR 122.2, 122.29, and 403.3(k), a new source is any building, structure, facility, or installation from which there is or may be a discharge of pollutants, the construction of which commenced (1) for purposes of compliance with New Source Performance Standards, after the promulgation of such standards being proposed today under CWA section 306; or (2) for the purposes of compliance with Pretreatment Standards for New Sources, after the publication of proposed standards under CWA section 307(c), if such standards are thereafter promulgated in accordance with that section.

Nitrification—Nitrification is the oxidation of ammonium salts to nitrites (via nitrosomonas bacteria) and the further oxidation of nitrite to nitrate via nitrobacter bacteria. Nitrification can be accomplished in either a single or two-stage activated sludge system. Indicators of nitrification capability are (1) biological monitoring for ammonia oxidizing bacteria (AOB) and nitrite oxidizing bacteria (NOB) to determine if nitrification is occurring, and (2) analysis of the nitrogen balance to determine if nitrifying bacteria reduce the amount of ammonia and increase the amount of nitrite and nitrate.

Nonconventional pollutants—Pollutants that are neither conventional pollutants nor toxic pollutants.

Non-detect value—A concentration-based measurement reported below the minimum level that can reliably be measured by the analytical method for the pollutant.

Non-water quality environmental impact—An environmental impact of a control or treatment technology, other than to surface waters.

NPDES—The National Pollutant Discharge Elimination System authorized under section 402 of the CWA. The Clean Water Act requires NPDES permits for discharge of pollutants from any point source into waters of the United States.

NRDC—Natural Resources Defense Council.

NSPS—New Source Performance Standards. As used in this notice, this term refers to standards for new sources under section 306 of the CWA.

OMB—Office of Management and Budget.

Outfall—The mouth of conduit drains and other conduits from which a plant discharges effluent into receiving waters.

Pharmaceutically active ingredient—Any substance considered to be an active ingredient by Food and Drug Administration regulations (21 CFR 210.3(6)(7)).

Pilot-scale operation—The trial operation of processing equipment, which is the intermediate stage between laboratory experimentation and full-scale operation in the development of a new process or product.

Point of Determination—The location where the process wastewater stream exits the pharmaceutical process equipment.

Point source category—A category of sources of water pollutants that are included within the definition of ''point source'' in section 502(14) of the Clean Water Act.

Pollutant (to water)—Dredged spoil, solid waste, incinerator residue, filter backwash, sewage, garbage, sewage sludge, munitions, chemical wastes, biological materials, certain radioactive materials, heat, wrecked or discarded equipment, rock, sand, cellar dirt, and industrial, municipal, and agricultural waste discharged into water. See CWA section 502(6); 40 CFR 122.2.

POTW or POTWs—Publicly owned treatment works, as defined at 40 CFR 403.3(o).

Pretreatment standard—A regulation specifying industrial wastewater effluent quality required for discharge to a POTW.

Primary fuel—The fuel that provides the principal heat input to a combustion device. To be considered primary, the fuel must be able to sustain operation of the combustion device without the addition of other fuels.

Priority pollutants—The toxic pollutants listed in 40 CFR part 403, Appendix A (printed immediately following 40 CFR 423.17).

Process changes—Alterations in process operating conditions, equipment, or chemical use that reduce the formation of chemical compounds that are pollutants and/or pollutant precursors.

Process unit—A piece of equipment, such as a chemical reactor or fermentation tank, associated with pharmaceutical manufacturing operations.

Process wastewater—Any water that, during manufacturing or processing, comes into direct contact with or results from the production or use of any raw material, intermediate product, finished product, byproduct, or waste product. Process wastewater includes surface runoff from the immediate process area that has the potential to become contaminated.

(1) For purposes of this part, the following materials are excluded from the definition of process wastewater:

1. Trimethyl silanol;

2. Any active anti-microbial materials;

3. Wastewater from imperfect fermentation batches; and

4. Process area spills

(2) For purposes of this part, the following waters and wastewaters are 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 water generated on site that are not process wastewaters.

The discharge of such waters and wastewaters must be regulated separately.

Process wastewater collection system—A piece of equipment, structure, or transport mechanism used in conveying or storing a process wastewater stream. Examples of process wastewater collection system equipment include individual drain systems, wastewater tanks, surface impoundments, and containers.

Process wastewater stream—When used in connection with CAA obligations, any HAP-containing liquid that results from either direct or indirect contact of water with organic compounds.

Process water—Water used to dilute, wash, or carry raw materials or any other materials used in pharmaceutical manufacturing processes.

PSES—Pretreatment standards for existing sources of indirect discharges, under section 307(b) of the CWA.

PSNS—Pretreatment standards for new sources of indirect discharges, under sections 307© of the CWA.

RCRA—Resource Conservation and Recovery Act of 1976, as amended (42 U.S.C. 6901, *et seq.*).

Research—Bench-scale activities or operations used in research and/or product development of a pharmaceutical product. The Research operations define subcategory E (40 CFR part 439, Subpart E).

SIC—Standard Industrial Classification. A numerical categorization system used by the U.S. Department of Commerce to denote segments of industry. An SIC code refers to the principal product, or group of products, produced or distributed, or to services rendered by an operating establishment. SIC codes are used to group establishments by the primary activity in which they are engaged.

Source Category—A category of major or area sources of hazardous air pollutants.

Source Reduction—The reduction or elimination of waste generation at the source, usually within a process. A source reduction practice is any practice that (1) reduces the amount of any hazardous substance, pollutant, or contaminant entering any waste stream or otherwise released into the environment (including fugitive emissions) prior to recycling, treatment, or disposal; and (2) reduces the hazards to public health and the environment associated with the release of such substances, pollutants, or contaminants.

Stationary source—Any building, structure, facility, or installation that emits or may emit any air pollutant. See CAA section 111(a)(3).

Toxic pollutants—the pollutants designated by EPA as toxic in 40 CFR 401.15.

Variability factor—The daily variability factor is the ratio of the estimated 99th percentile of the distribution of daily values divided by the expected value, or mean, of the distribution of the daily data. The monthly variability factor is the estimated 95th percentile of the monthly averages of the data divided by the expected value of the monthly averages.

VOC—Any organic pollutant with a Henry's Law Constant greater than or equal to 3.97×10^{-7} atm/gmole/m^3.

Waters of the United States—the same meaning set forth in 40 CFR 122.2.

Zero discharge (ZD)—No discharge of pollutants to waters of the United States or to a POTW.

List of Subjects

40 CFR Part 136

Environmental protection, Incorporation by reference, Reporting and recordkeeping requirements, Water pollution control.

40 CFR Part 439

Environmental protection, Pharmaceutical manufacturing pollution prevention, Waste treatment and disposal, Water pollution control.

Dated: July 30, 1998.

Carol M. Browner,

Administrator.

For the reasons set out in the preamble, title 40, chapter I of the Code of Federal Regulations is amended as follows:

PART 136—[AMENDED]

1. The authority citation for part 136 continues to read as follows:

Authority: Secs. 301, 304(h), 307, and 501(a) Pub. L. 95-217, Stat. 1566, *et seq.* (33 U.S.C. 1251, *et seq.*) (The Federal Water Pollution Control Act Amendments of 1972 as amended by the Clean Water Act of 1977).

2. Section 136.3 is amended by revising paragraph (a) introductory text and by adding a new Table IF in numerical order to the end of paragraph (a) and revising paragraph (b) introductory text and adding paragraph (b)(40) to read as follows:

§ 136.3 Identification of test procedures.

(a) Parameters or pollutants, for which methods are approved, are listed together with test procedure descriptions and references in Tables IA, IB, IC, ID, IE, and IF. The full text of the referenced test procedures are incorporated by reference into Tables IA, IB, IC, ID, IE, and IF. The references and the sources which are available are given in paragraph (b) of this section. These test procedures are incorporated as they exist on the day of approval and a notice of any change in these test procedures will be published in the **Federal Register**. The discharge parameter values for which reports are required must be determined by one of the standard analytical test procedures incorporated by reference and described in Tables IA, IB, IC, ID, IE, and IF, or by any alternate test procedure which has been approved by the Administrator under the provisions of paragraph (d) of this section and §§ 136.4 and 136.5. Under certain circumstances (paragraph (b) or (c) of this section or 40 CFR 401.13) other test procedures may be used that may be more advantageous when such other test procedures have been previously approved by the Regional Administrator of the Region in which the discharge occur, and providing the Director of the State in which such discharge will occur does

not object to the use of such alternate test procedure.

* * * * *

TABLE IF.—LIST OF APPROVED METHODS FOR PHARMACEUTICAL POLLUTANTS

Pharmaceuticals pollutants	CAS registry No.	Analytical method number
acetonitrile	75–05–8	1666/1671/D3371/D3695.
n-amyl acetate	628–63–7	1666/D3695.
n-amyl alcohol	71–41–0	1666/D3695
benzene	71–43–2	D4763/D3695/502.2/524.2.
n-butyl-acetate	123–86–4	1666/D3695.
tert-butyl alcohol	75–65–0	1666.
chlorobenzene	108–90–7	502.2/524.2.
chloroform	67–66–3	502.2/524.2/551.
o-dichlorobenzene	95–50–1	1625C/502.2/524.2.
1,2-dichloroethane	107–06–2	D3695/502.2/524.2.
diethylamine	109–89–7	1666/1671.
dimethyl sulfoxide	67–68–5	1666/1671.
ethanol	64–17–5	1666/1671/D3695.
ethyl acetate	141–78–6	1666/D3695.
n-heptane	142–82–5	1666/D3695.
n-hexane	110–54–3	1666/D3695.
isobutyraldehyde	78–84–2	1666/1667.
isopropanol	67–63–0	1666/D3695.
isopropyl acetate	108–21–4	1666/D3695.
isopropyl ether	108–20–3	1666/D3695.
methanol	67–56–1	1666/1671/D3695.
Methyl Cellosolve®	109–86–4	1666/1671
methylene chloride	75–09–2	502.2/524.2
methyl formate	107–31–3	1666.
4-methyl-2-pentanone (MIBK)	108–10–1	1624C/1666/D3695/D4763/524.2.
phenol	108–95–2	D4763.
n-propanol	71–23–8	1666/1671/D3695.
2-propanone (acetone)	67–64–1	D3695/D4763/524.2.
tetrahydrofuran	109–99–9	1666/524.2.
toluene	108–88–3	D3695/D4763/502.2/524.2.
triethlyamine	121–44–8	1666/1671.
xylenes	(Note 1)	1624C/1666.

Table 1F note:

1. 1624C: m-xylene 108–38–3, o,p-xylene E–14095 (Not a CAS number; this is the number provided in the Environmental Monitoring Methods Index (EMMI) database.); 1666: m,p-xylene 136777–61–2, o-xylene 95–47–6.

* * * * *

(b) The full texts of the methods from the following references which are cited in Tables IA, IB, IC, ID, IE,and IF are incorporated by reference into this regulation and may be obtained from the sources identified. All costs cited are subject to change and must be verified from the indicated sources. The full texts of all the test procedures cited are available for inspection at the National Exposure Research Laboratory, Office of Research and Development, U.S. Environmental Protection Agency, 26 West Martin Luther King Dr., Cincinnati, OH 45268 and the Office of the Federal Register, 800 North Capitol Street, NW., Suite 700, Washington, DC.

* * * * *

(40) EPA Methods 1666, 1667, and 1671 listed in the table above are published in the compendium titled Analytical Methods for the Determination of Pollutants in Pharmaceutical Manufacturing Industry Wastewaters (EPA 821–B–98–016). EPA Methods 502.2 and 524.2 have been incorporated by reference into 40 CFR 141.24 and are in Methods for the Determination of Organic Compounds in Drinking Water, EPA–600/4–88–039, December 1988, Revised, July 1991, and Methods for the Determination of Organic Compounds in Drinking Water-Supplement II, EPA–600/R–92–129, August 1992, respectively. These EPA test method compendia are available from the National Technical Information Service, NTIS PB91–231480 and PB92–207703, U.S. Department of Commerce, 5285 Port Royal Road, Springfield, Virginia 22161. The toll-free number is 800–553–6847. ASTM test methods D3371, D3695, and D4763 are available from the American Society for Testing and Materials, 100 Barr Harbor Drive, West Conshohocken, PA 19428–2959.

* * * * *

PART 439—[AMENDED]

1. The authority citation for part 439 is revised to read as follows:

Authority: Secs. 301, 304, 306, 307, 308, 402 and 501 of the Clean Water Act, as amended; 33 U.S.C. 1311, 1314, 1316, 1317, 1318, 1342 and 1361.

2. Part 439 is amended by revising the undesignated heading ''GENERAL PROVISIONS'' to read ''General''.

3. Section 439.0 is revised to read as follows:

§ 439.0 Applicability.

(a) This part applies to process wastewater discharges resulting from the research and manufacture of pharmaceutical products, which are generally, but not exclusively, reported under SIC 2833, SIC 2834 and SIC 2836 (1987 Standard Industrial Classification Manual).

(b) Although not reported under SIC 2833, SIC 2834 and SIC 2836, discharges from the manufacture of other pharmaceutical products to which this part applies include (but are not limited to):

(1) Products manufactured by one or more of the four types of manufacturing

processes described in subcategories A, B, C or D of this part, and considered by the Food and Drug Administration to be pharmaceutical active ingredients;

(2) Multiple end-use products (e.g., components of formulations, chemical intermediates, or final products) derived from pharmaceutical manufacturing operations and intended for use primarily in pharmaceutical applications;

(3) Pharmaceutical products and intermediates not subject to other categorical limitations and standards, provided the manufacturing processes generate process wastewaters that are similar to those derived from the manufacture of pharmaceutical products elsewhere (an example of such a product is citric acid);

(4) Cosmetic preparations that are reported under SIC 2844 and contain pharmaceutical active ingredients, or active ingredients that are intended for the treatment of a skin condition. (These preparations do not include products such as lipsticks or perfumes that serve to enhance appearance, or provide a pleasing odor, but do not enhance skin care. Also excluded are deodorants, manicure preparations, shaving preparations and non-medicated shampoos that do not function primarily as a skin treatment.)

(c) The provisions of this part do not apply to wastewater discharges resulting from the manufacture of the following products, or as a result of providing one or more of the following services:

(1) Surgical and medical instruments and apparatus reported under SIC 3841;

(2) Orthopedic, prosthetic, and surgical appliances and supplies reported under SIC 3842;

(3) Dental equipment and supplies reported under SIC 3843;

(4) Medical laboratory services reported under SIC 8071;

(5) Dental laboratory services reported under SIC 8072;

(6) Outpatient care facility services reported under SIC 8081;

(7) Health and allied services reported under SIC 8091, and not classified elsewhere;

(8) Diagnostic devices other than those reported under SIC 3841;

(9) Animal feed products that include pharmaceutical active ingredients such as vitamins and antibiotics, where the major portion of the product is non-pharmaceutical, and the resulting process wastewater is not characteristic of process wastewater from the manufacture of pharmaceutical products;

(10) Food and beverage products fortified with vitamins or other pharmaceutical active ingredients, where the major portion of the product is non-pharmaceutical, and the resulting process wastewater is not characteristic of process wastewater from the manufacture of pharmaceutical products;

(11) Pharmaceutical products and intermediates subject to the provisions of 40 CFR part 414, provided their manufacture results in less than 50 percent of the total flow of process wastewater that is regulated by 40 CFR part 414 at the facility.

4. Section 439.1 is revised to read as follows:

§ 439.1 General definitions.

As used in this part:

(a) The general definitions, abbreviations and methods of analysis in 40 CFR part 401 shall apply.

(b) The term *bench-scale operation* means the laboratory testing of materials, methods, or processes on a small scale, such as on a laboratory worktable.

(c) The term *cyanide (T)* means the parameter total cyanide.

(d) The term *in-plant monitoring point* means a location within a plant, where an individual process effluent can be exclusively monitored before it is diluted or mixed with other process wastewaters enroute to the end-of-pipe.

(e) The term *minimum level* means the level at which an analytical system gives recognizable signals and an acceptable calibration point.

(f) The term *nitrification capability* means the capability of a POTW treatment system to oxidize ammonia or ammonium salts initially to nitrites (via *Nitrosomonas* bacteria) and subsequently to nitrates (via *Nitrobacter* bacteria). Criteria for determining the nitrification capability of a POTW treatment system are: bioassays confirming the presence of nitrifying bacteria; and analyses of the nitrogen balance demonstrating a reduction in the concentration of ammonia or ammonium salts and an increase in the concentrations of nitrites and nitrates.

(g) The term *non-detect (ND)* means a concentration value below the minimum level that can be reliably measured by the analytical method.

(h) The term *pilot-scale operation* means processing equipment being operated at an intermediate stage between laboratory-scale and full-scale operation for the purpose of developing a new product or manufacturing process.

(i) The term *POTW* means publicly owned treatment works (40 CFR 403.3).

(j) The term *process wastewater,* as defined at 40 CFR 122.2 and for the purposes of this part, does not include the following:

(1) Trimethyl silanol, any active anti-microbial materials, process wastewater from imperfect fermentation batches, and process area spills. Discharges containing such materials are not subject to the limitations and standards of this part.

(2) Non-contact cooling water, utility wastewaters, general site surface runoff, groundwater (e.g., contaminated groundwaters from on-site or off-site groundwater remediation projects), and other non-process water generated on site. Discharges of such waters and wastewaters are not subject to the limitations and standards of this part.

(k) The term *non-conventional pollutants* means parameters that are neither conventional pollutants (40 CFR 401.16), nor ''toxic'' pollutants (40 CFR 401.15).

(l) The term *surrogate pollutant* means a regulated parameter that, for the purpose of compliance monitoring, is allowed to serve as a surrogate for a group of specific regulated parameters. Plants would be allowed to monitor for a surrogate pollutant(s), when the other parameters for which it stands are receiving the same degree of treatment as the surrogate pollutant(s) and all of the parameters discharged are in the same treatability class(es) as their respective surrogate pollutant(s). Treatability classes have been identified in Appendix A to this part for both steam stripping and biological treatment technologies, which are the respective technology bases for PSES/PSNS and BAT/NSPS limitations controlling the discharge of regulated organic parameters.

(m) The term *xylenes* means a combination of the three isomers: o-xylene, p-xylene, and m-xylene.

5. Section 439.3 is added under the undesignated center heading ''General'' to read as follows:

§ 439.3 General pretreatment standards.

Any source subject to this part that introduces process wastewater pollutants into a publicly owned treatment works (POTW) must comply with 40 CFR part 403.

6. Section 439.4 is added under the undesignated center heading ''General'' to read as follows:

§ 439.4 Monitoring requirements.

Permit limits and compliance monitoring are required for each regulated pollutant generated or used at a pharmaceutical manufacturing facility, except where the regulated pollutant is monitored as a surrogate parameter. Permit limits and compliance monitoring are not required for regulated pollutants that are neither

used nor generated at the facility. Except for cyanide, for which an alternate monitoring requirement is established in subparts A and C of this part a determination that regulated pollutants are neither used nor generated should be based on a review of all raw materials in use, and an assessment of the process chemistry, products and by-products resulting from each of the manufacturing processes. This determination along with recommendation of any surrogate must be submitted with permit applications for approval by the permitting authority, and reconfirmed by an annual chemical analysis of wastewater from each monitoring location, and the measurement of a non-detect value for each regulated pollutant or its surrogate. Permits shall specify that such determinations will be maintained in the facility's permit records with their discharge monitoring reports and will be available to regulatory authorities upon request.

Subpart A—[Amended]

7. Section 439.10 is revised to read as follows:

§ 439.10 Applicability.

This subpart applies to discharges of process wastewater resulting from the manufacture of pharmaceutical products by fermentation.

8. Section 439.11 is revised to read as follows:

§ 439.11 Specialized definitions.

For the purpose of this subpart:

(a) The term *fermentation* means process operations that utilize a chemical change induced by a living organism or enzyme, specifically, bacteria, or the microorganisms occurring in unicellular plants such as yeast, molds, or fungi to produce a specified product.

(b) The term *product* means pharmaceutical products derived from fermentation processes.

9. Section 439.12 is amended by removing the OMB control number citation and revising the section to read as follows:

§ 439.12 Effluent limitations attainable by the application of the best practicable control technology currently available (BPT).

Except as provided in 40 CFR 125.30 through 125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the application of BPT:

(a) The average monthly effluent limitation for BOD_5, expressed as mass loading (pounds, kilograms) per day, must reflect not less than 90 percent reduction in the long-term average daily BOD_5 load of the raw (untreated) process wastewater, multiplied by a variability factor of 3.0.

(1) The long-term average daily BOD_5 load of the raw process wastewater (i.e., the base number to which the percent reduction is applied) is defined as the average daily BOD_5 load during any calendar month, over 12 consecutive months within the most recent 36 months, and must include one or more periods during which production was at a maximum.

(2) To assure equity in the determination of NPDES permit limitations regulating discharges subject to this subpart, calculation of the long-term average daily BOD_5 load in the influent to the wastewater treatment system must exclude any portion of the load associated with separable mycelia and solvents, except for residual amounts of mycelia and solvents remaining after the practices of recovery and/or separate disposal or reuse. These residual amounts may be included in the calculation of the average influent BOD_5 loading.

(3) The practices of recovery, and/or separate disposal or reuse include: physical separation and removal of separable mycelia; recovery of solvents from waste streams; incineration of concentrated solvent wastestreams (including tar still bottoms); and concentration of broth for disposal other than to the treatment system. This part does not prohibit the inclusion of such wastes in raw waste loads in fact, nor does it mandate any specific practice, but rather describes the rationale for determining NPDES permit limitations. The effluent limitation for BOD_5 may be achieved by any of several, or a combination, of these practices.

(b) The average monthly effluent limitation for TSS, expressed as mass loading (pounds, kilograms) per day, must be calculated as 1.7 times the BOD_5 limitation determined in paragraph (a) of this section.

(c) Except as provided in paragraph (d) of this section, the effluent limitations for COD and pH are as follows:

Regulated parameter	Effluent limitation [1]	
	Maximum daily discharge	Average monthly discharge must not exceed
COD	1675	856
pH	([2])	([2])

[1] Mg/L (ppm).
[2] Within the range 6.0 to 9.0.

(d) If the average monthly COD concentrations in paragraph (c) of this section are higher than concentration values reflecting a reduction in the long-term average daily COD load in the raw (untreated) process wastewater of 74 percent multiplied by a variability factor of 2.2, then the average monthly effluent limitations for COD corresponding to the lower concentration values must be applied.

(e) The effluent limitations for cyanide are as follows:

Regulated parameter	Effluent limitation [1]	
	Maximum daily discharge	Average monthly discharge must not exceed
Cyanide (T)	33.5	9.4

[1] Mg/L (ppm).

(f) When monitoring for cyanide at the end-of-pipe is impractical because of dilution by other process wastewaters, compliance with the cyanide effluent limitations in paragraph (e) of this section must be demonstrated at in-plant monitoring points pursuant to 40 CFR 122.44(i) and 122.45(h). Under the same provisions, the permitting authority may impose monitoring requirements on internal wastestreams for any other parameter(s) regulated by this section.

(g) Compliance with the limitation in paragraph (e) or (f) of this section may be achieved by certifying to the permit issuing authority that the facility's manufacturing processes neither use nor generate cyanide.

10. Section 439.13 is revised to read as follows:

§ 439.13 Effluent limitations attainable by the application of the best conventional pollutant control technology (BCT).

Except as provided in 40 CFR 125.30 through 125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the application of BCT: Limitations for BOD_5, TSS and pH are the same as the corresponding limitations in § 439.12.

11. Section 439.14 is amended by removing the OMB control number citation and revising the section to read as follows:

§ 439.14 Effluent limitations attainable by the application of best available technology economically achievable (BAT).

Except as provided in 40 CFR 125.30 through 125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the application of BAT:

	Regulated parameter	Effluent limitations [1]	
		Maximum daily discharge	Average monthly discharge must not exceed
1	Ammonia (as N)	84.1	29.4
2	Acetone	0.5	0.2
3	4-Methyl-2-pentanone (MIBK)	0.5	0.2
4	Isobutyraldehyde	1.2	0.5
5	n-Amyl acetate	1.3	0.5
6	n-Butyl acetate	1.3	0.5
7	Ethyl acetate	1.3	0.5
8	Isopropyl acetate	1.3	0.5
9	Methyl formate	1.3	0.5
10	Amyl alcohol	10.0	4.1
11	Ethanol	10.0	4.1
12	Isopropanol	3.9	1.6
13	Methanol	10.0	4.1
14	Methyl Cellosolve	100.0	40.6
15	Dimethyl Sulfoxide	91.5	37.5
16	Triethyl Amine	250.0	102.0
17	Phenol	0.05	0.02
18	Benzene	0.05	0.02
19	Toluene	0.06	0.02
20	Xylenes	0.03	0.01
21	n-Hexane	0.03	0.02
22	n-Heptane	0.05	0.02
23	Methylene chloride	0.9	0.3
24	Chloroform	0.02	0.01
25	1,2-Dichloroethane	0.4	0.1
26	Chlorobenzene	0.15	0.06
27	o-Dichlorobenzene	0.15	0.06
28	Tetrahydrofuran	8.4	2.6
29	Isopropyl ether	8.4	2.6
30	Diethyl amine	250.0	102.0
31	Acetonitrile	25.0	10.2
32	pH	([2])	([2])

[1] Mg/L (ppm).
[2] Within the range of 6.0–9.0.

(a) The effluent limitations for COD are the same as the corresponding limitations in § 439.12(c) and (d).

(b) The effluent limitations for cyanide are as follows:

Regulated parameter	Effluent limitation [1]	
	Maximum daily discharge	Average monthly discharge must not exceed
Cyanide (T)	33.5	9.4

[1] Mg/L (ppm).

(c) When monitoring for cyanide at the end-of-pipe is impractical because of dilution by other process wastewaters, compliance with the cyanide effluent limitations in paragraph (b) of this section must be demonstrated at in-plant monitoring points pursuant to 40 CFR 122.44(i) and 122.45(h). Under the same provisions, the permitting authority may impose monitoring requirements on internal wastestreams for any other parameter(s) regulated by this section.

(d) Compliance with the limitation in paragraph (b) or (c) of this section may be achieved by certifying to the permit issuing authority that a facility's manufacturing processes neither use nor generate cyanide.

12. Section 439.15 is amended by removing the OMB control number citation and revising the section to read as follows:

§ 439.15 Standards of performance for new (point) sources (NSPS).

Any new source subject to this subpart must achieve the following performance standards:

	Regulated parameter	Effluent limitations [1]	
		Maximum daily discharge	Average monthly discharge must not exceed
1	BOD_5	267	111
2	TSS	472	166
3	COD	1675	856
4	Ammonia (as N)	84.1	29.4
5	Acetone	0.5	0.2
6	4-Methyl-2-pentanone (MIBK)	0.5	0.2
7	Isobutyraldehyde	1.2	0.5
8	n-Amyl acetate	1.3	0.5

Regulated parameter	Effluent limitations [1]	
	Maximum daily discharge	Average monthly discharge must not exceed
9 n-Butyl acetate	1.3	0.5
10 Ethyl acetate	1.3	0.5
11 Isopropyl acetate	1.3	0.5
12 Methyl formate	1.3	0.5
13 Amyl alcohol	10.0	4.1
14 Ethanol	10.0	4.1
15 Isopropanol	3.9	1.6
16 Methanol	10.0	4.1
17 Methyl Cellosolve	25.0	10.2
18 Dimethyl Sulfoxide	91.5	37.5
19 Triethyl Amine	250.0	102.0
20 Phenol	0.05	0.02
21 Benzene	0.05	0.02
22 Toluene	0.06	0.02
23 Xylenes	0.03	0.01
24 n-Hexane	0.03	0.02
25 n-Heptane	0.05	0.02
26 Methylene chloride	0.9	0.3
27 Chloroform	0.02	0.01
28 1,2-Dichloroethane	0.4	0.1
29 Chlorobenzene	0.15	0.06
30 o-Dichlorobenzene	0.15	0.06
31 Tetrahydrofuran	8.4	2.6
32 Isopropyl ether	8.4	2.6
33 Diethyl amine	250.0	102.0
34 Acetonitrile	25.0	10.2
35 pH	([2])	([2])

[1] Mg/L (ppm).
[2] Within the range of 6.0—9.0.

(a) The performance standards for cyanide are as follows:

Regulated parameter	Performance standards [1]	
	Maximum daily discharge	Average monthly discharge must not exceed
Cyanide (T)	33.5	9.4

[1] Mg/L (ppm).

(b) When monitoring for cyanide at the end-of-pipe is impractical because of dilution by other process wastewaters, compliance with the cyanide performance standards in paragraph (a) of this section must be demonstrated at in-plant monitoring points pursuant to 40 CFR 122.44(i) and 122.45(h). Under the same provisions, the permitting authority may impose monitoring requirements on internal wastestreams for any other parameter(s) regulated by this section.

(c) Any new source subject to the provisions of this section that commenced discharging after November 21, 1988 and prior to November 20, 1998 must continue to achieve the standards specified in the earlier version of this section until the expiration of the applicable time period specified in 40 CFR 122.29(d)(1), after which the source must achieve the standards specified in §§ 439.13 and 439.14.

(d) Compliance with the standard in paragraph (a) or (b) of this section may be achieved by certifying to the permit issuing authority that the facility's manufacturing processes neither use nor generate cyanide.

13. Section 439.16 is amended by removing the OMB control number citation and revising the section to read as follows:

§ 439.16 Pretreatment standards for existing sources (PSES).

Except as provided in 40 CFR 403.7 and 403.13, any existing source subject to this subpart must continue to achieve compliance with cyanide pretreatment standards and achieve compliance with all the other pretreatment standards by September 21, 2001.

Regulated parameter	Pretreatment standards [1]	
	Maximum daily discharge	Average monthly discharge must not exceed
1 Ammonia (as N) [2]	84.1	29.4
2 Acetone	20.7	8.2
3 4-Methyl-2-pentanone (MIBK)	20.7	8.2
4 Isobutyraldehyde	20.7	8.2
5 n-Amyl acetate	20.7	8.2
6 n-Butyl acetate	20.7	8.2
7 Ethyl acetate	20.7	8.2
8 Isopropyl acetate	20.7	8.2

	Regulated parameter	Pretreatment standards[1]	
		Maximum daily discharge	Average monthly discharge must not exceed
9	Methyl formate	20.7	8.2
10	Methyl Cellosolve	275.0	9.7
11	Isopropyl ether	20.7	8.2
12	Tetrahydrofuran	9.2	3.4
13	Benzene	3.0	0.6
14	Toluene	0.3	0.1
15	Xylenes	3.0	0.7
16	n-Hexane	3.0	0.7
17	n-Heptane	3.0	0.7
18	Methylene chloride	3.0	0.7
19	Chloroform	0.1	0.03
20	1,2-Dichloroethane	20.7	8.2
21	Chlorobenzene	3.0	0.7
22	o-Dichlorobenzene	20.7	8.2
23	Diethyl amine	255.0	100.0
24	Triethyl amine	255.0	100.0

[1] Mg/L (ppm).
[2] Not applicable to sources that discharge to a POTW with nitrification capability.

(a) Sources that discharge to a POTW with nitrification capability (defined at § 439.2(f)) are not required to achieve the pretreatment standard for ammonia.

(b) The pretreatment standards for cyanide are as follows:

Regulated parameter	Pretreatment standards[1]	
	Maximum daily discharge	Average monthly discharge must not exceed
Cyanide (T)	33.5	9.4

[1] Mg/L (ppm).

(c) When monitoring for cyanide at the end-of-pipe is impractical because of dilution by other process wastewaters, compliance with the cyanide standards in paragraph (b) of this section must be demonstrated at in-plant monitoring points pursuant to 40 CFR 403.6(e)(2) and (4). Under the same provisions, the permitting authority may impose monitoring requirements on internal wastestreams for any other parameter(s) regulated by this section.

(d) Compliance with the limitation in paragraph (b) or (c) of this section may be achieved by certifying to the permit issuing authority that the facility's manufacturing processes neither use nor generate cyanide.

14. Section 439.17 is amended by removing the OMB control number citation and revising the section to read as follows:

§ 439.17 Pretreatment standards for new sources (PSNS).

Except as provided in 40 CFR 403.7, any new source subject to this subpart must achieve the following pretreatment standards:

	Regulated parameter	Pretreatment standards[1]	
		Maximum daily discharge	Average monthly discharge must not exceed
1	Ammonia (as N)[2]	84.1	29.4
2	Acetone	20.7	8.2
3	4-Methyl-2-pentanone (MIBK)	20.7	8.2
4	Isobutyraldehyde	20.7	8.2
5	n-Amyl acetate	20.7	8.2
6	n-Butyl acetate	20.7	8.2
7	Ethyl acetate	20.7	8.2
8	Isopropyl acetate	20.7	8.2
9	Methyl formate	20.7	8.2
10	Methyl Cellosolve	275.0	59.7
11	Isopropyl ether	20.7	8.2
12	Tetrahydrofuran	9.2	3.4
13	Benzene	3.0	0.7
14	Toluene	0.3	0.1
15	Xylenes	3.0	0.7
16	n-Hexane	3.0	0.7
17	n-Heptane	3.0	0.7
18	Methylene chloride	3.0	0.7
19	Chloroform	0.1	0.03
20	1,2-Dichloroethane	20.7	8.2
21	Chlorobenzene	3.0	0.7
22	o-Dichlorobenzene	20.7	8.2
23	Diethyl amine	255.0	100.0

Regulated parameter	Pretreatment standards[1]	
	Maximum daily discharge	Average monthly discharge must not exceed
24 Triethyl amine	255.0	100.0

[1] Mg/L (ppm)
[2] Not applicable to sources that discharge to a POTW with nitrification capability.

(a) Sources that discharge to a POTW with nitrification capability (defined at § 439.2(f))are not required to achieve the pretreatment standard for ammonia.

(b) The pretreatment standards for cyanide are as follows:

Regulated parameter	Pretreatment standards[1]	
	Maximum daily discharge	Average monthly discharge must not exceed
Cyanide (T)	33.5	9.4

[1] Mg/L (ppm).

(c) When monitoring for cyanide at the end-of-pipe is impractical because of dilution by other process wastewaters, compliance with the cyanide standards in § 439.17(b) must be demonstrated at in-plant monitoring points pursuant to 40 CFR 403.6(e)(2) and (4). Under the same provisions, the permitting authority may impose monitoring requirements on internal wastestreams for any other parameter(s) regulated by this section.

(d) Any new source subject to the provisions of this section that commenced discharging after November 21, 1988 and prior to November 20, 1998 must continue to achieve the standards specified in the earlier version of this section until the expiration of the applicable time period specified in 40 CFR 122.29(d)(1), after which the source must achieve the standards specified in § 439.16.

(e) Compliance with the standards in paragraph (b) or (c) of this section may be achieved by certifying to the permit issuing authority that a facility's manufacturing processes neither use nor generate cyanide.

15. Section 439.20 is revised to read as follows:

§ 439.20 Applicability.

This subpart applies to discharges of process wastewater resulting from the manufacture of pharmaceutical products by extraction.

16. Section 439.21 is revised to read as follows:

§ 439.21 Specialized definitions.

For the purpose of this subpart:

(a) The term *extraction* means process operations that derive pharmaceutically active ingredients from natural sources such as plant roots and leaves, animal glands, and parasitic fungi by chemical and physical extraction.

(b) The term *product* means any substance manufactured by an extraction process, including blood fractions, vaccines, serums, animal bile derivatives, endocrine products and medicinal products such as alkaloids that are isolated from botanical drugs and herbs.

17. Section 439.22 is revised to read as follows:

§ 439.22 Effluent limitations attainable by the application of the best practicable control technology currently available (BPT).

Except as provided in 40 CFR 125.30 through 125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the application of BPT:

(a) The average monthly effluent limitation for BOD_5, expressed as mass loading (pounds, kilograms) per day, must reflect not less than 90 percent reduction in the long-term average daily BOD_5 load of the raw (untreated) process wastewater, multiplied by a variability factor of 3.0.

(1) The long-term average daily BOD_5 load of the raw process wastewater (i.e., the base number to which the percent reduction is applied) is defined as the average daily BOD_5 load during any calendar month, over 12 consecutive months within the most recent 36 months, and must include one or more periods during which production was at a maximum.

(2) To assure equity in the determination of NPDES permit limitations regulating discharges subject to this subpart, calculation of the long-term average daily BOD_5 load in the influent to the wastewater treatment system must exclude any portion of the load associated with separable mycelia and solvents, except for residual amounts of mycelia and solvents remaining after the practices of recovery and/or separate disposal or reuse. Residual amounts of these substances may be included in the calculation of the average influent BOD_5 loading.

(3) The practices of recovery, and/or separate disposal or reuse include: physical separation and removal of separable mycelia; recovery of solvents from wastestreams; incineration of concentrated solvent wastestreams (including tar still bottoms); and broth concentration for disposal other than to the treatment system. This part does not prohibit the inclusion of such wastes in raw waste loads in fact, nor does it mandate any specific practice, but rather describes the rationale for determining NPDES permit limitations. The effluent limitation for BOD_5 may be achieved by any of several, or a combination, of these practices.

(b) The average monthly effluent limitation for TSS, expressed as mass loading (pounds, kilograms) per day, must be calculated as 1.7 times the BOD_5 limitation determined in paragraph (a) of this section.

(c) Except as provided in paragraph (d) of this section, effluent limitations for COD and pH are as follows:

Regulated parameter	Effluent limitations[1]	
	Maximum daily discharge	Average monthly discharge must not exceed
COD	228	86
pH	([2])	([2])

[1] Mg/L (ppm).
[2] Within the range 6.0 to 9.0.

(d) If the average monthly COD concentrations in paragraph (c) of this section are higher than concentration values reflecting a reduction in the long-term average daily COD load in the raw (untreated) process wastewater of 74 percent multiplied by a variability factor of 2.2, then the average monthly effluent limitations for COD corresponding to the lower concentration values must be applied.

18. Section 439.23 is revised to read as follows:

§ 439.23 Effluent limitations attainable by the application of the best conventional pollutant control technology (BCT).

Except as provided in 40 CFR 125.30 through 125.32, any existing point

source subject to this subpart must achieve the following effluent limitations representing the application of BCT: Limitations for BOD_5, TSS and pH are the same as the corresponding limitations in § 439.22.

19. Section 439.24 is amended by removing the OMB control number citation and revising the section to read as follows:

§ 439.24 Effluent limitations attainable by the application of best available technology economically achievable (BAT).

Except as provided in 40 CFR 125.30 through 125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the application of BAT: Limitations for COD are the same as the corresponding limitations in § 439.22(c) and (d).

20. Section 439.25 is revised to read as follows:

§ 439.25 Standards of performance for new (point) sources (NSPS).

Any new source subject to this subpart must achieve the following performance standards:

Regulated parameter	Performance standards[1]	
	Maximum daily discharge	Average monthly discharge must not exceed
BOD_5	35	18
TSS	58	31
COD	228	86
pH	(2)	(2)

[1] Mg/L (ppm).
[2] Within the range 6.0 to 9.0.

(b) Any new source subject to the provisions of this section that commenced discharging after November 21, 1988 and prior to November 20, 1998 must continue to achieve the standards specified in the earlier version of this section, until the expiration of the applicable time period specified in 40 CFR 122.29(d)(1), after which the source must achieve the standards specified in §§ 439.23 and 439.24.

21. Section 439.26 is amended by removing the OMB control number citation and revising the section to read as follows:

§ 439.26 Pretreatment standards for existing sources (PSES).

Except as provided in 40 CFR 403.7 and 403.13, any existing source subject to this subpart must achieve the following pretreatment standards by October 22, 2001:

Regulated parameter	Pretreatment standards[1]	
	Maximum daily discharge	Average monthly discharge must not exceed
1 Acetone	20.7	8.2
2 n-Amyl acetate	20.7	8.2
Ethyl acetate	20.7	8.2
4 Isopropyl acetate	20.7	8.2
5 Methylene chloride	3.0	0.7

[1] Mg/L (ppm).

22. Section 439.27 is amended by removing the OMB control number citation and revising the section to read as follows:

§ 439.27 Pretreatment standards for new sources (PSNS).

(a) Except as provided in 40 CFR 403.7, this subpart must achieve the following pretreatment standards:

Regulated parameter	Pretreatment standards[1]	
	Maximum daily discharge	Average monthly discharge must not exceed
1 Acetone	20.7	8.2
2 n-Amyl acetate	20.7	8.2
3 Ethyl acetate	20.7	8.2
4 Isopropyl acetate	20.7	8.2
5 Methylene chloride	3.0	0.7

[1] Mg/L (ppm).

(b) Any new source subject to the provisions of this section that commenced discharging after November 21, 1988 and prior to November 20, 1998 must continue to achieve the standards specified in § 439.27, until the expiration of the applicable time period specified in 40 CFR 122.29(d)(1), after which the source must achieve the standards specified in § 439.26.

23. Section 439.30 is revised to read as follows:

§ 439.30 Applicability.

This subpart applies to discharges of process wastewater resulting from the manufacture of pharmaceutical products by chemical synthesis.

24. Section 439.31 is revised to read as follows:

§ 439.31 Specialized definitions.

For the purpose of this subpart:

(a) The term *chemical synthesis* means using one or a series of chemical reactions in the manufacturing process of a specified product.

(b) The term *product* means any pharmaceutical product manufactured by chemical synthesis.

25. Section 439.32 is amended by removing the OMB control number cite and revising the section to read as follows:

§ 439.32 Effluent limitations attainable by the application of the best practicable control technology currently available (BPT).

Except as provided in 40 CFR 125.30 through 125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the application of BPT:

(a) The average monthly effluent limitation for BOD_5, expressed as mass loading (pounds, kilograms) per day, must reflect not less than 90 percent reduction in the long-term average daily BOD_5 load of the raw (untreated) process wastewater, multiplied by a variability factor of 3.0.

(1) The long-term average daily BOD_5 load of the raw process wastewater (i.e., the base number to which the percent reduction is applied) is defined as the average daily BOD_5 load during any calendar month, over 12 consecutive months within the most recent 36 months, and must include one or more periods during which production was at a maximum.

(2) To assure equity in the determination of NPDES permit limitations regulating discharges subject to this subpart, calculation of the long-term average daily BOD_5 load in the influent to the wastewater treatment system must exclude any portion of the load associated with separable mycelia and solvents, except for residual amounts of mycelia and solvents remaining after the practices of recovery and/or separate disposal or reuse. Residual amounts of these substances may be included in the calculation of the average influent BOD_5 loading.

(3) The practices of recovery, and/or separate disposal or reuse include: physical separation and removal of separable mycelia; recovery of solvents from wastestreams; incineration of concentrated solvent wastestreams (including tar still bottoms); and concentration of broth for disposal other than to the treatment system. This part does not prohibit the inclusion of such wastes in raw waste loads in fact, nor does it mandate any specific practice, but rather describes the rationale for determining NPDES permit limitations. The effluent limitation for BOD_5 may be achieved by any of several, or a combination, of these practices.

(b) The average monthly effluent limitation for TSS, expressed as mass loading (pounds, kilograms) per day, must be calculated as 1.7 times the BOD_5 limitation determined in paragraph (a) of this section.

(c) Except as provided in paragraph (d) of this section, the effluent limitations for COD and pH are as follows:

Regulated parameter	Effluent limitation [1]	
	Maximum daily discharge	Average monthly discharge must not exceed
COD	1675	856
pH	([2])	([2])

[1] Mg/L (ppm).
[2] Within the range 6.0 to 9.0.

(d) If the average monthly COD concentrations in paragraph (c) of this section are higher than concentration values reflecting a reduction in the long-term average daily COD load in the raw (untreated) process wastewater of 74 percent multiplied by a variability factor of 2.2, then the average monthly effluent limitations for COD corresponding to the lower concentration values must be applied.

(e) The effluent limitations for cyanide are as follows:

Regulated parameter	Effluent limitation [1]	
	Maximum daily discharge	Average monthly discharge must not exceed
Cyanide (T)	33.5	9.4

[1] Mg/L (ppm).

(f) When monitoring for cyanide at the end-of-pipe is impractical because of dilution by other process wastewaters, compliance with the cyanide effluent limitations in § 439.32(e) must be demonstrated at in-plant monitoring points pursuant to 40 CFR 122.44(i) and 122.45(h). Under the same provisions, the permitting authority may impose monitoring requirements on internal wastestreams for any other parameter(s) regulated by this section.

(g) Compliance with the limitation in paragraph (e) or (f) of this section may be achieved by certifying to the permit issuing authority that the facility's manufacturing processes neither use nor generate cyanide.

26. Section 439.33 is revised to read as follows:

§ 439.33 Effluent limitations attainable by the application of the best conventional pollutant control technology (BCT).

Except as provided in 40 CFR 125.30 through 125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the application of BCT: Limitations for BOD5, TSS and pH are the same as the corresponding limitations in § 439.32.

27. Section 439.34 is amended by removing the OMB control number cite and revising the section to read as follows:

§ 439.34 Effluent limitations attainable by the application of best available technology economically achievable (BAT).

Except as provided in 40 CFR 125.30 through 125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the application of BAT:

	Regulated parameter	Effluent limitations [1]	
		Maximum daily discharge	Average monthly discharge must not exceed
1	Ammonia (as N)	84.1	29.4
2	Acetone	0.5	0.2
3	4-Methyl-2-pentanone (MIBK)	0.5	0.2
4	Isobutyraldehyde	1.2	0.5
5	n-Amyl acetate	1.3	0.5
6	n-Butyl acetate	1.3	0.5
7	Ethyl acetate	1.3	0.5
8	Isopropyl acetate	1.3	0.5
9	Methyl formate	1.3	0.5
10	Amyl alcohol	10.0	4.1
11	Ethanol	10.0	4.1
12	Isopropanol	3.9	1.6
13	Methanol	10.0	4.1
14	Methyl Cellosolve	25.0	10.2
15	Dimethyl Sulfoxide	91.5	37.5
16	Triethyl amine	250.3	101.5
17	Phenol	0.05	0.02
18	Benzene	0.05	0.02
19	Toluene	0.06	0.02
20	Xylenes	0.03	0.01
21	n-Hexane	0.03	0.02
22	n-Heptane	0.05	0.02
23	Methylene chloride	0.9	0.3
24	Chloroform	0.02	0.01
25	1,2-Dichloroethane	0.4	0.1
26	Chlorobenzene	0.15	0.06
27	o-Dichlorobenzene	0.15	0.06
28	Tetrahydrofuran	8.4	2.6
29	Isopropyl ether	8.4	2.6
30	Diethyl amine	250.0	102.0
31	Acetonitrile	25.0	10.2
32	pH	([2])	([2])

[1] Mg/L (ppm).
[2] Within the range of 6.0–9.0.E.

(a) Effluent limitations for COD are the same as the corresponding limitations in § 439.32(c) and (d).

(b) The effluent limitations for cyanide are as follows:

Regulated parameter	Effluent limitations [1]	
	Maximum daily discharge	Average monthly discharge must not exceed
Cyanide (T)	33.5	9.4

[1] Mg/L (ppm).

(c) When monitoring for cyanide at the end-of-pipe is impractical because of dilution by other process wastewaters, compliance with the cyanide effluent limitations in paragraph (a) of this section must be demonstrated at in-plant monitoring points pursuant to 40 CFR 122.44(i) and 122.45(h). Under the same provisions, the permitting authority may impose monitoring requirements on internal wastestreams for any other parameter(s) regulated by this section.

(d) Compliance with the limitation in § 439.34(b) or (c) may be achieved by certifying to the permit issuing authority that a facility's manufacturing processes neither use nor generate cyanide.

28. Section 439.35 is amended by removing the OMB control number cite and revising the section to read as follows:

§ 439.35 Standards of performance for new (point) sources (NSPS).

Any new source subject to this subpart must achieve the following performance standards:

	Regulated parameter	Effluent limitations [1]	
		Maximum daily discharge	Average monthly discharge must not exceed
1	BOD_5	267	111
2	TSS	472	166
3	COD	1675	856
4	Ammonia (as N)	84.1	29.4
5	Acetone	0.5	0.2
6	4-Methyl-2-pentanone (MIBK)	0.5	0.2
7	Isobutyraldehyde	1.2	0.5
8	n-Amyl acetate	1.3	0.5
9	n-Butyl acetate	1.3	0.5
10	Ethyl acetate	1.3	0.5
11	Isopropyl acetate	1.3	0.5
12	Methyl formate	1.3	0.5
13	Amyl alcohol	10.0	4.1
14	Ethanol	10.0	4.1
15	Isopropanol	3.9	1.6
16	Methanol	10.0	4.1
17	Methyl Cellosolve	100.0	40.6
18	Methyl Sulfoxide	91.5	37.5
19	Triethyl amine	250.0	102.0
20	Phenol	0.05	0.02
21	Benzene	0.05	0.02
22	Toluene	0.06	0.02
23	Xylenes	0.02	0.01
24	n-Hexane	0.03	0.02
25	n-Heptane	0.05	0.02
26	Methylene chloride	0.9	0.3
27	Chloroform	0.02	0.01
28	1,2-Dichloroethane	0.4	0.1
29	Chlorobenzene	0.15	0.05
30	o-Dichlorobenzene	0.15	0.06
31	Tetrahydrofuran	8.4	2.6
32	Isopropyl ether	8.4	2.6
33	Diethyl amine	250.0	102.0
34	Acetonitrile	25.0	10.2
35	pH	([2])	([2])

[1] Mg/L (ppm).
[2] Within the range of 6.0–9.0.

(a) The performance standards for cyanide are as follows:

Regulated parameter	Performance standards [1]	
	Maximum daily discharge	Average monthly discharge must not exceed
Cyanide (T)	33.5	9.4

[1] Mg/L (ppm).

(b) When monitoring for cyanide at the end-of-pipe is impractical because of dilution by other process wastewaters, compliance with the cyanide standards in paragraph (a) of this section must be demonstrated at in-plant monitoring points pursuant to 40 CFR 122.44(i) and 122.45(h). Under the same provisions, the permitting authority may impose monitoring requirements on internal wastestreams for any other parameter(s) regulated by this section.

(c) Any new source subject to the provisions of this section that commenced discharging after November 21, 1988 and prior to November 20, 1998 must continue to achieve the standards specified in the earlier version of this section until the expiration of the applicable time period specified in 40 CFR 122.29(d)(1), after

which the source must achieve the standards specified in §§ 439.33 and 439.34.

(d) Compliance with the standards in paragraph (a) or (b) of this section may be achieved by certifying to the permit issuing authority that a facility's manufacturing processes neither use nor generate cyanide.

29. Section 439.36 is amended by removing the OMB control number cite and revising the section to read as follows:

§ 439.36 Pretreatment standards for existing sources (PSES).

Except as provided in 40 CFR 403.7 and 403.13, any existing source subject to this subpart must continue to achieve compliance with cyanide pretreatment standards and achieve compliance with all other pretreatment standards by September 21, 2001.

	Regulated parameter	Pretreatment standards [1]	
		Maximum daily discharge	Average monthly discharge must not exceed
1	Ammonia (as N) [2]	84.1	29.4
2	Acetone	20.7	8.2
3	4–Methyl-2-pentanone (MIBK)	20.7	8.2
4	Isobutyraldehyde	20.7	8.2
5	n-Amyl acetate	20.7	8.2
6	n-Butyl acetate	20.7	8.2
7	Ethyl acetate	20.7	8.2
8	Isopropyl acetate	20.7	8.2
9	Methyl formate	20.7	8.2
10	Methyl Cellosolve	275.0	54.7
11	Isopropyl ether	20.7	8.2
12	Tetrahydrofuran	9.2	3.4
13	Benzene	3.0	0.7
14	Toluene	0.3	0.1
15	Xylenes	3.0	0.7
16	n-Hexane	3.0	0.7
17	n-Heptane	3.0	0.7
18	Methylene chloride	3.0	0.7
19	Chloroform	0.1	0.03
20	1,2–Dichloroethane	20.7	8.2
21	Chlorobenzene	3.0	0.7
22	o-Dichlorobenzene	20.7	8.2
23	Diethyl amine	255.0	100.0
24	Triethyl amine	255.0	100.0

[1] Mg/L (ppm).
[2] Not applicable to sources that discharge to a POTW with nitrification capability.

(a) Sources that discharge to a POTW with nitrification capability (defined at § 439.2(f)) are not required to achieve the pretreatment standard for ammonia.

(b) The pretreatment standards for cyanide are as follows:

Regulated parameter	Pretreatment standards [1]	
	Maximum daily discharge	Average monthly discharge must not exceed
Cyanide (T)	33.5	9.4

[1] Mg/L (ppm).

(c) When monitoring for cyanide at the end-of-pipe is impractical because of dilution by other process wastewaters, compliance with the cyanide pretreatment standards in paragraph (b) of this section must be demonstrated at in-plant monitoring points pursuant to 40 CFR 403.6(e) (2) and (4). Under the same provisions, the permitting authority may impose monitoring requirements on internal wastestreams for any other parameter(s) regulated by this section.

(d) Compliance with the pretreatment standards in paragraph (b) or (c) of this section may be achieved by certifying to the permit issuing authority that the facility's manufacturing processes neither use nor generate cyanide.

30. Section 439.37 is amended by removing the OMB control number cite and revising the section to read as follows:

§ 439.37 Pretreatment standards for new sources (PSNS).

Except as provided in 40 CFR 403.7, any new source subject to this subpart must achieve the following pretreatment standards:

	Regulated parameter	Pretreatment standards [1]	
		Maximum daily discharge	Average monthly discharge must not exceed
1	Ammonia (as N)[2]	84.1	29.4
2	Acetone	20.7	8.2
3	4-Methyl-2-pentanone (MIBK)	20.7	8.2
4	Isobutyraldehyde	20.7	8.2
5	n-Amyl acetate	20.7	8.2

	Regulated parameter	Pretreatment standards [1]	
		Maximum daily discharge	Average monthly discharge must not exceed
6	n-Butyl acetate	20.7	8.2
7	Ethyl acetate	20.7	8.2
8	Isopropyl acetate	20.7	8.2
9	Methyl formate	20.7	8.2
10	Methyl Cellosolve	275.0	59.7
11	Isopropyl ether	20.7	8.2
12	Tetrahydrofuran	9.2	3.4
13	Benzene	3.0	0.7
14	Toluene	0.3	0.1
15	Xylenes	3.0	0.7
16	n-Hexane	3.0	0.7
17	n-Heptane	3.0	0.7
18	Methylene chloride	3.0	0.7
19	Chloroform	0.1	0.03
20	1,2-Dichloroethane	20.7	8.2
21	Chlorobenzene	3.0	0.7
22	o-Dichlorobenzene	20.7	8.2
23	Diethyl amine	255.0	100.0
24	Triethyl amine	255.0	100.0

[1] Mg/L (ppm).
[2] Not applicable to sources that discharge to a POTW with nitrification capability.

(a) Sources that discharge to a POTW with nitrification capability (defined at § 439.2(f)) are not required to achieve the pretreatment standard for ammonia.

(b) The pretreatment standards for cyanide are as follows:

Regulated parameter	Effluent limitation [1]	
	Maximum daily discharge	Average monthly discharge must not exceed
Cyanide (T)	33.5	9.4

[1] Mg/L (ppm).

(c) When monitoring for cyanide at the end-of-pipe is impractical because of dilution by other process wastewaters, compliance with the cyanide pretreatment standards in paragraph (b) of this section must be demonstrated at in-plant monitoring points pursuant to 40 CFR 403.6(e) (2) and (4). Under the same provisions, the permitting authority may impose monitoring requirements on internal wastestreams for any other parameter(s) regulated by this section.

(d) Any new source subject to the provisions of this section that commenced discharging after November 21, 1988 and prior to November 20, 1998 must continue to achieve the standards specified in the earlier version of § 439.37, until the expiration of the applicable time period specified in 40 CFR 122.29(d)(1), after which the source must achieve the standards specified in § 439.36.

(e) Compliance with the standard in paragraph (b) or (c) of this section may be achieved by certifying to the permit issuing authority that a facility's manufacturing processes neither use nor generate cyanide.

31. Section 439.40 is revised to read as follows:

§ 439.40 Applicability.

This subpart applies to discharges of process wastewater resulting from the manufacture of pharmaceutical products by mixing, compounding and formulating operations.

32. Section 439.41 is revised to read as follows:

§ 439.41 Specialized definitions.

For the purpose of this subpart:

(a) The term *mixing, compounding, and formulating operations* means processes that put pharmaceutical products in dosage forms.

(b) The term *product* means any pharmaceutical product manufactured by blending, mixing, compounding, and formulating pharmaceutical ingredients. The term includes pharmaceutical preparations for both human and veterinary use, such as ampules, tablets, capsules, vials, ointments, medicinal powders, solutions, and suspensions.

33. Section 439.42 is amended by removing the OMB control number and revising the section to read as follows:

§ 439.42 Effluent limitations attainable by the application of the best practicable control technology currently available (BPT).

Except as provided in 40 CFR 125.30 through 125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the application of BPT:

(a) The average monthly effluent limitation for BOD_5, expressed as mass loading (pounds, kilograms) per day, must reflect not less than 90 percent reduction in the long-term average daily BOD_5 load of the raw (untreated) process wastewater, multiplied by a variability factor of 3.0.

(1) The long-term average daily BOD_5 load of the raw process wastewater (i.e., the base number to which the percent reduction is applied) is defined as the average daily BOD_5 load during any calendar month, over 12 consecutive months within the most recent 36 months, and must include one or more periods during which production was at a maximum.

(2) To assure equity in the determination of NPDES permit limitations regulating discharges subject to this subpart, calculation of the long-term average daily BOD_5 load in the influent to the wastewater treatment system must exclude any portion of the load associated with separable mycelia and solvents, except for residual amounts of mycelia and solvents remaining after the practices of recovery and/or separate disposal or reuse. Residual amounts of these substances may be included in the calculation of the average influent BOD_5 loading.

(3) The practices of recovery, and/or separate disposal or reuse include: physical separation and removal of separable mycelia; recovery of solvents from wastestreams; incineration of

concentrated solvent wastestreams (including tar still bottoms); and broth concentration for disposal other than to the treatment system. This part does not prohibit the inclusion of such wastes in raw waste loads in fact, nor does it mandate any specific practice, but rather describes the rationale for determining NPDES permit limitations. The effluent limitation for BOD_5 may be achieved by any of several, or a combination, of these practices.

(b) The average monthly effluent limitation for TSS, expressed as mass loading (pounds, kilograms) per day, must be calculated as 1.7 times the BOD_5 limitation determined in paragraph (a) of this section.

(c) Except as provided in paragraph (d) of this section, effluent limitations for COD and pH are as follows:

Regulated parameter	Effluent limitations[1]	
	Maximum daily discharge	Average monthly discharge must not exceed
COD	228	86
pH	(2)	(2)

[1] Mg/L (ppm).
[2] Within the range 6.0 to 9.0.

(d) If the average monthly COD concentrations in paragraph (c) of this section are higher than concentration values reflecting a reduction in the long-term average daily COD load in the raw (untreated) process wastewater of 74 percent multiplied by a variability factor of 2.2, then the average monthly effluent limitations for COD corresponding to the lower concentration values must be applied.

34. Section 439.43 is revised to read as follows:

§ 439.43 Effluent limitations attainable by the application of the best conventional pollutant control technology (BCT).

Except as provided in 40 CFR 125.30 through 125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the application of BCT: Limitations for BOD_5, TSS and pH are the same as the corresponding limitations in § 439.42.

35. Section 439.44 is amended by removing the OMB control number citation and revising the section to read as follows:

§ 439.44 Effluent limitations attainable by the application of best available technology economically achievable (BAT).

Except as provided in 40 CFR 125.30 through 125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the application of BAT. Limitations for COD are the same as the corresponding limitations in § 439.42 (c) and (d).

36. Section 439.45 is amended by removing the OMB control number citation and revising the section to read as follows:

§ 439.45 Standards of performance for new (point) sources (NSPS).

(a) Any new source subject to this subpart must achieve the following performance standards:

Regulated parameter	Performance standards[1]	
	Maximum daily discharge	Average monthly discharge must not exceed
BOD_5	35	18
TSS	58	31
COD	228	86
pH	(2)	(2)

[1] Mg/L (ppm).
[2] Within the range 6.0 to 9.0.

(b) Any new source subject to the provisions of this section that commenced discharging after November 21, 1988 and prior to November 20, 1998 must continue to achieve the standards specified in the earlier version of this section until the expiration of the applicable time period specified in 40 CFR 122.29(d)(1), after which the source must achieve the standards specified in § 439.43 and 439.44.

37. Section 439.46 is amended by removing the OMB control number cite, and revising the section to read as follows:

§ 439.46 Pretreatment standards for existing sources (PSES).

Except as provided in 40 CFR 403.7 and 403.13, any existing source subject to this subpart must achieve the following pretreatment standards by September 21, 2001:

Regulated parameter	Pretreatment standards[1]	
	Maximum daily discharge	Average monthly discharge must not exceed
1 Acetone	20.7	8.2
2 n-Amyl acetate	20.7	8.2
3 Ethyl acetate ..	20.7	8.2
4 Isopropyl acetate	20.7	8.2
5 Methylene chloride	3.0	0.7

[1] Mg/L (ppm).

38. Section 439.47 is amended by removing the OMB control number cite, and revising the section to read as follows:

§ 439.47 Pretreatment standards for new sources (PSNS).

(a) Except as provided in 40 CFR 403.7, any new source subject to this subpart must achieve the following pretreatment standards:

Regulated parameter	Pretreatment standards[1]	
	Maximum daily discharge	Average monthly discharge must not exceed
1 Acetone	20.7	8.2
2 n-Amyl acetate	20.7	8.2
3 Ethyl acetate ..	20.7	8.2
4 Isopropyl acetate	20.7	8.2
5 Methylene chloride	3.0	0.7

[1] Mg/L (ppm).

(b) Any new source subject to the provisions of this section that commenced discharging after November 21, 1988 and prior to November 20, 1998 must continue to achieve the standards specified in the earlier version of this section, until the expiration of the applicable time period specified in 40 CFR 122.29(d)(1), after which the source must achieve the standards specified in § 439.46.

39. Section 439.50 is revised to read as follows:

§ 439.50 Applicability.

This subpart applies to discharges of process wastewater resulting from pharmaceutical research.

40. Section 439.51 is revised to read as follows:

§ 439.51 Specialized definitions.

For the purpose of this subpart, the term product means products or services resulting from research and product development activities.

41. Section 439.52 is revised to read as follows:

§ 439.52 Effluent limitations attainable by the application of the best practicable control technology currently available (BPT).

Except as provided in 40 CFR 125.30 through 125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the application of BPT:

(a) The average monthly effluent limitation for BOD_5, expressed as mass loading (pounds, kilograms) per day, must reflect not less than 90 percent reduction in the long-term average daily BOD_5 load of the raw (untreated) process wastewater, multiplied by a

variability factor of 3.0. No facility shall be required to attain a limitation for BOD_5 that is less than the equivalent of 45 mg/L.

(b) The average monthly effluent limitation for COD, expressed as mass loading (pounds, kilograms) per day, must reflect not less than 74 percent reduction in the long-term average daily COD load of the raw (untreated) process wastewater, multiplied by a variability factor of 2.2. No facility shall be required to attain a limitation for COD that is less than the equivalent of 220 mg/L.

(c) The long-term average daily BOD_5 or COD mass loading of the raw process wastewater (i.e., the base number to which the percent reduction is applied) is defined as the average daily BOD_5 or COD load during any calendar month, over 12 consecutive months within the most recent 36 months.

(1) To assure equity in the determination of NPDES permit limitations regulating discharges subject to this subpart, calculation of the long-term average daily BOD_5 or COD load in the influent to the wastewater treatment system must exclude any portion of the load associated with solvents, except for residual amounts of solvents remaining after the practices of recovery and/or separate disposal or reuse. Residual amounts of these substances may be included in the calculation of the average influent BOD_5 or COD loading.

(2) The practices of recovery, and/or separate disposal or reuse include: recovery of solvents from wastestreams; and incineration of concentrated solvent wastestreams (including tar still bottoms). This part does not prohibit the inclusion of such wastes in raw waste loads in fact, nor does it mandate any specific practice, but rather describes the rationale for determining NPDES permit limitations. The effluent limitation for BOD_5 or COD may be achieved by any of several, or a combination, of these practices.

(d) The average monthly effluent limitation for TSS, expressed as mass loading (pounds, kilograms) per day, must be calculated as 1.7 times the BOD_5 limitation determined in paragraph (a) of this section.

(e) The pH must be within the range 6.0 to 9.0.

§§ 439.33 through 439.57 [Removed]

41. Sections 439.53 through 439.57 are removed.

Appendix A to part 439 [Added]

42. Appendix A is added to part 439 to read as follows:

Appendix A to Part 439—Tables

TABLE 1.—SURROGATE PARAMETERS FOR DIRECT DISCHARGERS

[Utilizing biological treatment technology]

Regulated parameter	Treatability class
Amyl alcohol	Alcohols.
Ethanol	
Isopropanol	
Methanol	
Phenol	
Isobutyraldehyde	Aldehydes.
n-Heptane	Alkanes.
n-Hexane	
Diethylamine	Amines.
Triethylamine	
Benzene	Aromatics.
Toluene	
Xylenes	
Chlorobenzene	
o-Dichlorobenzene	
Chloroform	Chlorinated Alkanes.
Methylene chloride	
1,2-Dichloroethane	
Ethyl acetate	Esters.
Isopropyl acetate	
n-Amyl acetate	
n-Butyl acetate	
Methyl formate	
Tetrahydrofuran	Ethers.
Isopropyl ether	
Acetone	Ketones.
4-Methyl-2-pentanone (MIBK).	

TABLE 1.—SURROGATE PARAMETERS FOR DIRECT DISCHARGERS—Continued

[Utilizing biological treatment technology]

Regulated parameter	Treatability class
Ammonia (aqueous).	Miscellaneous.
Acetonitrile	
Methyl Cellosolve	
Dimethyl Sulfoxide	

Notes:

1. Parameters in bold may be used as a surrogate to represent other parameters in the same treatability class.
2. Surrogates have not been identified for the ''Miscellaneous'' treatability class.

TABLE 2.—SURROGATE PARAMETERS FOR INDIRECT DISCHARGERS

[Utilizing steam stripping treatment technology]

Regulated parameters	Treatability class
Benzene	High strippability.
Toluene	
Xylenes	
n-Heptane	
n-Hexane	
Chloroform	
Methylene chloride	
Chlorobenzene	
Methyl cellosolve	
Ammonia (aqueous).	Medium strippability.
Diethyl amine	
Triethyl amine	
Acetone 4-Methyl-2-pentanone (MIBK).	
n-Amyl acetate	
n-Butyl acetate	
Ethyl acetate	
Isopropyl acetate	
Methyl formate	
Isopropyl ether	
Tetrahydrofuran	
1,2-Dichloroethane	
o-Dichlorobenzene	

Notes:

1. Parameters in bold may be used as a surrogate to represent other parameters in the same treatability class.

[FR Doc. 98–21027 Filed 9–18–98; 8:45 am]

BILLING CODE 6560–50–P