PART 439—PHARMACEUTICAL MANUFACTURING POINT SOURCE CATEGORY

Interim Final Rulemaking

Notice is hereby given that effluent limitations and guidelines for existing sources to be achieved by the application of best practicable control technology currently available as set forth in the interim form below are promulgated by the Environmental Protection Agency (EPA). The regulation set forth below constitutes the "best practicable control technology currently available" as set forth in Appendix B to this preamble.

Although the pollutant removal approach used in this regulation represents a departure from conventional pollutant reductions based on emissions, it is the only feasible alternative using the present data base. This approach should not be construed as widening or relaxing future industrial limitations. There may be a modification of the format utilized in this rulemaking when further analysis is conducted of expected new data. While the regulations published in interim form today do not present a specific numerical limitation, the effect of today's publication is the same as if numbers for BOD, COD and TSS were presented. The permit writer may arrive at effluent limits for BOD, COD and TSS by applying to the raw waste load for each plant a percent reduction known to be attainable, and a variability factor. This approach does not disallow or mandate in-house pollution control practices; it merely assures that the total pollution loading from all facilities is reduced on an equitable basis. This (D), (E), and (f) of the Federal Water Pollution Control Act as amended (33 U.S.C. 1251, 1311 and 1314) (b) and (c), 86 Stat. 816 et seq.; Pub. L. 92-520-500 (the Act). In the near future, the Agency intends to publish in proposed form effluent limitations and guidelines for existing sources to be achieved by the application of best available technology economically achievable, and standards of performance and pretreatment standards for existing sources and new point sources. A description and discussion of this legal authority is contained in Appendix A to this preamble.

The pharmaceutical manufacturing point source category was first studied to determine whether separate limitations are appropriate for different segments within the category. This analysis also included a determination of whether differences in raw material used, product produced, manufacturing process employed, age, size, wastewater constituents and other factors require development of separate limitations for different segments of the point source category. The raw waste characteristics for this point source were then identified. The control and treatment technologies existing within the category were identified in terms of the quantity and the chemical, physical, and biological characteristics of pollutants, and the effluent levels resulting from the application of each of the technologies. This information was then evaluated in order to determine what levels of technology constitute the "best practicable control technology currently available." The data upon which the above analysis was performed included EPA permit applications, EPA sampling and inspection reports, and industry submissions. A summary of the method of study, the several factors considered in subcategorization and the conclusions reached are set forth as Appendix B to this preamble.


Prior to this publication, many agencies and groups were consulted and given the opportunity to participate in the development of these limitations, guidelines and standards. All participating agencies have been informed of project developments. An initial draft of the Development Document was sent to all participants and comments were solicited on that report. A summary of these comments and the Agency's response and consideration of these is contained in Appendix C to this preamble.

The Agency today promulgates regulations which are explicitly addressed to the control of BOD, COD and pH. TSS is controlled for subcategories B, D and E.

The oxygen demanding properties of these wastes result from the presence of both organic and inorganic compounds in the wastewaters. The release of oxygen demanding substances will be reduced when the discharger employs recommended technology. To meet the 1977 levels, a discharger can either rely on in-plant treatment or an end of the pipe treatment. Another option available is a combination of both.

The Agency has studied the economic and inflationary impact of the costs of these regulations and has made the following conclusions. It was found that only a few plants may have significant difficulty in implementing a treatment technology based on biological treatment. None of the 68 plants that are affected by the 1977 regulations are expected to close or curtail production. This analysis meets all of the requirements of economic and inflationary impact statements and is hereby certified by the Administrator in accordance with Executive Order No. 11821.

The Agency is subject to an order of the United States District Court for the District of Columbia entered in "Natural Resources Defense Council v Train" et al. (Civ. No. 1609-73) which requires the promulgation of regulations for this interim form today. This order also requires that such regulations become effective immediately.
upon publication. In addition, it is necessary to promulgate regulations establishing limitations on the discharge of pollutants pursuant to this category so that the process of issuing permits to individual dischargers under section 402 of this Act is not delayed.

It has been determined pursuant to 5 U.S.C. 553(b) that notice and comment on the interim final regulations would be impracticable and contrary to the public interest. Good cause is also found for these regulations to become effective immediately upon publication.

Interested persons are encouraged to submit written comments. Comments should be submitted in triplicate to the Environmental Protection Agency, 401 M St., SW., Washington, D.C. 20460. Attention: Distribution Officer, WH-552. Comments on all aspects of the regulations are solicited. The Agency especially solicits comments and data on cost of waste treatment, including processing of mycella, solvents, and broths. In the event comments are in the nature of criticisms as to the adequacy of data which are available, or which may be relied upon by the Agency, comments should identify and, if possible, provide any additional data which may be available and should indicate why such data suggest amendment or modification of the regulation. In the event comments address the approach taken by the Agency in establishing an effluent limitation or guideline, EPA solicits suggestions as to what alternative approach should be taken and why and how this alternative better satisfies the detailed requirements of sections 301 and 304(b) of the Act.

A copy of all public comments will be available for inspection and copying at the EPA Public Information Reference Unit, Freedom of Information Act Officer, Office of Public Information, Environmental Protection Agency, 475 First Street, SW., Washington, D.C. 20460. A copy of preliminary draft contractor reports, the Development Document, and any other such materials supporting the study of the industry concerned will also be maintained at this location for public review and copying. The EPA information regulation, 40 CFR Part 2, provides that a reasonable fee may be charged for copying.

All comments received on or before January 17, 1977, and the availability of the Development Document supporting this interim final regulation will be considered. Steps postionally taken by the Environmental Protection Agency to facilitate public response within this time period are outlined in the advance notice concerning public review procedures published on August 6, 1973 (38 FR 21202).

In the event that the final regulation differs substantially from the interim final regulation set forth herein the Agency will consider modification of any permits issued in accordance with this interim final regulation.

Section 8 of the FWPCA authorizes the Small Business Administration, through its economic disaster loan program, to make loans to assist any small business concern in effecting additions to or alterations in their equipment, facilities, or methods of operation so as to meet water pollution requirements under the FWPCA, if the concern is likely to suffer a substantial economic injury without such assistance.

For further details on this Federal loan program write to EPA, Office of Analysis and Evaluation, WH-586, 401 M St., SW., Washington, D.C. 20460.

In consideration of the foregoing, 40 CFR Part 439 is hereby established as set forth below.

Dated: November 9, 1976.

JOHN QUARLES,
Acting Administrator.

Subpart A--Fermentation Products Subcategory

§ 439.10 Applicability; description of the fermentation products subcategory.

Subpart B--Extraction Products Subcategory

§ 439.20 Applicability; description of the extraction products subcategory.

Subpart C--Chemical Synthesis Products Subcategory

§ 439.30 Applicability; description of the chemical synthesis products subcategory.

§ 439.31 General definitions.

§ 439.32 Effluent limitations and guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available.

Subpart D--Milling/Compounding and Formulation Subcategory

§ 439.40 Applicability; description of the milling/compounding and formulation subcategory.

§ 439.41 General definitions.

§ 439.42 Effluent limitations and guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available.

Subpart E--Research Subcategory

§ 439.50 Applicability; description of the research subcategory.

§ 439.51 General definitions.

§ 439.52 Effluent limitations and guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available.

Authority: Secs. 301, 304(b) and (c) and 306(b), Federal Water Pollution Control Act, as amended (33 U.S.C. 1251, 1311, 1314(b) and (c) and 1318(b), 86 Stat. 816 et seq; Pub.L. 90-509) (the Act).
paragraph, which may be discharged by a fermentation products plant from a point source subject to the provisions of this paragraph after application of the best practicable control technology currently available:

1. The allowable effluent discharge limitation for the daily average mass of BOD5 in any calendar month shall be expressed in mass per unit time and shall specifically reflect not less than 74 percent reduction in the long term daily average raw waste content of BOD5 multiplied by a variability factor of 3.0.

2. The allowable effluent discharge limitation for the daily average mass of COD in any calendar month shall be expressed in mass per unit time and shall specifically reflect not less than 74 percent reduction in the long term daily average raw waste content of COD multiplied by a variability factor of 3.0.

3. The long term daily average raw waste load for the pollutant BOD5 and COD is defined as the average daily mass of each pollutant influent to the wastewater treatment system over a 12 consecutive month period within the most recent 36 months, which shall include the greatest production effort.

4. To assure equity in regulating discharges from the point sources covered by this subpart, the general definition and practice shall be applied and any one of several different factors are found to exist, the limitations should be adjusted for certain plants in this industry. An individual discharger or other interested persons may submit evidence or other available information, the Regional Administrator (or the State) will make a written finding that such factors or are not fundamentally different for that facility compared to those specified in the Development Document. If such fundamentally different factors are found to exist, the Regional Administrator or the State shall establish for the discharger effluent limitations in the NPDES permit either more or less stringent than the limitations established herein, to the extent dictated by such fundamentally different factors. Such limitations must be approved by the Administrator of the Environmental Protection Agency. The Administrator may approve or disapprove such limitations, other limitations, or initiate proceedings to revise these regulations.

5. The pH shall be within the range of 6.0–9.0 standard units.

Subpart B—Extraction Products Subcategory
§ 439.20 Applicability; description of the extraction products subcategory.

The provisions of this subpart are applicable to discharges resulting from the manufacture of pharmaceuticals by extraction.

§ 439.21 Specialized definitions.
For the purpose of this subpart:
(a) Except as provided below, the general definitions, abbreviations and methods of analysis set forth in Part 401 of this chapter shall apply to this subpart.
(b) The term “product” shall mean biological and natural extraction products. This subcategory shall include blood fractions, animal and derivatives, endocrine products and isolation of medicinal products, such as alkaloids, from botanical drugs and herbs.

§ 439.22 Effluent limitations and guidelines representing the degree of effluent reduction that may be achieved by application of the best practicable control technology currently available.

In establishing the limitations set forth in this section, EPA took into account all information it was able to collect, develop and publish with respect to factors (such as age and size of plant, raw materials, manufacturing processes, products produced, treatment technology available, energy requirements and costs) which can affect the industry subcategory and effluent levels established. It is, however, possible that data which would affect these limitations have not been included in the most recent 36 months, which shall include the greatest production effort.

The provisions of this subpart are applicable to discharges resulting from the manufacture of pharmaceuticals by chemical synthesis.

§ 439.30 Applicability; description of the chemical synthesis products subcategory.

The provisions of this subpart are applicable to discharges resulting from the manufacture of pharmaceuticals by chemical synthesis.

§ 439.31 Specialized definitions.
For the purpose of this subpart:
(a) Except as provided below, the general definitions, abbreviations and methods of analysis set forth in Part 401 of this chapter shall apply to this subpart.
(b) The term “product” shall mean chemical synthesis products.
§ 439.32 Effluent limitations and guidelines—representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available.

In establishing the limitations set forth in this section, it shall be considered all information it was able to collect, develop and solicit with respect to factors (such as age and size of plant, raw materials, manufacturing processes, production, treatment technology available, energy requirements and costs) which can affect the industry subcategory and effluent levels established. It is, however, possible that data which would affect these limitations have not been available and, as a result, these limitations should be adjusted for certain plants in the industry. An individual discharger or other interested person may submit evidence to the Regional Administrator (or to the State, if the State has the authority to issue NPDES permits) that factors relating to the equipment or facilities involved, the process applied, or other such factors related to such discharger are fundamentally different from those considered in the establishment of the guidelines. On the basis of such evidence or other available information, the Regional Administrator (or the State, if the State has the authority to issue NPDES permits) that factors relating to the equipment or facilities involved, the process applied, or other such factors related to such discharger are fundamentally different from those considered in the establishment of the guidelines. Such limitations must be approved by the Administrator of the Environmental Protection Agency. The Administrator may approve or disapprove such limitations, specify other limitations, or initiate proceedings to revise these regulations.

(a) The following limitations establish the quantity or quality of pollutants or pollutant properties, controlled by this paragraph and which are discharged chemical synthesis plants from a point source subject to the provisions of this paragraph after application of the best practicable control technology currently available:

(1) The allowable discharge for the pollutant parameters BOD5 and COD shall be expressed in mass per unit time and shall represent the specified wastewater treatment efficiency in terms of a residual discharge associated with an influent to the wastewater treatment plant corresponding to the maximum production for a given pharmaceutical plant.

(2) The allowable effluent discharge limitation for the daily average mass of BOD5 and COD in any calendar month shall specifically reflect not less than 74 percent reduction in the long term daily average raw waste content of BOD5 multiplied by a variability factor of 2.2.

(3) The allowable effluent discharge limitation for the daily average mass of COD in any calendar month shall specifically reflect not less than 74 percent reduction in the long term daily average raw waste content of COD multiplied by a variability factor of 2.2.

(4) The long term daily average raw waste load for the pollution BOD5 and COD shall be expressed in mass per unit time and shall represent the specified waste load for the pollution BOD5 and COD for the purpose of determining NPDES permit limitations (i.e., the base numbers to which the percent reductions are applied) shall exclude any waste load associated with solvents in those raw waste loads: Provided, That residual amounts of solvents remaining after the practice of recovery or reduced use or concentration are shown, or are not fundamental different for that facility compared to the specified in the Development Document. If fundamentally different factors are found to exist, the Regional Administrator (or the State) shall establish for the discharger effluent limitations in the NPDES permit either more or less stringent than the limitations established herein, to the extent dictated by such fundamentally different factors. Such limitations must be approved by the Administrator of the Environmental Protection Agency. The Administrator may approve or disapprove such limitations, specify other limitations, or initiate proceedings to revise these regulations.

(b) The following limitations establish the quantity or quality of pollutants or pollutant properties, controlled by this paragraph, which may be discharged by a mixing/compounding and formulation plant from a point source subject to the provisions of this paragraph after application of the best practicable control technology currently available:

(1) The allowable discharge for the pollutant parameters BOD5 and COD shall be expressed in mass per unit time and shall represent the specified wastewater treatment efficiency in terms of a residual discharge associated with an influent to the wastewater treatment plant corresponding to the maximum production for a given pharmaceutical plant.

(2) The allowable effluent discharge limitation for the daily average mass of BOD5 and COD in any calendar month shall specifically reflect not less than 90 percent reduction in the long term daily average raw waste content of BOD5 multiplied by a variability factor of 3.0.

(3) The allowable effluent discharge limitation for the daily average mass of COD in any calendar month shall specifically reflect not less than 90 percent reduction in the long term daily average raw waste content of COD multiplied by a variability factor of 3.0.

§ 439.40 Applicability; description of the mixing/compounding and formulation subcategory.

The provisions of this subpart are applicable to discharges resulting from mixing/compounding and formulation operations of pharmaceutical products.

§ 439.41 Specialized definitions.

For the purpose of this subpart:

(a) Except as provided below, the general definitions, abbreviations and methods of analysis set forth in Part 401 of this chapter shall apply to this subpart.

(c) The term "product" shall mean products from plants in which blend, mix, compound, and formulate pharmaceutical ingredients. Pharmaceutical preparations for human and veterinary use such as ampules, tablets, capsules, vials, ointments, medicinal powders, solutions and suspensions are included.

§ 439.42 Effluent limitations and guidelines—representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available.

In establishing the limitations set forth in this section, EPA took into account all information it was able to collect, develop and solicit with respect to factors (such as age and size of plant, raw materials, manufacturing processes, production, treatment technology available, energy requirements and costs) which can affect the industry subcategory and effluent levels established. It is, however, possible that data which would affect these limitations have not been available and, as a result, these limitations should be adjusted for certain plants in this industry. An individual discharger or other interested person may submit evidence to the Regional Administrator (or to the State, if the State has the authority to issue NPDES permits) that factors relating to the equipment or facilities involved, the process applied, or other such factors related to such discharger are fundamentally different from those considered in the establishment of the guidelines. On the basis of such evidence or other available information, the Regional Administrator (or the State) shall establish for the discharger effluent limitations in the NPDES permit other than the limitations established herein, to the extent dictated by such fundamentally different factors. Such limitations must be approved by the Administrator of the Environmental Protection Agency. The Administrator may approve or disapprove such limitations, specify other limitations, or initiate proceedings to revise these regulations.

(a) The following limitations establish the quantity or quality of pollutants or pollutant properties, controlled by this paragraph, which may be discharged by a mixing/compounding and formulation plant from a point source subject to the provisions of this paragraph after application of the best practicable control technology currently available:

(1) The allowable discharge for the pollutant parameters BOD5 and COD shall be expressed in mass per unit time and shall represent the specified wastewater treatment efficiency in terms of a residual discharge associated with an influent to the wastewater treatment plant corresponding to the maximum production for a given pharmaceutical plant.

(b) The allowable effluent discharge limitation for the daily average mass of BOD5 and COD in any calendar month shall specifically reflect not less than 90 percent reduction in the long term daily average raw waste content of BOD5 multiplied by a variability factor of 3.0.

(c) The allowable effluent discharge limitation for the daily average mass of COD in any calendar month shall specifically reflect not less than 90 percent reduction in the long term daily average raw waste content of COD multiplied by a variability factor of 3.0.
The long term daily average raw waste load for the pollutant BOD5 and COD is defined as the average daily mass of each pollutant influent to the waste-water treatment system over a 12 consecutive month period within the most recent 36 months, which shall include the greatest production effort.

(5) To assure equity in regulating discharges from the point sources covered by this subpart, the point source category, calculation of raw waste loads of BOD5 and COD for the purpose of determining NPDES permit limitations (i.e., the base numbers to which the percent reductions are applied) shall exclude any waste load associated with solvents in those raw waste loads; provided, That residual amounts of solvents remaining after the practice of recovery and/or separate disposal or reuse may be included in calculation of raw waste loads. These practices of removal, disposal or reuse include recovery of solvents from waste streams and incineration of concentrated solvent waste streams (including tar still bottoms). This regulation does not prohibit inclusion of such wastes in the raw waste loads in fact, nor does it mandate any specific practice, but rather describes the rationale for determining the permit conditions. These limits may be one of several or a combination thereof of programs and practices.

(6) The average of daily TSS values for any calendar month shall not exceed 52 mg/l.

(7) The pH shall be within the range of 6.0 to 9.0 standard units.

Subpart E—Research Subcategory

§ 439.50 Applicability; description of the research subcategory.

The provisions of this subpart are applicable to discharges resulting from pharmaceutical research.

§ 439.51 Specialized definitions.

For the purpose of this subpart:

(a) Except as provided below, the general definitions and methods of analysis set forth in Part 401 of this chapter shall apply to this subpart.

(b) The term "product" shall mean products or service resulting from pharmaceutical research, which includes microbiological, biological and chemical operations.

§ 439.52 Effluent limitations and guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available.

In establishing the limitations set forth in this section, EPA took into account all information it was able to collect, develop and solicit with respect to factors (such as age and size of plant, raw materials, manufacturing processes, products produced, treatment technology available, energy requirements and costs) which can affect the industry subcategorization and effluent levels established. It is, however, possible that data which would affect these limitations have not been available and, as a result, these limitations should be adjusted for certain plants in this industry. An individual discharger or other interested persons may submit evidence to the Regional Administrator (or to the State, if the State has the authority to issue NPDES permits) that factors relating to the equipment or facilities used, the processes used or other such factors related to such discharger are fundamentally different from the factors considered in the establishment of the guidelines. On the basis of such evidence or other available information, the Regional Administrator (or the State) will make a written finding that such factors are or are not fundamentally different for that facility compared to those specified in the Development Document. If such fundamentally different factors are found to exist, the Regional Administrator or the State shall establish for the discharger’ effluent limitations in the NPDES permit other more or less stringent than the limitations established based to the extent dictated by such fundamentally different factors. Such limitations must be approved by the Administrator of the Environmental Protection Agency. The Regional Administrator may approve or disapprove such limitations, specify other limitations, or initiate proceedings to revise these regulations.

(2) The following limitations establish the quantity or quality of pollutants or pollutant properties, controlled by this paragraph, which may be discharged by a research subcategory point source subject to the provisions of this paragraph after application of the best practicable control technology currently available:

(3) The allowable effluent discharge limitation for the daily average mass of BOD5 in any calendar month shall represent the specified wastewater treatment efficiency in terms of a residual discharge associated with an influent to the wastewater treatment plant corresponding to the maximum research effort for a given pharmaceutical plant.

(2) The allowable effluent discharge limitation for the daily average mass of COD in any calendar month shall represent the specified wastewater treatment efficiency in terms of a residual discharge associated with an influent to the wastewater treatment plant corresponding to the maximum research effort for a given pharmaceutical plant.

(3) The allowable effluent discharge limitation for the daily average mass of COD in any calendar month shall reflect not less than 74 percent reduction in the long term daily average raw waste content of BOD5 multiplied by a variability factor of 3.0.

(4) The long term daily average raw waste load for the pollutant BOD5 and COD is defined as the average daily mass of each pollutant influent to the waste-water treatment system over a 12 consecutive month period within the most recent 36 months.

(5) To assure equity in regulating discharges from the point sources covered by this subpart of the point source category, calculation of raw waste loads of BOD5 and COD for the purpose of determining NPDES permit limitations (i.e., the base numbers to which the percent reductions are applied) shall exclude any waste load associated with solvents in those raw waste loads; provided, That residual amounts of solvents remaining after the practice of recovery and/or separate disposal or reuse may be included in calculation of raw waste loads. These practices of removal, disposal or reuse include recovery of solvents from waste streams and incineration of concentrated solvent waste streams (including tar still bottoms). This regulation does not prohibit inclusion of such wastes in the raw waste loads in fact, nor does it mandate any specific practice, but rather describes the rationale for determining the permit conditions. These limits may be achieved by any one of several or a combination thereof of programs and practices.

The average of daily TSS values for any calendar month shall not exceed 52 mg/l.

(7) The pH shall be within the range of 6.0 to 9.0 standard units.

Appendix A—Local Authority

Section 301(b) of the Act requires the Administrator to publish regulations providing guidelines for effluent limitations setting forth the degree of effluent reduction attainable through the application of the best practicable control technology currently available as defined by the Administrator pursuant to section 304(b) of the Act. Section 301(b) also requires the Administrator to publish regulations providing guidelines for effluent limitations setting forth the degree of effluent reduction attainable through the application of the best practicable control technology currently available as defined by the Administrator pursuant to section 304(b) of the Act.
The effluent limitations and guidelines set forth herein were developed in the following manner. The point source category was first studied for a number of reasons: (1) to determine whether separate limitations are appropriate for different segments within the category, (2) to establish a determination of whether differences in raw materials, products, manufacturing process employed, size, wastewater constituents and other factors require development of separate limitations for different segments of the point source category. The raw waste characteristics for each such segment were then identified. This included an analysis of the source of the waste, the volumes of the waste water in the operation and the constituents of all wastewaters. The constituents of the wastewaters were subject to effluent limitations.

The existing control and treatment technologies with which the point source was examined. This included an identification of each distinct control and treatment technology, including both inclusive and end-of-process technologies, which exist or is capable of being designed for each segment. It also included an identification of, in terms of the amount of constituents and the chemical, physical, and biological characteristics of pollutants resulting from the application of each of the technologies. Problems with each treatment and control technology were identified. In addition, the non-water quality environmental impact, such as the effects of the application of these technologies upon other pollution problems, including air, solid waste, noise and radiation were examined. The energy requirements of each control and treatment technology were determined as well as the cost of the application of such technologies.

The information outlined above was then evaluated to determine which of technology constitute the "best practicable control technology currently available." In identifying such technologies, various factors were considered. These included the total cost of application of technology, the age of equipment and facilities involved, the process employed, the engineering aspects of the application of various types of control technologies, process changes, non-water quality environmental impact (including energy requirements), potential benefits to be achieved by reducing pollution from this point source category and other factors.

The data upon which the above analysis was performed included EPA permit applications, EPA inspection and permit issuance reports, and industry submissions.

(2) Summary of conclusions with respect to the fermentation products subcategory (Subpart B), the chemical synthesis products subcategory (Subpart C), the mixing/combinations subcategory (Subpart D), and the research subcategory (Subpart E) of the pharmaceutical manufacturing category.

(1) Subcategory A. For the purpose of establishing effluent limitations and guidelines, the pharmaceutical industry was divided into subcategories. Factors such as type of production process, type of manufacturing process, treatability of wastewaters, and other means were used to establish separate limitations and guidelines for each of the subcategories. In general, the largest distinguishing factors are product yields, treatment and treatability based on production volumes and specific wastewater requirements. This broad base subcategory approach allows the application of effluent limitations and guidelines for a complex mix of pharmaceutical production activity. For example, an inherent waste to the fermentation products manufacturing operations (Subcategory A) is the generation of considerable amounts of mycelial biomass. The removal of this material is a necessary step in the manufacturing operations of the other four subcategories.

(2) Waste characteristics. The known significant wastewater pollutants and pollutant properties resulting from the pharmaceutical industry include pH, total suspended solids, BOD5, COD, TOC, metals, organic solvents, and waste medicinal chemicals. BOD5, COD, and TOC, which are primary measurements for organic pollution, are evident in wastewaters from the pharmaceutical manufacturing point source category.

(3) Process characteristics. Sources of wastewater pollutants in the pharmaceutical industry include aqueous wastes resulting from fermentation operations, decanting systems, solvent extraction units, ion exchange regeneration, distillation vacuum, exhaust scrubbers, caustic scrubbers, destruction of waste or returned products, process equipment cleanouts, production area washdowns, formulation equipment cleanup, and spill washdowns. Unlike many other point source categories, these wastes cannot be separated on a unit of production basis due to the non-continuous nature of processes. As a result, it was not possible to produce the same or similar products, the variety of refining options for a given product or class of products, the differing conversion efficiencies of raw materials to final products, the low absolute yields of some active ingredients, and the physical form of final products. Therefore, the removal efficiencies of the applicable and practical technology were applied. In this particular regulation, the degree of effluent reduction for BOD5 and COD shall have the same meaning as percent removal or percent removal efficiency.

In determining efficiencies to be used, the historical data from existing plants in the point source category were evaluated to discover the best operating wastewater treatment plants. The average efficiencies of the best treatment plants within a subcategory and the best treatment plant that should be applied to these subcategories. The average values from an array of eleven plants identified as the best wastewater treatment plants for all subcategories were as follows:

<table>
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<th>BOD5 removal</th>
<th>COD removal</th>
<th>Effluent TSS</th>
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For subcategories A and C, the maximum value for the average of daily TSS values for any calendar month for subcategories B, D, and E, exemplary plants number 14, 24 and 25 were averaged as a "variable factor of 3.0 was applied. This variability factor represents the 89 percent probability to long term average.

For subcategories A and C, the maximum value for the average of daily TSS values for any calendar month for subcategories B, D, and E, exemplary plants number 14, 24 and 25 were averaged as a "variable factor of 3.0 was applied. This variability factor represents the 89 percent probability to long term average.

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<tr>
<th>Plant No.</th>
<th>Subcategory</th>
<th>BOD5 removal (percent)</th>
<th>COD removal (percent)</th>
<th>TSS in effluent (milligrams per liter)</th>
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This plant may or may not be lacking in secondary settling and secondary settling and may be reported that this plant has had difficulty meeting its TSS permit limits in the past.
As noted above, in most industries, process wastewater pollutants are generally proportional to the level of production; however, specifications and removal of COD and BOD5 across the wastewater treatment system is a more appropriate basis for this point source category than concentrations and standards based on a unit of production. The COD parameter is a secondary control mechanism; the COD percent removal is that which can be expected to be implemented in the wastewater treatment system. However, this does not preclude the use of a physical/chemical wastewater treatment alternative to attain the equivalent COD reduction.

The variability factor is applied to the long term daily average effluent residual to arrive at the allowable effluent discharge limitations for the daily average mass of BOD5 in any calendar month for a given pharmaceutical plant. This factor for BOD5 is 0.9; the COD variability factor is 2.5. Both the BOD5 and COD variability factors represent the ratio of the 99 percent probability to long term daily average.

Although the BPT regulation published in the Federal Register and supported by this document does not indicate the maximum daily limitations for BOD5, COD and TSS, it is expected that the permit writers will handle this issue on a case by case basis. Similarly, those known pollutants, but not identified in this discussion, whose specific location may be assigned appropriate effluent limitation values by the permit writer using authority of the SWPC. In compliance with regulations published in 40 CFR Parts 124 and 125. The constituents contained in the wastewater discharges, whether associated with the chemical or product produced, Suspended solids are present as a result of most production processes. These may generally be removed by sedimentation basins, clarifiers, filters, centrifuges and evaporation.

(iv) Treatment and control technology. Wastewater treatment and control technologies have been studied for this point source category to determine the best practicable control technology currently available.

The following discussion of treatment technology provides the basis for the effluent limitations and guidelines. This discussion does not preclude the selection of other wastewater treatment alternatives which provide equivalent or better levels of treatment.

Pharmaceutical wastewaters vary in quantities and quality depending on the type of manufacturing process. Wastewater from subcategories B, D, and E are more readily treatable than wastes from subcategories A and G, but subcategory B-chemical products could be adequately treated in properly designed facilities. The results of an industry survey indicate that a variety of in-plant abatement techniques are utilized by pharmaceutical plants and overall, in-plant wastewater control measures are being practiced throughout the industry. Therefore, these techniques can be incorporated as part of the technology available to achieve compliance. Research has shown that biological treatment methods are the most prevalent end-of-pipe wastewater treatment systems utilized by the industry.

**IN-PLANT POLLUTION ABATEMENT**

It is within the manufacturing facility itself that maximum reduction, reuse, and elimination of wastewaters can be accomplished. In the pharmaceutical industry, the beneficial use of wastewaters varies from plant to plant. In some plants, wastewater quality and quantity varies within the industry, but the most prevalent practice is to have the wastes disposed of by a private contractor or by-site incineration. In-plant treatment processes are considered satisfactory to achieve the most efficient manner possible. There are several instances of the kinds of changes which have been implemented within plants surveyed:

1. The use of barometric condensers can result in significant water contamination, depending upon the nature of the materials entering the discharge wastewater stream. This could be substantially reduced by substituting a heat exchanger for water sprays. An alternative, several surface condensers to reduce hydraulic or organic loads.

2. Water-sealed vacuum pumps often create water pollution problems. Several plants are using a scaling water recirculation system with bag filters. This practice has resulted in significant reduction of COD and possibly other constituents of pollutants and volume of wastewater generated.

3. The recovery of waste solvents is a common practice among plants using solvents in gas mask manufacture, subcategory B-chemical products. In the pharmaceutical industry, combined with strict regulations from the Food and Drug Administration, require most producers to operate their plants in the most efficient manner possible. There are numerous examples of good housekeeping practices that have been observed at plants during the survey which could result in a substantial reduction in the concentration of effluents to the sewers. One practice that can be incorporated as part of the technology available to achieve compliance. This practice has resulted in significant reduction of COD and possibly other constituents of pollutants and volume of wastewater generated.

4. The recovery of waste solvents is a common practice among plants using solvents in gas mask manufacture, subcategory B-chemical products. In the pharmaceutical industry, combined with strict regulations from the Food and Drug Administration, require most producers to operate their plants in the most efficient manner possible. There are numerous examples of good housekeeping practices that have been observed at plants during the survey which could result in a substantial reduction in the concentration of effluents to the sewers. One practice that can be incorporated as part of the technology available to achieve compliance. This practice has resulted in significant reduction of COD and possibly other constituents of pollutants and volume of wastewater generated.

5. The recovery of waste solvents is a common practice among plants using solvents in gas mask manufacture, subcategory B-chemical products. In the pharmaceutical industry, combined with strict regulations from the Food and Drug Administration, require most producers to operate their plants in the most efficient manner possible. There are numerous examples of good housekeeping practices that have been observed at plants during the survey which could result in a substantial reduction in the concentration of effluents to the sewers. One practice that can be incorporated as part of the technology available to achieve compliance. This practice has resulted in significant reduction of COD and possibly other constituents of pollutants and volume of wastewater generated.

6. Several techniques have been employed by various plants in subcategory D ( Biological Extraction Products) to reduce the volume of contamination wastes discharged to end-of-pipe treatment systems. The common practice of "open bore" wastes by evaporation and distillation of drying the contaminated waters. The resulting dry product is disposed of by incineration or a combination of a process or a combination of processes. The results of this practice are demonstrated in the following example:

7. Several plants in subcategory D (Biological Extraction Products) segregate the organic and inorganic solvents. The organic fraction is examined for off-specification solid products to divert them to a landfill or reformulated them when possible. Plants in other subcategories, when reprocessing is not possible, either incinerate off-specification batches or collect them in drums and dispose of them via a private disposal contractor.

**Process Technology**

Many of the newer pharmaceutical plants are being designed with reduced reliance on water use as part of the overall planning and design criteria. Improvements which have been implemented in the pharmaceutical industry, combined with strict regulations from the Food and Drug Administration, require most producers to operate their plants in the most efficient manner possible. There are numerous examples of good housekeeping practices utilized throughout the industry. A few of the better practices used by exemplary plants are described in the following discussion.

1. All of the plants visited in subcategory D (mixing/comounding and formulation) carried out their routine cleaning most efficiently by vacuum cleaning. Most facilities utilized "house" vacuum systems equipped with bag filters. This practice has resulted in a substantial reduction of combustible material to the sewer.

2. Quality control laboratories are an integral part of the pharmaceutical industry, and solvent and toxic substance disposal is a serious concern. The following evidence of the apparent industry-wide commitment to good housekeeping. Standard practices in general to collect and disposal toxic wastes and the recycling of chemical substances. Solvents are recovered and recycled to strip solvents beyond the economical recovery point.

3. One plant producing a large amount of organic arsenic eliminated the discharge of this toxic substance by recovering the arsenic. Arsenic-laden waste streams are segregated and concentrated before being re-used. Non-recoverable arsenic residues are drummed and shipped to an approved landfill.

4. Several techniques have been employed by various plants in subcategory D (Biological Extraction Products) to reduce the volume of contamination wastes discharged to end-of-pipe treatment systems. The common practice of "open bore" wastes by evaporation and distillation of drying the contaminated waters. The resulting dry product is disposed of by incineration or a combination of processes. The results of this practice are demonstrated in the following example:

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**Recycle/reuse practices**

Recycle/reuse can be accomplished either by returning wastewater to its original use, or by using it to satisfy a demand for lower...
quality water. The recycle/reuse practices within the pharmaceutical industry are varied and only a few examples are described briefly below:

1. Minimizing the use of once-through cooling water by recycling through cooling towers is used in numerous plants and results in tremendously decreased total wastewater discharge.

2. Dilute waste scrubber waters are collected and sent back to the plant’s chenical wastes, the mercury-biological treatment system utilized to treat them. This practice is not applicable to all segments of the industry, it is a substantial reduction in water usage and should be considered in situations where it does not pose a serious threat of product contamination.

3. Several plants use waste deionized water for cooling, tower makeup.

4. Waste cooling water from one plant was collected in a pond and held as a source of water for fire protection.

AT-SOURCE

The survey indicated that at-source in-plant abatement measures to protect down-stream biological treatment plants were practiced by a number of plants within this point source category. Those manufacturing plants utilizing at-source pretreatment were usually found in subcategories A and C. The particular pretreatment processes utilized are discussed below:

CYANIDE DESTRUCTION

The purpose of the cyanide treatment is to reduce high cyanide levels found in waste streams by alkaline chlorination prior to discharging the waste into an activated sludge treatment system. The treatment of cyanide wastes by alkaline chlorination involves the addition of chlorine to a waste stream at pH 9-10. In order to provide efficient treatment of the waste, an activated sludge system using chlorine gas is utilized to reduce the cyanide levels prior to oxidation and by-

processes. Wastewater is treated in roughing and final treatment as follows:

1. Strong waste streams.
2. Weak waste streams.
3. Contaminated stormwater from process areas and tanks.
4. Special wastes such as spent caustics, spent acids, waste solvents, and metal-bearing wastes.
5. Non-contact cooling water.
6. Stormwater drainage streams.

SEWAGE REGRESSION

In order to provide efficient treatment of the wastes originating within a pharmaceutical plant segregation of concentrated waste loads, and biological treatment of intermediate-strength waste results.

Separation of stormwater runoff is practiced through the industry and, as discussed previously, allows for the isolation and treatment of contaminated run-off. The isolation of wastes containing pollutants that may require specialized treatment such as steel, arsenic, ammonia and cyanide is also a demonstrated practice in the pharmaceutical industry, which permits effective removal of all pollutants.

Segregation of non-contact cooling water is also practiced within the industry. This practice is utilized to reduce the quantity of wastewater that must be treated, but also fa- cilities water reuse either prior to or after treatment.

END-OF-PIPE CONTROL TECHNOLOGY

In the pharmaceutical manufacturing point source category, end-of-pipe control technology relies heavily upon the use of activated sludge treatment. The treatment most often consists of equalization basins to minimize shock organic loads, neutralization for pH control and clarification to remove sediments. The use of activated sludge treatment has been accomplished in separate basins provided for the purpose, but it can be done in equalization basins. In many cases, activated sludge treatment chemicals are done on the basis of monitoring the pH in the activated sludge process itself.

Other pretreatment methods observed in- clude cooling of waste and use of roughing filters to reduce organic loadings. Effluent polishing was utilized by many plants, and some observed included filters, coagulants, and adsorbers.

The raw waste loads for subcategories A and C are significantly higher than other subcategories. The high raw waste loads found in subcategory A are a direct result of low or nonexistent end-of-pipe treatment of waste.
Depending on the individual plant's product mix, it may be necessary to neutralize the wastewater in order to make it more amenable to biological treatment. Neutralization facilities are provided for subcategories B, D and E; however, neutralization is not required for subcategory C.

For all subcategories, a single-stage activated sludge process was selected because of its demonstrated ability to efficiently treat pharmaceutical wastes. Although a single-stage activated sludge treatment system had been selected for the purpose of developing cost models and it properly operated, it would not be necessary to remove TSS before biological treatment.

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(3) In the contractor's draft development document, it is suggested that some of the waste disposal problems be turned over to a private disposal contractor. Commenters stated that this was a feasible way to handle the situation and that it was good business practice. However, the revised approach does not include this suggestion.

(4) A commenter stated that the original draft Development Document was inadequate in that the data obtained was improperly interpreted. Specifically, the wide range in the amount of waste produced per unit of product for any representative list of pharmaceutical products made by medium to large pharmaceutical plants is convincing evidence that the nature of the product and the process rather than production level is the dominant factor. The commenter stated that it is possible to set quantitative standards for either allowable BWL's or discharge of pollutants for each unit of production. Some regulated pollutant reductions of RWL is a better means of regulation.

In response to the several points outlined in this comment, the Agency has revised the BPT effluent limitations and guidelines. In general, the actual limitations are based on wastewater treatment efficiencies presently being achieved by the better plants within the category. The data was made of raw waste load reductions possible by the use of identified in-plant and end-of-pipe treatment technologies. The effluent reduction capabilities of the identified BPT end-of-pipe treatment were calculated on the basis as a percent of removal across the wastewater treatment plants for each of the five subcategories to eliminate difficulties encountered in the poor correlations between BWL's and production.

(4) Commenters were relieved that the comments for each subcategory were identified for each product and production schedule. Furthermore, BWL's were determined on a collective basis for each subcategory—BWL's for the individual products were calculated. Consequently, the commenters concluded that there is no way to determine BWL's for individual products or assess treatability. Furthermore, in the commenters' opinion, categorization serves no purpose since there is so much variation of the various parameters within a subcategory as there is between subcategories.

These comments are made when the draft document utilized production based limitations. Since then, this document has been revised and production based limitations are being considered. The problems delineated in the comment have been accommodated with the revised approach.

(5) One commenter stated that the process information given is far more necessary to delineate waste sources, quantities and characteristics. These regulations do not reveal proprietary or confidential data. However, the Agency intends to publish a public background information in the Development Document to show wastes and wastewaters are generated.

Furthermore, it is incumbent on the Agency to indicate, where possible, how in-plant pollution abatement methods can reduce effluent. Since then, this situation requires a description of the production of crude product or refining options in a general way.

(6) A commenter stated that exemplary is not defined in the document and the comment is concerned with exemplary parts of the regulation for source treatment plants with no recognition given to the individual circumstances affecting each plant.

A definition will be incorporated into the Development Document supporting this particular point source category. To the extent possible, a full range of plants will be examined in each subcategory.

(7) A commenter indicated that the proposed treatment efficiencies for BPT for BOD5, COD and TOC are either premature and unnecessary or unreasonably high. An industry handling a more complex waste than the average POTW could not be expected to provide substantively greater BOD5 removal. To require pharmaceutical wastewater treatment plants to achieve higher treatment efficiencies than POTWs does not reason because the operators of POTWs do not know what wastes to expect from day to day. Therefore, a properly designed equipment. On the other hand, a pharmaceutical manufacturer has the design and operational flexibility to adapt the plant and/or the amount of pollution abatement equipment in place. A mix product changes over time and a medical company can change its equipment configurations and wastewater treatment processes to handle new situations.

In the response to the several points outlined in this comment, the Agency has completely revised the BPT effluent limitations and guidelines. To answer the illustrative difficulties of the in-plant and end-of-pipe categorical treatment technologies. The effluent reduction capabilities of the identified BPT end-of-pipe treatment were specified on the basis of percent removal across the wastewater treatment plants for each of the five subcategories to eliminate difficulties encountered in the poor correlations between BWL's and production.

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This comment is made when the draft document utilized production based limitations. Since then, this document has been revised and production based limitations are being considered. The problems delineated in the comment have been accommodated with the revised approach.

(9) A commenter stated that it would not be fair to base effluent limitations for a "vertical production" plant on data derived from producing plants. The comment was that not all vertical production plants were used for the same category. They said that such classification serves no purpose since there is so much variation of the various parameters within a subcategory as there is between subcategories.

This comment is made when the draft document utilized production based limitations. Since then, this document has been revised and production based limitations are being considered. The problems delineated in the comment have been accommodated with the revised approach.

(10) A commenter noted that the comment includes only a few percent of the overall treated wastewater, and the restrictions of the reduced flow rate is not easily achieved. Hence, the in-plant and vertical production from plant to plant are not very high. Consequently, if a horizontal manufacturing plant changed its internal operations and production, its output of wastewater would be reduced. The commenter concluded that such a simplification would probably be required.

In the response to the several points outlined in this comment, the Agency has revised the BPT effluent limitations and guidelines. Mos...
and availability of control and treatment technologies. More stringent standards may be applied for an average pharmaceutical waste treatment plant for the identified subcategory. The Agency does not hold out any waste treatment plant, applicable to even plant wastewater within the subcategory. It is acknowledged that a good design procedure that should be followed in each case in order to develop design criteria.

(29) The statement that the wastewater from the pharmaceutical industry is not currently in use in this category. The Agency is developing additional data in this regard and will update the discussion of this point at a future date. In any case the individual company would be faced with a cost trade-off between reducing the volume of sludge versus transportation, storage and handling costs of the larger quantity of sludge on an "as is" basis.

(30) A commenter indicated that consideration should be given to the actual hydraulic and organic load of the individual plants involved in this category and not included as a subcategory.

Neutralization facilities are included in the cost models for subcategory D and G. The commenter noted that equalization and neutralization should be used only in those situations where there is a benefit to the wastewater treatment plant, applicable to the identified subcategory. The Agency is not holding out any wastewater treatment plant for the identified subcategory. The Agency does not hold out any wastewater treatment plant, applicable to even plant wastewater within the subcategory. It is acknowledged that a good design procedure that should be followed in each case in order to develop design criteria.

A number of other comments were received and considered by the Agency and are not included in this response. Appropriate consideration and response will be made at the time of publication of the regulations applicable to this subcategory (new and existing sources). Interested persons are encouraged to submit written comments. Comments should be submitted in triplicate to the Director, Environmental Protection Agency, 401 M St., SW., Washington, D.C. 20460, Attention: Division Officer, WH-502.

All comments received on or before January 17, 1977, and the availability of the Development Document supporting this interim final regulation will be considered. Steps previously taken by the Environmental Protection Agency to facilitate public response within this time period are outlined in the advance notice concerning public review procedures published on August 6, 1973 (38 F.R. 21922).

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