

**ENVIRONMENTAL PROTECTION AGENCY****40 CFR Part 439**

[FRL-5165-2]

RIN 2060-AC49

**Effluent Limitations Guidelines, Pretreatment Standards, and New Source Performance Standards: Pharmaceutical Manufacturing Category****AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Proposed rule.

**SUMMARY:** This proposed rule would limit the discharge of pollutants into waters of the United States and the introduction of pollutants into publicly owned treatment works by existing and new facilities that manufacture pharmaceuticals. The proposed rule establishes limitations on pollutants, but does not specify the technology to be employed to achieve compliance. The Agency intends that this proposed rule will have a common technology basis with a rule yet to be proposed to control air emissions to allow coordinated and cost effective compliance planning by the industry.

This proposed rule would annually reduce priority pollutant discharges from this industry by an estimated 15.7 million pounds and total pollutant discharges by 139 million pounds at an estimated annual cost of \$80 million (1994 \$). The benefits include reductions in both carcinogenic and non-carcinogenic risk, ecological and recreational benefits due to improved water quality, and benefits to publicly owned treatment works such as improved worker health and safety.

As a result of consultation with stakeholders, the preamble solicits comments and data not only on issues raised by EPA, but also on those issues raised by State and local governments who will be implementing these regulations and by industry representatives who will be affected by them.

**DATES:** Comments on the proposed rule must be received by July 31, 1995 at the address noted below. EPA will conduct a public hearing on the effluent pretreatment standards included in the proposed rule. EPA will publish in the **Federal Register** an announcement of the public hearing.

**ADDRESSES:** Send written comments on this proposal in triplicate and in electronic form if possible to Mr. David Hoadley, Engineering and Analysis Division (4303), U.S. EPA, 401 M Street

SW., Washington, DC 20460. The public record supporting the proposed effluent limitations guidelines and standards is in the Water Docket located in the basement of the EPA Headquarters building, Room L102, 401 M Street SW., Washington, DC 20460, telephone number (202) 260-3027. EPA regulations at 40 CFR part 2 provide that a reasonable fee may be charged for copying.

**FOR FURTHER INFORMATION CONTACT:**

Background documents supporting the proposed regulations are described in the "Background Documents" section below. Contact the Office of Water Resource Center, RC-4100, at the U.S. EPA, Washington, DC address shown above, telephone (202) 260-7786, for the voice mail publication request line. For additional information on the engineering aspects of the regulation, contact Dr. Frank H. Hund, Engineering and Analysis Division (4303), U.S. EPA, 401 M Street SW., Washington, DC 20460, at (202) 260-7182. For additional information on the economic and statistical aspects of the regulation, contact Mr. Neil Patel at the address above at (202) 260-5405. For additional engineering information on the preliminary air emissions control aspects of this rule, contact Mr. Randy McDonald, Office of Air Quality Planning and Standards (MD-13), Research Triangle Park, NC 27711, at (919) 541-5402.

**SUPPLEMENTARY INFORMATION:****Overview**

The preamble describes the definitions, acronyms, and abbreviations used in this notice; the background documents that support these proposed regulations; the legal authority of this rule; a summary of the proposal; background information; and the technical and economic methodologies used by the Agency to develop these proposed regulations. This preamble also solicits comment and data on all aspects of this rulemaking, including on specific areas of interest.

**Confidential Business Information**

EPA notes that many documents in the record supporting this proposed rule have been claimed as confidential business information and, therefore, are not included in the record that is available to the public in the Water Docket. To support the rulemaking, EPA is presenting certain information in aggregated form or is masking plant identities to preserve confidentiality claims. Further, the Agency has withheld from disclosure some data not

claimed as confidential business information because release of this information could indirectly reveal information claimed to be confidential.

Plant-specific data that have been claimed as confidential business information are available to the company that submitted the information. To ensure that all CBI is protected in accordance with EPA regulations, any requests for company-specific data should be submitted on that company's letterhead and signed by a responsible official authorized to receive such data. The request must list the specific data requested and include the following statement, "I certify that EPA is authorized to transfer confidential business information submitted by my company, and that I am authorized to receive it." Organization of this document:

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### I. Definitions, Acronyms, and Abbreviations

**1989 Pharmaceutical Screener Questionnaire**—A short questionnaire distributed by EPA to all known pharmaceutical facilities in June 1989 in order to identify plants which manufacture pharmaceutical products.

**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.

**Annual average**—The mean concentration, mass loading or production-normalized mass loading of a pollutant over a period of 365 consecutive days (or such other period of time determined by the permitting authority to be sufficiently long to encompass expected variability of the concentration, mass loading or production-normalized 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 439, subpart B).

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

**BOD<sub>5</sub>**—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<sub>5</sub> is not related to the oxygen requirements in chemical combustion.

**Boiler**—Any enclosed combustion device that extracts useful energy in the form of steam and is not an incinerator.

**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 439, subpart C).

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

**Closed vent system**—A system that is not open to the atmosphere and is composed of piping, ductwork,

connections, and, if necessary, flow-inducing devices that transport gas or vapor from an emission point to a control device or back into the process.

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.

Combustion device—An individual unit of equipment, including but not limited to, an incinerator or boiler, used for the thermal oxidation of organic hazardous air pollutant vapors.

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

Continuous discharge—Discharge that occurs without interruption throughout the operating hours of the facility.

Control Techniques Guidance (CTG)—A document prepared to provide State and local air pollution authorities with an information base for proceeding with analysis of Reasonably Available Control Technology (RACT) to meet Clean Air Act statutory requirements.

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<sub>5</sub>), 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.

Emission point—Any location within a source from which air pollutants are emitted, including an individual process vent, an opening within a wastewater collection and treatment system, or an open piece of process equipment.

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 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 notice, 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.

Individual drain system—The system used to convey process wastewater streams away from the pharmaceutical manufacturing process equipment or tank, or process wastewater collection and treatment system unit. The term includes all process drains and junction boxes, together with their associated sewer lines and other junction boxes, manholes, sumps and lift stations. The individual drain system is designed to segregate the vapors within the system from other drain systems. A separate storm sewer system, which is a drain and collection system designed and operated for the purpose of collecting storm runoff at a facility, and which is segregated from all other individual drain systems, is excluded from this definition.

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<sup>6</sup>) grams, or one metric ton.

Metric ton—One thousand (10<sup>3</sup>) 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 439, subpart D).

Modification—As defined in section 112(a) of the Clean Air Act, modification is any physical change in, or change in the method of operation of, a major source which increases the actual emissions of any hazardous air pollutant emitted by such source by more than a de minimis amount or which results in the emission of any hazardous air pollutant not previously emitted by more than a de minimis amount.

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.

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 Generation—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 emission point—A gas stream that contains hazardous air pollutants discharged during operation of process equipment. Process emission points include gas streams that are discharged directly to the atmosphere, discharged to the atmosphere via vents or open process equipment, or discharged after diversion through a product recovery device.

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(c) 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 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).

**Support Document(s)**—see section II for titles.

**TDD**—Technical Development Document

**TEQ**—Toxic Equivalent.

**TSCA**—Toxic Substances Control Act (15 U.S.C. 2601, *et seq.*).

**TSS**—Total Suspended Solids.

**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**—Volatile Organic Compound—means any organic compound, excluding carbon monoxide, carbon dioxide, carbonic acid, metallic carbides or carbonates, and ammonium carbonate, which participates in atmospheric photochemical reactions other than those that the Administrator designates as having negligible photochemical reactivity. The Administrator has designated the following organic compounds as negligibly reactive: methane; ethane; methylene chloride; methyl chloroform; CFC-113; CFC-111; CFC-12; CFC-22; CFC-23; CFC-114; CFC-115; HCFC-123; HFC-134a; HCFC-141b; HCFC-142b; HCFC-124; HFC-125; HFC-134; HFC-143a; HFC-152a; and perfluorocarbon compounds which fall into these classes: (i) Cyclic, branched, or linear, completely fluorinated alkanes; (ii) cyclic, branched, or linear, completely fluorinated ethers with no unsaturations; cyclic, branched, or linear, completely fluorinated tertiary amines with no unsaturations; and (iv) sulfur containing perfluorocarbons with no unsaturations and with sulfur bonds only to carbon and fluorine. 40 CFR 51.100(s)(1).

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

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

## II. Background Documents

The rule proposed today is supported by several major documents: (1) EPA's technical conclusions concerning the wastewater regulations are detailed in the "Development Document for Proposed Effluent Limitations Guidelines and Standards for the Pharmaceutical Manufacturing Point Source Category," hereafter referred to as the Technical Development Document (TDD) (EPA 821-R-95-019), (2) the Agency's economic analysis is found in the "Economic Impact and Regulatory Flexibility Analysis of Proposed Effluent Guidelines for the Pharmaceutical Manufacturing Industry," hereafter called the Economic Impact Analysis (EPA 821-R-95-018), (3) the regulatory impact analysis (including the Agency's assessment of environmental benefits) is detailed in the "Regulatory Impact Assessment of Proposed Effluent Guidelines for the Pharmaceutical Manufacturing Industry," hereafter called the Regulatory Impact Assessment (EPA 821-R-95-017), (4) an analysis of the incremental costs and pollutant removals for the proposed effluent limitations guidelines and standards is presented in "Cost-effectiveness Analysis of Proposed Effluent Limitations Guidelines for the Pharmaceutical Manufacturing Industry," (EPA 821-R-95-015), (5) analytical methods used in the development of the proposed effluent limitations guidelines and standards are found in "Analytical Methods for the Determination of Pollutants in Pharmaceutical Manufacturing Industry Wastewater," a compendium of analytical methods (EPA 821-R-95-014), and (6) the statistical (EPA 821-R-95-016) support for today's proposed effluent limitations guidelines and standards is found in "Statistical Support Document for the Proposed Effluent Limitations Guidelines for the Pharmaceutical Manufacturing Industry."

## III. Legal Authority

This regulation is being proposed under the authority of sections 301, 304, 306, 307, 308, and 501 of the Clean Water Act, 33 U.S.C. 1311, 1314, 1316, 1317, 1318, and 1361.

## IV. Summary and Scope of the Proposed Rule

In today's notice, EPA proposes effluent limitations guidelines and standards for process wastewater generated by the pharmaceutical manufacturing industry. Section IX of this notice discusses the rationale for

the proposed guidelines and standards. This summary section highlights the technology bases and other key aspects of the proposed rule. The technology descriptions in this section are presented in abbreviated form; more detailed descriptions are included in the TDD.

Today's notice presents the Agency's proposed regulatory approach and several others that EPA considered. The Agency's proposal is based on comments received from interested parties during the development of this proposed rule, and on detailed evaluation of the available data. As indicated below in the discussion of the specifics of the proposal, the Agency welcomes comment on all options, issues, rationale, and proposed decisions and encourages commenters to submit additional data during the comment period (see section XIV of this preamble). In particular, the Agency welcomes comments on the treatment technologies that EPA has selected as the basis for the limitations and standards being proposed today. For example, EPA bases its proposed standards for new sources primarily on steam stripping with distillation technology. For most existing sources, EPA bases the proposed limitations and standards primarily on steam stripping technology, which is less costly and less energy intensive than distillation technology.

EPA expects a variety of human health, environmental, and economic benefits to result from these reductions in effluent loadings and, in some cases, air emissions. In particular, the benefits include: 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 risk; ecological and recreational benefits due to improved water quality; and benefits to publicly owned treatment works (POTWs) from reductions in interference, passthrough, and sludge contamination problems and improvements in worker health and safety. EPA monetized the estimated benefits for reductions in air emissions of ozone precursors and cancer risk reductions, but is unable to quantify the dollar magnitude of benefits from the other benefit categories. Therefore, the reported benefit estimate understates the total benefits of the proposed rule. EPA estimates that the annual benefits resulting from the proposed rule will range from \$231,000 to \$7.6 million (\$1994).

EPA has internally coordinated among relevant program offices in

developing this rule. Section X of this preamble describes close coordination between the Office of Water and the Office of Air and Radiation on this proposed water rule and an air rule that will be proposed at a later date for the pharmaceutical manufacturing industry. As explained in detail in Section X, the Agency intends that direct and indirect dischargers will be able to employ a single steam stripper design to achieve the requirements of both final rules. It is also the Agency's intent, upon promulgation, that both rules will apply to essentially the same high concentration, low volume process wastewater streams in which the bulk of the volatile organic pollutants are contained (see Section X for details). The practical effect of this approach will be that only a relatively small portion (i.e., substantially less than half) of all process wastewaters will require control of volatile organic pollutants (e.g., by steam stripping) to achieve compliance with both rules. In the air rule, EPA also will develop air emission standards for other emission points (e.g., process vents, process area fugitive emissions, etc.). Also, Section XII of this preamble describes coordination between the Office of Water and the Office of Solid Waste and Emergency Response regarding the hazardous waste implications of this proposed water rule, including recovering ignitable nonhalogenated organics and reusing them as "clean fuels."

The Agency has worked with the Food and Drug Administration (FDA) to explore pollution prevention opportunities to the maximum extent feasible. EPA shared with FDA information and data gathered from the industry in responses to EPA's detailed Section 308 questionnaire. This was done to assist FDA in evaluating the environmental impacts of revised drug manufacturing processes (as described in "supplement" applications) and of new drug manufacturing processes. These reviews will ensure that opportunities for solvent use minimization/elimination and water-based manufacturing processes (e.g., water-based tablet coating) are considered and adopted within the constraints of maintaining the efficacy of both existing and new pharmaceutical products.

EPA has involved stakeholders and interested parties, including state and local governments, in the process of developing this rule. Since the inception of the project in 1986, there have been periodic meetings with the industry and its trade association, the Pharmaceutical Research and Manufacturers of America (PhRMA), to

discuss progress on the rulemaking. The Agency also has met with the Natural Resources Defense Council (NRDC) to discuss progress on this rulemaking. Because most of the facilities affected by this proposal are indirect dischargers, the Agency conducted an outreach survey in 1990 to a limited number of POTWs substantially affected by one or more pharmaceutical manufacturing facilities to solicit their input on the need for this proposed rule and pertinent technical issues.

The Agency also held a public meeting on May 23, 1994. EPA representatives of the Office of Water and the Office of Air and Radiation outlined the underlying technical basis and options being considered for this proposal, the efforts to coordinate the future air rule and this proposed water rule, and took comments and questions from the audience. The Agency also consulted recently with representatives of selected POTWs regarding underlying technical aspects of this proposal.

The Agency plans to have additional discussions with stakeholders and interested parties during the comment period to minimize the potential for unfunded mandates and to help ensure that the Agency has the views of such parties and the best possible data upon which to base a decision for the final rule. EPA's final rule may be based upon any technologies, rationale or approaches that are a logical outgrowth of this proposal, including any options discussed in this or subsequent **Federal Register** documents.

#### *A. Effluent Limitations Guidelines and Standards*

##### *1. Subcategorization*

EPA is proposing to maintain the subcategorization scheme under the existing effluent limitations guidelines and standards for this industry (in part 439). The rationale for maintaining the existing subcategorization scheme is detailed in section IX.A.

##### *2. Best Practicable Control Technology Currently Available (BPT)*

EPA is proposing to revise the BPT effluent limitations guidelines for biochemical oxygen demand (BOD<sub>5</sub>), COD, and total suspended solids (TSS) for four subcategories of the pharmaceutical manufacturing industry. These proposed revisions are based on the application of advanced biological treatment. EPA also is proposing to revise the BPT effluent limitations guidelines for CN (Total Cyanide) for facilities with subcategory A and/or C operations, based on in-plant cyanide destruction technology. As discussed in

Section IX.E., below, EPA also is proposing to repeal the existing BPT cyanide limitations for facilities with subcategory B and/or D operations. The proposed BPT effluent limitations are defined by the performance of the average of the best plants in the subcategory. The development of proposed BPT effluent limitations is discussed in section IX.E.1 of this notice and in Section 8 of the TDD.

3. Best Conventional Pollutant Control Technology (BCT)

EPA is proposing to revise the BCT effluent limitations guidelines for BOD<sub>5</sub> and TSS for four subcategories of the pharmaceutical manufacturing industry. In all cases, the proposed BCT effluent limitations are equal to the proposed BPT effluent limitations. The development of proposed BCT effluent limitations is further explained in section IX.E.2.

4. Best Available Technology Economically Achievable (BAT)

The Agency is proposing to revise the BAT effluent limitations guidelines for four subcategories of the pharmaceutical manufacturing industry to control priority and nonconventional pollutants. Table IV.A-1 is a summary of the technology basis for the proposed BAT effluent limitations for each subcategory.

TABLE IV.A-1.—PROPOSED TECHNOLOGY BASIS FOR BAT EFFLUENT LIMITATIONS

Proposed subpart	Name of subcategory	Proposed technology basis
A .....	Fermentation .....	In-plant steam stripping and cyanide destruction followed by advanced biological treatment.
B .....	Natural Extraction .....	Advanced biological treatment.
C .....	Chemical Synthesis .....	In-plant steam stripping and cyanide destruction followed by advanced biological treatment.
D .....	Mixing/Compounding/Formulating .....	Advanced biological treatment. <sup>1</sup>

<sup>1</sup> Same technology basis as for proposed BPT limitations.

The pollutants that EPA proposes to regulate and the points of monitoring to establish compliance with the limitations vary for each subcategory and are described in sections IX.C and IX.E.3.

5. New Source Performance Standards (NSPS)

*a. Priority and Nonconventional Pollutants.* EPA is proposing revised NSPS for four subcategories of the pharmaceutical manufacturing industry. For facilities with subcategory A and/or C and B and/or D operations, EPA is proposing NSPS to be more stringent than the proposed BAT effluent

limitations and is basing those standards primarily on steam stripping with distillation technology. The development of proposed NSPS for priority and nonconventional pollutants is discussed in section IX.E.4.

*b. Conventional Pollutants.* EPA is proposing to revise NSPS pertaining to discharges of BOD<sub>5</sub>, COD and TSS for four subcategories of the pharmaceutical manufacturing industry at a level equal to the discharge characteristics of the best performing plant. A summary of the pollutants and subcategories proposed to be regulated is presented in section IX.C. The development of proposed

NSPS for conventional pollutants and COD is discussed in section IX.E.4.

6. Pretreatment Standards for Existing Sources (PSES)

EPA is proposing to revise PSES for four subcategories of the pharmaceutical manufacturing industry for the priority and nonconventional pollutants to be controlled by technologies summarized in Table IV.A-2. EPA also co-proposes two different pass-through determinations for 33 less strippable volatile organic pollutants. PSES are further discussed in section IX.E.5.

TABLE IV.A-2.—PROPOSED TECHNOLOGY BASIS FOR PSES EFFLUENT LIMITATIONS

Proposed subpart	Name of subcategory	Proposed technology basis
A .....	Fermentation .....	In-plant cyanide destruction; in-plant steam stripping.
B .....	Natural Extraction .....	In-plant steam stripping.
C .....	Chemical Synthesis .....	In-plant cyanide destruction; in-plant steam stripping.
D .....	Mixing/Compounding/Formulating .....	In-plant steam stripping.

7. Pretreatment Standards for New Sources (PSNS)

EPA is proposing to revise PSNS for four subcategories of the pharmaceutical manufacturing industry for the same priority and nonconventional pollutants controlled by the proposed PSES, but based on steam stripping with distillation technology. As under PSES, EPA co-proposes two different pass-through determinations for 33 less strippable volatile organic pollutants.

PSNS are further discussed in section IX.E.6.

8. Best Management Practices (BMPs)

The Agency is not proposing today BMPs for the pharmaceutical manufacturing point source category. However, the Agency is soliciting comment on whether BMPs are applicable to pharmaceutical manufacturing facilities and, if so, what they should be. See Section XIV of this preamble, solicitation number 31.

*B. Scope of the Proposed Rule*

The rule proposed today covers four subcategories of the pharmaceutical manufacturing point source category. As discussed in Section IX.A.4, below, EPA does not propose to revise the effluent limitations guidelines applicable to Subcategory E (Pharmaceutical Research) facilities and subcategory E operations at facilities with subcategory A through D operations. These activities will be covered by the existing BPT effluent limitations regulations for this

subcategory and subject to BAT and BCT limitations, where appropriate, set on a case-by-case basis using best professional judgment (BPJ).

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 this proposal include:

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 if they are manufactured by a pharmaceutical manufacturer by processes that generate wastewaters that in turn closely correspond to those of pharmaceutical products;

g. Cosmetic preparations covered by SIC Code No. 2844 that function as a skin treatment. (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, and shaving preparations that do not function primarily as a skin treatment.); and

h. Pharmaceutical research that includes biological, microbiological, and chemical research, product development, clinical and pilot-scale activities. (This does not include farms that breed, raise, and/or hold animals

for research at another site. This also does not include ordinary feedlot or farm operations utilizing feed that contains pharmaceutically active ingredients.) Pilot-scale and product development operations conducted at research facilities would be subject to the specific manufacturing subcategory limitations and standards corresponding to the subcategory wastewater that the research facility's wastewater resembles. For example, a pilot chemical synthesis operation that generates wastewater that is similar to wastewater generated by chemical synthesis manufacturing would be subject to the subcategory C limitations and standards.

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 pharmaceuticals manufacturing category may be found in section 2 of the TDD.

## V. Background

### A. Clean Water Act

#### 1. Statutory Requirements of Regulations

The objective of the Clean Water Act (CWA) is to "restore and maintain the chemical, physical, and biological integrity of the Nation's waters". Section 101(a) of the CWA. To assist in achieving this objective, EPA issues effluent limitations guidelines, pretreatment standards, and new source performance standards for industrial dischargers. These guidelines and standards are summarized below:

a. *Best Practicable Control Technology Currently Available (BPT)*—section 304(b)(1) of the CWA. BPT effluent limitations guidelines apply to all discharges from existing direct dischargers. BPT guidelines are based on the average of the best performance achieved by plants in a category or subcategory utilizing currently available technology. In establishing BPT, EPA considers the cost of achieving effluent reductions in relation to the effluent reduction benefits, the age of equipment and facilities, 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 CWA. Where existing performance is uniformly inadequate within a category or subcategory, BPT may be transferred from a different subcategory or category.

b. *Best Conventional Pollutant Control Technology (BCT)*—section 304(b)(4) of the CWA. The 1977 amendments to the CWA established BCT as an additional level of control for discharges of conventional pollutants from existing industrial point sources. Section 304(a)(4) designates the following as conventional pollutants: biochemical oxygen demanding pollutants (measured as BOD<sub>5</sub>), 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). See 40 CFR 401.16. In addition to other factors specified in section 304(b)(4)(B), the CWA requires that BCT limitations be established in light of a two part "cost-reasonableness" test. EPA issued a methodology for the development of BCT limitations on July 9, 1986 (51 FR 24974).

c. *Best Available Technology Economically Achievable (BAT)*—section 304(b)(2) of the CWA. In general, BAT effluent limitations guidelines represent the best economically achievable performance of plants in the industrial subcategory or category, based on available technology. The CWA establishes BAT as a principal means of controlling the direct discharge of toxic and nonconventional pollutants to waters of the United States. 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. 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 category or subcategory. BAT may be based upon process changes or internal controls, even when these technologies are not common industry practice.

d. *New Source Performance Standards (NSPS)*—section 306 of the CWA. NSPS are based on the best available demonstrated treatment 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 controls attainable through the application of the best available control technology for all pollutants (i.e., 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.

*e. Pretreatment Standards for Existing Sources (PSES)—section 307(b) of the CWA.* 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 CWA authorizes EPA to establish pretreatment standards for pollutants that pass through POTWs or interfere with treatment processes or sludge disposal methods at POTWs. Pretreatment standards are technology-based and are analogous to BAT effluent limitations guidelines. See Section IX.E.5. (ii) for discussion of EPA's pass-through methodology.

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 establish pretreatment standards that apply to all nondomestic dischargers. For national instances of pass-through, EPA performs an analysis based on the procedures set forth at 52 FR 1586 (January 14, 1987).

*f. Pretreatment Standards for New Sources (PSNS)—section 307(b) of the CWA.* Like PSES, PSNS are designed to prevent the discharge of pollutants that pass through, interfere with, or are otherwise incompatible with the operation of a POTW. PSNS are to be issued at the same time as NSPS. New indirect 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.

*g. Best Management Practices (BMPs).* Section 304(e) of the CWA gives the Administrator the authority to publish regulations, in addition to the effluent limitations guidelines and standards listed above, to control plant site runoff, spillage or leaks, sludge or waste disposal, and drainage from raw material storage that the Administrator determines are associated with or ancillary to the industrial manufacturing or treatment process of the regulated point source category and that she (he) determines may contribute significant amounts of pollutants to waters of the United States.

## 2. Prior Regulations

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–E). The five subcategories of the pharmaceutical manufacturing industry (40 CFR 439) are:

- 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 BOD<sub>5</sub> and 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 total suspended solids (TSS) limitations 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 promulgated revised BPT and BAT, PSES, and PSNS regulations for Subparts A–D covering the toxic pollutant cyanide and the conventional pollutants BOD<sub>5</sub>, TSS and pH and the nonconventional pollutant COD. The 1983 regulations kept intact the percent reduction regulations for BOD<sub>5</sub> and COD established in 1976 but added floor concentration-based limitations for these parameters applicable to subcategories B and D. In addition, limitations for TSS based on each plant's BOD<sub>5</sub> discharge were promulgated for subcategories A–D. EPA also promulgated BPT, BAT, PSES and PSNS for pH (6.0–9.0) and BAT concentration-based limitations controlling the discharge of cyanide from subcategory A–D plants. The Agency also proposed NSPS for BOD<sub>5</sub>, TSS and pH in the October 1983 notice, but did not publish NSPS for these parameters. That proposal is being replaced by today's NSPS proposal.

On December 16, 1986, at 51 FR 45094, EPA promulgated BCT effluent limitations for BOD<sub>5</sub>, TSS and pH for

subcategories A–D. That final rule set BCT effluent limitations equal to the existing BPT effluent limitations for BOD<sub>5</sub>, TSS, and pH.

## 3. Litigation History

The effluent limitations guidelines and standards for the pharmaceutical manufacturing industry have never been the subject of litigation.

## 4. Section 304(m) Requirements

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 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 (D.D.C.)). (The suit originally challenged EPA's failure to publish the plan by the statutory deadline.) The plaintiffs charged that EPA's plan did not meet the requirements of section 304(m). On January 31, 1992, EPA entered into a consent decree (the "304(m) Decree"), which established schedules for, among other things, EPA's proposal and promulgation of approximately 20 effluent guidelines including those for the pharmaceutical manufacturing point source category.

On May 18, 1994, the Agency published a second plan (see 59 FR 25859). The plan projected proposal and promulgation dates for several industrial categories including the pharmaceutical manufacturing category.

## B. Clean Air Act

Title III of the 1990 Clean Air Act Amendments was enacted to reduce the amount of nationwide emissions of hazardous air pollutants. It comprehensively amended section 112 of the Clean Air Act (CAA).

Section 112(b) lists the 189 chemicals, compounds, or groups of chemicals deemed by Congress to be hazardous air pollutants (HAPs). These toxic air pollutants are to be regulated by national emission standards for hazardous air pollutants (NESHAP). Section 112(c) requires the

Administrator to use this list of HAPs to develop and publish a list of source categories for which NESHAP will be developed. EPA must list all known categories and subcategories of "major sources."

The term major source is defined in paragraph 112(a)(1) to mean 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 (tons/yr) or more of any HAP or 25 tons/yr or more of any combination of HAPs. The term stationary source, from section 111 of the CAA, means any building, structure, facility, or installation that emits or may emit any air pollutant. The term area source, as defined in section 112(a)(2), means any stationary source of HAPs that is not a major source.

Notice of the initial list of categories of major and area sources of HAPs was published on July 16, 1992 (57 FR 31576), under authority of section 112(c). This notice listed pharmaceutical manufacturing as a category of major sources of HAPs. Notice of the schedule for the promulgation of emission standards for the listed categories, under authority of section 112(e), was given on December 3, 1993 (58 FR 63941). Under this notice, emission standards for the pharmaceutical production industry would be promulgated no later than November 15, 1997.

Section 112(d) of the CAA directs the Administrator to promulgate emission standards for each category of HAP sources listed under section 112(c). Such standards are applicable to both new and existing sources and must require the maximum degree of reduction in emissions of the hazardous air pollutants subject to this section (including a prohibition on such emissions, where achievable) that the Administrator, taking into consideration the cost of achieving such emission reduction, and any non-air quality health and environmental impacts and energy requirements, determines is achievable for new and existing sources in the category or subcategory to which such emission standard applies. See 42 U.S.C. 7412(d)(2).

Section 112(d)(3) provides that the maximum degree of reduction in emissions that is deemed achievable for new sources shall not be any less stringent than the emission control that is achieved in practice by the best controlled similar source. For existing sources, the standards may not be less stringent than the average emission limitation achieved by the best

performing 12 percent of existing sources in each category of 30 or more sources.

Once this minimum control level (referred to as the floor) has been determined for new or existing sources for a category, the Administrator must set a standard based on maximum achievable control technology (MACT) that is no less stringent than the floor. The Administrator may set MACT standards that are more stringent than the floor if such standards are achievable considering the cost, environmental, and other impacts listed in section 112(d)(2). Such standards must then be met by all sources within the category.

#### *C. Resource Conservation and Recovery Act (RCRA)*

Subtitle C of RCRA, 42 U.S.C. 6921–39b, directs EPA to establish a comprehensive "cradle to grave" system regulating the generation, transport, storage, treatment and disposal of hazardous wastes. The hazardous wastes subject to this comprehensive management scheme include any solid waste, or combination of solid wastes, that because of its quantity, concentration, or physical, chemical, or infectious characteristics may cause or significantly contribute to an increase in mortality or an increase in serious irreversible, or incapacitating reversible, illness; or pose a substantial present or potential hazard to human health or the environment when improperly treated, stored, transported, or disposed of, or otherwise managed. 42 U.S.C. 6903(5).

RCRA defines "solid waste" to include any garbage, refuse, sludge from a waste treatment plant, water supply treatment plant, or air pollution control facility and other discarded material. 42 U.S.C. 6903(27). The Act does not specify what characteristics of a waste render it hazardous to human health or the environment; instead, it directs EPA to develop and promulgate criteria for identifying the characteristics of hazardous waste and for listing hazardous waste, taking into account toxicity, persistence, and degradability in nature, potential for accumulation in tissue, and other related factors such as flammability, corrosiveness, and other hazardous characteristics. 42 U.S.C. 6921. Pursuant to this directive, EPA has adopted a two track scheme for identifying hazardous wastes. So-called "characteristic wastes," regulated under 40 CFR 261.20–24, exhibit at least one of four specified characteristics: ignitability, corrosivity, reactivity, or toxicity. Such wastes are deemed automatically subject to regulation under RCRA subtitle C, and retain the

designation of hazardous waste until they cease to exhibit any of the characteristics. See 40 CFR 261.3(d)(1).

The other type of hazardous wastes, "listed wastes," comprises wastes specifically classified as hazardous by EPA rule. See 40 CFR 261.11 (setting out criteria EPA considers in determining whether a solid waste should be a listed hazardous waste). Under EPA regulations, a listed hazardous waste retains that classification, even if has been treated in some fashion, until the waste has been demonstrated to be no longer hazardous. See 40 CFR 261.3(c)–(d) (the "derived-from" rule).

Once a waste has been identified or listed by EPA, RCRA permits its disposal on the land if the waste has been treated to meet standards established by EPA pursuant to 42 U.S.C. 6924(m). Section 6924(m)(1) instructs EPA to specify those levels or methods of treatment, if any, that substantially diminish the toxicity of the waste or substantially reduce the likelihood of migration of hazardous constituents from the waste so that short-term and long-term threats to human health and the environment are minimized. EPA has concluded that requiring hazardous wastes to be treated in accordance with the best demonstrated available technology ("BDAT") is sufficient to satisfy this criterion. See 51 FR 40,572, 40,578 (1986). These standards can apply even after a characteristic waste no longer exhibits a characteristic. 40 CFR 261.3(d)(1).

In addition to meeting treatment standards before land disposal, hazardous wastes are also subject to cradle-to-grave control from point of generation to point of final disposition. Generators prepare manifests to assure proper tracking of all hazardous wastes. Facilities treating, storing or disposing of such wastes are subject to design and operating standards established by EPA. Such standards ordinarily are embodied in an operating permit issued by EPA to the facility. In addition to meeting design and operating standards, facilities must commit sufficient money to assure that the facility will be properly closed, or that proper post-closure care of the wastes will occur.

#### *D. Pollution Prevention Act of 1990*

In the Pollution Prevention Act of 1990 (42 U.S.C. 13101 *et seq.*), Congress declared pollution prevention the national policy of the United States. The Pollution Prevention Act declares that pollution should be prevented or reduced whenever feasible; pollution that cannot be prevented should be recycled or reused 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 other release into the environment should be chosen only as a last resort and should be conducted in an environmentally safe manner. See 42 U.S.C. 13101(b).

Today's proposed rule is consistent with this policy. The technology basis for the proposed NSPS and PSNS for facilities with subcategory A, B, C and/or D operations includes steam stripping with distillation. Today's proposed PSES for facilities with subcategory A, B, C and/or D operations, as well as today's proposed BAT limitations for facilities with subcategory A and/or C operations, are based on steam stripping. Both technologies allow for the recovery from wastewaters and possible reuse of organic solvents. As part of today's proposal, the Agency also investigated whether solvent use could be minimized and/or eliminated through process changes but concluded that such opportunities may be limited to specific process operations at some facilities. The Agency encourages research regarding solvent use reduction and/or elimination procedures for existing as well as future pharmaceutical manufacturing operations. The Agency solicits comment on process change (source reduction) opportunities for pharmaceutical manufacturing and products. See section XIV, solicitation number 12.0.

#### *E. Common Sense Initiative*

On August 19, 1994, the Administrator established the Common Sense Initiative (CSI) Council in accordance with the Federal Advisory Committee Act (U.S.C. App. 2, Section 9(c)) requirements. A principal goal of the CSI includes developing recommendations for optimal approaches to multi-media controls for six industrial sectors including Metal Plating and Finishing, Electronics and Computers, Auto Manufacturing, and Iron and Steel Manufacturing. The following are the six overall objectives of the CSI program, as stated in the "Advisory Committee Charter."

1. Regulation. Review existing regulations for opportunities to get better environmental results at less cost. Improve new rules through increased coordination.

2. Pollution Prevention. Actively promote pollution prevention as the standard business practice and a central ethic of environmental protection.

3. Recordkeeping and Reporting. Make it easier to provide, use, and

publicly disseminate relevant pollution and environmental information.

4. Compliance and Enforcement. Find innovative ways to assist companies that seek to comply and exceed legal requirements while consistently enforcing the law for those that do not achieve compliance.

5. Permitting. Improve permitting so that it works more efficiently, encourages innovation, and creates more opportunities for public participation.

6. Environmental Technology. Give industry the incentives and flexibility to develop innovative technologies that meet and exceed environmental standards while cutting costs.

The pharmaceutical manufacturing rulemaking effort was not among those included in the Common Sense Initiative. However, the Agency believes that the CSI objectives already have been incorporated into the pharmaceutical manufacturing industry rulemaking. Nonetheless, given the multimedia considerations affecting this rulemaking, the Agency will continue to pursue these objectives. The Agency particularly will focus on avenues for giving state and local authorities flexibility in implementing this rule, and giving the industry flexibility to develop innovative and cost-effective compliance strategies. In developing this rule, EPA took advantage of several opportunities to gain the involvement of various stakeholders. Section XIII.F of this preamble describes consultations with state, local, and tribal governments and other parties including the industry. EPA has internally coordinated among relevant program offices in developing this rule. Section X of this preamble describes coordination between the Office of Water and the Office of Air and Radiation concerning this proposed water and a related air rule that will be proposed at a later date. Also, Section XII of this preamble describes coordination between the Office of Water and the Office of Solid Waste and Emergency Response regarding the hazardous waste implications of this proposed water rule. See Section XIV of this preamble for pertinent comment and data solicitations. The effluent guideline development process for the pharmaceutical manufacturing industry will continue to implement the principles of the Common Sense Initiative.

#### **VI. Regulatory Development Under the Clean Water Act**

This section describes the Agency's approach for developing proposed effluent limitations guidelines and standards applicable to the

pharmaceutical manufacturing industry under the CWA. In developing this rule, EPA first collected information about the industry, next identified potential control and treatment technology bases for the effluent limitations and standards EPA proposes to establish, and then, using methodologies, assumptions, and data described in the economic and regulatory impact analyses (See Section XI of this preamble), estimated and analyzed the total environmental and economic impacts of basing limitations and standards on various combinations of these control technologies. Finally, EPA selected the control technologies upon which it based the proposed effluent limitations and standards.

#### *A. Background*

The pharmaceutical manufacturing industry releases significant amounts of pollutants to surface waters, and POTWs, and ambient air. Section V of this notice discusses in greater detail the legal authorities available to EPA to address these pollutant releases.

#### *B. Goals*

EPA has several technical and policy goals regarding the development of the proposed effluent limitations guidelines and standards. These goals include: (1) Protecting the public health and the environment by attaining significant reductions in pharmaceutical manufacturing industry pollutant releases to water and other media; (2) minimizing the cost of complying with the rule; (3) promoting and facilitating coordinated compliance planning within the industry; (4) promoting and facilitating pollution prevention; and (5) taking into account the multimedia nature of pollution control.

In light of the multimedia nature of the environmental releases from this industry, the Agency has closely coordinated this effluent guidelines rulemaking with the rulemaking and related activities of the Office of Air and Radiation (OAR) and the Office of Solid Waste and Emergency Response (OSWER).

#### *C. Technical Approach*

##### **1. Information Collection**

EPA's first step in developing these proposed regulations was to develop a plant-specific database, using information gathered under section 308 of the CWA, of all facilities potentially subject to the limitations and standards. See Section VIII below. Information and data were gathered by EPA from a number of sources, including EPA's wastewater sampling program, the 1989

screeener questionnaire, and the 1990 survey questionnaire. The information collected includes the processes and control technologies in use, current control levels, and pollutant releases. EPA also updated survey data through telephone calls and letters to specific facilities in an attempt to ensure that the database reasonably reflects the current status of the industry. The Agency recognizes that the industry is dynamic, and that processes and equipment change over time. Accordingly, EPA will consider information and data submitted in a timely manner by interested parties in response to this proposal for the purpose of updating the database prior to promulgation.

EPA placed information collected about the industry into plant-specific databases. These databases consist mainly of the 1990 survey responses provided by 244 plants but also contain information from EPA's sampling program. EPA then estimated costs of implementing the proposed technology bases in order to analyze the economic impacts of achieving the proposed effluent limitations guidelines and standards. The Agency used the plant-specific databases and other components to calculate wastewater discharges and the costs of complying with the proposed effluent limitations and standards. This comprehensive information provides a strong basis for ensuring that the proposed regulations meet the statutory requirements, and allows consideration of other factors such as multimedia pollutant reduction.

## 2. Summary of Public Participation

Beginning in 1989, EPA met on at least a biennial basis with industry representatives from the Pharmaceutical Research and Manufacturers of America (PhRMA) to discuss the development of the screener and detailed questionnaires that EPA intended to distribute under section 308 of the CWA. The Agency received input from the industry representatives that was invaluable in the development of these information collection instruments. Following the completion of the screener and detailed questionnaires, EPA has continued to meet informally with PhRMA representatives to discuss progress in the rulemaking effort. EPA has also met informally with the Natural Resources Defense Council regarding this rulemaking and has made available to environmental groups and other members of the public the information that was provided to the industry.

On May 23, 1994, EPA held a public meeting on the pharmaceutical rulemaking (see 59 FR 21740, April 26, 1994). Following the meeting EPA sent

copies of revised meeting handout materials to all attendees and to interested parties who could not attend. In addition, by letter dated August 12, 1994, EPA provided written responses to questions submitted by PhRMA concerning issues raised at the public meeting. These documents are in the rulemaking docket.

## 3. Development of Effluent Limitations Control Technology Options

After evaluating a variety of control and treatment technologies and their use in the industry, EPA selected BPT, BAT, BCT, PSES, NSPS, and PSNS control technology options upon which it bases this proposed rule. This process is described in Section IX of this notice.

## 4. Analyses of Regulatory Alternatives

EPA conducted a series of analyses to assess the economic and environmental impacts of various combinations of BPT, BCT, BAT, NSPS, PSES, and PSNS control options. EPA then compared the projected effluent loadings and air emissions resulting from each regulatory alternative to baseline pollutant releases estimated as of January 1, 1991, based on the 1990 survey data. EPA also estimated the costs of implementing the various control options and other environmental and economic impacts for each alternative above the baseline level of control which EPA determined as treatment technologies in place in 1990. EPA evaluated each alternative in order to determine the effectiveness of the control technologies represented and to ascertain the reductions in effluent loadings and air emissions below the baseline that each control technology option could attain. The Agency also determined the environmental effects of these technologies with a goal toward minimizing the cross-media transfer of pollutants between water and air.

EPA also evaluated the possibility of basing BAT and PSES on process changes involving solvent use minimization or elimination. After evaluating information provided in response to the section 308 detailed questionnaire survey regarding pollution prevention measures on-going at pharmaceutical manufacturing facilities, the Agency concluded that no option involving solvent use elimination or minimization is technically available at this time. Nonetheless, the Agency is encouraging the industry to conduct research into eliminating or minimizing the use of solvents for existing processes and to design future manufacturing processes that eliminate or minimize the use of

volatile solvents. See Section XIV, solicitation number 12.0.

## VII. Description of the Industry

### A. Pharmaceutical Manufacturing Facilities

Presented below is a brief description of the pharmaceutical manufacturing industry. Other characteristics of the industry are detailed in Sections IX.B., IX.C., IX.D., and IX.E. of this notice and in Section 3 of the TDD. Based upon responses to EPA's 1989 Screener Survey of Pharmaceutical Manufacturing Facilities, the Agency estimates that there are 566 manufacturing facilities located in 39 States, Puerto Rico, and the Virgin Islands. The major pharmaceutical manufacturing areas in the U.S. are the Northeast, the Midwest, and Puerto Rico.

### B. Manufacturing Processes

#### 1. Fermentation

Fermentation is the usual method for producing most steroids and antibiotics. The fermentation process involves three basic steps: inoculum and seed preparation, fermentation or growth, and product recovery. Production of a pharmaceutically active ingredient begins with spores from the plant master stock. The spores are activated with water, nutrients, and warmth and are then propagated through the use of agar plates, test tubes, and flasks until enough mass is produced for transfer to the seed tank. Following adequate propagation in the seed tank, microorganisms from the seed tank are transferred to a fermenter tank along with the sterilized nutrients and the tank is then sparged with air to begin the fermentation or growth process. After a period ranging from 12 hours to a week, depending on the specific process, the fermenter batch whole broth is ready for filtration, which removes mycelia (i.e., the remains of the microorganisms). The filtered aqueous broth containing product and residual nutrients is then ready to enter the product recovery phase.

There are three common methods of product recovery: solvent extraction, direct precipitation, and ion exchange or adsorption. The most common method, solvent extraction, involves the use of an organic solvent to remove or extract the pharmaceutically active ingredient or product from the aqueous broth. Numerous solvent extractions are usually necessary to remove an acceptable yield of product from the contaminant mixture. Another common recovery method, direct precipitation, involves the use of aqueous solutions of

heavy metals such as copper and zinc to precipitate the product as a metal salt from the aqueous broth, after which the broth is filtered and the product is extracted from the solid residue. Ion exchange or adsorption involves removal of the product from the broth using solid materials such as ion exchange resin, adsorptive resin or activated carbon to bond with the product. The product is extracted from the solid phase material using solvent extraction followed by solvent evaporation.

## 2. Biological and Natural Extraction

Biological and natural extraction is used to manufacture pharmaceutically active ingredients whose molecular structure is too complex for chemical synthesis or fermentation methods. Extraction involves the collection and processing of large volumes of plant or animal matter to produce small quantities of product. Initially, this large volume material is subject to a large, usually organic solvent-based, extraction procedure to obtain a first product cut or extraction. This cut is purified in many successive extraction operations. At each stage of the extraction process, the volume of material used becomes smaller. In the end, the volume of product may be only a few thousandths of the mass of material handled in the earlier procedures. Generally, the yield from extraction procedures is very small and pharmaceutical companies use extraction only when they have no other alternative.

Recently, pharmaceutical manufacturers have been developing bioengineered microorganisms that can produce pharmaceutically active ingredients. Pharmaceutical manufacturers sometimes use extraction procedures to obtain and purify these ingredients, but EPA understands generally that the amounts of water and solvents used in these procedures at this time are minimal. Nonetheless, EPA is soliciting information and data to better characterize wastewaters from these operations (see Section XIV at solicitation number 11.0).

## 3. Chemical Synthesis

Chemical synthesis involves the use of a series of chemical reactions to produce pharmaceutically active ingredients, usually starting with common feedstock chemicals as raw materials. The product of each successive chemical reaction then becomes the reactant in the next chemical reaction until the final reaction step of the synthesis is reached when the pharmaceutically active

ingredient product is generated. More pharmaceutically active ingredients are manufactured by chemical synthesis than by any other process.

## 4. Mixing/Compounding/Formulating

Before active ingredients can be used as pharmaceuticals, they must be prepared in dosage forms. The primary dosage forms utilized by the industry include tablets, capsules, liquids and ointments. For example, in tablet-making, manufacturers blend pharmaceutically inactive materials filler (e.g., starch) and binder (e.g., corn starch) with the active ingredient(s) and form tablets using a tablet press machine. Mixing, compounding, and formulating operations are utilized by more plants than any other process operation.

## VIII. Summary of Data Gathering Efforts

### A. Technical and Economic Data

#### 1. 1989 Screener Survey of the Pharmaceutical Industry

In 1988, the Agency developed a short questionnaire for distribution to all known or suspected pharmaceutical manufacturers. The purpose of the questionnaire was to identify facilities that could be affected by future effluent limitations guidelines and standards applicable to the pharmaceutical manufacturing industry. The Information Collection Review (ICR) package for this questionnaire was sent to OMB in May 1989 and approved in June 1989. The questionnaire was sent to 1163 facilities in July of 1989. The Agency received 962 responses.

#### 2. 1990 Pharmaceutical Manufacturing Industry Survey

In early 1989, EPA began to develop a questionnaire to gather the technical and financial information necessary for this rulemaking. EPA met with industry representatives during the questionnaire development process in an effort to keep the industry informed of the Agency's plans and to solicit informed comments on questionnaire design. Before pretesting the questionnaire, EPA sent a preliminary version of the questionnaire to the Pharmaceutical Manufacturers Association (now known as the Pharmaceutical Research and Manufacturers of America) for distribution and review by representatives of member companies. The Agency then incorporated all appropriate comments of the industry representatives into a pretest version of the questionnaire. In 1990, EPA sent pretest versions of the questionnaire to eight facilities for response and

comment. Along with their responses, the pretest candidates provided information on the amount of time required to complete the questionnaire and suggestions for improving the questionnaire as an information gathering instrument.

The pretest suggestions were used to develop a final version of the questionnaire, which was part of an ICR package that was sent to OMB for approval in May 1990. In August of that year, OMB cleared part A (technical section) of the questionnaire and some questions in part B (economic and financial) but denied clearance for most of the part B plant-specific financial and economic questions. In order to accommodate OMB's and industry's concerns about the need for responses to plant-specific economic and financial questions, the Agency developed a certification procedure. This procedure allowed industry respondents to certify that future pharmaceutical category regulations would not impact their facility above a certain dollar amount. A respondent making the certification was not required to respond to most of the part B questions.

In May 1991, the Agency submitted a revised ICR package to OMB, including the certification option discussed above. OMB approved the questionnaire and EPA sent the final questionnaire to 280 facilities in September 1991. EPA received responses from 244 of the 304 facilities still engaged in pharmaceutical manufacturing with solvent use.

### 3. Sampling and Analytical Program

Between 1986 and 1991, EPA conducted a sampling program at 13 pharmaceutical manufacturing facilities to: (1) Characterize the pollutants in the wastewater being discharged directly to surface waters and indirectly to POTWs; (2) generate pollutant treatment system performance data from facilities with well-operated advanced biological treatment systems (those systems attaining better than BPT annual average effluent quality); and (3) obtain treatability data from steam stripping units.

Prior to 1986, the Agency had focused on five conventional pollutants and 126 priority pollutants in the pharmaceutical manufacturing industry's wastewater. Beginning in 1986, the Agency expanded the analysis of pharmaceutical wastewater and wastewater treatment plant sludges to determine the presence and levels of all the pollutants on the "Industrial Technology Division (ITD) List of Analytes" (hereinafter, the "List of Analytes").

During the sampling program, EPA gathered analytical data to characterize the wastewater from five direct dischargers and eight indirect dischargers. Treatment system performance data were gathered from three advanced biological treatment systems and two biological pretreatment systems. Treatment unit performance data documenting the performance of five steam stripping columns were also gathered. The performance of one resin adsorption column and one cyanide destruction unit was also documented.

*a. Bench-, Pilot-, and Full-Scale Studies.* Between October and December 1991, EPA conducted bench-scale and pilot-scale tests to study: (1) Air stripping technology (with ammonia capture) for ammonia removal from pharmaceutical plant final effluent; and (2) steam stripping technology for removal of volatile organic pollutants from pharmaceutical plant process wastewaters.

EPA conducted the air stripping and steam stripping pilot studies at a pharmaceutical manufacturing facility with fermentation, chemical synthesis, formulation, and research operations. The objective of the air stripping study was to examine the feasibility of obtaining at least 90 percent ammonia removal using air stripping technology. A portion of the total facility effluent was used as the feed to the pilot-scale air stripping study.

The objectives of the steam stripping study were to demonstrate the achievement of the lowest practical concentrations of volatile organic pollutants in the treated effluent, using the available bench- and pilot-scale steam stripping test equipment, and to collect sufficient data to document these concentrations using the available bench- and pilot-scale data. On-site pilot-scale testing was conducted for two of the three streams. EPA elected not to run pilot-scale tests on one of the streams because the stream flow from that process area was insufficient for pilot-scale testing during the study time period. Performance data for this third process wastewater stream were collected using bench-scale equipment.

In September 1993, EPA conducted an on-site treatment performance study using a pharmaceutical manufacturing facility's existing distillation column that treated wastewaters containing methanol. The objective of the study was to achieve the lowest practical concentrations of methanol (within the operating constraints of the facility) in the treated effluent and to collect sufficient data to document these concentrations. All of the studies are

discussed in more detail in sections 5 and 8 of the TDD.

#### *B. Air Emission Data*

In July 1993, pursuant to section 114 of the Clean Air Act, EPA distributed questionnaires seeking data on air emissions to 396 pharmaceutical manufacturing facilities. The scope of the survey included all manufacturing operations that were covered by the SIC Code Nos. 2833, 2834, and 2836 and that also emitted hazardous air pollutants. Research facilities were not included. The questionnaire requested production data, process flow diagrams, emissions data, emission control technology data, and information on source reduction measures. EPA will use this data and information in developing standards to be promulgated under the Clean Air Act for the pharmaceutical manufacturing industry. EPA will compare these data and information, to the extent it is appropriate, to the data and information collected under the Clean Water Act to ensure that the best and most consistent data are used in both rulemaking efforts. See Section X below.

### **IX. Development of Effluent Limitations Guidelines and Standards**

#### *A. Industry Subcategorization*

##### 1. Introduction

In developing today's proposed rule, EPA considered whether different effluent limitations and standards were appropriate for different groups of plants or subcategories within the pharmaceutical manufacturing industry. Factors considered included: processes employed, effluent characteristics, costs, age of equipment and facilities, size, location, engineering aspects of the application of various types of control techniques, process changes, and non-water quality environmental impacts. In determining which subcategories were appropriate for this proposed rule, EPA, using recently available data, evaluated the scheme for establishing subcategories regulated under the current effluent limitations guidelines and standards applicable to this industry.

##### 2. Current Subcategorization

The current subcategorization of this industry dates back to 1976 and was developed using data from the mid-1970s. The current subcategories are as follows:

- Subpart A Fermentation
- Subpart B Biological and Natural Extraction
- Subpart C Chemical Synthesis
- Subpart D Mixing/Compounding/  
Formulating

Subpart E Pharmaceutical Research

##### 3. Rationale for Maintaining the Current Subcategorization

Prior to finalizing the 1983 regulation, the Agency evaluated the original subcategorization scheme developed for the 1976 interim final regulations. This evaluation is discussed in section 4 of the 1983 technical development document and in the preamble to the final regulation at 48 FR 49808 (October 27, 1983). The Agency concluded at that time that the original subcategorization scheme based on manufacturing process type was the most appropriate one for the Pharmaceutical Manufacturing Point Source Category. In determining whether this scheme is appropriate for the rule being proposed today, the Agency evaluated the wastewater and production data obtained from the detailed questionnaire responses as well as plant sampling data in light of the current scheme. The Agency compared the wastewater flow and pollutant characteristics data (influent and effluent BOD<sub>5</sub>, TSS, and COD) obtained from the 1990 detailed questionnaire responses with the data presented in Section 4 of the 1983 TDD. EPA concluded that the similarities and data trends reported for both subcategory A and C and subcategory B and D facilities were identical to those reported in 1983 for analogous data. Consequently, the Agency concluded that the current subcategorization scheme continues to be appropriate for today's proposed rule. As was the case with the 1983 final regulation, the limitations and standards being proposed today for subcategory A are identical to those proposed for subcategory C and those limitations and standards being proposed for subcategory B are identical to those being proposed for subcategory D. The Agency invites comments regarding this regulatory scheme. The subcategorization analysis is discussed in more detail in section 4 of the TDD for this rulemaking. See Section XIV, solicitation number 4.0.

##### 4. Subcategory Regulation Not Revised

EPA is not proposing new or revised effluent limitations and standards for the Pharmaceutical Research Subcategory (Subcategory E). Rather, research activities falling within this subcategory will continue to be subject to the BPT regulations established for that subcategory in the 1983 regulations for this industry. The 1983 regulations did not establish BCT, BAT, NSPS, PSES, or PSNS effluent limitations and standards for the research subcategory, and today's proposed revisions to 40

CFR part 439 will not change this. However, process wastewater generated by research activities falling within this subcategory will continue to be subject to BCT and BAT limitations, as appropriate, established on a best professional judgment (BPJ) basis. In addition, indirect dischargers will be subject to local limits, as appropriate.

In its preamble to the 1983 regulations, EPA explained that it was specifically excluding subcategory E pharmaceutical research from all limitations and standards in the regulation other than BPT limitations because these operations do not involve production and wastewater generation in appreciable quantities on a regular basis. See 48 FR 49808, 49816 (Oct. 27, 1983). EPA also noted that research activities conducted at mixed and single subcategory plants (A, B, C, and D only) would be covered by that regulation. In today's Notice, EPA proposes to exclude subcategory E research operations from all limitations and standards in the proposed rule, other than the existing BPT limitations, at both stand alone and mixed subcategory plants. However, in order to clarify the scope of Subcategory E as described in the 1983 preamble, EPA proposes to define Subcategory E research operations specifically as bench-scale activities related to the development of pharmaceutical products. Bench-scale activities, in contrast to pilot-scale operations, do not involve production or wastewater generation in appreciable quantities on a regular basis and therefore describe the activities historically encompassed within Subcategory E, Pharmaceutical Research.

Consequently, under this proposal, bench-scale research activities that generate process wastewater at manufacturing facilities or at stand-alone Subcategory E facilities will be covered by the current subcategory E BPT limitations on BOD<sub>5</sub>, COD, TSS and pH. This means that if a facility engaging in bench-scale research operations also engages in pharmaceutical manufacturing operations covered by subcategories A, B, C, or D, the process wastewater from the bench-scale research operations would be subject only to subcategory E regulations (and on a case-by-case basis BCT and BAT limitations based on BPJ, as appropriate). Conversely, if a facility engages in research operations on a pilot-scale level, then the wastewater generated by those operations would be subject to the standards and limitations applicable to the manufacturing subcategory (A, B, C, or D) that the wastewater most resembles. See 40 CFR 439.50 et seq.

The proposal that subcategory E applies to all bench-scale research operations irrespective of their proximity to pharmaceutical manufacturing process operations represents a change from the interpretation expressed by EPA in the preamble to the 1983 rule. In that preamble, EPA indicated that research activities conducted at mixed and single subcategory plants (A, B, C, and D only) would be covered by the regulations corresponding to the particular subcategory. Accordingly, the Agency is soliciting comment on whether facilities with both subcategory E and subcategory A, B, C, or D process operations should be subject to the standards and limitations corresponding to the manufacturing subcategory (A, B, C, or D) and not to subcategory E BPT limitations as proposed here. See Section XIV, solicitation number 5.2.

#### *B. Water Use, Wastewater Discharge and Characterization*

This section describes current water use and wastewater recycling practices, discharge practices and the general characteristics of wastewater at the plants that manufacture pharmaceuticals in the United States. A more detailed presentation can be found in Section 5 of the TDD. Almost all pharmaceutical manufacturing processes require the use of water, although use and discharge practices and the characteristics of the wastewater will vary depending on the process operations at individual facilities.

##### *1. Water Use and Wastewater Generation*

*a. Water Use.* EPA estimates the average daily wastewater generation by the pharmaceutical manufacturing industry to be 266 million gallons, based on the responses to questions in part A section 4 of the 1990 Pharmaceutical Manufacturing Survey. Pharmaceutical manufacturers use water for process operations and for other nonprocess purposes such as noncontact cooling and sanitation.

The water is used or generated in pharmaceutical manufacturing process operations in several ways, thereby generating process wastewater:

- Water of reaction: Water formed during the chemical reaction.
- Process solvent: Water used to transport or support the chemicals involved in the reaction process; this water is usually removed from the process through a separation step, such as centrifugation, decantation, drying, or stripping.
- Process stream washes: Water added to a process stream (i.e., the

carrier, spent acid, or spent base) that has been separated from the reaction mixture, in order to purify the stream by washing away impurities in the stream.

- Product washes: Water added to the reaction medium to purify an intermediate or final product by washing away the impurities (this water is subsequently removed through a separations step); or water used to wash the crude product after it has been removed from the reaction medium.

- Spent Acid/Caustic: Spent acid and caustic streams, which may consist primarily of water, that are discharged from the process during the separation steps following the reaction step in which acid and basic reagents are used to facilitate, catalyze, or participate in the reactions.

- Condensed steam: Steam used as a sterilizing medium and in steam strippers for solvent recovery and wastewater treatment.

Other sources of process wastewater associated with pharmaceutical manufacturing operations include:

- Air pollution control scrubber blowdown: Water or acidic or basic compounds used in air emission control scrubbers to control fumes from reaction vessels, storage tanks, incinerators, and other process equipment.

- Equipment and floor washes: Water used to clean process equipment during unit shutdowns and floors during general housekeeping or for spill cleanup.

- Pump seal water: Direct contact water used to cool packing material and lubricate pumps.

In addition to process wastewater, non-process wastewater may be generated during pharmaceutical manufacturing. This non-process wastewater may include noncontact cooling water (used in heat exchangers), noncontact ancillary water (e.g., boiler blowdown, bottle washing), sanitary wastewater, and wastewater from other sources such as stormwater.

*b. Water Conservation.* In response to the 1990 detailed survey questionnaire, 137 of the 244 responding pharmaceutical manufacturers reported implementing water conservation measures with regard to process wastewater. Such water conservation measures include: careful monitoring of water use, installation of automatic monitoring and alarm systems on in-plant discharges, implementation of alternative production processes requiring less water, conversion from barometric to surface condensers, reuse of wastewater from other manufacturing processes, reuse of noncontact water as process makeup water, and treatment of contact cooling water to allow reuse.

## 2. Wastewater Discharge

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

## 3. Wastewater Characterization

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

*a. Conventional Pollutants: BOD<sub>5</sub>, TSS, and pH.* BOD<sub>5</sub>, the quantity of oxygen used in the aerobic stabilization of wastewater streams, is the most widely used measure of general organic pollution in wastewater. BOD<sub>5</sub> discharges from facilities with subcategory A and/or C operations are significantly higher than those discharges from facilities with subcategory B and/or D operations because fermentation and chemical synthesis process operations generate substantially greater concentrations of organic material (on average ten times higher untreated BOD<sub>5</sub> concentrations) than extraction or mixing, compounding, and formulating processes.

TSS is the portion of the total solids that can be filtered out of a solution using a 1-micron filter. (Total solids in wastewater is defined as the residue remaining after evaporation at just above the boiling point.) Discharges of TSS for this industry are generally proportional to the amount of BOD<sub>5</sub> discharged and, as a result, A and/or C subcategory facilities discharge significantly more TSS than do B and/or D facilities.

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

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

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

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

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

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

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

### C. Selection of Pollutant Parameters

#### 1. Pollutants Regulated

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

Conventional Pollutants:

BOD<sub>5</sub> and TSS

Priority Pollutants:

Benzene

Chlorobenzene

Chloroform

Chloromethane	Cyclohexane	Isopropyl Acetate*
Cyanide	Diethyl Ether*	Isopropyl Ether*
o-Dichlorobenzene*	Diethylamine*	Methanol*
1,2-Dichloroethane*	N,N-Dimethylacetamide	Methylamine*
Methylene Chloride	Dimethylamine*	Methyl Cellosolve (2-Methoxyethanol)
Phenol	N,N-Dimethylaniline*	Methyl Formate*
Toluene	N,N-Dimethylformamide	Methyl Isobutyl Ketone (MIBK)*
Nonconventional Pollutants:	Dimethyl Sulfoxide	2-Methyl Pyridine*
Acetone*	1,4-Dioxane*	Petroleum Naphtha*
Acetonitrile	Ethanol*	Polyethylene Glycol 600
Ammonia (aqueous)	Ethyl Acetate*	n-Propanol*
n-Amyl Acetate*	Ethylene Glycol	Pyridine*
Amyl Alcohol*	Formaldehyde	Tetrahydrofuran*
Aniline*	Formamide*	Trichlorofluoromethane
2-Butanone (MEK)*	Furfural*	Triethylamine*
n-Butyl Acetate*	n-Heptane	Xylenes
n-Butyl Alcohol*	n-Hexane	
tert-Butyl Alcohol*	Isobutyraldehyde*	
COD (Chemical Oxygen Demand)	Isopropanol*	

\*Under co-proposal (2) these pollutants will not be regulated.

TABLE IX.C-1. POLLUTANTS REGULATED IN PROPOSED EFFLUENT LIMITATIONS GUIDELINES AND STANDARDS FOR FACILITIES WITH SUBCATEGORY A AND/OR C OPERATIONS

Pollutants regulated	Effluent regulation					
	BPT	BCT	BAT	NSPS	PSES	PSNS
BOD <sub>5</sub> .....	X	X		X		
TSS .....	X	X		X		
COD .....	X		X	X		
CN .....	X		X <sup>2</sup>	X <sup>2</sup>	X <sup>2</sup>	X <sup>2</sup>
Ammonia .....			X	X	X	X
Nonconv Vol. Orgs .....			X	X	X <sup>3</sup>	X <sup>3</sup>
Pri. Pol. Vol. Orgs .....			X	X	X	X
Phenol .....			X	X		
Nonconv. Svol. Orgs <sup>1</sup> .....			X	X	(4)	(4)

<sup>1</sup> Dimethyl sulfoxide, N,N-dimethyl acetamide, N,N-dimethyl formamide, ethylene glycol and formaldehyde.

<sup>2</sup> For purposes of proposal, CN limits for BAT, NSPS, PSES, and PSNS are the same as BPT.

<sup>3</sup> Does not include two pollutants which do not pass through (acetonitrile and polyethylene glycol 600).

<sup>4</sup> Limits are not being proposed at this time for these pollutants.

TABLE IX.C-2. POLLUTANTS REGULATED IN PROPOSED EFFLUENT LIMITATIONS GUIDELINES AND STANDARDS FOR FACILITIES WITH SUBCATEGORY B AND D OPERATIONS

Pollutants regulated	Effluent regulation					
	BPT	BCT	BAT	NSPS	PSES	PSNS
BOD <sub>5</sub> .....	X	X		X		
TSS .....	X	X		X		
COD .....	X		X	X		
Nonconv. Vol. Orgs .....			X	X	X <sup>2</sup>	X <sup>2</sup>
Pri. Pol. Vol. Orgs .....			X	X	X	X
Phenol .....			X	X		
Nonconv. Svol Orgs <sup>1</sup> .....			X	X	(3)	(3)

<sup>1</sup> Dimethyl sulfoxide, N,N-dimethyl acetamide, N,N-dimethyl formamide, ethylene glycol and formaldehyde.

<sup>2</sup> Does not include two pollutants which do not pass through (acetonitrile and polyethylene glycol 600).

<sup>3</sup> Limits are not being proposed at this time for these pollutants.

*b. Conventional pollutants.*

Biochemical oxygen demand (BOD<sub>5</sub>) and total suspended solids (TSS) are conventional pollutants that have been regulated in this industry by previous BPT and BCT effluent limitations guidelines. These parameters are important because they quantify the biodegradable organic matter and suspended solids generated by all plants in all subcategories of the

pharmaceutical industry. EPA estimates that 3.3 million pounds per year of BOD<sub>5</sub> and 6.4 million pounds per year of TSS are discharged by the 35 facilities EPA has identified as direct dischargers. Most direct discharger plants have some level of secondary biological treatment in-place designed to treat BOD<sub>5</sub> and TSS. EPA is proposing to establish NSPS and to revise the BPT and BCT effluent

limitations for these pollutants in all subcategories. EPA does not propose to set limitations for BOD<sub>5</sub> and TSS applicable to indirect dischargers because EPA has determined that these pollutants can be adequately treated by POTWs. EPA is not proposing to use them as indicators for other pollutants in this industrial category, although this will be given further evaluation.

*c. Priority pollutants.* The priority pollutants selected for control include cyanide, phenol and various solvents used by the industry. EPA estimates that direct and indirect discharging facilities discharge 0.5 and 1.8 million pounds per year, respectively, of the 10 priority pollutants addressed in this proposal. EPA is proposing to promulgate BPT, BAT, NSPS, PSES, and PSNS for some or all of these pollutants in subcategories A, B, C, and D.

*d. Nonconventional pollutants.* Nonconventional pollutants include ammonia, COD (Chemical Oxygen Demand), and various volatile and semivolatile organic compounds that are used for the most part as solvents by the industry. EPA estimates that 0.8 and 0.5 million pounds per year of ammonia and 32 and 78 million pounds per year of COD are discharged by direct and indirect discharging facilities, respectively. With respect to COD, EPA is proposing to revise existing BPT limitations and promulgate new BAT limitations and NSPS for subcategories A, B, C, and/or D. With respect to ammonia, EPA is proposing to promulgate BAT, NSPS, PSES, and PSNS for subcategories A and/or C. EPA has determined that ammonia is not a pollutant of concern in wastewaters of facilities with subcategory B and/or D operations and hence does not propose limits for ammonia for those subcategories. See Section 5 of the TDD. See Section XIV, solicitation numbers 20.0 and 23.0. For PSES, EPA is co-proposing a finding of no pass-through for 33 priority and nonconventional pollutants.

## 2. Pollutants Not Regulated

EPA is not proposing effluent limitations or standards for 85 priority and nonconventional pollutants identified as potentially present in pharmaceutical wastewaters. In Section 6 of the TDD, EPA describes for each pollutant or group of pollutants the reasons each is excluded from this proposal. EPA bases its decision to exclude these pollutants or groups of pollutants on one or more of the following reasons:

(1) The pollutant or group of pollutants is deemed not present in pharmaceutical wastewaters, because it was not detected in the effluent with the use of analytical methods promulgated pursuant to section 304(h) of the Clean Water Act or with other state-of-the-art methods;

(2) The pollutant or group of pollutants is present only in trace amounts and is neither causing nor likely to cause toxic effects in humans or aquatic life;

(3) The pollutant or group of pollutants is detected in the effluent from only one or a small number of sources;

(4) The pollutant or group of pollutants is effectively controlled by the technologies used as a basis for limitations on other pollutants, including those limitations and standards proposed today; or

(5) Insufficient data are available to establish effluent limitations or standards for that pollutant or group of pollutants.

In addition, EPA proposes to control phenol discharged by direct dischargers (through BAT and NSPS) but not by indirect dischargers (through PSES and PSNS) because pass-through has not been demonstrated for phenol. See the discussion on the analysis of pollutant pass-through in Section IX.E.5.a. of this preamble. EPA also is proposing to exclude two nonconventional pollutants from control by PSES and PSNS regulations (acetonitrile and polyethylene glycol 600) because pass-through has not been demonstrated for these pollutants. In addition, as noted in Section C above, EPA is proposing two alternative pass-through for PSES for 33 priority and nonconventional pollutants. Under one of the proposed alternatives, EPA proposes to exclude 33 pollutants because EPA has some doubt as to whether these pollutants pass through. Under the other co-proposal, EPA proposes PSES for those pollutants based on a determination that they do pass through according to the data presently available to EPA.

## D. Available Technologies

### 1. Pollution Prevention Technologies Considered

EPA requested pollution prevention and process information regarding organic solvent use from pharmaceutical manufacturing facilities in its 1990 questionnaire. The responses indicate that while plants can make some process changes that would result in some source reduction, the opportunities to minimize or eliminate solvent use by changes in existing processes are limited, especially for facilities with subcategory A and/or C operations. Fermentation (A) and chemical synthesis (C) processes often involve complicated procedures which utilize solvents according to an exact recipe. In most cases, any change in the specific process or the amount of solvent used may result in a significant reduction in the yield of product obtained. Nonetheless, some Subcategory D (Mixing/Compounding/Formulating) facilities have utilized

aqueous-based solvents instead of organic solvents to coat tablets, thereby eliminating solvent use for that operation. This approach is generally not applicable to all tablet coating operations because most coating materials are not soluble in aqueous solvents.

Pharmaceutical plants sometimes cite an administrative, as well as a technical, impediment to pollution prevention. That is, once a pharmaceutical company gains approval from the Food and Drug Administration (FDA) to manufacture a pharmaceutically active ingredient or drug via a specific procedure, it may not deviate significantly from the approved procedure without additional FDA approval. Thus, if a company wishes to alter significantly an approved manufacturing procedure for any reason, including pollution prevention, it must submit a "supplement" application to FDA, which must be approved before the company can use the altered procedure.

EPA understands that FDA historically needs to take a long period of time to process these requests for approval. However, since the enactment of the "Prescription Drug User Fee Act of 1992," 21 U.S.C. 379 *et seq.*, Pub. L. 102-571, Oct. 29, 1992, the FDA has committed to using the revenues generated under that Act to expedite the prescription drug review and approval process, which include decisions on manufacturing supplements relating to pollution prevention-oriented process changes. EPA understands that the FDA hopes to eliminate its backlog of overdue manufacturing supplements by the end of Fiscal Year 1995 and to achieve, by Fiscal Year 1997, its goal of reviewing and acting upon every complete manufacturing supplement within six months of submission. EPA believes that such expeditious processing of supplements will eliminate impediments that presently discourage pharmaceutical plants from making process changes necessary to achieve source reductions.

In addition to evaluating opportunities for source reduction, EPA also examined potential treatment technologies to determine whether any might promote recovery, recycling, and reuse of chemicals in process wastewater generated by pharmaceutical manufacturing operations, such as solvents. After evaluating the various technologies available to treat solvent-laden wastewaters, EPA concluded that in-plant technologies such as steam stripping and steam stripping with distillation offered the best opportunity for recovery of solvents from wastewater. As discussed in greater

detail in Section IX.E.3 below, steam stripping technology and steam stripping with distillation technology are applied in-plant and minimize the dilution effects of commingling process wastewater streams and the transfer of volatile pollutants to air associated with other technologies. These technologies also allow the pharmaceutical manufacturing operation to recover the stripped solvents from the treatment process in an efficient and cost-effective manner from concentrated streams. These recovered solvents can then be recycled back into the process from which they were removed, reused in other manufacturing operations (e.g., in this industry or in other industries), or reused as "clean fuel" for boilers or other combustion devices. For further discussion of "clean fuels," see section XII.B of this preamble.

## 2. In-Plant Technologies Considered

EPA considered the following in-plant technologies to control solvent- and cyanide-laden wastewater generated by pharmaceutical manufacturing: (1) Steam stripping; (2) steam stripping with distillation; and (3) cyanide destruction. EPA concludes that steam stripping technology is the best technology available for removing high loadings and high concentrations of volatile organic pollutants from wastewater, and accordingly proposes BAT limitations for facilities with subcategory A and/or C operations on that technology basis. Fourteen plants reported using steam stripping technology and one facility reported using distillation technology for wastewater treatment in 1990. The demonstrated removal efficiencies for both technologies treating streams with high concentrations of highly strippable volatiles are greater than 99 percent. A detailed discussion of steam stripping and steam stripping with distillation (using fractional distillation columns with rectifying sections for difficult to strip volatile organic pollutants) and their use in the pharmaceutical manufacturing industry may be found in Section 7 of the TDD.

## 3. End-of-Pipe Technologies Considered

The end-of-pipe treatment technologies currently employed by the industry include: preliminary or primary treatment (neutralization, equalization, and primary clarification); biological or equivalent treatment (aerated stabilization basins with and without settling basins, oxidation ponds, and activated sludge systems); and physical/chemical treatment (multimedia filtration and chemically assisted clarification). In addition, EPA

has designated as advanced biological treatment a treatment configuration consisting of primary treatment plus some form of activated sludge treatment, which achieves better than 90 percent BOD<sub>5</sub> and 74 percent COD reduction from raw waste levels. EPA evaluated each of these available technologies in developing the limitations and standards proposed today. In addition to these technologies, the Agency also considered granular activated carbon (GAC) adsorption technology, which is an appropriate and available end-of-pipe treatment technology for pharmaceutical wastewater. All of the various technologies mentioned above are discussed in detail in Section 7 of the TDD.

All 35 direct dischargers responding to EPA's detailed questionnaire reported having some form of primary treatment in place in 1990. Thirty-one facilities reported having some form of biological or secondary treatment in place, either air- or oxygen-activated sludge treatment followed by secondary clarification and, in some cases, multimedia filtration and polishing ponds. One plant reported using GAC technology as end-of-pipe technology, and one plant reported using GAC technology in-plant.

### *E. Rationale for Selection of Technology Bases for Proposed Regulations*

#### 1. BPT

*a. Introduction.* EPA is today proposing revised BPT effluent limitations guidelines based on the Best Practicable Control Technology Currently Available (BPT) for BOD<sub>5</sub>, TSS, and COD for subcategories A, B, C, and D of the pharmaceutical manufacturing industry. EPA is also proposing to revise existing BPT limitations for cyanide for facilities with subcategory A and/or C operations and to repeal the existing BPT cyanide limitations for facilities with B and/or D operations. The Clean Water Act explicitly authorizes EPA to revise all effluent limitations guidelines, including those based on best practicable technology, at least annually if appropriate. See CWA section 304(b). In the 1987 amendments to the Clean Water Act, Congress further required EPA to establish a schedule for the annual review and revision of promulgated effluent guidelines in accordance with section 304(b). See CWA section 304(m). Moreover, as discussed in Section V.A.4, above, EPA entered into a consent decree that requires EPA to propose and promulgate effluent guidelines for the pharmaceutical manufacturing industry,

as appropriate, including those authorized by section 304(b) for existing dischargers. See 304(m) Decree at 4-5. Because BPT guidelines are among those listed in section 304(b), EPA thus is required by the 304(m) Decree to propose and take final action on BPT guidelines for this industry, unless not appropriate.

EPA has determined that revising BPT limitations for the pharmaceutical manufacturing industry is indeed appropriate and important. The existing BPT guidelines for BOD<sub>5</sub>, TSS, COD and cyanide for this industry, which were most recently revised in 1983, are based on secondary treatment data collected in the mid-1970s and cyanide destruction technology data collected in the early 1980s. Data from the 1990 detailed questionnaire indicate that there have been significant improvements in secondary treatment and cyanide destruction technologies in the industry since that time. Accordingly, the technology underpinnings of the current BPT limitations no longer reflect the "average of the best" technology currently available. Moreover, substantial environmental benefits would ensue from more stringent BPT limitations. For example, there would be significant reductions in the levels of COD and cyanide in addition to BOD<sub>5</sub> and TSS from current levels if BPT were revised. EPA has determined that revising the BPT limitations to reflect the best practicable control technology currently available is appropriate at this time.

*b. Pollutants of concern.* EPA is proposing to revise BPT effluent limitations controlling the discharge of BOD<sub>5</sub>, TSS, COD, and, for facilities with subcategory A and/or C operations, cyanide (CN). EPA has determined that cyanide is not a pollutant of concern for facilities with subcategory B and/or D operations. Limitations for the pollutant parameter, pH, are not being revised.

*c. Determination of technology basis of BPT.* To determine the technology basis and performance level that constitutes BPT, EPA developed a database consisting of 1988 and 1989 effluent data supplied in response to the 1990 detailed questionnaire and its pretest form. The Agency determined that more than 29 of 35 direct dischargers and 23 indirect dischargers utilized biological treatment (activated sludge treatment). In addition, 10 direct and indirect discharging plants reported some form of cyanide destruction technology in place. Other technologies utilized include wastewater incineration (12 plants), effluent filtration (6 plants), and polishing ponds (8 plants).

*d. Determination of performance level defining BPT.* EPA used 1989 and 1990 data supplied in the response to the 1990 detailed questionnaire regarding BOD<sub>5</sub>, TSS, and COD effluent and effluent concentrations and loadings in order to calculate long-term average concentrations for BOD<sub>5</sub>, TSS, and COD. EPA then used this information to determine the performance level defining proposed BPT for BOD<sub>5</sub>, TSS, and COD. EPA has determined that the level of performance necessary for a plant to be considered as a best performer with respect to advanced biological treatment was full compliance with the existing BPT limitations.

In order to develop BPT limitations for BOD<sub>5</sub>, TSS, and COD for facilities with subcategory A and/or C and B and/or D operations, EPA first identified those plant datasets that indicated full compliance with the 1983 BPT regulation. BPT in the 1983 regulation was based on activated sludge treatment, which is considered a principal component of advanced biological treatment. Under the intent of the 1983 regulation, facilities with subcategory A and/or C operations must achieve long-term average reductions of 90 and 74 percent in BOD<sub>5</sub> and COD, respectively, and average TSS concentrations equal to 1.7 times their average influent BOD<sub>5</sub> concentrations. As an initial matter, EPA did not consider plants for this rulemaking unless they were consistently achieving such long-term BOD<sub>5</sub> and COD percent reductions and related TSS concentrations.

Having identified the plants that are complying with the 1983 BPT requirements, EPA then undertook to determine which could be considered best performers in the two subcategory groups. To do this, EPA usually develops editing criteria to analyze available performance data. EPA concluded that no such editing criteria were necessary in this case, however, because performance data for the plants employing advanced biological treatment to fully comply with the intent of the 1983 BPT regulation showed that all were achieving similar good performance. Five thus emerged as best performers among facilities with subcategory A and/or C operations; for facilities with subcategory B and/or D operations, EPA identified two as best performers. The Agency then calculated long-term average performance concentrations for BOD<sub>5</sub>, TSS, and COD using datasets from the best performing A and C and B and D plants. The limitations derived from these concentrations represent the "average of

the best" performance with respect to advanced biological treatment in the pharmaceutical manufacturing industry.

With respect to the development of the BPT cyanide limitations for facilities with subcategory A and/or C operations, EPA identified ten facilities that used some form of cyanide destruction technology to destroy or oxidize the cyanide in their waste streams. The existing BPT limits for CN were based on alkaline chlorination technology. After evaluating the performance data characteristic of the various cyanide destruction technologies employed, EPA concluded that hydrogen peroxide oxidation appeared to meet the statutory requirements for BPT most effectively. In reaching this decision, EPA used influent and effluent cyanide data from one of these facilities to determine the effectiveness of this form of treatment in reducing cyanide concentrations. This facility achieved substantially more effective treatment than the other two facilities that used the same cyanide destruction technology. As a result, the proposed cyanide limitations for facilities with subcategory A and/or C operations are based on the performance of hydrogen peroxide oxidation technology. EPA is proposing to repeal the current BPT limitations for cyanide for facilities with subcategory B and/or D operations because cyanide is not a pollutant of concern for those operations. See Section 9 of the TDD for discussion of the cyanide content of raw wastewaters generated by facilities with subcategory B and/or D operations.

The development of the variability factors used to determine BPT effluent limitations for BOD<sub>5</sub>, TSS, COD, and cyanide from the LTA is discussed in section IX.F below. A detailed explanation of the development of the proposed BPT effluent limitations is found in Section 2.2 of the statistical support document. Additional discussion of the basis for developing treatment effectiveness data for cyanide destruction is presented in Section 8 of the TDD.

## 2. BCT

*a. Methodology for determining revised BCT limits.* EPA is today proposing revised BCT effluent limitations guidelines based on the Best Conventional Pollutant Control Technology (BCT) for four subcategories (A, B, C, and D) of the pharmaceutical manufacturing industry. These proposed guidelines, for the conventional pollutants BOD<sub>5</sub> and TSS, are based on the average performance of the best plants in these subcategories that employ advanced biological treatment (the technology basis of the

proposed BPT limitations). In developing and proposing revised BCT limits, EPA considered whether there are technologies that achieve greater removals of conventional pollutants than the proposed BPT, and whether those technologies are cost-reasonable according to the BCT cost test. In the four subcategories for which EPA proposes revised limitations today, EPA identified no technologies that achieve greater removals of conventional pollutants than those associated with the proposed BPT limits that are also cost-reasonable under the BCT cost test, and accordingly proposes BCT limits equal to the proposed BPT limits for those subcategories. The technologies considered for facilities with subcategory A and/or C operations included effluent filtration, polishing ponds, and the combination of effluent filtration and polishing ponds. EPA considered only effluent filtration for facilities with subcategory B and/or D operations.

EPA's analysis had several steps. First, EPA considered how best to define the BPT "baseline" for these purposes. In performing the BCT cost tests, the BPT baseline serves as the starting point against which more stringent technologies are analyzed. EPA considered three possible baselines: (i) the revised BPT limits proposed in today's notice; (ii) the actual long-term average discharge of conventional pollutants from plants in this industry, based on EPA's 1990 survey data; and (iii) a level of control equal to the amount of discharge allowed under existing BPT regulations. Of these, the first is the most stringent and the third is the least stringent level of control. EPA has selected the proposed revised BPT limits because the revised BPT limitations reflect the average performance of the best facilities in the industry as required by the Clean Water Act. Moreover, dischargers would be required to meet these limitations irrespective of the BCT analysis and hence they provide a more realistic starting point against which to analyze potentially more stringent candidate BCT technologies.

As the second step in determining whether to revise BCT limits, EPA identified candidate BCT technologies. Three candidate technologies were identified for facilities with subcategory A and/or C operations. Each incorporates advanced biological treatment plus one of the following: (1) Multimedia filtration; (2) polishing ponds; or (3) polishing ponds followed by multimedia filtration. The only option evaluated for facilities with subcategory B and/or D operations was

multimedia filtration. EPA was able to evaluate these candidate technologies for facilities with subcategory A and/or C operations and for facilities with subcategory B and/or D operations by estimating costs and pollutant removals on a plant-by-plant basis. The design parameters and other engineering assumptions for these cost and pollutant removal estimates applicable to both A and/or C and B and/or D facilities are explained in Section 10 of the TDD. Section 7 of the TDD also discusses EPA's evaluation and selection of the various candidate BCT technologies. The Agency solicits comment on the above described candidate technologies, and other candidate technologies that might be more cost-effective than multimedia filtration, polishing ponds, or the combination thereof. See Section XIV of this preamble, solicitation number 30.0.

EPA found that all candidate technology options failed the BCT cost test in the two subcategory groups (A and C, and B and D). As a result, EPA is today proposing to set BCT equal to proposed BPT in these two subcategory groups. See the Section 14 of the TDD for a complete discussion of the BCT methodology as applied in each of the subcategories.

b. *Alternative methodology for developing BCT limits.* EPA performed an alternative BCT analysis, in addition to the foregoing. This alternative analysis is based on the possibility that, notwithstanding today's proposal, BPT limits for this industry ultimately are not revised. In performing this analysis, EPA considered four candidate technology options for facilities with subcategory A and/or C operations and two candidate technology options for facilities with subcategory B and/or D operations. The technologies identified above plus advanced biological treatment is the first candidate technology option in each case. The analysis also uses, as its baseline, the level of control equal to the discharge allowed under the existing BPT regulations. This baseline was used in the development of the 1986 BCT limitations for the pharmaceutical manufacturing industry. EPA concluded from this alternative analysis that all candidate technology options fail the BCT cost test using the baseline for the 1986 analysis. Section 14 of the TDD provides more discussion of all BCT cost test analyses.

### 3. BAT

a. *Introduction.* EPA today is proposing both new and revised BAT effluent limitations guidelines based on the Best Available Technology

Economically Achievable (BAT) for four subcategories (A, B, C, and D) of the pharmaceutical manufacturing industry. The BAT effluent limitations proposed today would control certain priority and nonconventional pollutants discharged from plants in these subcategories at an end-of-pipe location. In developing these proposed effluent limitations, EPA identified technologies appropriate for individual priority and nonconventional pollutants.

b. *Establishing BAT limits.* EPA has identified 56 pollutants for possible control by BAT limitations for facilities with subcategory A and/or C operations. The proposed BAT limitations for these subcategories for cyanide and COD are identical to those established under BPT. EPA also is proposing limitations for ammonia for facilities with subcategory A and/or C operations based on incidental removal through steam stripping and advanced biological treatment. Of the remaining 53 priority and nonconventional pollutants for which limitations are being proposed today for facilities with subcategory A and/or C operations, 45 are volatile organic pollutants, which are treatable by steam stripping and steam stripping with distillation technologies. For facilities with subcategory A and/or C operations, EPA is today proposing BAT limitations for those pollutants based on steam stripping technology followed by end-of-pipe advanced biological treatment. The remaining eight pollutants are nonstrippable organic compounds, which are biodegradable. Consequently, EPA is proposing advanced biological treatment as the basis for BAT limitations for these pollutants for facilities with subcategory A and/or C operations.

For facilities with subcategory B and/or D operations, EPA has identified 54 pollutants for control by the proposed BAT limitations based on advanced biological treatment (the technology selected as the basis for the proposed BPT). As discussed under BPT, cyanide is not a pollutant of concern for subcategory B and/or D operations and EPA is proposing to repeal the current BAT limitations for cyanide for facilities with subcategory B and/or D operations. EPA also has determined that ammonia is not a pollutant of concern for these subcategories. EPA is proposing to set BAT limitations for COD for facilities with subcategory B and/or D operations at the levels achieved by compliance with the proposed BPT limitations.

c. *Rationale for BAT limitations by subcategory.* Section V.A.1 summarizes the factors to be considered in establishing the BAT level of control. In general, BAT represents the

performance of the best available technology economically achievable among plants with shared characteristics. Where existing pollution control technologies are uniformly inadequate, BAT may be transferred from a different subcategory or industrial category. BAT limitations may be based upon process changes, as well as upon measures that are not common industry practice.

The Agency is today proposing BAT effluent limitations for facilities with subcategory A, B, C, and D operations. The rationale for the proposed effluent limitations in each subcategory is presented in the following paragraphs.

#### (1) Fermentation and Chemical Synthesis Subcategories, Subparts A and C

The technology basis for the current BAT limitations is cyanide destruction plus end-of-pipe biological treatment.

In establishing the proposed BAT effluent limitations, EPA considered four regulatory options to reduce the generation of priority and nonconventional pollutants by facilities with subcategory A and/or C operations. These options are as follows:

##### *Option (1)—In-plant cyanide destruction plus advanced biological treatment with nitrification.*

This option is identical to the technology selected as the basis for the proposed BPT limitations for facilities with subcategory A and/or C operations, except that provisions for nitrification are added.

##### *Option (2)—In-plant cyanide destruction and steam stripping plus advanced biological treatment.*

This option adds in-plant steam stripping to the technology described in option 1 for the purpose of removing strippable volatile organic pollutants prior to dilution from commingled wastestreams and air stripping in treatment basins and impoundments at the end of the pipe. Steam stripping will also remove ammonia, thereby obviating the need to add nitrification to end-of-pipe biological treatment.

##### *Option (3)—In-plant cyanide destruction and steam stripping with distillation plus advanced biological treatment.*

This option adds in-plant fractional distillation to the technology described in Option 2 for the fractional purpose of achieving greater removal of difficult to strip volatile organic pollutants (such as methanol) prior to dilution from commingled wastestreams and air stripping in treatment basins and impoundments at the end of the pipe.

##### *Option (4)—In-plant cyanide destruction and steam stripping with*

*distillation plus advanced biological treatment plus end-of-pipe Granular Activated Carbon (GAC) adsorption technology.*

This option adds Granular Activated Carbon adsorption treatment to the technology described in Option 3 for the purpose of achieving additional removal of the pollutant parameter COD beyond that achieved by Option 3.

EPA selected Option 2 as the proposed technology basis for BAT limitations for facilities with subcategory A and/or C operations because EPA believes this option represents the best available technology economically achievable, considering all statutory factors.

The Agency found that the annual incremental increase in electrical power consumption for all facilities to achieve Option 2 was 13,200 MW. This increase is equivalent to an increase of approximately 0.25 percent of the pharmaceutical industry's purchased electrical energy usage in 1990. Using the industry's 1990 purchased electrical energy usage as a baseline, the estimated incremental increases for electrical power consumption for the remaining options were, for Option 3, an increase of 13,800 MW and, for Option 4, an increase of 17,900 MW. With respect to energy needs associated with steam generation for steam stripping and distillation, the Agency found that Option 2 would result in 720,000 MW of incremental energy consumption, or approximately an 8 percent increase above the industry's 1990 total energy consumption. For Option 3, EPA found that 2,220,000 MW of incremental energy consumption, or a 25 percent increase above the industry's 1990 total energy consumption, would be required. EPA did not select Option 3 as proposed BAT because of this large increase in energy consumption required for steam generation. This decision is consistent with the CWA's requirement that EPA take into account energy requirements in selecting BAT. While steam generation under Option 2 requires slightly higher energy consumption than the 1990 baseline, the Agency notes that the potential for solvent recovery and reuse will substantially offset these energy expenditures. See Section XII.B of this preamble for further discussion of "clean fuels." Further discussion of these non-water quality environmental and energy impacts also is presented in Sections 12 and 15 of the TDD.

EPA also is proposing standards to control COD, based upon advanced biological treatment. These proposed BAT limitations are based on the performance of the "best" performers among facilities with subcategory A

and/or C operations. EPA believes that a substantial portion of the raw waste load COD can be removed in plant, prior to advanced biological treatment, by application of steam stripping technology—upon which the proposed BAT limitations for priority pollutants and the other nonconventional pollutants are based. However, EPA lacks sufficient data at this time to quantify the removal of COD achievable through in-plant steam stripping, and in turn the further removal of remaining COD load achievable by advanced biological treatment, and therefore does not propose its subcategory A and/or C BAT limitations for COD based on that combination of technologies. EPA solicits data and comments concerning the establishment of EPA for COD for subcategories A and C based on steam stripping plus advanced biological treatment. See Section XIV, solicitation number 20.

In estimating the energy consumption for steam generation associated with Option 3, EPA assumed, based on available data, that very high volumes of wastewater would need to be stripped and distilled, thus requiring high demands for steam. EPA believes that this assumption is very conservative because the Agency assumed from the 308 questionnaire responses that wastewater streams containing high concentrations of volatile organic pollutants could not be segregated from streams containing minimal or no concentrations of these pollutants. EPA believes that stream segregation is possible. EPA further expects that more recent data will show that the volume of wastewater that would be subject to steam stripping and distillation is substantially lower than the volume assumed in this proposal. Such lower volumes would also invariably result in higher concentrations of the volatile organic pollutants to be stripped. Considerably less steam, and hence considerably less energy, would be necessary to strip (Option 2) or distill (Option 3) such pollutants from low volume, high concentration wastewater. If more recent data fulfills this expectation, the Agency may reconsider Option 3 for A and/or C subcategory facilities. Therefore, EPA invites comments and data regarding the volume of wastewater that may require steam stripping and the pollutant concentrations in those wastestreams. See Section XIV, solicitation numbers 6.0 and 15.6. EPA also solicits comments on the use of distillation technology for the purpose of obtaining additional removal of pollutants such as methanol that are difficult to steam

strip. See Section XIV, solicitation number 15.9.

The Agency considered other non-water quality environmental impacts of the selected option, including the role which this proposal may play in the minimization, recycle, and disposal of characteristic (ignitable) volatile organic wastes. EPA has determined that Options 2 and 3 will generate 52,200 and 61,000 metric tons per year of condensates, respectively (more than Option 1 because of the use of steam stripping and steam stripping with distillation technologies). The condensates may include both halogenated and nonhalogenated solvents. Plants may choose to purify these condensates and then recycle/reuse the purified solvents as raw materials or use the condensate streams as fuel for incinerators either on or off site. If plants choose the latter approach, EPA has determined that adequate commercial incinerator capacity exists. Although EPA believes that most facilities will either recycle or incinerate their steam stripping condensates on-site because, in many cases, adequate recycle or incineration capability exists on-site, the Agency has adopted the conservative approach in its BAT cost estimates by assuming all condensates will be disposed of by off-site incineration. Because Option 3 features distillation in addition to steam stripping and achieves greater organic pollutant removal, resulting in a higher volume of condensates, EPA determined that the estimated costs of off-site incineration of the resulting condensates would be about 10 percent higher for Option 3 than for Option 2. Because the cost differential between Options 2 and 3 represents only a small part of the total costs associated with Option 3, EPA did not regard it as a significant factor. Accordingly, EPA concluded that the generation of condensates as a result of steam stripping and steam stripping with distillation technology does not provide a basis for choosing between technology Options 2 and 3 as the basis for BAT limitations for facilities with subcategory A and/or C operations. A more complete discussion of the Agency's waste minimization and combustion strategy and its relationship to this industry and rulemaking is presented in Section XII.B of this preamble and in Section 7 of the TDD.

The Agency also considered the effect of Options 1, 2, 3, and 4 on the current levels of air emissions from wastewaters at facilities with subcategory A and/or C operations. EPA used the WATER7 computer model employed by the EPA Office of Air and Radiation (OAR) in the

recently promulgated Hazardous Organic NESHAP (HON) for the Synthetic Organic Chemical Manufacturing Industry (SOCMI), in conjunction with Section 308 questionnaire responses, to evaluate the 1990 levels of air emissions from wastewater for this industry. The results of the analyses were used to estimate air emission increases or decreases for the regulatory options. The Agency estimates that Option 1 would result in a minimal increase in air emissions, while Options 2 and 3 would decrease air emissions by 5,300 and 6,350 metric tons per year, respectively. Option 4 would achieve the same air emission reduction as Option 3. In EPA's view, these beneficial non-water quality environmental impacts militate in favor of selecting a technology option employing steam stripping or distillation (i.e., Options 2, 3 or 4).

The Agency did not find that the age of equipment and facilities involved provided any basis for choosing among the options. The Agency also evaluated whether the engineering aspects of the options were compatible with the manufacturing processes employed and potential process changes at facilities with subcategory A and/or C operations. EPA concluded that the engineering aspects of all four options were compatible with current manufacturing processes and possible process changes at these facilities, and the results of this evaluation did not provide a basis for selecting an option.

(2) Biological and Natural Extraction and Mixing/Compounding/Formulating Subcategories, Subparts B and D

EPA considered four regulatory options to reduce the generation of priority and nonconventional pollutants by facilities with subcategory B and/or D operations. In selecting and evaluating these technology options for BAT for these facilities, EPA examined the 1990 questionnaire data supplied by the fourteen facilities with subcategory B and/or D operations only that discharge directly into surface waters. Among other things, EPA undertook to characterize the process wastewater from these facilities in order to identify the best technologies available to treat the pollutants of concern. The data supplied by these facilities indicate that the process wastewater of these direct dischargers is significantly different, in terms of the pollutants present and their concentrations, from the process wastewater of indirect discharging facilities with subcategory B and/or D operations. EPA is unable to account for this marked difference, because the processes employed by the direct and

indirect dischargers with subcategory B and/or D operations seem to be the same, and therefore EPA has some doubts that these data depict the typical wastestreams of direct dischargers with subcategory B and/or D operations. Although EPA proposes BAT limitations for these facilities based on the conclusions it drew from the data, EPA also solicits comment on those conclusions and invites additional data concerning the processes and wastewater characteristics (flow and pollutant concentration) of these facilities. See Section XIV, solicitation number 7.0. Because new data for 1991–1994 may establish greater similarities between the process wastewaters of direct and indirect dischargers with operations than are evident today, EPA is also considering and specifically inviting comment on whether it should promulgate BAT limitations based on the model treatment technology selected by EPA as the basis for its proposed PSES limitations for facilities with subcategory B and/or D operations. See Section IX.E.5 for a discussion of the reasoning underlying that proposal.

In addition, in the event a facility with subcategory B and/or D operations changes its mode of discharge and decides to discharge its wastewater directly to surface waters (rather than through a POTW), EPA is considering establishing BAT limitations for such dischargers that reflect the wastewater characteristics reported by the indirect dischargers with subcategory B and/or D operations. The possibility that an indirect discharger may change its mode of discharge and thus become subject to BAT limitations rather than to PSES further suggests to EPA that it should consider the entire universe of data from facilities with subcategory B and D operations—not just those currently with direct discharges—in setting BAT limits. Therefore, EPA seeks comment on whether it should promulgate BAT limitations for this subcategory based on steam stripping technology, which EPA has determined is appropriate technology for the wastestreams reported by indirect dischargers in this subcategory. See Section XIV, solicitation number 7.0.

The four options considered by EPA are as follows:

*Option (1)—Advanced biological treatment.*

This option is identical to the proposed technology basis for BPT for facilities with subcategory B and/or D operations.

*Option (2)—In-plant steam stripping plus advanced biological treatment.*

This option adds in-plant steam stripping to the technology described in

Option 1 for the purpose of removing strippable organic pollutants prior to dilution from commingled wastewater streams and air stripping in treatment basins and impoundments at the end of the pipe.

*Option (3)—In-plant steam stripping with distillation plus advanced biological treatment.*

This option adds in-plant fractional distillation to the technology described in Option 2 for the fractional purpose of achieving greater removal of difficult to strip volatile organic pollutants (such as methanol) prior to dilution from commingled wastestreams and air stripping in treatment basins and impoundments at the end of the pipe.

*Option (4)—Steam stripping with distillation plus advanced biological treatment plus end-of-pipe Granular Activated Carbon (GAC) adsorption technology.*

This option adds Granular Activated Carbon adsorption treatment to the technology described in Option 3 for the purpose of achieving additional removal of the pollutant COD beyond that achieved by Option 3.

EPA is proposing Option 1 as the technology basis for BAT limitations for facilities with subcategory B and/or D operations because, on the basis of the data submitted by the direct dischargers in these subcategories, EPA determined that this technology basis is the best available technology economically achievable for these pollutants. However, as discussed above, EPA is seriously considering and specifically invites comment on setting BAT limitations for these plants based on the PSES model technology for facilities with subcategory B and/or D operations. In making the proposed BAT determination, EPA analyzed data for each facility identified through the 1989 Pharmaceutical Screener Questionnaire and the 1990 Detailed Questionnaire as engaging in subcategory B and/or D operations. The results of the screener questionnaire indicate that, nationwide, 14 pharmaceutical manufacturing plants with direct discharges engage only in subcategory B and/or D operations (excluding subcategory E research activities). These 14 facilities reported to EPA in response to the 1990 detailed questionnaire that they discharge BOD<sub>5</sub>, TSS, COD, six solvents and no priority pollutants. Of the six solvents, the facilities reported discharging only two in quantities exceeding a combined subcategory total of 1000 lbs/year. EPA's analysis of the questionnaire data indicates that the total nonconventional pollutant loadings discharged, on average, for each facility with subcategory B and/or D operations in

1990 was 1,660 pounds/year. In addition, these 14 facilities reported in their questionnaire responses that they emit from wastewater a total of 170 pounds/year of volatile organic pollutants. Subsequent analysis by EPA using its WATER7 model indicates that these 14 facilities may actually emit closer to 35,000 pounds/year from wastewater. See Section 12 of TDD for discussion of difference between questionnaire results and WATER7 results. By way of comparison, facilities with subcategory A and/or C operations reported in the 1990 questionnaire that they emit from wastewater a total of 3.2 million pounds/year of volatile organic and priority pollutants, and the WATER7 model projected 14 million pounds/year of those pollutants from wastewater.

Based on its evaluation of the data available to it, EPA proposes to base BAT limitations for facilities with subcategory B and/or D operations on advanced biological treatment (PSES Option 1 minus cyanide destruction). In view of the comparatively small quantities of pollutants reported to be discharged and emitted from wastewater from the 14 existing facilities with subcategory B and/or D operations only, EPA has determined that the chosen technology basis for the proposed BAT limit is best suited to the type of wastewater the data describe for direct discharges in these subcategories. Other technology options, which incorporate steam stripping or steam stripping with distillation technologies, are designed to remove large quantities and many varieties of solvents from process wastewater. They are not optimal treatment technologies for the type of wastestreams reported by the 14 direct dischargers in these subcategories, because the 1990 data indicate that these direct dischargers discharge only 6 solvents (in contrast to the 45 solvents reported to be discharged by the facilities with subcategory A and/or C operations), and then in relatively small amounts (an average of 1,660 pounds/year for facilities with subcategory B and/or D operations, compared to an average of 14,600 pounds/year for facilities with subcategory A and/or C operations). Accordingly, based on the data available to EPA for these facilities from the 1990 questionnaire, EPA is not proposing steam stripping or steam stripping with distillation as part of the technology basis for BAT for facilities with subcategory B and/or D operations.

However, in the event that new data for these facilities show that the wastestreams of these facilities actually resemble those of the indirect dischargers in these subcategories, EPA

proposes to base the BAT limitations on steam stripping technology, which EPA has determined is the best available technology for wastestreams of that character. See Section IX.E.5. Accordingly, EPA specifically invites comments on establishing BAT limitations equal to the proposed PSES for those pollutants, including those that EPA has determined pass through as part of co-proposal (1). See Section XIV, solicitation number 7. In addition, if EPA promulgated BAT limitations based on steam stripping or steam stripping with distillation, EPA would include BAT limitations on phenol, acetonitrile and polyethylene glycol 600 (based on advanced biological treatment), which are present in the wastestreams of indirect dischargers but which EPA does not propose to regulate under either PSES co-proposal because EPA has concluded that they do not pass through POTWs.

The Agency has estimated that the facilities with subcategory B and/or D operations would incur total post-tax annualized costs of \$0.71 million in complying with Option 1. The estimated total post-tax annualized costs for complying with other options are \$1.5 million for Option 2, and \$2.9 million for Option 3. The Agency estimated that none of the options would result in any closures or unemployment. These impacts, and the methodology behind them, are explained in greater detail in Section XI.B of this preamble and in the Economic Impact Analysis. Based upon these findings, EPA concluded that all four options are economically achievable. EPA selected Option 1 because it determined that option represented that best available technology from among all the economically achievable options.

In evaluating the non-water quality environmental impacts of the options, specifically electrical power consumption, the Agency found that the annual incremental increase in electrical power consumption for all facilities to achieve Option 1 was 265 megawatts (MW) beyond current usage (the same as for the proposed BPT limits). This is equivalent to an increase of approximately 0.005 percent of the pharmaceutical industry's purchased electrical energy usage in 1990. The incremental increases for electrical power consumption for the remaining options were: for Options 2 and 3, an increase of 182 MW and 364 MW, respectively, for all facilities for which EPA estimated compliance costs; and for Option 4 an increase of 911 MW for all facilities for which EPA estimated compliance costs. Further discussion of these non-water quality environmental

impacts are presented in Section 12 of the Technical Development Document.

The Agency considered other non-water quality environmental impacts of the proposed option, including the role which this proposal may play in the minimization, recycle, and disposal of characteristic (ignitable) volatile organic wastes. EPA has determined that Options 2, 3 and 4 will generate 76 metric tons per year of condensates as a result of the use of steam stripping or steam stripping with distillation technologies at direct discharging plants. Based on the small increase in condensate generation associated with Options 2, 3 and 4 EPA has concluded that the recovery opportunities or incineration issues prompted by condensate generation do not provide a basis for choosing one of the technology options as the basis for proposed BAT limitations for facilities with subcategory B and/or D operations. The Agency also considered the effect of these four options on the current levels of air emissions from wastewater at facilities with subcategory B and/or D operations. To do this, EPA used the WATER7 computer model to evaluate the 1990 levels of air emissions from wastewater for facilities with subcategory B and/or D operations. The results of the analyses were used to estimate air emission increases or decreases for the regulatory options. The Agency estimates that Option 1 would result in a minimal increase in air emissions, while Options 2, 3 and 4 would decrease air emissions by 16 metric tons per year. EPA concluded that the changes from current emission levels are not significant enough to justify selection of Options 2, 3 and 4.

EPA also concluded that the engineering aspects of all four options were compatible with current manufacturing processes employed and potential process changes at facilities with subcategory B and/or D operations and thus did not provide a basis for selecting an option. Similarly, the age of equipment and facilities involved did not provide any basis for selecting among the options.

The selection of Option 1 as BAT for facilities with subcategory B and/or D operations reflects, in large part, EPA's conclusion, based on currently available data, that BPT level biological treatment can degrade the relatively small load of organic pollutants generated by these facilities with a low occurrence of air emissions during advanced biological treatment. The Agency has noted, however, that this industry is dynamic with respect to its production processes. Thus, volatile organic pollutant loading data requested by EPA for 1991-1994

may lead to a different conclusion regarding the need for and feasibility of controlling volatile organic pollutants. See Section XIV, solicitation number 7.

*d. Point of regulation.* EPA considered three different points of compliance monitoring for facilities with subcategory A and/or C operations in establishing the proposed BAT effluent limitations for control of strippable and nonstrippable organic pollutants, and cyanide and ammonia. These points are located: (1) In-plant prior to dilution by non-process wastewater, commingling with other process wastewater streams not containing the regulated pollutants at treatable levels, and any conveyance, equalization, or other treatment units that are open to the atmosphere; (2) in-plant after commingling with other regulated process wastewater streams but prior to open-air primary treatment; and (3) at the final effluent point or end-of-pipe.

EPA is proposing BAT limitations for 45 volatile and semivolatile pollutants for facilities with subcategory B and/or D operations based on advanced biological treatment at the end of the pipe because currently available data does not support basing such limitations on in-plant steam stripping or steam stripping with distillation technologies. For facilities with subcategory A and/or C operations, EPA is proposing to set BAT limitations based on advanced biological treatment at the end of the pipe for eight semivolatile organic pollutants and COD because these pollutants are not strippable. For these facilities, EPA also proposes to enforce limits on cyanide inside the discharger's facility at in-plant location (1). EPA is proposing BAT limitations for 37 volatile and semivolatile pollutants plus ammonia for facilities with subcategory A and/or C operations based on in-plant steam stripping followed by advanced biological treatment at the end of the pipe.

In the usual case, compliance monitoring for NPDES permits occurs at the end of the pipe. See 40 CFR 122.45(a). However, the NPDES regulations also authorize permitting authorities to impose in-plant monitoring requirements on a case-by-case basis. 40 CFR 122.45(h). Those regulations provides that when permit effluent limitations or standards imposed at the point of discharge are impractical or infeasible, limitations or standards may be imposed on internal wastestreams before mixing with other wastestreams or cooling waters. *Id.* Under that regulation, the permit writer must describe in the fact sheet the exceptional circumstances that make such limits necessary. Section

122.45(h)(2) lists examples of exceptional circumstances that could justify such in-plant monitoring requirements. EPA also proposes to provide in the regulations that the BAT limitations set forth in the tables for subcategories A and C do not apply for any pollutant for which the permit writer finds it necessary to specify in-plant monitoring requirements under 40 CFR 122.44(i) and 122.45(h). EPA proposes that limitations for those pollutants would be established on a best professional judgment basis pursuant to 40 CFR 125.3. Permit writers in such cases should use as guidance the standards proposed as PSES for the particular pollutants as set forth at §§ 439.16(a)(1) and 439.36(a)(1) of the proposed regulation, because the proposed standards for those pollutants reflect in-plant monitoring based or the steam-stripping component of the BAT technology.

In the event that EPA decides to specify an in-plant monitoring location for the 12 highly strippable volatile organic pollutants, EPA would also propose to establish different BAT limitations corresponding to that location. EPA would likely use as a model the proposed pretreatment standards for existing sources in these subcategories for the reasons set forth above.

In developing this proposal, EPA considered establishing in-plant monitoring locations for all 45 volatile organic pollutants for facilities with subcategory A and/or C operations. EPA had several reasons for considering that approach. First, EPA was concerned that limits imposed at the end of the pipe for these pollutants could be impractical or infeasible to enforce. The limitations being proposed for the 45 volatile organic pollutants are based on BAT model technology steam stripping followed by advanced biological treatment. Many of these proposed limitations are only marginally above the levels at which these pollutants can be detected in the wastestreams. Dilution of these regulated wastestreams with other streams not containing the regulated pollutants, followed by incidental air stripping in primary and secondary treatment units, would in most cases cause the pollutants to be present at or below detection by current analytical methods. Thus, EPA was concerned that neither the discharger nor the permitting authority could practicably or feasibly determine, at the end of the pipe, whether the limits in fact were being met. Second, EPA was also concerned that monitoring for some pollutants at the point of discharge would be impractical and infeasible as

measures of the performance of the BAT control technologies, because EPA would have no way of knowing whether reductions in wastewater discharges are being achieved by application of the control technology or by air emissions in wastewater conveyance and treatment facilities. Companies are not required to install EPA's model BAT technology and can choose how they wish to achieve the limitations in these regulations. (EPA uses such information to review existing effluent limitations and to determine, consistent with sections 304(b) and 304(m) of the Clean Water Act, whether revisions are necessary.) Third, in-plant monitoring requirements could promote pollution prevention opportunities for recycle and reuse of volatile organic pollutants, including nonhalogenated volatile organic compounds (e.g., methanol), derived from application of in-plant technologies, like steam stripping. These compounds are considered "clean fuels." See Section XII.B for a discussion of "clean fuels." Reuse of these compounds as fuel could also help reduce a discharger's energy needs, a factor EPA must consider under section 304(b) of the Clean Water Act.

In considering whether to establish in-plant limitations for the 45 volatile organic pollutants, EPA also weighed the likelihood that wastewater pollutants will be transferred to the air in the course of primary or secondary treatment. Based on its analyses using the WATER7 model and questionnaire response data, EPA believes that wastewater from subcategory A and/or C facilities can indeed produce significant air emissions. EPA also believes that the steam stripping component of the proposed BAT technology will significantly reduce the likelihood of these emissions, because it achieves a removal efficiency of 99% for most of these pollutants. EPA further emphasizes that air stripping is not part of the proposed BAT technology.

Although EPA concluded that it has the legal authority to establish in-plant monitoring requirements, EPA has determined as a matter of policy that proposing such requirements today to account for these emissions would be premature because of the impending rulemaking for this industry under the Clean Air Act. As discussed in greater detail in Section X below, EPA expects to propose MACT standards for the pharmaceutical industry on the basis of the same steam stripper design employed in this water rulemaking. EPA also expects in the Clean Air Act rulemaking to regulate all volatile organic hazardous air pollutants (HAPs), including many of the 45 volatile

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

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

#### 4. NSPS

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

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

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

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

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

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

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

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

EPA considered the potential cost of the proposed NSPS technology for new plants, as well as the costs associated with Option 2, which EPA did not select. EPA concluded that costs associated with any option would not be so great as to present a barrier to entry, because EPA anticipated no economic impacts for existing source subcategory A and C plants if they were to implement the proposed NSPS technology. The Agency also considered energy requirements and other non-water quality environmental impacts when comparing the GAC technology (Option 2) with Option 1. EPA concluded that there would be only a slight difference in the energy requirements associated with Options 1 and 2. There are no significant differences in the other non-water quality environmental impacts between the two options considered. EPA did not select Option 2 as the proposed basis for NSPS because, as noted above, EPA does not have sufficient data to quantify the amount of COD removed after application of steam stripping with distillation technology and therefore could not determine whether granular activated carbon technology is appropriate to remove remaining COD loads. See Section 16 of the TDD for further discussion of NSPS for all four subcategories.

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

performers with subcategory A and/or C operations. EPA believes that a substantial portion of the raw waste load COD can be removed in plant, prior to advanced biological treatment, by application of steam stripping with distillation technology—upon which the proposed NSPS for priority pollutants and the other nonconventional pollutants are based. However, EPA lacks sufficient data at this time to quantify the removal of COD achievable through in-plant steam stripping with distillation, and in turn the further removal of remaining COD load achievable by advanced biological treatment, and therefore is not able to propose subcategory A and/or C NSPS for COD based on that combination of technologies. EPA solicits data and comments concerning the establishment of NSPS for COD for subcategories A and C based on steam stripping with distillation plus advanced biological treatment. See Section XIV, solicitation number 20.

(ii) Conventional pollutants. EPA today is proposing NSPS for BOD<sub>5</sub> and TSS for the fermentation and chemical synthesis subcategories (A and C). As noted above for the proposed revised BPT limitations, EPA is not proposing to change the pH limitations incorporated in the existing NSPS. Based upon data available for this subcategory, the technology basis for these proposed standards—advanced biological treatment—represents the best available demonstrated level of performance (the one best performer) for the control of BOD<sub>5</sub> and TSS in these subcategories.

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

(2) Biological and Natural Extraction and Mixing/Compounding/Formulating Subcategories, Subparts B and D. EPA today is proposing New Source Performance Standards (NSPS) for 56 priority, nonconventional and conventional pollutants for facilities with Biological and Natural Extraction and Mixing/Compounding/Formulating (B and D) subcategory operations. These proposed standards are based on the best available demonstrated control technology, process, operating method, or other alternative. In developing these proposed standards, the Agency

considered factors including the cost of achieving effluent reductions, non-water quality environmental impacts, and energy requirements.

(i) Priority and Nonconventional Pollutants. EPA today is proposing New Source Performance Standards for 54 priority and nonconventional pollutants for facilities with subcategory B and D operations. In developing NSPS for these subcategories, EPA evaluated two technology options described earlier in Section IX.E.3.c.(2). The two options are: (1) In-plant steam stripping with distillation plus advanced biological treatment; and (2) Option 1 plus Granular Activated Carbon adsorption treatment.

EPA is today proposing Option 1 as the NSPS technology basis for subcategories B and/or D. In making this selection, EPA analyzed all of the questionnaire data supplied by facilities with subcategory B and/or D operations and projected the types and volume of volatile organic pollutants that would be present in treatable levels in process wastewaters from new facilities in these subcategories. Although the 1990 questionnaire data indicated that process wastewater from the 14 direct dischargers contained fewer pollutants in lower concentrations than the process wastewater of indirect dischargers (therefore justifying proposed effluent limitations based on advanced biological treatment alone, not including steam stripping with distillation), EPA has determined that there is no basis to conclude that data would adequately depict the wastewater characteristics of a new direct discharger. Thus, EPA relied instead on the entire universe of facilities with subcategory B and/or D operations, irrespective of their direct or indirect discharger status, on the theory that these facilities are more plentiful and hence statistically more significant. Because EPA has no basis for concluding that the wastewater characteristics are related to the manner of discharge, EPA saw no reason to confine its NSPS analysis to the 14 existing direct dischargers and to ignore the 67 indirect dischargers that reported data. In evaluating all of the data available to it for these subcategories from the 1990 questionnaire, EPA concluded that the vast majority of facilities with subcategory B and/or D operations have process wastewater with a comparatively wide variety of volatile organic pollutants in comparatively high concentrations, as reported by 67 of the 188 existing indirect discharging plants with subcategory B and/or D operations. EPA considers wastestreams of these 67

plants to be more typical of the wastestreams EPA expects to find in new sources in this subcategory. Therefore, EPA concluded that the process wastewater of new facilities with subcategory B and/or D operations was more likely to resemble the more typical subcategory B and/or D wastestreams, not the atypical wastestreams reported by the 14 existing direct dischargers in those subcategories. Based on that conclusion, EPA selected, as the proposed technology basis for NSPS for facilities with subcategory B and/or D operations, in-plant steam stripping with distillation treatment followed by end-of-pipe advanced biological treatment, which EPA has concluded represents the best available demonstrated treatment technology. EPA selected a more stringent NSPS technology than its chosen BAT technology because new sources have the opportunity to segregate their process wastewater in such a way as to minimize the amount of wastewater that will require steam stripping with distillation, thereby reducing the adverse energy impacts that prevented EPA from selecting this technology as BAT. See Section 5 of the TDD for further discussion of process wastewaters that EPA projects would be generated by facilities with subcategory B and D operations.

EPA considered the potential cost of the proposed NSPS technology for new plants. EPA concluded that costs associated with either option would not be so great as to present a barrier to entry. EPA predicted no economic impacts (i.e., closures) for existing source subcategory B and D plants if they were to implement the equivalent technology options considered as possible BAT for those subcategories. The Agency noted, however, that the BAT technology option (based primarily on steam stripping with distillation) was inappropriate treatment for the small reported quantities of volatile organic loadings, because the resulting small pollutant removals did not warrant the additional cost of steam stripping with distillation. See Section IX.E.3.c.(2) above.

The Agency also considered energy requirements and other non-water quality environmental impacts when comparing the GAC technology (Option 2) with Option 1. EPA concluded that there would be only a slight difference in the energy requirements associated with Options 1 and 2. There are no significant differences in the other non-water quality environmental impacts between the two options considered. EPA did not select Option 2 as the proposed basis for NSPS because, as

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

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

(ii) Conventional Pollutants. EPA today is proposing NSPS for BOD<sub>5</sub> and TSS for facilities with Biological and Natural Extraction and Mixing/Compounding/Formulating subcategories (B and D). As noted above for the proposed NSPS for facilities with subcategory A and/or C operations, EPA is not proposing to change the pH limitations incorporated in the existing NSPS for facilities with subcategory B and D operations. Based upon data available for this subcategory, the technology basis selected for these proposed standards—advanced biological treatment—represents the most stringent demonstrated level of performance (the one best performer) for the control of BOD<sub>5</sub> and TSS in these subcategories.

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

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

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

#### 5. PSES

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

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

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

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

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

In determining whether to propose pretreatment standards for the four manufacturing subcategories, EPA first identified the pollutants of concern present in the wastewater characteristic of the particular subcategories. EPA determined from the available data that as many as ten priority pollutants and 45 nonconventional pollutants could be present, in varying amounts and frequencies, in the wastestreams of facilities in all four manufacturing subcategories (excluding cyanide and ammonia for subcategories B and D.) In selecting the pollutants for analysis and in performing the pass-through determination, EPA made three threshold decisions in view of the data available to it.

First, with respect to subcategories B and D, EPA used wastestream data pertaining to indirect discharging facilities rather than direct discharging facilities, because, for reasons EPA is unable to explain, the available data indicated that the wastestreams of direct dischargers were significantly different from and hence unrepresentative of the wastestreams for indirect dischargers in those subcategories. Accordingly, EPA concluded that it would be most appropriate to identify the pollutants of concern and ultimately evaluate the need for pretreatment standards based on the wastewater characteristic of the indirect dischargers that would be subject to such standards.

Second, based on that wastestream data, EPA identified cyanide destruction plus steam stripping followed by advanced biological treatment for subcategory A and/or C facilities and advanced biological treatment for subcategory B and/or D facilities as the best available technology economically achievable to remove the pollutants of concern from those wastestreams. EPA then used these technologies in its pass-through analysis as the basis for comparing the removal efficiencies accomplished through secondary treatment by POTWs.

Third, EPA made pass through determinations by pollutant for all four manufacturing subcategories together, because the data from indirect dischargers data available to EPA indicate that steam stripping is applicable to all four subcategory wastestreams at indirect discharging facilities. Based on these decisions, EPA then compared removal efficiencies achievable by well-operated POTWs employing secondary treatment with those achievable by direct dischargers employing the relevant technology for those subcategories. In co-proposal (1), EPA determined for subcategories A and C that 52 pollutants pass through

POTWs and for subcategories B and D that 50 pollutants pass through, based on the information available to it at this time.

For subcategories A and C, EPA also concluded that ammonia passes through because POTWs generally do not have the nitrification capability that comprises part of the technology basis for the proposed BAT limitations for those subcategories. With respect to cyanide for subcategories A and C, EPA found that this pollutant passes through POTWs because the removal of cyanide by BAT-level cyanide destruction units at direct discharging plants with subcategory A and C operations is significantly greater than the documented removals by POTWs with advanced secondary treatment. These findings regarding ammonia and cyanide are not affected by alternative co-proposals (1) and (2).

Based on the pass-through determination in co-proposal (1), EPA proposes to set pretreatment standards for 45 priority and nonconventional organic pollutants for all subcategories in addition to cyanide and ammonia for subcategories A and C. In determining whether these volatile and semi-volatile organic pollutants pass through POTWs, EPA employed its traditional pass through methodology as described above. EPA determined that dischargers in all subcategories could remove up to 99 percent or more of the volatile and semi-volatile organic pollutants from their wastestreams using the BAT technology basis which includes in-plant steam stripping for subcategory A and/or C facilities.

Relying on data reported in the Domestic Sewage Study, EPA then ascertained the removal efficiencies achieved by POTWs for those pollutants using secondary treatment. In evaluating removal efficiencies by POTWs for volatile and semi-volatile pollutants, EPA notes the fact that some of the removal occurring after wastewater leaves a manufacturing facility results from volatilization of these pollutants in the head works and unit operations preceding biological treatment of the POTWs. EPA has consistently refused in these circumstances to regard transfers of pollutants from wastewater to the air as treatment. See, e.g., 59 FR at 50665 (Pesticides guidelines); 58 FR at 36885 (Organic Chemicals, Plastics and Synthetic Fibers guidelines). Therefore, because of this volatilization, the quantity of a particular volatile or semi-volatile pollutant actually available to be removed by the POTW's secondary treatment works was less than the quantity of that pollutant present in the wastestream at the time it entered the

POTW collection system. Thus, the POTW treated—and hence removed—a smaller percentage of the pollutant than it would have achieved through its secondary treatment if volatilization en route had not occurred. For a detailed discussion of volatilization in the context of EPA's pass through determinations for all pollutants in all subcategories, see Section 17 of the TDD.

The pass-through determinations reflected in co-proposal (1) are supported by POTWs that treat wastewater generated by pharmaceutical manufacturing facilities. In a letter sent to EPA dated February 14, 1995, the Association of Metropolitan Sewerage Agencies (AMSA) urged EPA to establish national pretreatment standards for organic pollutants found in pharmaceutical wastewater. A copy of this letter is in the rulemaking docket. AMSA argued that a decision by EPA not to regulate these pollutants at the national level would shift the financial, technical and legal burden of regulation to POTWs, which would need to establish local limits for these pollutants on a plant-by-plant, pollutant-by-pollutant basis. Among other things, AMSA asserted that many of its POTW member organizations lack the on-site technical expertise to develop limits for the wide variety of volatile organic pollutants of potential concern. It further asserted that even where such expertise exists, the costs associated with establishing local limits in the absence of federal standards would be so significant that they would amount to unfunded mandates. AMSA also noted that pretreatment standards established at the national level would facilitate the enforcement of limits to protect against volatility, exfiltration and flammability concerns. AMSA concluded that promulgation of national pretreatment standards such as those contained in co-proposal (1) would be the most environmentally sound, timely, and cost effective method of addressing these pollutants of concern. EPA solicits comment on these arguments in support of co-proposal (1). See Section XIV, solicitation number 24.4.

Under co-proposal (2), EPA is considering a finding of no pass-through for 33 priority and nonconventional pollutants in all four subcategories. EPA is soliciting comments and data with respect to this finding. See Section XIV, solicitation number 24.3. EPA has developed co-proposal (2) because of concerns expressed by industry representatives that EPA's pass-through analysis under co-proposal (1) may not be correct for some of the 33 volatile organic pollutants such as methanol,

ethanol, and acetone. EPA believes that the additional data and comments received concerning the pass-through analysis for these 33 volatile organic pollutants will enable the Agency to make a final pass-through determination for these pollutants. EPA notes that co-proposal (2) does not affect EPA's pass-through findings regarding the 12 highly strippable organic pollutants (and cyanide and ammonia for subcategories A and C) for which EPA proposes to establish PSES independently.

EPA is not proposing pretreatment standards for several pollutants found in subcategory A, B, C and D facility wastestreams for the following reasons. (This part of the proposal is not affected by the issues addressed in co-proposals (1) and (2).) EPA has concluded for all four manufacturing subcategories that phenol does not pass through for the reasons set forth in the **Federal Register** Notices announcing the promulgation of effluent limitation guidelines and standards for the Pesticide Chemicals and Organic Chemicals, Plastics and Synthetic Fibers (OCPSF) industries. See 59 FR 50638, 50664-65 (September 28, 1993); 58 FR 36872, 36885-86 (July 9, 1993). In addition, EPA does not have sufficient data at this time to determine whether *acetonitrile* and *polyethylene glycol 600* pass through POTWs and therefore does not propose pretreatment standards to control them. Similarly, EPA lacks sufficient data to make a pass-through determination for COD generated by facilities with subcategory A and/or C operations, although EPA is concerned that certain refractory organic waste materials measured as COD that are generated by such facilities may pass through POTWs. (EPA has made a preliminary judgment that COD generated by facilities with subcategory B and/or D operations does not pass through POTWs. EPA will review this judgment based on new data as it becomes available.) EPA therefore is soliciting data and comments in order to make a pass-through determination with respect to *acetonitrile*, *polyethylene glycol 600*, and COD. See Section XIV of this preamble, solicitation numbers 26 and 27.3. In addition, as noted above, EPA is not proposing pretreatment standards for five nonconventional organic pollutants (formaldehyde, N,N-dimethyl formamide, N,N dimethyl acetamide, ethylene glycol, and dimethyl sulfoxide) for any subcategory because, although EPA has determined that they pass through based on the BAT-level technology, EPA has concluded that the PSES technology (in-plant steam stripping) is an inappropriate basis for pretreatment

standards because these pollutants are not strippable. Moreover, EPA currently has insufficient data to select a treatment technology that would be an appropriate basis for such standards. EPA is considering package biological treatment of selected wastestreams for this purpose and solicits comments and data on this and other possible technology bases for pretreatment standards. See Section XIV, solicitation numbers 27.1 and 27.2. EPA also solicits comment and data regarding other pollutants that may pass through or interfere with POTWs, e.g., sulfates and sulfides. See Section XIV, solicitation number 28.

*b. Options Considered.* EPA considered four technology options for PSES under two different regulatory co-proposal scenarios for facilities with subcategory A, B, C, and D operations. Under co-proposal (1), EPA would propose PSES for 12 highly strippable organic pollutants (plus cyanide at an in-plant location (1) for subcategory A and/or C facilities) and 33 less strippable pollutants (plus ammonia for subcategory A and/or facilities) at the point of discharge to the POTW sewer. In-plant location (1) is described in IX.E.3.d. above. Under co-proposal (2), EPA would propose PSES only for the 12 highly strippable organic pollutants, plus cyanide at an in-plant location (1) and ammonia at the point of discharge to the POTW sewer for subcategory A and/or C facilities. As discussed in subsection a, above, EPA would not propose any pretreatment standards for the 33 less strippable organic pollutants under co-proposal (2) because of issues raised concerning EPA's pass-through analysis for those pollutants.

Under co-proposals (1) and (2), EPA considered basing PSES on the following four technology options for facilities with subcategory A and/or C operations for those pollutants found to pass through:

*Option (1) In-plant steam stripping plus in-plant cyanide destruction.*

Standards based on this option would control up to eight priority and 38 nonconventional volatile organic pollutants plus cyanide (depending on the pass-through co-proposal considered). Twelve pollutants plus cyanide would be controlled at the in-plant location (1) and 34 pollutants (including ammonia) at the point of discharge to the POTW sewer.

*Option (2) In-plant steam stripping/distillation plus in-plant cyanide destruction.*

Standards based on this option would control up to eight priority and 38 nonconventional volatile organic pollutants plus cyanide (depending on

the pass-through co-proposal considered). Distillation affords significantly greater removal of volatile organic pollutants that are difficult to strip, such as methanol. Under this option, 22 volatile organic pollutants plus cyanide would be controlled at the in plant location (1) and 24 pollutants (including ammonia) would be controlled at the point of discharge to the POTW sewer.

*Option (3) In-plant steam stripping/distillation plus in-plant cyanide destruction plus advanced biological treatment.* The addition of advanced biological treatment would achieve additional volatiles removal beyond that achieved by the technology described in Option 2 as well as significant reductions in discharge levels of COD. Advanced biological treatment would also reduce discharge levels of nonstrippable organic pollutants that are biodegradable.

*Option (4) In-plant steam stripping/distillation plus in-plant cyanide destruction plus advanced biological treatment plus granular activated carbon (GAC) treatment.* The addition of granular activated carbon treatment to the technology described in Option 3 would further reduce COD discharge levels.

EPA considered the same four technology options for PSES for facilities with subcategory B and/or D operations, excluding in-plant cyanide destruction (cyanide and ammonia are not regulated pollutants at subcategory B and/or D facilities). EPA has selected Option 1 for PSES under both co-proposals for indirect discharging facilities with subcategory A and/or C operations. The Agency has evaluated the costs of this option based on co-proposal (1) and found that there would be no closures among affected facilities (for which costs were estimated by EPA) as a result of these costs. Therefore EPA determined the costs of Option 1 to be economically achievable based on co-proposal (1). EPA also found the other options to be economically achievable. EPA selected Option 1 because it determined that this option represents the best available technology among all economically achievable options, insofar as it achieves pollutant reductions necessary to prevent pass-through of volatile organic pollutants, allows for recovery and recycling of volatile organic pollutants, and reduces non-water quality environmental impacts caused by air emissions of pollutants from wastewater. See Section XII.B of this preamble for a discussion of the Administrator's waste minimization and combustion strategy. Although Options 2, 3, and 4 would

achieve essentially the same decrease in the emission of wastewater pollutants to the air as Option 1, the increase in energy use requirements associated with Options 2, 3, and 4 would be equivalent to an increase of 31 percent above the 1990 pharmaceutical industry energy use. For this reason, EPA selected Option 1 over Options 2, 3, and 4.

EPA did not select Options 3 or 4 because EPA has not determined whether refractory organic materials measured as COD that are generated by facilities with subcategory A and/or C operations pass through POTWs and therefore is not proposing standards based on potentially unnecessary technology. Moreover, as noted above in EPA's discussion of the proposed BAT limitations for these subcategories, even assuming COD does pass through, EPA lacks data to estimate the COD reductions achievable by steam stripping and thus cannot compare COD reductions achievable by Options 2, 3, and 4.

EPA has also selected Option 1 as the proposed technology basis for PSES (minus cyanide destruction) for facilities with subcategory B and/or D operations. Under co-proposal (1), EPA would propose PSES for 12 highly strippable organic pollutants at in-plant location (1) and 33 less strippable pollutants at the point of discharge to the POTW sewer. In-plant location (1) is described in IX.E.3.d., above. Under co-proposal (2), EPA would propose PSES only for the 12 highly strippable organic pollutants at in-plant location (1).

In selecting steam stripping (PSES Option 1 minus cyanide destruction) as the technology basis for the proposed PSES for facilities with B and/or D subcategory operations, EPA relied upon the 1990 questionnaire data supplied by 188 facilities with subcategory B and/or D operations that send their wastewater to POTWs for treatment. For reasons that EPA is not able to explain, these data show that the wastestreams characteristic of indirect dischargers with subcategory B and/or D operations are significantly different (for regulatory purposes) than the wastestreams of direct dischargers with subcategory B and/or D operations. See Section IX.E.3.c(2) for discussion of basis for proposed BAT limitations for facilities with subcategory B and D operations. In view of this reported difference, EPA has based today's proposed pretreatment standards on a different technology—steam stripping—than the BAT limitations proposed for the direct dischargers in this subcategory, which are based on advanced biological treatment.

The data supplied by the 188 indirect facilities in this subcategory show that these facilities discharge BOD<sub>5</sub>, TSS, COD, 18 nonconventional pollutants and four priority pollutants. See Section 9 of the TDD. EPA's analysis of the questionnaire data indicates that the total nonconventional and priority pollutant loadings discharged, on average, for each indirect discharger with subcategory B and D operations in 1990 was 14,600 pounds/year (in contrast to the average of 1,660 pounds/year reported by the 14 direct dischargers in these subcategories). The 188 facilities also reported in their questionnaire responses that they emit from wastewater a total of 1.5 million pounds/year of volatile organic pollutants (in contrast to the emissions totaling 170 pounds/year reported by the direct dischargers). Subsequent analysis by EPA using its WATER7 model indicates that these indirect dischargers may actually emit closer to 3.3 million pounds/year from wastewater (in contrast to the emissions totaling 35,000 pounds/year for the direct dischargers). See Section 12 of TDD for discussion of difference between questionnaire results and WATER7 model results. Based on its evaluation of the data available to it, EPA proposes to base pretreatment standards for facilities with subcategory B and D operations on in-plant steam stripping (Option 1). This technology is designed to remove large quantities and many varieties of solvents from process wastewater. According to the data supplied by the 188 indirect dischargers with subcategory B and D operations, EPA has concluded that the wastewater characteristic of these facilities—with its comparatively high volume and concentration of solvents—is well-suited to this form of treatment. Accordingly, EPA has determined for the reasons set forth above in connection with establishing BAT limitations for facilities with A and C subcategory operations, see Section IX.E.3.c(1) above, that in-plant steam stripping is the most appropriate technology basis for pretreatment standards for facilities with subcategory B and/or D operations. Even though EPA's 1990 data indicates that subcategory B and/or D facilities discharge only 22 priority and nonconventional pollutants, EPA is proposing to establish pretreatment standards for 45 priority and nonconventional pollutants because all 45 pollutants potentially can be discharged to POTWs. (EPA is soliciting comment on mechanisms by which dischargers that do not use or generate

pollutants for which standards are proposed can be exempted from monitoring for those pollutants. See Section XIV, solicitation number 38.) In addition, EPA found that none of the 67 facilities (of the 188 indirect dischargers with subcategory B and D operations) that would incur costs as a result of the proposed PSES limitations would close as a result of this option. Therefore EPA determined that the costs of the pollutant reduction achieved by this option were economically achievable.

In considering the various technology options available as possible bases for the proposed pretreatment standards for these subcategories, EPA rejected advanced biological treatment as a viable technology option and therefore did not consider it. Because indirect discharging facilities with subcategory B and/or D operations generate levels of BOD<sub>5</sub>, TSS and COD comparable to levels found in ordinary domestic sewage, EPA concluded that biological treatment afforded by POTWs is adequate for these levels of pollutants. Accordingly, EPA has determined that BOD<sub>5</sub>, TSS and, preliminarily, COD from facilities with subcategory B and/or D operations do not pass through. Thus, advanced biological treatment at these facilities prior to POTW treatment would be duplicative.

The Agency considered age, size, processes, other engineering factors, and non-water quality environmental impacts in developing the proposed PSES for all four subcategories. The Agency did not identify any basis for establishing different pretreatment standards based on age, size, processes, or other engineering factors. EPA has concluded that the technology upon which EPA proposes to base PSES for facilities with subcategory B and/or D operations would significantly decrease air emissions and would be consistent with the Administrator's waste minimization and combustion strategy. See Section XII.B of this preamble for a discussion of this strategy. EPA did not choose Option 2 because, although this option would result in approximately the same decrease in air emissions as Option 1, it would result in a significant increase in total energy use over that required under Option 1. (See section 16 of the TDD and the BAT discussion above.)

*c. Point of Regulation.* EPA is proposing to specify an in-plant compliance monitoring location for each of the 12 highly strippable volatile organic pollutants for which EPA is proposing PSES. (This is not affected by the co-proposals addressing the 33 less strippable pollutants.) This location is described as in-plant location (1) in

section E.3.d., above. For facilities with subcategory A and/or C operations, EPA also proposes to require in-plant monitoring for cyanide based upon cyanide destruction technology.

EPA acknowledges that it reached a different conclusion regarding the point of regulation for direct dischargers with subcategory A and/or C operations. As discussed in section E.3.d., above, EPA is proposing to specify end-of-pipe monitoring requirements for the 12 highly strippable volatile organic pollutants in deference to the forthcoming Clean Air Act rule for this industry, which will control air emissions of these pollutants. EPA also noted in that section, however, that the permit writer has the authority under the NPDES permit regulations to establish limits in-plant on a case-by-case basis when it would be impractical or infeasible to monitor for the pollutants at the end of the pipe because of dilution or other considerations. Indeed, EPA observed that the BAT limitations being proposed for the 12 highly strippable volatile organic pollutants in subcategories A and C are at levels that are only marginally above the analytical minimum levels established for these pollutants and expressed its concern that dilution or air stripping might make detection of the pollutants infeasible at the end of the pipe. Nevertheless, EPA concluded that this concern could be addressed for direct dischargers on a case-by-case basis by the permit writer and therefore proposed that establishing in-plant compliance requirements on a national level was not essential.

EPA is proposing to reach a different conclusion for indirect dischargers. Like the proposed BAT limitations, the proposed pretreatment standards for existing dischargers are only marginally above the minimum levels established for these pollutants. Similarly, EPA is concerned that dilution with process and non-process wastewater might cause the pollutants to be undetectable by current analytical methods. Under EPA regulations, however, indirect dischargers are prohibited from substituting dilution for treatment, except where dilution is expressly authorized by an applicable pretreatment standard. See 40 CFR 403.6(d). This prohibition theoretically could be enforced by POTWs through the establishment of local limitations at in-plant locations on a pollutant-by-pollutant, case-by-case basis in the same way that a permit writer could do so for direct dischargers. By establishing in-plant monitoring requirements, the POTW, like the permit writer, would be able to determine whether compliance

is being achieved by dilution or by treatment. The difference, however, is this pollutant-by-pollutant, case-by-case solution to the detection and dilution problems may impose a financial and technical burden on POTWs. There are six times as many indirect dischargers as direct dischargers, and unlike state and EPA permit writers, POTWs commonly lack the on-site technical expertise to establish and justify in-plant monitoring requirements on a case-by-case basis. Even when such expertise exists, EPA is concerned that the accompanying burden and expense would be significant. Therefore, EPA is proposing to establish in-plant points of regulation on a nationwide level.

EPA is proposing pretreatment standards in large measure because of the concern registered by some POTWs that discharges containing substantial concentrations of these volatile organic pollutants may interfere with the operation of the sewerage system and the health and safety of employees of the POTW system. EPA solicits comment and supporting data regarding whether this objective may be satisfied by assuring that discharges to the POTW sewer are near or at the level of detection. See Section XIV, solicitation number 24.0. In addition, as discussed in Section X, EPA is developing a separate rulemaking under the requirements of Section 112 of the Clean Air Act to address the air emissions from pharmaceutical plants, including the emissions of these 12 highly strippable volatile organic pollutants. EPA's air rulemaking may complement this proposal so that standards set at the point of discharge to the POTW sewer may satisfy EPA's objectives in this rulemaking. EPA expects to propose these air emission standards next year. As a result, EPA is also considering whether to establish limits for the 12 highly strippable volatile organic pollutants at the point of discharge to the POTW sewer. See Section XIV, solicitation number 24.5.

## 6. PSNS

Section 307(c) of the Act requires EPA to promulgate pretreatment standards for new sources (PSNS) at the same time it promulgates new source performance standards (NSPS). New indirect discharging plants, like new direct discharging plants, have the opportunity to incorporate the best available demonstrated technologies, including process changes, in-plant controls, and end-of-pipe treatment technologies.

Any new source subject to part 439 that was a "new source" as defined under 40 CFR 122.29 prior to the date on which the pretreatment standards for

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

EPA considered three technology options for PSNS under two different regulatory co-proposal scenarios for facilities with subcategory A and/or C operations. Under co-proposal (1), EPA would propose PSNS for 12 highly strippable organic pollutants plus cyanide at an in-plant location (1) and 33 less strippable pollutants plus ammonia at the point of discharge to the POTW sewer. Under co-proposal (2), EPA would propose PSNS only for the 12 highly strippable organic pollutants, plus cyanide at in-plant location (1) and for ammonia at the end-of-pipe (3).

Under co-proposals (1) and (2), EPA considered the following three technology options for facilities with subcategory A and/or C operations for those pollutants found to pass through:

*Option (1):* In-plant steam stripping with distillation plus in-plant cyanide destruction.

*Option (2):* In-plant steam stripping with distillation plus in-plant cyanide destruction plus advanced biological treatment.

*Option (3):* In-plant steam stripping with distillation plus in-plant cyanide destruction plus advanced biological treatment plus granular activated carbon (GAC) treatment.

Under co-proposals (1) and (2), EPA considered the following two technology options for facilities with subcategory B and/or D operations for those pollutants found to pass through:

*Option (1):* In-plant steam stripping with distillation.

*Option (2):* In-plant steam stripping with distillation plus granular activated carbon (GAC) treatment.

EPA selected a more stringent PSNS technology than its chosen PSES technology because new sources have the opportunity to segregate their

process wastewater in such a way as to minimize the amount of wastewater that will require steam stripping with distillation, thereby reducing the adverse energy impacts that prevented EPA from selecting this technology as PSES.

EPA is proposing to set pretreatment standards for new sources based on PSNS Option 1 (steam stripping with distillation plus cyanide destruction) for priority and nonconventional pollutant for indirect discharging facilities with subcategory A and/or C operations. Similarly, EPA is proposing to set pretreatment standards for new sources based on PSNS Option 1 (steam stripping with distillation) for facilities with subcategory B and/or D operations.

EPA considered the cost of the proposed PSNS technologies for new plants. EPA has concluded that such costs are not so great as to present a barrier to entry, as demonstrated by the fact that currently operating plants are using these technologies. The Agency also considered energy requirements and other non-water quality environmental impacts when comparing the three PSNS technology options for facilities with subcategory A and/or C operations and the two PSNS technology options for facilities with subcategory B and/or D operations. EPA concluded that there would be only a slight difference in the energy requirements associated with Options 1, 2, and 3 for subcategory A and/or C facilities and with Options 1 and 2 for subcategory B and/or D facilities. There are no significant differences in the other non-water quality environmental impacts between the options considered.

#### 7. BMP

EPA is not proposing any Best Management Practices (BMPs) today for the Pharmaceutical Manufacturing Category. However, EPA is soliciting comment on whether BMPs are applicable to the pharmaceutical manufacturing industry and, if so, what they should include. See Section XIV, solicitation number 31.0. See also the TDD at Appendix B for specific BMPs that EPA is considering adopting.

#### F. Determination of Long-Term Averages, Variability Factors, and Limitations

A detailed description of the statistical methodology used for the calculation of limitations is described in the Statistical Support Document. A summary of the methodology follows.

Limitations were based on actual concentrations of constituents measured in wastewaters treated by BAT

treatment systems when such data were available. Limitations were transferred based on engineering analysis when actual monitoring data were unavailable. For steam stripping and distillation technology, engineering analysis involved grouping constituents on the basis of their Henry's Law Constant. For biological treatment, the engineering analysis involved grouping constituents on the basis of their chemical structure and published data on relative biodegradability.

The calculation of the BAT daily limitations for constituents other than cyanide was performed by the following steps. The arithmetic long-term mean concentration was calculated for each facility dataset representing BAT treatment technology, and the median of the means was determined. A modified delta-lognormal distribution, the distribution model used by EPA in the Organic Chemicals, Plastics and Synthetic Fibers (OCPSF) and Pesticides Manufacturing rulemakings, was fit to daily concentration data from each facility dataset that had enough detected concentration values for parameter estimation. Variability factors were then computed for each of these datasets, and the average variability factor was determined. Finally, the daily maximum limitation was calculated by multiplying the median long-term mean by the average variability factor. The monthly average maximum limitation was calculated similarly except that the variability factor corresponding to the 95th percentile of the distribution of monthly averages was used instead of the 99th percentile of daily concentration measurements. The monthly average maximum limitation calculation assumes four measurements per month, or one per week.

The modified delta-lognormal distribution models the data as a mixture of non-detects and measured values. This distribution was selected because the data for most constituents consisted of a mixture of measured values and non-detects. The modified delta-lognormal distribution assumes that all non-detects have a value equal to the detection limit and the detected values follow a lognormal distribution.

A beta distribution rather than a delta-lognormal was used to model cyanide data. The BAT treatment for cyanide requires the reprocessing of wastewater if effluent cyanide concentrations exceed 1 ppm. Therefore, the cyanide data from a properly operated treatment system should range between 0 and 1 ppm. Such data are appropriately modelled by the beta distribution. The parameters of the beta distribution were estimated from the cyanide dataset by

the method of moments. Parameter estimates were then substituted in the beta distribution from which the daily limitation (99th percentile) was calculated. The monthly average cyanide (based on 4 daily measurements) limitation was estimated in a similar fashion.

The calculation of the proposed BPT limitations was based on measured concentrations of BOD<sub>5</sub>, COD, and TSS measured in wastewaters treated by BPT systems. A 1-day and 30-day limitation was determined for each BPT facility dataset from a modified delta-lognormal distribution that was fit to the data. These limitations were then averaged across the datasets to determine the overall 1-day and 30-day maximum limitations. An intermediate step involved adjusting the modeled variability to account for day-to-day correlation in concentrations of BOD<sub>5</sub>, COD, and TSS. The adjustment was based on a lag-1 autocorrelation time series model estimated from adjacent day observations, the same approach adopted in the OCPSF rulemaking. For datasets having an insufficient number of adjacent day observations to estimate an autocorrelation an average value was assumed.

#### G. Costs

The Agency estimated the cost for the pharmaceutical manufacturing industry to achieve each of the effluent limitations and standards proposed today. These estimated costs are summarized in this section and discussed in more detail in section 10 of the Technical Development Document. All cost estimates are expressed in 1990 dollars (the year for which EPA received questionnaire responses and data submissions). The cost components reported in this section are engineering estimates of the capital cost of purchasing and installing equipment and the annual operating and maintenance costs associated with that equipment. The total annualized cost, which is used to estimate economic impacts, better describes the actual compliance cost that a company will incur because it allows for interest, depreciation, and taxes. A summary of the economic impact analysis for the proposed regulation is contained in Section XI.B of today's notice. See also the Economic Impact Analysis.

##### 1. BPT

The Agency used a plant-specific engineering cost assessment to estimate the costs of achieving the proposed BPT limitations. If a plant's reported 1990 discharges of BOD<sub>5</sub>, TSS, COD and, in the case of facilities with subcategory A

and/or C operations, cyanide were less than the long-term average loads achievable by the technology basis for today's proposed BPT limitations, the plant was estimated to have no compliance costs. If the resulting pollutant loads exceeded the proposed BPT long-term average loads, EPA estimated costs for treatment system upgrades and, in the case of cyanide, in-plant hydrogen peroxide oxidation technology. Based on this analysis, EPA concluded that 20 pharmaceutical manufacturing facilities would incur costs to comply with the proposed BPT limitations. EPA estimated the total capital expenditures for complying with the proposed BPT limitations to be \$15.3 million and the annual operating and maintenance (O&M) costs to be \$7.5 million. The estimated cost for implementing the proposed BPT limitations is summarized for the A and C and B and D subcategories below in Table IX.G.1.

2. BAT

EPA estimated the costs to comply with today's proposed BAT limitations

on priority and nonconventional pollutants on plant-by-plant and pollutant-by-pollutant basis. If the loading data provided by the facility in its Section 308 questionnaire response indicated that its discharge was above the proposed limitation target load for a given pollutant, EPA developed cost estimates for the control technology EPA believes is appropriate for that pollutant (e.g., steam stripping for all strippable pollutants).

For direct dischargers with subcategory A and C operations, BAT costs include, where necessary, the costs for in-plant steam stripping followed by end-of-pipe advanced biological treatment upgrades to comply with the proposed limitations for priority and nonconventional pollutants. The operation and maintenance costs include monitoring of strippable pollutants in-plant and nonstrippable biodegradable pollutants at the end-of-pipe.

For direct dischargers with subcategory B and D operations, BAT costs include the costs for end-of-pipe advanced biological treatment upgrades.

The upgrades are designed around treating conventional pollutants to specific targets, equivalent to BPT long-term mean performance. In a few cases, additional compliance costs were estimated for direct discharging facilities with subcategory B and D operations that already achieve these conventional pollutant upgrade targets, but require more closely controlled treatment system operation to comply with the priority and nonconventional pollutant BAT limitations.

The BAT operation and maintenance costs for subcategories B and D include monitoring for priority and nonconventional pollutants at the end-of-pipe. EPA estimated the total capital expenditures for complying with the proposed BAT limitations to be \$57.0 million, and the annual operating and maintenance (O&M) costs to be \$36.8 million. These costs are not incremental and include the advanced biological treatment upgrades also presented under BPT. See Table IX.G.2-1 for a breakdown of the costs by subcategory.

TABLE IX.G.1.—COST OF IMPLEMENTING PROPOSED BPT REGULATIONS

[In millions of 1990 dollars]

Subcategory	No. of plants	Capital costs	Annual O&M costs
Fermentation (A) and Chemical Synthesis (C) .....	15	14.7	7.0
Biological and Natural Extraction (B) and Mixing/Compounding/Formulating (D) .....	5	0.6	0.5

TABLE IX.G.2.—COST OF IMPLEMENTING PROPOSED BAT REGULATIONS

[In millions of 1990 dollars]

Subcategory	No. of plants	Capital costs	Annual O&M costs
Fermentation (A) and Chemical Synthesis (C) .....	23	56.4	35.7
Biological and Natural Extraction (B) and Mixing/Compounding/Formulating (D) .....	13	0.64	1.1

3. PSES

EPA developed PSES costs for compliance with the proposed pretreatment standards for strippable priority and nonconventional pollutants in the same manner that it developed BAT compliance costs for these pollutants. In developing these costs, EPA based the number of pollutants

proposed to be regulated under PSES on the pass-through findings of PSES co-proposal (1), which include the 33 less strippable volatile organic pollutants. EPA did not include cost estimates for nonstrippable nonconventional pollutants in the PSES costs because EPA is requesting comment on its technology basis for controlling the

discharge of these pollutants. See Section XIV, solicitation numbers 27.1 and 27.2. The estimated total capital expenditure for complying with the proposed PSES limitations are \$91.8 million and the annual operating and maintenance (O & M) costs are \$54.1 million. See table IX.G.3 for a breakdown of the costs by subcategory.

TABLE IX.G.3.—COST OF IMPLEMENTING PROPOSED PSES REGULATIONS

[In millions of 1990 dollars]

Subcategory	No. of plants	Capital costs	Annual O&M costs
Fermentation (A) and Chemical Synthesis (C) .....	71	70.8	46.4
Biological and Natural Extraction (B) and Mixing/Compounding/Formulating (D) .....	75	21.0	7.7

**H. Pollutant Reductions**

The Agency estimated the reduction in the mass of pollutants that would be discharged from pharmaceutical manufacturing plants after the implementation of the regulations being proposed today. The reduction in pollutant mass is attributable both to in-plant treatment technologies and improved end-of-pipe treatment. In-plant technologies such as steam stripping achieve pollutant load reductions by physical removal or extraction of volatile organic pollutants. Other technologies such as end-of-pipe biological treatment and in-plant

cyanide destruction achieve pollutant reduction by chemically or biochemically altering the nature of the pollutants (e.g., by converting them to different substances like carbon dioxide and water). Additional information on the methodology used to estimate the pollutant reductions resulting from the implementation of the proposed effluent limitations and standards is included in Section 9 of the Technical Development Document.

**1. Conventional Pollutants**

For each subcategory, the Agency developed an estimate of the annual

average mass loadings of BOD<sub>5</sub> and TSS that would be discharged after the implementation of the proposed BPT limitations. Since EPA proposes to set BCT limitations for conventional pollutants equal to the proposed BPT limitations for all subcategories, there would be no further reduction in BOD<sub>5</sub> and TSS achieved through BCT. Then EPA subtracted these loadings from the discharge loadings reported in the Section 308 questionnaire responses for 1990. The resultant pollutant reductions for BOD<sub>5</sub> and TSS are summarized in Table IX.H.1.

TABLE IX.H.1.—BPT, BOD<sub>5</sub> AND TSS REDUCTIONS

Subcategories	BOD <sub>5</sub> reduction (lbs. per yr.)	TSS reduction (lbs. per yr.)
A and C .....	931,000	2,150,000
B and D .....	10,000	4,820

**2. Priority Pollutants**

For the ten priority pollutants EPA proposes to regulate, EPA estimated the removals achieved by the various BPT, BAT, and PSES technologies based on

raw waste load data provided by plants in their Section 308 questionnaire responses. In estimating these pollutant reductions, EPA did not include pollutant reductions being achieved by

existing technology, including advanced biological treatment, already in place. The resultant priority pollutant reductions are summarized in Table IX.H.2.

TABLE IX.H.2.—BPT, BAT AND PSES PRIORITY POLLUTANT REDUCTIONS

Subcategories	BPT reduction (cyanide) (lbs. per yr.)	BAT reduction (lbs. per yr.)	PSES reduction (lbs. per yr.)
A and C .....	38	2,650,000	7,140,000
B and D .....	<sup>1</sup> N/A	0	694,000

<sup>1</sup> Cyanide is not a pollutant of concern for facilities with subcategory B and D operations.

**3. Nonconventional Pollutants**

For the 45 nonconventional pollutants (excluding COD) for which limitations and standards are being proposed, EPA estimated the removals achieved by the

various proposed BPT, BAT, and PSES technology bases, using raw waste load data provided by plants in their Section 308 questionnaire responses. In estimating these pollutant reductions, EPA did not include pollutant

reductions being achieved by technology already in place, including in many cases advanced biological treatment. The resultant priority pollutant reductions are summarized in Table IX.H.3.

TABLE IX.H.3.—BPT, BAT AND PSES NONCONVENTIONAL POLLUTANT REDUCTIONS

Subcategories	BPT reduction (lbs. per yr.) COD only	BAT reduction (lbs. per yr.)	PSES reduction (lbs. per yr.)
A and C .....	9,840,000	16,800,000	30,900,000
B and D .....	59,600	22,600	3,440,000

**I. Regulatory Implementation**

**1. Applicability**

The regulation proposed today is just that—a proposed regulation. As such, although it represents EPA's best judgment at this time, it is not intended to be relied upon by permit writers in establishing effluent limitations. Indeed,

because EPA solicits comment and data (see specific solicitation numbers 1.2 and 1.3) regarding the proposed effluent limitations and standards specified in today's notice as well as on the technologies upon which they are based, the proposed limitations and standards and any conclusions set forth in this notice are subject to change.

**2. Upset and Bypass Provisions**

A "bypass" is an intentional diversion of waste streams from any portion of a treatment facility. An "upset" is an exceptional incident in which there is unintentional and temporary noncompliance with technology-based permit effluent limitations because of factors beyond the reasonable control of

the permittee. EPA's regulations concerning bypasses and upsets are set forth at 40 CFR 122.41(m) and (n).

### 3. Variances and Modifications

The CWA requires application of the effluent limitations established pursuant to section 301 or the pretreatment standards of section 307 to all direct and indirect dischargers. However, the statute provides for the modification of these national requirements in a limited number of circumstances. Moreover, the Agency has established administrative mechanisms to provide an opportunity for relief from the application of national effluent limitations guidelines and pretreatment standards for categories of existing sources for toxic, conventional and nonconventional pollutants.

*a. Fundamentally Different Factors Variances.* EPA will develop effluent limitations or standards different from the otherwise applicable requirements if an individual discharging facility is fundamentally different with respect to factors considered in establishing the limitation or standards applicable to the individual facility. Such a modification is known as a "fundamentally different factors" (FDF) variance.

Early on, EPA, by regulation, provided for FDF modifications from BPT effluent limitations, BAT limitations for toxic and non-conventional pollutants and BCT limitation for conventional pollutants for direct dischargers. For indirect dischargers, EPA provided for FDF modifications from pretreatment standards. FDF variances for toxic pollutants were challenged judicially and ultimately sustained by the Supreme Court. *Chemical Manufacturers Ass'n v. NRDC*, 479 U.S. 116 (1985).

Subsequently, in the Water Quality Act of 1987, Congress added new section 301(n) of the Act explicitly to authorize modification of the otherwise applicable BAT effluent limitations or categorical pretreatment standards for existing sources if a facility is fundamentally different with respect to the factors specified in section 304 (other than costs) from those considered by EPA in establishing the effluent limitations or pretreatment standard. No FDF variance is available for new sources subject to NSPS or PSNS. Section 301(n) also defined the conditions under which EPA may establish alternative requirements. Under section 301(n), an application for approval of an FDF variance must be based solely on (1) information submitted during the rulemaking raising the factors that are fundamentally

different or (2) information the applicant did not have an opportunity to submit. The alternate limitation or standard must be no less stringent than justified by the difference and not result in markedly more adverse non-water quality environmental impacts than the national limitation or standard.

EPA regulations at 40 CFR Part 125 Subpart D, authorizing the Regional Administrators to establish alternative limitations and standards, further detail the substantive criteria used to evaluate FDF variance requests for direct dischargers. Thus, 40 CFR 125.31(d) identifies six factors (e.g., volume of process wastewater, age and size of a discharger's facility) that may be considered in determining if a facility is fundamentally different. The Agency must determine whether, on the basis of one or more of these factors, the facility in question is fundamentally different from the facilities and factors considered by the EPA in developing the nationally applicable effluent guidelines. The regulation also lists four other factors (e.g., infeasibility of installation within the time allowed or a discharger's ability to pay) that may not provide a basis for an FDF variance. In addition, under 40 CFR 125.31(b)(3), a request for limitations less stringent than the national limitation may be approved only if compliance with the national limitations would result in either (a) a removal cost wholly out of proportion to the removal cost considered during development of the national limitations, or (b) a non-water quality environmental impact (including energy requirements) fundamentally more adverse than the impact considered during development of the national limits. EPA regulations provide for an FDF variance for indirect dischargers at 40 CFR 403.13. The conditions for approval of a request to modify applicable pretreatment standards and factors considered are the same as those for direct dischargers.

The legislative history of Section 301(n) underscores the necessity for the FDF variance applicant to establish eligibility for the variance. EPA's regulations at 40 CFR 125.32(b)(1) are explicit in imposing this burden upon the applicant. The applicant must show that the factors relating to the discharge controlled by the applicant's permit which are claimed to be fundamentally different are, in fact, fundamentally different from those factors considered by the EPA in establishing the applicable guidelines. The pretreatment regulations incorporate a similar requirement at 40 CFR 403.13(h)(9).

*b. Economic Variances.* Section 301(c) of the CWA authorizes a variance from

the otherwise applicable BAT effluent guidelines for nonconventional pollutants due to economic factors. The request for a variance from effluent limitations developed from BAT guidelines must normally be filed by the discharger during the public notice period for the draft permit. Other filing time periods may apply, as specified in 40 CFR 122.21(l)(2). Specific guidance for this type of variance is available from EPA's Office of Wastewater Management.

*c. Water Quality Variances.* Section 301(g) of the CWA authorizes a variance from BAT effluent guidelines for certain nonconventional pollutants due to localized environmental factors. These pollutants include ammonia, chlorine, color, iron, and total phenols.

*d. Permit Modifications.* Even after EPA (or an authorized State) has issued a final permit to a direct discharger, the permit may still be modified under certain conditions. (When a permit modification is under consideration, however, all other permit conditions remain in effect.) A permit modification may be triggered in several circumstances. These could include a regulatory inspection or information submitted by the permittee that reveals the need for modification. Any interested person may request modification of a permit modification be made. There are two classifications of modifications: major and minor. From a procedural standpoint, they differ primarily with respect to the public notice requirements. Major modifications require public notice while minor modifications do not. Virtually any modification that results in less stringent conditions is treated as a major modification, with provisions for public notice and comment. Conditions that would necessitate a major modification of a permit are described in 40 CFR 122.62. Minor modifications are generally non-substantive changes. The conditions for minor modification are described in 40 CFR 122.63.

*e. Removal credits.* As described previously, many industrial facilities discharge large quantities of pollutants to POTWs where their wastewaters mix with wastewater from other sources, domestic sewage from private residences and run-off from various sources prior to treatment and discharge by the POTW. Industrial discharges frequently contain pollutants that are generally not removed as effectively by treatment at the POTWs as by the industries themselves.

The introduction of pollutants to a POTW from industrial discharges may pose several problems. These include

potential interference with the POTW's operation or pass-through of pollutants if inadequately treated. As discussed, Congress, in section 307(b) of the Act, directed EPA to establish pretreatment standards to prevent these potential problems. Congress also recognized that, in certain instances, POTWs could provide some or all of the treatment of an industrial user's wastewater 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 concentration of a pollutant in the 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 Part 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 (3d 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 that 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 that 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 November 25, 1992, EPA promulgated the Round One sewage sludge regulations establishing standards, including numerical pollutant limits, for the use or disposal

of sewage sludge. 58 FR 9248<sup>1</sup>. EPA established pollutant limits for ten metals when sewage sludge is applied to land, for three metals when it is disposed of on a surface disposal site and for seven metals and a total hydrocarbon operational standard, a surrogate for organic pollutant emissions, when sewage sludge is incinerated. These requirements are codified at 40 CFR Part 503.

The Phase One regulations partially fulfilled the Agency's commitment under the terms of a consent decree that settled a citizens suit to compel issuance of the sludge regulations. *Gearhart, et al. v. Reilly*, Civil No. 89-6266-JO (D.Ore). Under the terms of that decree, EPA must propose and take final action on the Round Two sewage sludge regulations by December 15, 2001.

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 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 the POTW's sewage sludge. See 40 CFR 403.7(a)(3)(iv)(C). Thus, given compliance with the requirements of EPA's removal credit regulations,<sup>2</sup> following promulgation of the pretreatment standards being proposed here, 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. If the POTW uses or disposes of its sewage sludge by land application, surface disposal or incineration, removal credits may be available for the following metal pollutants (depending on the method of use or disposal): arsenic, cadmium, chromium, copper, iron, lead, mercury, molybdenum, nickel, selenium and zinc. Given compliance with section 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, 1,1-dichloroethane, 1,2-dibromoethane, ethylbenzene, methylene chloride, toluene, tetrachloroethene, 1,1,1-trichloroethane, 1,1,2-trichloroethane and trans-1,2-dichloroethene.

Some facilities may be interested in obtaining removal credit authorization for other pollutants being considered for regulation in this rulemaking for which removal credit authorization would not otherwise be available under Part 403. Under sections 307(b) and 405 of the CWA, EPA may authorize removal credits only when EPA determines that, if removal credits are authorized, that the increased discharges of a pollutant to POTWs resulting from removal credits will not affect POTW sewage sludge use or disposal adversely. As discussed in the preamble to amendment to the Part 403 regulations (58 FR 9382-83), EPA has interpreted these sections to authorize removal credits for a pollutant only in one of two circumstances. Removal credits may be

<sup>2</sup> Under Section 403.7, a POTW is authorized to give removal credits only under certain conditions. These include applying for, and obtaining, approval from the Regional Administrator (or Director of a State NPDES program with an approved pretreatment program), a showing of consistent pollutant removal and an approved pretreatment program. See 40 CFR § 403.7(a)(3)(i), (ii), and (iii).

<sup>1</sup> The U.S. Court of Appeals for the District of Columbia Circuit has remanded portions of these regulations not pertinent here for modification or additional justification. *Leather Industries of America, Inc. v. EPA*, 40 F.3d 392 (D.C. Cir. 1994).

authorized for any categorical pollutant (1) for which EPA have established a numerical pollutant limit in Part 503; or (2) which EPA has determined will not threaten human health and the environment when used or disposed of in sewage sludge. The pollutants described in paragraphs (1)–(3) above include all those pollutants that EPA either specifically regulated in Part 503 or evaluated for regulation and determined would not adversely affect sludge use and disposal.

Consequently, in the case of a pollutant for which EPA did not perform a risk assessment in developing the Phase One sewage sludge regulations, removal credit for pollutants will only be available when the Agency determines either a safe level for the pollutant in sewage sludge or that regulation of the pollutant is unnecessary to protect public health and the environment from the reasonably anticipated adverse effects of such a pollutant.<sup>3</sup> Therefore, any person seeking to add additional categorical pollutants to the list for which removal credits are now available would need to submit information to the Agency to support such a determination. The basis for such a determination may include information showing the absence of risks for the pollutant (generally established through an environmental pathway risk assessment such as EPA used for Phase One) or data establishing the pollutant's presence in sewage sludge at low levels relative to risk levels or both. Parties, however, may submit whatever information they conclude is sufficient to establish either the absence of any potential for harm from the presence of the pollutant in sewage sludge or data demonstrating a "safe" level for the pollutant in sludge. Following submission of such a demonstration, EPA will review the data and determine whether or not it should propose to amend the list of pollutants for which removal credits would be available.

EPA has already begun the process of evaluating a number of pollutants for adverse potential to human health and the environment when present in sewage sludge. In May, 1993, pursuant to the terms of the consent decree in the *Gearhart* case, the Agency notified the United States District Court for the

District of Oregon that, based on the information then available at that time, it intended to propose 31 pollutants for regulation in the Round Two sewage sludge regulations. These are acetic acid (2,4-dichlorophenoxy), aluminum, antimony, asbestos, barium, beryllium, boron, butanone (2-), carbon disulfide, cresol (p-), cyanides (soluble salts and complexes), dioxins/dibenzofurans (all monochloro to octochloro congeners), endsulfan-II, fluoride, manganese, methylene chloride, nitrate, nitrite, pentachloronitrobenzene, phenol, phthalate (bis-2-ethylhexyl), polychlorinated biphenyls (co-planar), propanone (2-), silver, thallium, tin, titanium, toluene, trichlorophenoxyacetic acid (2, 4,5-), trichlorophenoxypropionic acid ([2-(2,4,5-)], and vanadium).

The Round Two regulations are not scheduled for proposal until December, 1999 and promulgation in December 2001. However, given the necessary factual showing, as detailed above, EPA could conclude before the contemplated proposal and promulgation dates that regulation of some of these pollutants is not necessary. In those circumstances, EPA could propose that removal credits should be authorized for such pollutants before promulgation of the Round Two sewage sludge regulations. However, given the Agency's commitment to promulgation of effluent limitations and guidelines under court-supervised deadlines, it may not be possible to complete review of removal credit authorization requests by the time EPA must promulgate these guidelines and standards.

#### 4. Relationship of Effluent Limitations to NPDES Permits and Monitoring Requirements

Effluent limitations act as a primary mechanism to control the discharges of pollutants to waters of the United States. These limitations are applied to individual facilities through NPDES permits issued by the EPA or authorized States under section 402 of the Clean Water Act.

The Agency has developed the limitations and standards for this proposed rule to cover the discharge of pollutants for this industrial category. In specific cases, the NPDES permitting authority may elect to establish technology-based permit limits for pollutants not covered by this proposed regulation, on a case-by-case basis using best professional judgment. See section 402(a)(1)(B) of the Clean Water Act; 40 CFR 125.3. In addition, if State water quality standards or other provisions of State or Federal law require limits on pollutants not covered by this regulation

(or require more stringent limits on covered pollutants), the permitting authority must apply those limitations. See, e.g., section 301(b)(1)(C) of the Clean Water Act.

For determination of effluent limits where there are multiple products or multiple categories and subcategories, the effluent guidelines would be applied using a flow-weighted combination of the appropriate guideline for each category or subcategory. Where a facility has added a new production facility in conjunction with an existing production facility, the effluent guidelines would also be applied by using a flow-weighted combination of the NSPS limit for the new line and the BAT and BCT standards to the existing lines to derive the limitations. However, as stated above, if State water quality standards or other provisions of State or Federal law require limits on pollutants not covered by this regulation (or require more stringent limits on covered pollutants), the permitting authority must apply those limitations regardless of the limitation derived using the production-weighted combinations.

The Agency does not consider certain wastewaters or materials to be process wastewaters; therefore, these proposed effluent limitations guidelines and standards would not apply to the discharge of such wastewaters. Such materials include, for example, any active anti-microbial materials, wastewater from imperfect fermentation batches, or process area spills. Any pharmaceutical manufacturing facility wishing NPDES authorization to discharge any materials and/or non-process wastestream(s) must specifically disclose this in its permit application. If the permitting authority wishes to authorize this discharge, the permit must specifically authorize the discharge of the specified materials and/or non-process wastestream(s). The effluent limitations in the permit must also reflect a separate analysis, done by the permitting authority on a best professional judgment basis, of the levels of pollutants in such materials and/or non-process wastestream(s) that are commensurate with the application of BPT, BCT, BAT, and PSES. Caution should be exercised in permitting such discharges. Treatment systems may not be designed to accommodate these types of materials and their discharge could adversely affect the treatment systems and receiving waters.

Working in conjunction with the effluent limitations are the monitoring conditions set out in an NPDES permit. An integral part of the monitoring conditions are the monitoring points. The point at which a sample is collected

<sup>3</sup>In the Round One sewage sludge regulation, EPA concluded, on the basis of risk assessments, that certain pollutants (see Appendix G to Part 403) did not pose an unreasonable risk to human health and the environment and did not require the establishment of sewage sludge pollutant limits. As discussed above, so long as the concentration of these pollutant in sewage sludge are lower than a prescribed level, removal credits are authorized for such pollutants.

can have a dramatic effect on the monitoring results for that facility. Therefore, it may be necessary to require internal monitoring points in order to assure compliance. Authority to address internal waste streams is provided in 40 CFR 122.44(i)(1)(iii) and 122.45(h). In some instances, today's proposed rule establishes internal monitoring points to ensure compliance with the effluent limitations guidelines and standards. Permit writers may establish additional internal monitoring points to the extent consistent with EPA's regulations.

#### 5. Best Management Practices

EPA is not proposing in today's notice best management practices (BMPs) pursuant to Section 304(e) of the Clean Water Act. BMPs established under Section 304(e) may be different from effluent limitations guidelines and standards principally because BMPs are specific requirements for conduct, not performance standards. When EPA sets technology-based effluent limits, those limits may be achieved by any technology a discharger chooses. However, when EPA establishes BMPs under Section 304(e) of the CWA, and those BMPs are incorporated into a dischargers permit, the discharger must perform those specific BMPs. The fact that a discharger had met all its technology-based effluent limits would not be a defense, if the discharger were charged with a permit violation for failing to perform its BMPs.

BMPs for the pharmaceutical manufacturing industry, which might include spill prevention, control provisions, and other aspects to prevent the release of raw materials, solvents, and process chemicals to wastewaters, would control the release of constituents listed in sections 307(a) and 311(e) of the CWA, such as methylene chloride, toluene, chloroform, and chloromethane (methyl chloride).

The EPA believes these BMPs are important because: discharges of raw materials, process chemicals and other materials are not recognized process wastewaters and contribute to significant portions of untreated wastewater loadings and to final effluent discharge loadings of oxygen demanding substances and priority and nonconventional pollutants. Prevention and control of discharges of materials used in pharmaceutical manufacturing processes will result in less demand for make-up chemicals; energy efficiency through recovery of process materials; more effective and less costly wastewater treatment system operations; reduced formation of wastewater treatment sludges; and reduced

atmospheric emissions of hazardous air pollutants (HAPs) and other volatile organic pollutants.

EPA is soliciting comment on whether BMPs are applicable to pharmaceutical manufacturing facilities in any or all subcategories for which effluent limitations guidelines and standards are being proposed. The principal focus of the BMPs are prevention and control of losses of raw materials, process chemicals and other process materials from spills and equipment leaks. More information related to the BMPs is outlined in Section XIV regarding solicitation of comments and data (see specific solicitation number 31.0). Appendix B of the Technical Development Document presents details on the specifics of BMPs that may be appropriate.

#### 6. Analytical Methods

Section 304(h) of the Clean Water Act (CWA) directs the EPA to promulgate guidelines establishing test procedures (methods) for the analysis of pollutants. These methods are used to determine the presence and concentration of pollutants in wastewater, and for compliance monitoring. Dischargers seeking NPDES permits must supply information on the characteristics of their effluent, analyzed in accordance with approved test procedures, as part of their permit applications. 40 CFR 122.21(g)(7). Similarly, holders of NPDES permits are required to conduct monitoring in accordance with such test procedures. 40 CFR 122.41(j)(4). Information and analysis performed in accordance with these methods are also required under the pretreatment program, 40 CFR 403.12(d)(5)(vi), and as a condition for receiving a conditional removal credit under 40 CFR 403.7(d).

EPA has promulgated analytical methods for monitoring discharges to surface water at 40 CFR part 136, and has promulgated methods for parameters specific to a given industrial category and for other purposes at parts 400-480 of the CFR. In today's notice, EPA also proposes to establish appropriate analytical methods at 40 CFR part 439 to support regulation of discharges in the pharmaceutical manufacturing industrial point source category. Those methods are presented in "Analytical Methods for the Determination of Pollutants in Pharmaceutical Industry Wastewater," a compendium of analytical methods and are incorporated herein by reference. See Section XIV, solicitation number 33.

Methods 1624 and 1625 are two of the previously promulgated methods applicable to the determination of volatile and semivolatile organic

pollutants in water and wastewater for the proposed effluent guidelines. They employ gas chromatography coupled to a mass spectrometer (GC/MS) to separate and quantify volatile and semivolatile organic pollutants. Detected pollutants are quantified by isotope dilution. For volatile organic pollutants, samples of water or solids suspended in water are purged by a stream of inert gas into the gaseous phase where they are concentrated into a trap. Subsequent heating of the trap introduces the concentrated volatile organics into a GC/MS for separation and quantification. The sensitivity of these methods are sufficient to detect and quantify volatile and semivolatile organics at parts per billion (ppb) levels in environmental samples. EPA also solicits comment on whether it may be appropriate to allow facilities to use analytical methods for organic pollutants other than those used to generate data upon which this proposal is based. See Section XIV, solicitation number 38.3.

Many of the non-conventional pollutants that may be released from the pharmaceutical manufacturing industry are not included in methods previously promulgated for monitoring effluents from other industries. For this reason it has been necessary to develop methods for these pollutants. Some are amenable to extraction from aqueous solution and can be analyzed by GC/MS after extraction and concentration. Method 1665 has been developed for these analytes. Others may be concentrated by purging from aqueous solution and trapping in a column containing sorbent material. For these substances, purge-and-trap followed by GC/MS analysis as described in Method 1666 was developed. Some highly water soluble analytes, however, could not be extracted from aqueous solution and could not be efficiently purged from water. For this reason, it was necessary to develop a direct aqueous injection technique for GC/MS analysis by Method 1666. A subset of these highly water soluble substances, all containing nitrogen, were found not to chromatograph well on the column used. For this reason, a third technique, Method 1668, was developed using a different GC column and detection by electrolytic conductivity. Formaldehyde is not extractable from water and can not be readily analyzed by either purge-and-trap GC/MS or direct aqueous injection. For this reason a fourth approach, Method 1667, was developed for formaldehyde and the other aldehydes included in the analyte list. A complete description of these

methods can be found in the Methods Compendium mentioned previously.

Methods 410.1 and 410.2 are two of several methods allowed for determination of chemical oxygen demand (COD) in water and wastewater. Other methods allowed for the determination of COD in this industry are those in 40 CFR part 136 that use analytical technologies equivalent to the technologies used in EPA methods 410.1 and 410.2, specifically oxidation by potassium dichromate and titration with ferrous ammonium sulfate, as described below. Method 410.2 is specific for levels of COD less than 50 mg/L, and Method 410.1 for levels greater than 50 mg/L. Other methods for COD that are intended for brines (e.g., EPA method 410.3) and that are interfered with by color (e.g., EPA method 410.4) and the methods in 40 CFR part 136 equivalent to these methods are allowed for monitoring pharmaceutical manufacturing wastewaters.

#### **X. Regulation of the Pharmaceutical Manufacturing Industry Under the Clean Air Act Amendments of 1990**

Section 112 of the Clean Air Act Amendments of 1990 (CAAA) requires EPA to develop National Emission Standards for Hazardous Air Pollutants (NESHAP) based on maximum achievable control technology (MACT) for sources that emit 10 or more tons per year of a single hazardous air pollutant (HAP) or 25 or more tons per year of a mixture of HAP. The CAAA contain a list of 189 pollutants identified as HAPs. It also establishes a schedule for issuing these standards over a ten-year period. Pharmaceutical plants are among the source categories for which MACT standards must be promulgated by November 15, 1997.

EPA's Office of Water, which is developing the effluent limitations and standards being proposed today, has been working closely with EPA's Office of Air and Radiation since the beginning of this effluent guidelines effort in order to ensure that the present rulemaking is consistent, within the constraints of the governing statutes, with the air emissions standards EPA will be promulgating for the pharmaceutical manufacturing industry. As noted in Section V.A above, EPA's promulgation of this effluent guideline—including the date of this proposal—is subject to a court-ordered schedule, which at this time requires EPA to issue this regulation in final form by August 1996. Meanwhile, EPA has established November 15, 1997, as the date by which it will promulgate air emissions standards for this industry. See Section

V.B above. In determining priorities for promulgating standards for this and other industries, EPA was required by section 112(e) of the Clean Air Act to consider several factors, including anticipated adverse effects on public health and the environment. Thus, the promulgation date for the pharmaceutical industry NESHAP reflects EPA's consideration of these statutory criteria, as well as resource limitations that reinforced the Agency's need to rank its rulemakings in priority order. Despite the different schedules and resource constraints necessitating separate rulemakings under the Clean Water Act and Clean Air Act for the pharmaceutical manufacturing industry, EPA is making every effort to reconcile these activities.

Consistent with this intent, EPA is providing the following information to put the affected public on notice that EPA is developing regulations and guidance to reduce air emissions from wastewater operations at pharmaceutical manufacturing facilities under the Clean Air Act. Section X of this notice also sketches in preliminary form the approach EPA is considering to regulate such air emissions and provides preliminary cost and emission reduction information associated with that approach. By this notice, EPA solicits comment on the possible combined effect of the proposed Clean Water Act regulation and the tentative Clean Air Act approach for the pharmaceutical manufacturing industry. See Section XIV, solicitation number 32. This notice is also intended to provide the industry with an opportunity to plan for integrated least-cost multimedia compliance.

##### *A. Preliminary Development of Air Emissions Standards*

EPA is in the early stages of developing the MACT standard for pharmaceutical plants; the standards will require the control of several different emission points, including organic air emissions from wastewater operations. EPA recently promulgated a similar MACT standard for organic HAP emissions from the Synthetic Organic Chemical Manufacturing Industry (SOCMI). This rule, often referred to as the Hazardous Organic NESHAP or HON, was published on April 22, 1994 (59 FR 19402). On January 7, 1993, EPA published amendments to the Benzene Waste Operations NESHAP, which controls benzene emissions from wastewater operations based upon Clean Air Act authority predating the 1990 amendments (40 CFR part 61 subpart FF).

The control approach that EPA is considering for the pharmaceutical manufacturing industry is similar to the approach EPA used in the SOCMHON and the Benzene Waste Operations NESHAP to control organic air emissions from wastewater collection and treatment operations. That approach consists first of identifying a subset of wastewater streams that require control through a combination of wastewater flowrate and concentration action levels, and second, the control requirements for these affected streams. The flowrate and concentration of each wastewater stream would be determined to reflect the characteristics at the point of generation of the wastewater stream.

The point of generation is defined to be where each individual wastewater stream exits production process equipment prior to any form of wastewater treatment. The characteristics of a wastewater stream at the point of generation are used to determine which streams to control because this is where the organic concentration is the highest and the flow is the lowest. The use of the point of generation characteristics in this way results in the identification of the most cost effective streams for control. If the characteristics of the streams were determined at some point downstream of the point of generation, there would be losses of organics due to air emissions and an increase in the wastewater flowrate due to mixing with other wastewater streams, both of which would result in the subsequent control of the stream being less cost effective. In addition, if wastewater treatment were allowed before the point of generation, the treatment unit, such as an air stripper, would not be required to have air emission control.

The flowrate action level is generally expressed as the liters per minute of wastewater flow. Values of flowrate used in previous regulatory analyses range from 0.02 to 10 liters per minute.

The concentration action level is based on the "volatile organic" concentration of the wastewater stream rather than the total concentration. EPA has developed a test method, Method 305 in Appendix A of 40 CFR part 63, to determine the volatile organic HAP concentration for use with wastewater MACT standards. The purpose of this test method is to determine a relative measure of the emission potential of a typically controlled wastewater stream by measuring essentially all of an organic HAP compound that is likely to be emitted in significant quantities while measuring essentially none of an organic HAP compound that is unlikely

to be emitted. Previous regulatory analyses have used an action level of 10,000 ppmw at any flowrate and coupled with a range of action levels from 10 to 1,000 ppmw tied to a flowrate cutoff as described above.

Examples of the use of these action levels in recent rules include the Benzene Waste Operations NESHAP, which has action levels of 0.02 liters per minute and 10 ppmw benzene, and the HON, which has a 10,000 ppmw volatile organic HAP concentration action level at any flow rate coupled with an action level pair of 10 liters per minute and 1,000 ppmw volatile organic HAP concentration.

The control requirements for affected wastewater streams include managing the identified wastewater streams in controlled units during collection and treatment to remove or destroy the organics. This control approach includes: (1) Suppression or control of air emissions from the point of wastewater generation to the treatment device by installing controls on the sewer system, tanks, and containers used to transport the wastewater; (2) treatment of the wastewater to remove or destroy the organics; (3) control of air emissions from the treatment device (e.g., the non-condensable air emissions from the stripper condenser); and (4) control or recycling of the organics removed by the treatment device (e.g., the condensed residuals collected by the stripper condenser). See also Section XII.B of this preamble for discussion of the Administrator's strategy for waste minimization and combustion (incineration) of ignitable organic wastes.

The treatment device used as the basis for the HON is a steam stripper, the same device proposed as the primary technology basis for today's proposed limits and standards. The HON requirements are performance standards, so that any device that achieves the desired performance can be used. In addition, the HON allows several compliance alternatives including the use of open biological treatment units to treat the wastewater if a controlled collection and treatment system is used up to the unit and the unit can be demonstrated to achieve the required level of biological degradation. The HON requires the use of the procedures outlined in Appendix C of 40 CFR part 63 to demonstrate that the organics are being degraded by the biological treatment unit and not emitted to the air.

The CAAA also requires EPA to establish Control Techniques Guideline (CTG) documents for the States to use to develop VOC emissions control plans

for ozone nonattainment areas. Industrial wastewater, which includes the pharmaceutical manufacturing industry, is one of the source categories for which EPA is developing a CTG document (see the draft document entitled "Control of Volatile Organic Compound Emissions from Industrial Wastewater," EPA-453/D-92-056, September 1992; available in the public docket for this Clean Water Act rulemaking). Based on this guidance, certain States will write rules for VOC emissions from wastewater operations at pharmaceutical plants located in ozone nonattainment areas. These rules are expected to be similar to the MACT standards, except they would control additional wastewater streams based on their potential for VOC emissions rather than HAP emissions. The concentration action level used in the draft CTG is based on the volatile organic concentration, which is determined by Method 25D in Appendix A of 40 CFR part 60.

The volatile organic HAP and flowrate action levels for the MACT standard for pharmaceutical plants have not yet been determined. For this notice, EPA has conducted a preliminary analysis of the impacts of a set of control options (action levels) for direct and indirect dischargers of A and C, and B and D effluent guideline subcategory production process wastewaters based on the approaches used in the HON. EPA emphasizes that this analysis is still preliminary. Wastewater data from the recent Section 308 pharmaceutical industry questionnaire responses were used in the analysis; however, a number of assumptions were made. See the draft document entitled "Control of Volatile Organic Compound Emissions from Industrial Wastewater, EPA-453/D-92-056, September 1992, for presentation of the assumptions and methodology used for this preliminary analysis. During the development of the MACT standard, this analysis will be refined based on new information and comments from the public.

Tables X.A.1 and X.A.2 summarize the results of this preliminary analysis. Two sets of preliminary results are presented based on two ways to evaluate the existing data for effluent guideline subcategory A, B, C, and D plants. The actual results of a rule based on any of the control options could be very different than these preliminary impacts. Table X.A.1 presents results based on applying the controls described above to wastewater streams that are equal to or greater than the identified action levels as the streams were reported in the Section 308 questionnaire responses. This database

reflects the characteristics of combined process area wastewater streams, not the point of generation of the wastewater. Table X.A.2 presents results based on the same criteria, but the Section 308 questionnaire wastewater data have been disaggregated in an attempt to simulate the characteristics at the point of generation. This disaggregation was performed in the manner described in Appendix B of the draft CTG document.

The control options (action levels), which encompass different combinations of volatile organic HAP (VOHAP) and wastewater stream flowrates, identified in both tables are ones that were considered in the development of the HON. All of the control options would require control of any wastewater stream that has 10,000 ppmw or greater volatile organic HAP concentration. The least stringent control option identified would require all wastewater streams with a flow of 10 liters per minute or greater and a 1,000 ppmw or greater volatile organic HAP concentration be equipped with controls. Wastewater streams below these criteria would not require control. Other more stringent control options would have lower action levels and require more wastewater streams to be controlled. The most stringent control option shown would require all streams with a flow of 1.0 liters per minute or greater and a 100 ppmw or greater volatile organic HAP concentration be controlled.

The analysis will be refined, and these results, along with other statutory criteria in the Clean Air Act, will be considered before a MACT standard for the pharmaceutical manufacturing industry is proposed. Information on the controls that may be required for wastewater streams exceeding the action levels, however, is provided in today's notice to allow pharmaceutical manufacturing facility owners and operators to consider these additional controls in their planning and to allow the public to comment on the combined effect of the MACT standard and today's proposed effluent limitations guidelines.

It is the Agency's intent for both the effluent guidelines being proposed today and the MACT standards to be proposed at a later date that upon promulgation the in-plant technology basis of both rules will be applicable to essentially the same high concentration low volume process wastewater streams in which the bulk of the volatile organic pollutants are contained, as represented preliminarily by Tables X.A.1 and X.A.2. The practical effect of this approach will be that only a relatively small portion (i.e., substantially less

than half) of all process wastewaters will require control by a treatment device (e.g., steam stripping) to achieve both rules. EPA has been informed by the industry that additional data will be submitted (some data have been submitted) in order to characterize, in greater detail than available in

responses to the Section 308 questionnaire, the individual process wastewater streams at the point of generation. This additional data and any other information available to EPA will be considered prior to promulgation in identifying the small portion of process wastewater streams that would require

control of volatile organic pollutants under both the effluent guideline and the MACT standard for this industry. The methodology to be used in analyzing these data will likely be the same as presented above and the preliminary results of which are presented in the following tables.

TABLE X.A.1.—PRELIMINARY IMPACTS OF CONTROL OPTIONS FOR A, B, C, AND D SUBCATEGORY PHARMACEUTICAL PLANTS BASED ON PROCESS AREA STREAMS

Control Option	VOHAP conc. <sup>1</sup> cutoff (PPMW)	Flow cutoff (LPM)	Total flow controlled by option (percent)	HAP emissions (MG/yr)	HAP emission reduction (percent)	Total annual cost (\$M/yr)	HAP cost effectiveness (\$/MG HAP ER <sup>2</sup> )
Baseline .....	.....	.....	.....	12,500	.....	.....	.....
1 .....	1,000	10	46	1,650	87	19.0	1,750
2 .....	800	5	47	1,640	87	19.8	1,830
3 .....	500	1	72	1,520	88	26.1	2,380
4 .....	200	1	75	1,510	88	27.6	2,520
5 .....	100	1	80	1,500	88	29.5	2,680

**Notes:**

<sup>1</sup>“VOHAP CONC. CUTOFF” means the volatile organic HAP concentration determined by Method 305 in 40 CFR Part 63, Appendix A.

<sup>2</sup>“\$/MG HAP ER” means the dollars per megagram of HAP emission reduction by the given control option, which is determined by dividing the annual cost of the option by the annual emission reduction.

- All options include an action level of 10,000 ppmw volatile organic HAP concentration at any flowrate.
- Total industry wastewater flow equals 75,300 liters per minute.

TABLE X.A.2.—PRELIMINARY IMPACTS OF CONTROL OPTIONS FOR A, B, C, AND D SUBCATEGORY PHARMACEUTICAL PLANTS BASED ON DISAGGREGATED STREAMS

Control Option	VOHAP conc. <sup>1</sup> cutoff (PPMW)	Flow cutoff (LPM)	Total flow controlled by option (percent)	HAP emissions (MG/yr)	HAP emission reduction (percent)	Total annual cost (\$M/yr)	HAP cost effectiveness (R/MG HAP ER <sup>2</sup> )
Baseline .....	.....	.....	.....	12,500	.....	.....	.....
1 .....	1,000	10	7	2,790	78	6.6	680
2 .....	800	5	10	2,440	80	8.0	800
3 .....	500	1	16	2,120	83	10.6	1,020
4 .....	200	1	25	1,680	87	13.7	1,270
5 .....	100	1	29	1,630	87	15.9	1,460

**Notes:**

<sup>1</sup>“VOHAP CONC.” means the volatile organic HAP concentration determined by Method 305 in 40 CFR Part 63 Appendix A.

<sup>2</sup>“\$/MG HAP ER” means the dollars per megagram of HAP emission reduction by the given control option, which is determined by dividing the annual cost of the option by the annual emission reduction.

- All options include an action level of 10,000 ppmw volatile organic HAP concentration at any flowrate.
- Total industry wastewater flow equals 75,300 liters per minute.

**B. Potential Interaction of Proposed Effluent Limitations Guidelines and Future Air Emission Standards**

Because both the effluent limitations guidelines and standards being proposed today and the future MACT standards for this industry are likely to regulate similar pollutants and to reflect similar technology bases, EPA acknowledges that there is considerable interest in the industry concerning the potential interaction of these rulemakings. In this section, EPA addresses various issues that thus far have come to EPA’s attention.

The effluent limitations guidelines and standards proposed today for nonconventional and priority pollutants are based on actual performance data obtained for specific pollutants over a

range of influent concentrations. The future MACT standards for HAPs emissions from pharmaceutical wastewater, like the HON, probably will employ data on Volatile Organic HAP concentration and flow rate of the wastewater stream to determine applicability of its standards to covered sources. Like the HON, the pharmaceuticals NESHAP will probably authorize percent reduction standards, effluent concentration limitations and mass removal requirements as options for measuring compliance.

EPA considered proposing percent reduction limitations and standards in this water rulemaking, but for the following reasons has determined that such limitations and standards would not adequately control the discharge of

wastewater pollutants of concern, particularly volatile pollutants. First, in EPA’s view, effluent limitations guidelines and standards based on percent reduction do not reflect the performance of the best available technology in removing wastewater pollutants for the pharmaceutical manufacturing industry. EPA’s analysis of actual performance data shows that the proposed concentration-based effluent limitations and standards can be met, regardless of variations in the influent concentrations of the target volatile compounds, using well-designed and well-operated technology. Second, percent reduction effluent limitations, as previously promulgated under the Clean Water Act for this industry, may discourage source

reduction programs (programs whose goal is to reduce raw waste loadings of volatiles) because plants with high raw waste loadings of volatiles can more easily comply with percent reduction regulations than plants with moderate or low volatile loadings. Finally, the percent reduction approach for effluent limitations guidelines and standards imposes special burdens on permit writers and facilities. The percent reduction approach would require the gathering and evaluation of long-term raw waste data from each facility in order to develop plant-specific limitations on individual pollutants, and to demonstrate continuing compliance with the limitations.

The Agency solicits comments and data on potential alternative formats for effluent limitations guidelines and standards, such as percent removal limitations and standards and minimum treatment threshold concentrations for individual wastewater streams. See Section XIV of this preamble, solicitation number 32.4.

Another issue arises in connection with the design of the steam stripper being proposed as a technology basis for various limitations and standards in today's rule. Today's notice proposes performance standards, based on a specific steam stripper design, that correspond to the wastestreams being treated. EPA also expects that the MACT standards for this industry also will be a performance standard based on a specific steam stripper design. However, the control approach contained in the air rule will include four components: (1) Suppression or control of air emissions from the point of generation to the treatment device by installing controls on the sewer system, tanks, and containers used to transport the wastewater; (2) a treatment device (such as a steam stripper); (3) control of air emissions from the treatment device itself (e.g., the non-condensable air emissions from the steam stripper condenser); and (4) control or recycling of the organics removed by the treatment device (e.g., the condensed residuals collected by the steam stripper condenser). The treatment device itself is a major component of the air emissions control approach for wastewater. It is the Agency's intent that a facility that installs steam stripping for the purpose of complying with this proposed rule also will achieve the requirements of the MACT standards to be developed for this industry. By the time public comments on the effluent guideline are being considered, EPA will have a better understanding of the stripper design that will serve as the basis for the MACT standards to be

proposed for this industry. This understanding, as well as the public comments on the water rule, will be considered in formulating the final effluent guideline as it pertains to stripper design. The Agency's intent is that the same stripper design will be able to achieve the requirements of both final rules, and will be applicable both to direct dischargers (BAT) and indirect dischargers (PSES). It is possible, however, that the stripper design upon which today's proposed water rule is based could change before promulgation based upon additional data and any comments received. Any information or comment on this subject is welcomed. See Section XIV, solicitation number 32.3. EPA also will develop air emission standards for other emission points (e.g., process vents, process area fugitive emissions, etc.).

A third issue relates to the possibility that the future MACT standard for the pharmaceutical manufacturing industry will allow plants to use an enclosed collection system to suppress emissions while transporting the wastewaters containing volatile pollutants to a central treatment unit, which in turn can be controlled for air emissions. In today's notice, EPA has selected in-plant steam stripping for controlling volatile organic pollutants. Under this proposal, plants would be required to treat all wastewater streams that contain regulated volatile organic pollutants at concentrations greater than the long-term average concentrations established for these regulated pollutants. However, a plant could choose to meet the proposed effluent limitations guidelines and standards by combining all such streams and treating the combined wastestreams at a central treatment unit prior to their dilution by wastestreams that do not contain volatile organic pollutants. This approach to the treatment of wastestreams containing volatile organic pollutants not only would satisfy the proposed regulations, but also appears to be more efficient than treating individual wastestreams at the wastewater generation source. However, in certain cases individual plants may find that streams containing recoverable quantities of individual volatile organic pollutants (e.g., methanol) may be more cost-effectively managed as segregated binary streams (i.e., water and one solvent), rather than mixing them with streams containing all other volatile organic pollutants generated at the facility, prior to either steam stripping or steam stripping/distillation. EPA solicits data and comment on this option. See Section

XIV of this preamble, solicitation number 32.5.

A fourth issue concerns the possibility that the future MACT standards will allow the use of open biological treatment units to treat organic compounds with limited volatility (e.g., methanol) from enclosed primary treatment systems, provided that a facility-specific emission limit or a 95 percent destruction of the organic HAP by biodegradation is achieved. In demonstrating the destruction, losses due to air emissions and effluent discharge would not be considered destruction. EPA did not select this technology as BAT for subcategories A and C because all known A and C direct discharger plants have open biological treatment systems and no air emissions data were available from plants with biological treatment systems that demonstrate 95 percent biodegradation of volatiles. In addition, the use of biodegradation for volatiles treatment eliminates the potential for their recovery and reuse. Nevertheless, EPA solicits comment on whether it is appropriate and feasible, considering recycle opportunities and control of air emissions, to develop a separate subcategory for the effluent limitations guidelines and standards with alternate limits that would allow for end-of-pipe biological treatment in place of or in combination with in-plant steam stripping for volatile organic pollutants. See Section XIV of this preamble, solicitation number 32.6.

#### **XI. Impacts of Regulatory Options Considered in this Rulemaking**

The purpose of this section is to analyze the projected economic impacts and non-water quality environmental impacts associated with the various technology options considered as possible bases for the limitations and standards proposed in today's notice.

##### *A. Regulatory Options*

In developing the proposed effluent limitations and standards set forth in today's notice, EPA developed technology options based upon a variety of different technologies and combinations of technologies. EPA developed technology options for direct dischargers and indirect dischargers, and for different industry subcategory groupings, *i.e.*, facilities with subcategory A and C operations and facilities with subcategory B and D operations. For direct dischargers, EPA proposes limitations and standards based on options for Best Practicable Control Technology Currently Available (BPT), Best Conventional Pollutant Control Technology (BCT), Best

Available Technology Economically Achievable (BAT), and New Source Performance Standards (NSPS) options. For indirect dischargers, EPA proposed

Pretreatment Standards for Existing Sources (PSES) and Pretreatment Standards for New Sources (PSNS), based on a variety of technology options

considered. Table XI.A-1 presents the technology options considered in this rulemaking. The economic impact analysis discussed below reflects each of these options.

TABLE XI.A-1.—TECHNOLOGY OPTIONS CONSIDERED IN THE ECONOMIC IMPACT ANALYSIS

Type of option	Name	Description
<b>Direct Dischargers</b>		
Best Practicable Technology (BPT).	BPT-A/C#1	Current biological treatment
	BPT-A/C#2	Cyanide destruction + advanced biological treatment.
	BPT-A/C#3	Cyanide destruction + advanced biological treatment + effluent filtration.
	BPT-A/C#4	Cyanide destruction + advanced biological treatment + polishing pond.
	BPT-A/C#5	Cyanide destruction + advanced biological treatment + effluent filtration + polishing pond.
Best Conventional Technology (BCT)*.	BPT-B/D#1	Current biological treatment.
	BPT-B/D#2	Advanced biological treatment.
	BPT-B/D#3	Advanced biological treatment + effluent filtration.
	BCT-A/C#1	Advanced biological treatment + effluent filtration.
	BCT-A/C#2	Advanced biological treatment + polishing pond.
Best Available Technology (BAT)	BCT-A/C#3	Advanced biological treatment + effluent filtration + polishing pond.
	BCT-B/D#1	Advanced biological treatment.
	BCT-B/D#2	Advanced biological treatment + effluent filtration.
	BAT-A/C#1	Cyanide destruction + advanced biological treatment with nitrification, where necessary.
	BAT-A/C#2	Cyanide destruction + in-plant steam stripping + advanced biological treatment.
	BAT-A/C#3	In-plant cyanide destruction + in-plant steam stripping/distillation + advanced biological treatment.
	BAT-A/C#4	In-plant cyanide destruction + in-plant steam stripping/distillation + advanced biological treatment + granular activated carbon.
	BAT-B/D#1	Advanced biological treatment.
	BAT-B/D#2	In-plant steam stripping + advanced biological treatment.
	BAT-B/D#3	In-plant steam stripping/distillation + advanced biological treatment.
New Source Performance Standard (NSPS).	BAT-B/D#4	In-plant steam stripping/distillation + advanced biological treatment + granular activated carbon.
	NSPS-A/C#1	In-plant cyanide destruction + in-plant steam stripping/distillation + advanced biological treatment.
	NSPS-A/C#2	In-plant cyanide destruction + in-plant steam stripping/distillation + advanced biological treatment + granular activated carbon.
	NSPS-B/D#1	Advanced biological treatment + in-plant steam stripping/distillation.
	NSPS-B/D#2	In-plant steam stripping/distillation + advanced biological treatment + granular activated carbon.
<b>Indirect Dischargers</b>		
Pretreatment Standards for Existing Sources (PSES).	PSES-A/C#1	In-plant steam stripping + cyanide destruction.
	PSES-A/C#2	In-plant steam stripping/distillation + in-plant cyanide destruction.
	PSES-A/C#3	In-plant steam stripping/distillation + in-plant cyanide destruction + end-of-pipe advanced biological treatment.
	PSES-A/C#4	In-plant steam stripping/distillation + in-plant cyanide destruction + advanced biological treatment + granular activated carbon.
	PSES-B/D#1	In-plant steam stripping.
	PSES-B/D#2	In-plant steam stripping/distillation.
Pretreatment Standard for New Sources (PSNS).	PSES-B/D#3	In-plant steam stripping/distillation + granular activated carbon.
	PSNS-A/C#1	In-plant steam stripping/distillation + in-plant cyanide destruction.
	PSNS-A/C#2	In-plant steam stripping/distillation + in-plant cyanide destruction + end-of-pipe advanced biological treatment.
	PSNS-A/C#3	In-plant steam stripping/distillation + in-plant cyanide destruction + end-of-pipe advanced biological treatment + granular activated carbon.
	PSNS-B/D#1	In-plant steam stripping/distillation.
	PSNS-B/D#2	In-plant steam stripping/distillation + granular activated carbon.

\* In the Development Document, BCT-A/C#1, #2, and #3 in this table actually correspond to Options 3, 4, and 5, and BCT-B/D#1 and #2 in this table actually correspond to Options 2 and 3. The options not listed in this table were never considered in the EIA because they are equal to or less stringent than the requirements of the selected BPT options, and thus no incremental costs are incurred.

EPA has selected the following technology options as bases for the effluent limitations and standards proposed in today's notice:

- For direct discharging A/C facilities, BPT-A/C#2 is the technology

basis for conventional pollutants and BAT-A/C#2 is the technology basis for priority and nonconventional pollutants.

- For direct discharging B/D facilities, BPT-B/D#2 is the technology basis for

conventional pollutants and BAT-B/D#1 is the technology basis for nonconventional pollutants.

- NSPS-A/C#1 is the technology basis for new A/C facilities that are direct dischargers.

- NSPS-B/D#1 is the technology basis for new B/D facilities that are direct dischargers (this option is identical to BAT-B/D#3).
- PSES-A/C#1 is the technology basis for A/C facilities that are indirect dischargers.
- PSES-B/D#1 is the technology basis for B/D facilities that are indirect dischargers.
- PSNS-A/C#1 is the technology basis for new A/C facilities that are indirect dischargers (this option is identical to PSES-A/C#2).
- PSNS-B/D#1 is the technology basis for new B/D facilities that are indirect dischargers (this option is identical to PSES-B/D#2).

**B. Economic Impact Considerations**

**1. Introduction**

EPA's economic impact assessment is documented in the report titled "Economic Impact Analysis of Proposed Effluent Limitations Guidelines and Standards for the Pharmaceutical Manufacturing Industry" (hereinafter

EIA). This report estimates the economic effect of compliance with the proposed regulation in terms of annualized costs, facility closures, changes in rate of return on assets and the interest coverage ratio at the company level, and profit losses at the company level. In addition, impacts on affected communities, foreign trade, specific demographic groups, and new sources also are considered. Finally, a Regulatory Flexibility Analysis detailing the impacts on small businesses within the pharmaceutical industry is included in the EIA. The methodologies for these analyses are detailed in the EIA. The major source of information for this EIA is the 1990 Detailed Questionnaire, which was conducted under the authority of Section 308 of the Clean Water Act.

**2. Projected Facility Economic Impacts**

The annual costs of regulatory compliance may have a negative effect on facility earnings. Facility closures are identified when the salvage value (i.e., liquidation value) of the facility exceeds

the present value of its future earnings. A post-compliance facility closure analysis was performed for all technology options.

*a. Annual Costs.* The aggregate post-tax annualized costs for all the regulatory options are given in Tables XI.B.2-1 through XI.B.2-3. The annualized costs for the selected options for this proposed rulemaking are shown in Table XI.B.2-4. The aggregate post-tax annualized costs were estimated at \$30.6 million (1994 \$) for facilities with subcategory A and C operations to implement BAT Option 2 (BAT-A/C#2), \$0.8 million (1994 \$) for facilities with subcategory B and D operations to implement BAT Option 1 (BAT-B/D#1), \$39.5 million (1994 \$) for facilities with subcategory A and C operations to implement PSES Option 1 (PSES-A/C#1), and \$9.1 million (1994 \$) for facilities with subcategory B and D operations to implement PSES Option 1 (PSES-B/D#1), for a total of \$80.0 million (1994 \$) for the selected options.<sup>4</sup>

TABLE XI.B.2-1.—ESTIMATED COMPLIANCE COSTS FOR A/C DIRECT DISCHARGERS  
[Millions of 1994 dollars]

Option No.	Total capital costs	Total O&M costs	Total post-tax annualized costs	Average annual cost per facility <sup>1</sup>
<b>BPT Option Costs</b>				
BPT-A/C#1 .....	0	0	0	0
BPT-A/C#2 .....	16.9	8.1	6.5	0.3
BPT-A/C#3 .....	25.0	8.6	7.7	0.3
BPT-A/C#4 .....	42.8	24.9	19.0	0.8
BPT-A/C#5 .....	50.5	26.8	21.0	0.9
<b>BCT Option Costs</b>				
BCT-A/C#1 .....	19.3	3.4	4.1	0.17
BCT-A/C#2 .....	37.1	18.9	15.0	0.62
BCT-A/C#3 .....	44.8	21.8	17.5	0.73
<b>BAT Option Costs</b>				
BAT-A/C#1 .....	17.2	9.8	7.5	0.3
BAT-A/C#2 .....	64.5	40.8	30.6	1.3
BAT-A/C#3 .....	77.8	66.3	46.8	1.9
BAT-A/C#4 .....	106.1	130.6	87.0	3.6

Footnotes:

<sup>1</sup> Total Post-Tax Annualized Costs divided by the total number of A/C direct discharge facilities.

*b. Post-compliance Facility Closures.* The selected options result in no closures of any facilities. When the most stringent options are considered, one

direct discharging facility with subcategory A and C operations is predicted to close under BAT-A/C#4, and one indirect discharging facility

with subcategory B and D operations is predicted to close under PSES-B/D#3. No other options were determined to result in any other facility closures.

<sup>4</sup>The Development Document presents costs in 1990 dollars. These costs are inflated to 1994 dollars in this preamble using a factor of 1.143 derived from *Engineering News Record* "Construction Cost Index."

TABLE XI.B.2-2.—ESTIMATED COMPLIANCE COSTS FOR B/D DIRECT DISCHARGERS  
[Millions of 1994 dollars]

Option No.	Total capital costs	Total O&M costs	Total post-tax annualized costs	Average annual cost per facility <sup>1</sup>
<b>BPT Option Costs</b>				
BPT-B/D#1 .....	0	0	0	0
BPT-B/D#2 .....	0.69	0.59	0.42	0.030
BPT-B/D#3 .....	3.4	0.86	0.87	0.062
<b>BCT Option Costs</b>				
BCT-B/D#1 .....	0.64	0.51	0.37	0.026
BCT-B/D#2 .....	3.3	0.78	0.82	0.058
<b>BAT Option Costs</b>				
BAT-B/D#1 .....	0.74	1.3	0.81	0.058
BAT-B/D#2 .....	2.0	1.1	0.84	0.060
BAT-B/D#3 .....	3.4	2.2	1.7	0.12
BAT-B/D#4 .....	11.8	3.5	3.3	0.24

## Footnotes:

<sup>1</sup> Total Post-Tax Annualized Costs divided by the total number of B/D direct discharge facilities.

TABLE XI.B.2-3.—ESTIMATED COMPLIANCE COSTS FOR INDIRECT DISCHARGERS (PSES)  
[Millions of 1994 dollars]

Option No.	Total capital costs	Total O&M costs	Total post-tax annualized costs	Average annual cost per facility <sup>1</sup>
<b>A/C Facilities</b>				
PSES-A/C#1 .....	80.9	53.1	39.5	0.4
PSES-A/C#2 .....	103.0	93.6	65.3	0.7
PSES-A/C#3 .....	164.6	120.9	87.8	1.0
PSES-A/C#4 .....	213.7	203.0	140.6	1.6
<b>B/D Facilities</b>				
PSES-B/D#1 .....	28.8	10.2	9.1	0.06
PSES-B/D#2 .....	34.8	19.4	15.0	0.10
PSES-B/D#3 .....	70.8	112.2	72.5	0.5

## Footnotes:

<sup>1</sup> Total Post-Tax Annualized Costs divided by the total number of indirect discharge facilities.

TABLE XI.B.2-4.—ESTIMATED COMPLIANCE COSTS FOR SELECTED REGULATORY OPTIONS  
[Millions of 1994 dollars]

Option No.	Total capital costs	Total O&M costs	Total post-tax annualized costs	Average annual cost per facility <sup>1</sup>
BAT-A/C#2 .....	64.5	40.8	30.6	1.3
BAT-B/D#1 .....	0.7	1.3	0.8	0.06
PSES-A/C#1 .....	80.9	53.1	39.5	0.4
PSES-B/D#1 .....	28.8	10.2	9.1	0.06
Total <sup>2</sup> .....	174.9	105.4	80.0	0.29

## Footnotes:

<sup>1</sup> Total Post-Tax Annualized Costs divided by the total number of facilities for each subcategory.<sup>2</sup> Total number of facilities includes seven non-discharging facilities.

### 3. Projected Owner Company-Level Economic Impacts

Firm failures are identified when the return on assets and the interest

coverage ratio, common financial indicators, fall below benchmarks for the industry.

Table XI.B.3.b2-1 presents the results of the postcompliance analysis under

the selected regulatory options. This analysis determined that none of the firms owning direct discharging facilities with subcategory A and C or B and D operations are expected to

experience significant impacts (i.e., firm failure) as a result of implementing the selected regulatory options. In addition, only two firms with indirect discharging facilities with subcategory A and C operations and one firm owning an indirect discharging facility with subcategory B and D operations would be expected to experience significant impacts as a result of compliance costs. Thus, a total of three firms are projected

to fail under the conservative assumption of no costs being passed through to consumers. Overall, these firms represent 3.8 percent of all firms with indirect discharging facilities with subcategory A and C operations, 1.4 percent of firms with subcategory B and D operations, and 2.3 percent of all regulated firms. As indicated by the Profitability Analysis, 15 firms (11 percent of firms in the postcompliance

analysis) are anticipated to have major impacts short of firm failure (i.e., will experience a change in ROA of greater than 5 percent). Impacts are most likely overstated, however, because this analysis assumes that firms cannot pass any increased costs through to consumers. If half the costs can be passed through to consumers there would be no firm failures.

TABLE XI.B.3.b2-1.—PROJECTED FIRM FAILURE: 1 POST COMPLIANCE ANALYSIS <sup>2</sup>

	Total No. of firms	Regulatory impact on firms			
		No significant impact		Significant impact	
		No.	Percent	No.	Percent
Firms with A/C Direct Facilities .....	15	15	100.0	0	0.0
Firms with B/D Direct Facilities .....	7	7	100.0	0	0.0
Firms with A/C Indirect Facilities .....	53	51	96.2	2	3.8
Firms with B/D Indirect Facilities .....	72	71	98.6	1	1.4
All Firms <sup>3</sup> .....	133	130	97.7	3	2.3

**Note:** Analysis excludes three firms because of lack of financial data.

<sup>1</sup> Firm failure is defined when a firm's return on assets or interest coverage ratio falls below industry benchmarks. This analysis assumes no costs can be passed through to consumers.

<sup>2</sup> This scenario analyzes impacts from regulating A/C Direct Facilities under options BAT-A/C#2 and BPT-A/C#2, B/D Direct Facilities under options BAT-B/D#1 and BPT-B/D#2, A/C Indirect Facilities under option PSES-A/C#1, and B/D Indirect Facilities under option PSES-B/D#1.

<sup>3</sup> Number of firms for All Firms may be less than the total firms by subcategory because some firms have more than one type of facility. Total number of All Firms includes firms that have nondischarging facilities.

4. Projected Employment Losses and Gains and Community-Level Economic Impacts

Based on facility closures and firm failures, the employment losses analysis sums the number of jobs lost in the postcompliance scenario and compares these losses to community employment measures. Job gains are calculated based on the cost of manufacturing, installing, and operating compliance equipment.

No employment losses were projected to occur as a result of regulatory options for direct dischargers. For indirect dischargers, however, total projected primary employment losses resulting from the selected regulatory options were 78 full time equivalent (FTE) positions among indirect discharging facilities with subcategory A and C operations and 13 FTEs among indirect discharging facilities with subcategory B and D operations, for a total of 91 FTEs or 0.07 percent of total employment for the affected portion of the industry. Secondary employment losses were predicted to be 541 FTEs.

None of these losses is expected to result in a change of employment rates of more than 1 percent in the affected communities.

Employment losses are offset to some extent by the need to hire workers to manufacture, install, and maintain the pollution control equipment. Primary employment gains are expected to total 68 annual FTEs for manufacturing

equipment, 10 annual FTEs for installing equipment, and 0 to 889 annual FTEs for operating and maintaining equipment for a total of 78 to 967 annual FTE gains. The sum of primary and secondary gains is calculated to range from 218 FTEs to 2,890 FTEs. Net gains and losses thus range from a loss of 323 FTEs to a gain of 2,349 FTEs.

5. Projected Foreign Trade Impacts

The impact of effluent guidelines on pharmaceutical exports and the U.S. balance of trade was found to be negligible. The one firm/facility predicted to close as a result of the effluent guidelines had pharmaceutical exports totaling \$0.09 million (1994 \$). The loss of these exports would have virtually no effect on U.S. pharmaceutical exports, which, according to the U.S. Department of Commerce, totalled \$5.7 billion in 1991.

6. Regulatory Flexibility Analysis

*a. Purpose of the Regulatory Flexibility Analysis.* The Regulatory Flexibility Act requires the federal government to consider the impacts on small entities as part of rulemaking procedures. The goal of the analysis is to ensure that small entities potentially affected by a new regulation will not be disproportionately burdened. Small entities have limited resources, and it is the responsibility of the regulating

federal agency to avoid, if possible, disproportionately or unnecessarily burdening such entities.

*b. Projected Impacts on Small Businesses.* (i) Size Distribution. Small firms make up 76 percent of the 190 firms in the survey universe. The largest percentage of firms are in the 100 to 499 employees size group (37 percent of all firms in the survey universe).

(ii) Recordkeeping and Reporting Requirements. The proposed effluent guidelines for the pharmaceutical industry are revisions to existing effluent guidelines and, accordingly, most of the recordkeeping and reporting requirements to which the industry would be subject are not new requirements. There are some new monitoring requirements. The new monitoring costs total \$10.3 million (1994 \$) annually, and are 15 percent of the total annual compliance cost for the selected options. Large firms incur the largest proportion of the new monitoring costs (61 percent of total monitoring costs).

(iii) Other Federal Requirements. EPA is aware of no federal rules that duplicate, overlap, or conflict with the proposed effluent guidelines for the pharmaceutical industry.

(iv) Significant Alternatives to the Proposed Rule. No significant alternatives to the proposed rule will substantially reduce impacts on small entities, thus the Agency believes the

stated objectives of the Clean Water Act are met with this proposed rule and the impacts to small firms have been considered, where possible.

(v) **Projected Impacts on Small Firms.** Projected Impacts on small firms measured as firm failure are as follows. Two of the three firms that were projected to fail in the firm-level analysis under the selected regulatory options have fewer than 750 employees, although only 2 percent of small firms in the postcompliance analysis are affected in this manner. In addition, 14 of 15 firms found to experience a significant decline in ROA (over 5 percent) have fewer than 750 employees. These firms represent about 14 percent of all small firms in the post-compliance analysis.

When cash flow is analyzed, however, impacts seem less disproportionate. Except in the 19 to 99 employees group, the total present value of compliance costs as a percentage of the present value of net income is smaller among small firms than among large firms. Over all small firms (or all large firms), the present value of compliance costs is less than 1 percent of the present value of net income.

The above analyses indicate that although small firms do bear a large portion of the impacts such as firm failures, these impacts are felt by a very small percentage of all small firms. Additionally, the percentages of the present value of compliance costs to the present value of net income are expected to be smaller, on average, among small firms than among large firms; thus, impacts to small firms are not expected to be disproportionate to those for large firms.

#### 7. Projected Distributional Impacts

*a. Impacts on Drug Prices.* Assuming that all costs are passed on to consumers and that price increases will reflect 100 percent of the cost increases to manufacturers, the following observations can be made. For all the selected regulatory options, the ratio of compliance costs to total pharmaceutical costs was 1.6 percent. Most facilities would incur compliance costs less than 1 percent of total pharmaceutical costs. Only three facilities (1 percent of all facilities) would incur compliance costs greater than 10 percent of total pharmaceutical costs.

*b. Impacts on Specific Demographic Groups.* When possible uses for products produced by a sampling of highly affected facilities (those where compliance costs exceed 10 percent of total pharmaceutical costs) were investigated, it appeared that children,

women, and the elderly were likely to be the major consumers of many of these products. It was further determined that individuals who lack any health insurance, those who are covered by government insurance, and those who are covered by nonwork-related medical insurance might be least likely to have drug coverage. These groups include Hispanics, young adults, African Americans, young children, and the elderly. Thus, young adult women, children, and the elderly are likely to be the most heavily affected by potential cost increases, if such increases can be passed through to consumers.

Because on average any potential price increases are likely to be very low (1.6 percent), impacts on mass consumers of drugs such as HMOs, governments, and, indirectly, third-party insurers should be minimal.

#### 8. Projected Impacts on New Sources

The projected selected options for new sources are NSPS-A/C#1, NSPS-B/D#1, PSNS-A/C#1, and PSNS-B/D#1. In all cases, the requirements for new sources are more stringent than those for existing sources. However, the difference in cost between new source requirements and existing source requirements for typical facilities are relatively small when compared to the average facility costs of production. In most cases, existing facilities would be required to retrofit in-plant steam stripping systems, whereas new sources would have to install in-plant steam stripping/distillation systems. Because designing in pollution control equipment in a new source is typically less expensive than retrofitting the same equipment in an existing source, the cost differential between the selected requirements for existing sources and those higher existing source options that are technically equivalent to new source requirements should be an upper limit on the differential annual cost faced by new sources. Where this differential is not substantial relative to the typical costs of doing business in this industry, no significant barrier to entry is likely to exist.

The average per-facility compliance costs were investigated to determine what the cost differentials would be between proposed new source and existing source requirements. The average per-facility cost differentials ranged from about a \$39,000 to a \$674,000 difference (1994 \$) (for A/C direct dischargers), depending on the type of facility. The maximum \$674,000 difference generates the highest percentage of compliance cost differential to pharmaceuticals manufacturing cost—about 1.4 percent

of total manufacturing costs and about 3.0 percent of pharmaceutical manufacturing costs. Since this cost differential is likely to be less than that assumed here, this small premium estimated to be paid by new sources is not likely to have much impact on the decision to enter the market. Furthermore, these same options, when applied to existing sources, were found to have nearly identical impacts on existing sources as the selected options for existing sources. Thus no significant barriers to entry are estimated to result from the proposed new source requirements.

#### 9. Regulatory Impact Assessment

The Agency has prepared a regulatory impact assessment (RIA) for the proposed regulatory alternative. The RIA responds to the requirements in Executive Order 12866 to assess both the costs and benefits to society of significant regulatory actions. Significant regulatory actions are those that impose an annual cost to the economy of \$100 million or more, or have certain other regulatory, policy or economic impacts. The RIA is detailed in "Regulatory Impact Assessment of the Proposed Effluent Guidelines for the Pharmaceutical Manufacturing Industry" (see Section II for availability of this and other supporting documents). This RIA was submitted to OMB for review as required by Executive Order 12866.

The RIA analyzes the effects of current air and water emissions and assesses the benefits of reductions in these emissions resulting from the proposed regulation. EPA expects a variety of human health, environmental, and economic benefits to result from these reductions in effluent loadings and air emissions. 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 risk; ecological and recreational benefits due to improved water quality; and benefits to publicly owned treatment works (POTWs) from reductions in interference, pass through, and sludge contamination problems and improvements in worker health and safety. EPA monetizes the estimated benefits for reductions in air emissions of ozone precursors and cancer risk reductions, but is unable to quantify the dollar magnitude of benefits from the other benefit categories. Air benefits are estimated separately for Section 308

survey air emissions data and for air emissions estimated by the WATER7 model which estimates the maximum emissions.

*a. Human Health/Agricultural Benefits from Reductions in Emissions of Ozone Precursors.* The proposed effluent guidelines are expected to result in reductions in ambient ozone concentrations due to reductions in VOC emissions. Controlling VOC emissions is beneficial because VOCs are precursors to ozone, which negatively affects human health and the environment.

(1) Human Health Benefits.

The RIA estimates that the annual human health benefits resulting from reductions in VOC emissions due to the proposed rule range from \$31,000 to \$1.9 million (1994 \$). EPA monetizes these benefits using a benefits-transfer-based approach. Specifically, the estimated reductions in VOC emissions in nonattainment areas (1,396 Mg) are multiplied by an existing estimate of the range of the value of a unit reduction in VOC emissions (\$22/Mg to \$1,382/Mg, 1994 \$). This range is taken from an existing study that evaluated the human health benefits of ozone reductions in nonattainment areas.

(2) Welfare Benefits from Increased Agricultural Crop Yields.

Studies of the relationship between ambient ozone concentrations and greenhouse-controlled ozone concentrations and agricultural crop yields demonstrate that ozone negatively affects crop yields. Reductions in crop yields in turn affects agricultural production, crop prices, and incomes of agricultural producers, and thus affects social welfare. Thus, reductions in ozone concentrations that lead to improved crop yields will generate welfare benefits.

The RIA estimates that the annual agricultural-related economic welfare benefits from reductions in VOC emissions range from \$186,000 to \$315,000 (1994 \$). To generate these welfare benefit estimates, EPA applies an existing estimate of the benefits per unit reduction in VOC emissions (\$134/Mg to \$226/Mg, 1994 \$) to the total expected reduction in VOC emissions in nonattainment areas. The existing value estimates were developed using economic models that estimate the net change in social welfare resulting from higher crop yields as a result of lower ambient ozone levels in rural areas.

*b. Human Health Benefits Due To Cancer Risk Reduction.* The benefits from the proposed rule include human health benefits from reductions in excess cancer risk. EPA expects the proposed 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 the RIA, EPA estimates that the proposed guidelines will result in 0.02 to 0.35 excess cancer cases avoided per year nationwide. The estimated value of the human health benefits from these cancer risk reductions ranges from \$14,000 to \$5.4 million (1994 \$) 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 \$0.7 million to \$15.4 million (1994 \$). This estimated range is based on a review of literature pertaining to the value of life.

*c. Human Health Benefits from Reductions in Noncarcinogenic Risk.*

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. The proposed rule might generate human health benefits by reducing exposure to these substances, thus reducing the risks of these associated effects.

As in the case of the cancer risk assessment, systemic risks from exposure to air emissions and consumption of contaminated fish tissue and drinking water are evaluated. Modeled pollutant concentration levels are compared to human health criteria or estimated toxic effect levels. Based on this analysis, reductions in air emissions might result in reduced systemic risk, with benefits ranging from reduced risk to zero individuals (since estimated baseline risks are low) to reduced risk to 126,000 individuals due to reduced exposure to two toxic pollutants. No systemic risk 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. Ecological and Recreational Benefits Due to Improved Water Quality.*

EPA expects the proposed effluent guidelines 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., provision of habitat), and passive use values. 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 of recreational experiences of users, such as anglers fishing in the affected streams. In the RIA, EPA considers the value of the recreational benefits resulting from the proposed rule, but does not evaluate the other types of ecological and environmental benefits due to data limitations.

To estimate the benefits from the improvements in water quality expected to result from this rule, instream concentration estimates are modeled and then compared to EPA's freshwater acute and chronic aquatic life criteria to evaluate whether these discharges pose risk to aquatic organisms. The projected reductions in toxic loadings to surface waters are significant. Pollutant loadings are estimated to decline by 57 percent, from 39.9 million pounds per year under current conditions to 17.1 million pounds per year under the proposed rule. The analysis comparing instream concentration levels to aquatic life water quality criteria estimates that current discharge loadings result in excursions of aquatic water quality criteria at two locations. The analysis also indicates that no excursions are expected to occur at these two sites under the proposed rule.

EPA estimates that the annual recreational benefits associated with the expected changes in water quality are on the order of thousands of dollars. EPA evaluates these recreational benefits, applying a simple model that considers the change in consumer welfare likely to result from improved catch rates by recreational anglers at these two sites. EPA assumes that catch rates improve due to larger fish populations that are assumed to result from improved water quality.

*e. Benefits from Reductions in Loadings Discharged to POTWs.* The RIA considers three potential sources of benefits to POTWs from the proposed regulation: Reductions in the likelihood of interference, pass through, and sewage sludge contamination problems, reductions in health and safety risks to POTW workers, and 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 RIA does not quantify these benefits due to data limitations.

First, regarding potential interference, pass through and sewage sludge contamination problems, the proposed 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 analytic 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 six POTWs for seven pollutants under current conditions. Inhibition problems are projected to occur at five POTWs for three pollutants after the proposed rule. Sufficient data are not available to further quantify this benefit category.

Furthermore, toxic substances in effluent discharges to POTWs pose health risks to POTW workers. The proposed 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 toxic pollutants, the proposed rule is estimated to reduce occupational risk at six POTWs. Data are not available to monetize this benefit category.

Finally, in implementing local programs to control pollutants discharged to their systems, authorized POTWs often must set numerical limits on toxic loadings in discharges to the POTW, based on national categorical pretreatment standards or local limits determined by the POTW. In setting these local limits, POTWs sometimes need to undertake analyses to determine which pollutants warrant local limits and at what numerical level. Conducting these analyses is expensive, costing on the order of hundreds of thousands of dollars. Several POTWs contacted as part of EPA's survey of POTWs indicated that they will benefit from the establishment of national pretreatment standards by avoiding these analytical costs. In addition, they indicated that the pretreatment standards will bolster the legal authority of the limits they set. EPA solicits comments on this issue. See Section XIV, solicitation number 24.4.

*f. Summary of Benefits.* EPA estimates that the annual benefits resulting from the proposed rule will range from \$231,000 to \$7.6 million (1994 \$). Table XI.B.9.f summarizes these benefits by category. The range reflects the uncertainty in evaluating the effects of the proposed rule and in placing a dollar value on these effects. As indicated in the table, these benefit ranges do not reflect many of the benefit categories expected to result under the proposed rule, including human health benefits associated with potential reductions in chronic effects from ozone exposure, human health benefits associated with reductions in acute effects in attainment areas, agriculture-related benefits from reductions in emissions of ozone precursors in attainment areas, ecological and recreational benefits from improvements in water quality, benefits from avoided interference and pass through problems and improved worker health and safety at POTWs, and human health benefits from potential reductions in systemic risk. Therefore the reported benefit estimate understates the total benefits of the proposed rule.

TABLE XI.B.9.f.—POTENTIAL ECONOMIC BENEFITS FROM THE PROPOSED EFFLUENT GUIDELINES FOR THE PHARMACEUTICAL INDUSTRY

Benefit category	Thousands of 1994 dollars per year
Reductions in Emissions of Ozone Precursors: <sup>1</sup>	
Human Health .....	31–1,929.
Agricultural .....	186–315.
Cancer Risk Reductions .....	14–5,401.
Non-carcinogenic Risk Reductions .....	Unquantified.
Ecological and Recreational Benefits .....	Unquantified.
POTW Reductions in Interference and Sludge Inhibition .....	Unquantified.
Total quantifiable benefits .....	231–7,646.

<sup>1</sup> The estimates presented only include benefits associated with reductions in acute health effects and improvements in agricultural yields in nonattainment areas. Potential welfare benefits associated with forest yield, materials damage, and visibility are not addressed in this analysis.

*g. Costs to Society.* A major component of social cost (beyond the cost to industry of compliance) is the cost to government of providing the tax deductions on pollution control costs to industry. In addition, there are other monetary and nonmonetary outlays made by government. Government administrative costs and costs of reallocating displaced workers are two

additional monetary costs. Nonmonetary costs include losses in consumers' or producers' surpluses in product markets, discomfort or inconvenience, loss of time, and slowing the rate of innovation. The social costs estimated here, which include compliance costs to industry and the costs of government tax subsidies, therefore, are a very large

portion of, but not the true total social cost of the proposed regulation. The costs reported here are thus only a close estimate of this true cost.

The estimate of total annual social costs for all selected options is shown in Table XI.B.9.g. Total social costs resulting from the proposed effluent guideline are estimated to be \$123.9 million (1994 \$).

TABLE XI.B.9.g.—SOCIAL COSTS FOR SELECTED REGULATORY OPTIONS  
[Millions of 1994 dollars]

Option No.	Total capital costs	Total O&M costs	Total annualized costs <sup>1</sup>
BAT-A/C#2 .....	64.5	40.8	47.6
BAT-B/D#1 .....	0.7	1.3	1.3

TABLE XI.B.9.g.—SOCIAL COSTS FOR SELECTED REGULATORY OPTIONS—Continued  
[Millions of 1994 dollars]

Option No.	Total capital costs	Total O&M costs	Total annualized costs <sup>1</sup>
PSES-A/C#1 .....	80.9	53.1	61.6
PSES-B/D#1 .....	28.8	10.2	13.3
Total <sup>2</sup> .....	174.9	105.4	123.9

Footnotes:

<sup>1</sup> The total annualized costs of compliance are calculated prior to accounting for the tax deductibility of the pollution control costs.

<sup>2</sup> Total number of facilities includes seven non-discharging facilities.

**Note:** These numbers are for all facilities and do not reflect closures predicted by the analyses in this report.

*h. Benefit-Cost Comparison.* Because not all of the benefits resulting from the regulatory alternative can be valued in terms of dollars, a complete cost-benefit comparison cannot be performed. The social cost of the alternatives considered in the proposed rule, discussed in the preceding section is estimated to be \$123.9 million (1994 \$). The sum of total benefits that can be valued in dollar terms ranges from \$0.2 to \$7.6 million per year (1994 \$) (see Table XI.B.9.h).

TABLE XI.B.9.h.—COMPARISON OF ANNUAL BENEFITS AND COSTS FOR THE PHARMACEUTICAL RULEMAKING  
[Thousands of 1994 dollars]

Benefits	
Cancer risk reductions .....	14–5,401
Reductions in emissions of ozone precursors .....	31–1,929
Human health .....	186–315
Agricultural benefits .....	.....
Total quantifiable benefits .....	231–7,646
Costs	
Total Annual Costs to Industry .....	80,000
Total Annual Social Costs .....	123,900

**XII. Relationship of Proposed Effluent Guidelines to EPA's Hazardous Waste Initiatives**

*A. Relationship to Rulemaking Activities Under RCRA*

1. Introduction and Overview of Land Ban Regulations

EPA's Office of Solid Waste Phase 3 proposed land disposal restriction regulations under the Resource Conservation and Recovery Act (RCRA) for certain hazardous wastes streams common to the pharmaceutical manufacturing industry on February 16, 1995. These regulations will be codified at 40 CFR Part 268 after they are finalized (scheduled for January 1996).

The proposed RCRA regulations signed on February 16, 1995 cover decharacterized ignitable (I), corrosive (C), reactive (R) and toxic (TC) wastes (i.e., wastes that initially exhibit a characteristic but, as a result of dilution, no longer do so when they are land disposed) that are managed in surface impoundments whose ultimate discharge is regulated under the Clean Water Act. These regulations also potentially apply to decharacterized wastes disposed in Class I

nonhazardous deep injection wells regulated under the Safe Drinking Water Act's Underground Injection Control program. The definitions of these waste streams are listed in Table XII.A. The September 1992 Third decision in *Chemical Waste Management v. EPA*, 976 F.2d 2 (D.C. Cir. 1992) requires EPA to assure that decharacterized wastes disposed in surface impoundments are treated to the same extent they would be if disposed in surface disposal units. However, the opinion specifically allows this showing of equivalent treatment to be measured at the eventual discharge point, so that treatment occurring in the wastewater treatment system (including the surface impoundment) can be taken into account.

2. The Land Disposal Restrictions Program

*a. Introduction to RCRA Land Disposal Restrictions.* The Hazardous and Solid Waste Amendments (HSWA) to RCRA, enacted on November 8, 1984, largely prohibit the land disposal of untreated hazardous wastes. Once a hazardous waste is prohibited from land disposal, the statute provides only two options for legal land disposal: Meet the

treatment standard for the waste prior to land disposal, or dispose of the waste in a land disposal unit that has been found to satisfy the statutory no migration test. A no migration unit is one from which there will be no migration of hazardous constituents for as long as the waste remains hazardous. RCRA sections 3004 (d), (e), (g)(5).

The treatment standards may be expressed as either constituent concentration levels or as specific methods of treatment. These standards must substantially diminish the toxicity of the waste or substantially reduce the likelihood of migration of hazardous constituents from the waste so that short-term and long-term threats to human health and the environment are minimized. RCRA section 3004(m)(1). For purposes of the restrictions, the RCRA program defines land disposal to include any placement of hazardous waste in a landfill, surface impoundment, waste pile, injection well, land treatment facility, salt dome formation, salt bed formation, or underground mine or cave. Discharge of wastewater streams containing hazardous wastes to surface impoundments is considered temporary land disposal. RCRA section 3004(k).

EPA has implemented these requirements by requiring treatment standards for hazardous wastes to be based on performance of Best Demonstrated Available Technology (BDAT).

*b. Regulation of Characteristic Wastes.* On May 8, 1990, EPA promulgated land disposal prohibitions and treatment standards for hazardous wastes that exhibited one or more of the following characteristics: ignitability, corrosivity, reactivity, or EP toxicity (40 CFR 261.21–261.24). These regulations established treatment standards for the characteristic wastes in one of four forms: (1) A concentration level equal to, or greater than, the characteristic level; (2) a concentration level less than the characteristic level; (3) a specified treatment technology (e.g., for ignitable wastes containing high levels of total organic carbon); and (4) a treatment standard of “deactivation” which allowed the use of any technology, including dilution, to remove the characteristic.

Such treatment frequently occurs in centralized wastewater management systems subject to regulation under the Clean Water Act or Safe Drinking Water Act. Furthermore, the deactivation can occur as a result of mixing wastewaters together (for example, to equalize wastewater flow into a centralized wastewater management unit). This mixing, however, is a type of dilution, and dilution is normally an impermissible means of achieving a land disposal regulation (LDR) treatment standard. EPA addressed at length the question of whether dilution incidental to such centralized wastewater management should be allowed. See generally 55 FR 22653–59 (June 1, 1990). The Agency found, generally, that mixing waste streams to eliminate certain characteristics was appropriate and permissible for corrosive wastewaters and, in some cases, reactive or ignitable wastewaters. Furthermore, EPA stated that the dilution prohibition did not normally apply to characteristic wastewaters that are managed in treatment trains, including surface impoundments, whose ultimate discharge is regulated

under the pretreatment and NPDES programs under sections 307(b) and 402 of the CWA, or in Class I underground injection well systems regulated under the Safe Drinking Water Act (SDWA). The Agency stated that the treatment requirements and associated dilution rules under the CWA are generally consistent with the dilution rules under RCRA, and that the Agency should rely on the existing CWA provisions. The Agency also singled out certain particularly toxic wastewaters to which the dilution prohibition still applies notwithstanding management in CWA systems. 40 CFR 268.3(b). Similarly, EPA stated that a regulatory program had been established under the SDWA to prevent underground injection that endangers drinking water sources.

*c. The Third Third Court Decision.* On September 25, 1992, the United States Court of Appeals for the District of Columbia Circuit ruled on the various petitions for review filed against the 1990 land disposal rule, also known as the Third Third rule. See *Chemical Waste Management v. EPA*, 976 F.2d 2, cert. denied, 113 S.Ct. 1961 (1993). The court issued three principal holdings of the case with respect to characteristic wastes. First, EPA may require treatment under RCRA section 3004(m) to more stringent levels than those at which wastes are identified as hazardous, *Id.* at 12–14. Second, section 3004(m) requires that treatment standards address both short-term and long-term potential harms posed by hazardous wastes, and consequently must result in destruction and removal of hazardous constituents as well as removal of the characteristic property, *Id.* at 16, 17, 23. As a consequence, dilution without destruction or removal of hazardous constituents is permissible as an exclusive method of treatment only for those characteristic wastes that do not contain hazardous constituents “in sufficient concentrations to pose a threat to human health or the environment” (*i.e.*, the minimize threat level in section 3004(m)). *Id.* at 16. Third, situations where characteristic hazardous wastes are diluted, lose their characteristic(s) and are then managed in centralized wastewater management

land disposal units (*i.e.*, subtitle D surface impoundments or Class I nonhazardous injection wells) are legal only if it can be demonstrated that hazardous constituents are removed or destroyed to the same extent they would be pursuant to otherwise-applicable RCRA treatment standards. *Id.* at 7.

As a consequence of these holdings, the court held that the deactivation standard for ignitable and corrosive wastes did not fully comply with RCRA section 3004(m). This was because that standard could be achieved by dilution, and dilution fails to destroy or remove the underlying hazardous constituents that can be present in the wastes. *Id.*

3. Phase 3 and the Pharmaceutical Effluent Guidelines

The RCRA regulations EPA proposed on February 16, 1995 are known as the Phase 3 rule. In response to the D.C. Circuit court decision requiring treatment beyond dechlorination or dilution for ignitable, corrosive, reactive and characteristically toxic wastes, the proposed rule addresses underlying hazardous constituents of these wastes.

EPA believes that the practices of disposal of spent solvents used extensively in pharmaceutical processes for cleaning out batch units result in the discharge of significant amounts of characteristically ignitable (D001) hazardous waste. Many of these streams are disposed in surface impoundments and will be covered by the Phase 3 proposal.

The Phase 3 rule sets out EPA’s general approach to have the RCRA standards be the same as BAT under the CWA. This is because the BAT standards reflect an industry-specific evaluation of best treatment for that industry’s wastewater. Thus, the RCRA technology-based standards will typically match those of the Clean Water Act. This approach works well for the pharmaceutical manufacturing industry because the Clean Water Act rule effluent limitations guidelines and standards are being revised contemporaneously with the Phase 3 LDR rules, and thus reflect current BAT.

TABLE XII.A.—IGNITABLE/CORROSIVE/REACTIVE/TOXICITY CHARACTERISTIC WASTES D001, D002, D003 AND D004–32

D001 .....	IGNITABLE.
D001 .....	Liquid—flash point<60 C—High TOC—261.21(a)(1).
D001 .....	Liquid—flash point<60 C—Low TOC—261.21(a)(1).
D001 .....	Nonliquid—burns vigorously/persistently—261.21(a)(2).
D001 .....	Ignitable compressed gas—49 CFR 173.300—261.21(a)(3).
D001 .....	Oxidizer—49 CFR 173.151—261.21(a)(4).
D002 .....	CORROSIVE.
D002 .....	pH<2—261.22(a)(1).
D002 .....	pH>10—261.22(a)(1).

TABLE XII.A.—IGNITABLE/CORROSIVE/REACTIVE/TOXICITY CHARACTERISTIC WASTES D001, D002, D003 AND D004–32—Continued

D002	Corrodes steel—261.22(a)(2).
D003	REACTIVE.
D003	Violent change without detonating—261.23(a)(1).
D003	Violent reaction with water—261.23(a)(2).
D003	Generates toxic gases—261.23(a)(3).
D003	Contains CN or S—261.23(a)(4).
D003	Capable of detonating under stress—261.23(a)(5).
D003	Capable of detonating spontaneously—261.23(a)(6).
D003	Forbidden, Class A or Class B explosive—261.23(a)(7).
D004–D043	TOXICITY CHARACTERISTIC (TC) WASTES.
D004	Arsenic.
D005	Barium.
D006	Cadmium.
D007	Chromium.
D008	Lead.
D009	Mercury.
D010	Selenium.
D011	Silver.
D012	Endrin.
D013	Lindane.
D014	Methoxychlor.
D015	Toxaphene.
D016	2,4-D.
D017	Silvex.
D018	Benzene.
D019	Carbon tetrachloride.
D020	Chlordane.
D021	Chlorobenzene.
D022	Chloroform.
D023	o-Cresol.
D024	m-Cresol.
D025	p-Cresol.
D026	Cresol.
D027	1,4-Dichlorobenzene.
D028	1,2-Dichloroethylene.
D029	1,1-Dichloroethylene.
D030	2,4-Dinitrotoluene.
D031	Heptachlor and epoxide.
D032	Hexachlorobenzene.
D033	Hexachlorobutadiene.
D034	Hexachloroethane.
D035	Methyl ethyl ketone.
D036	Nitrobenzene.
D037	Pentachlorophenol.
D038	Pyridine.
D039	Tetrachloroethylene.
D040	Trichloroethylene.
D041	2,4,5-Trichlorophenol.
D042	2,4,6-Trichlorophenol.
D043	Vinyl chloride.

*B. Coordination With Waste Minimization and Combustion Strategy*

In May 1994, the Administrator announced a Draft Hazardous Waste Minimization and Combustion Strategy that is pertinent to this rulemaking for the pharmaceutical manufacturing industry. The Draft Strategy provides the central framework for EPA's federal effort to maximize the source reduction and recycling of hazardous wastes under RCRA. The Draft Strategy focuses on a number of specific goals, including reducing the amount and toxicity of hazardous waste that is generated, particularly when such reductions would benefit more than one

environmental medium. The Draft Strategy also encompasses a number of other features, including public outreach, public involvement and environmental justice, permitting, enforcement, risk assessments, and good science.

1. Waste Minimization

The Draft Strategy has both short-term and a longer-term phases. In the short-term, EPA will address the source reduction and environmentally sound recycling of halogenated (and metal-bearing) combustible wastes. The longer-term effort will encompass all RCRA hazardous wastes, taking a more

comprehensive approach to how wastes are generated and managed, and the role waste minimization can play as a preferred "mode of management" over other forms of waste management (e.g., treatment, storage, and disposal). This source reduction (waste minimization) strategy should reduce the long-term demand for combustion and other waste management facilities. Section VI of this preamble presents EPA's efforts toward increasing opportunities for source reduction (e.g., process changes) in the pharmaceutical manufacturing industry.

The Agency also has released a draft report by the EPA Office of Solid Waste's Definition of Solid Waste Task

Force. This report, *Reengineering RCRA for Recycling*, presents recommendations of the Task Force to improve the regulation of hazardous waste recycling under RCRA. One of the recommendations of the Task Force was that provision should be made to exempt "clean" waste-derived fuels from the regulatory requirements of RCRA for hazardous wastes. "Clean fuels" are fuels with "*de minimis*" levels of halogens (primarily chlorine in this case) or toxic metals, especially fuels that are characteristically hazardous only because of ignitability. EPA has initiated a rulemaking effort to address the recommendations of the Task Force, including the recommendation on "clean fuels."

In the case of the pharmaceutical manufacturing industry, the volatile organic pollutants that are generated in the largest quantities are non-halogenated volatile organic pollutants, including methanol, ethanol, isopropanol, and acetone. Implementation of in-plant steam stripping or steam stripping with distillation technology affords the opportunity to recover these potentially "clean fuels" for recycle in industrial boilers, such as those on-site at pharmaceutical manufacturing facilities.

Implementation of in-plant steam stripping or steam stripping with distillation technology also affords the opportunity to recover halogenated volatile organic pollutants (e.g., methylene chloride) for recycle in the pharmaceutical manufacturing process. Recovered chlorinated solvents that are not of sufficient quality for reuse in pharmaceutical manufacturing processes may be sold for reuse in other industries.

## 2. Combustion

The Draft Strategy also addresses rigorous controls on hazardous waste combustion facilities using best available technologies to ensure that these facilities do not impose unacceptable risk to human health and the environment. EPA's regulatory activities are scheduled to be directed toward upgrading technical standards for residual wastes and emissions from hazardous waste combustion facilities, including incinerators, cement kilns, light-weight aggregate kilns, and smelter furnaces, as well as boilers and industrial furnaces.

EPA estimates that approximately 115,000 metric tons per year of solvents (halogenated and nonhalogenated) would be recovered from in-plant steam stripping technology at pharmaceutical manufacturing facilities. There is currently adequate capacity at

commercial incinerators to combust the entire mass of solvents (in excess of 1 million metric tons per year) if none was recovered and recycled. However, it is the Agency's policy, as stated in the Draft Waste Minimization and Combustion Strategy, that the most appropriate mode of management for solvents removed from pharmaceutical manufacturing wastewaters by steam stripping is recycle of "clean fuels" in boilers, recycle in the process, or recycle at other facilities.

## XIII. Administrative Requirements

### A. Changes In Format and Name

EPA is not proposing any changes in format to part 439 of the Code of Federal Regulations.

### B. Docket and Public Record

The Record for this rulemaking is available for public review at EPA Headquarters, 401 M Street SW, Washington, DC 20460. The Record supporting the effluent limitations guidelines in part 439 is located in the Office of Water Docket, Room L102 (in the basement of Waterside Mall). The Docket is staffed by an EPA contractor, Labat-Anderson, Inc., and interested parties are encouraged to call for an appointment. The telephone number for the Water Docket is (202) 260-3027.

EPA notes that many documents in the record supporting these proposed rules have been claimed as confidential business information and, therefore, are not included in the record that is available to the public in the Water Docket. To support the rulemaking, EPA is presenting certain information in aggregated form or is masking plant identities to preserve confidentiality claims. Further, the Agency has withheld from disclosure some data not claimed as confidential business information because release of this information could indirectly reveal information claimed to be confidential.

### C. Clean Water Act Procedural Requirements

As required by the Clean Water Act, EPA will conduct a public hearing on the pretreatment standards portion of the proposed rule. The location and time of this public hearing will be announced in a future notice.

### D. Executive Order 12866

Under Executive Order 12866, (58 FR 51735 (October 4, 1993)) requires EPA and other agencies to assess the potential costs and benefits of all significant regulatory actions, and submit these actions to the Office of Management and Budget (OMB). Significant regulatory actions are those

that impose a cost on the economy of \$100 million or more annually or have certain other regulatory, policy, or economic impacts. Today's rule meets the criteria of a significant regulatory action as set forth in section 3(f) of the Executive Order. The regulatory analysis for this proposed rule is presented in "Regulatory Impact Assessment of Proposed Effluent Guidelines for the Pharmaceutical Industry." This analysis (referred to as the RIA) is summarized in section XI.B. Today's proposed rule and the RIA were submitted to the OMB for review.

### E. Regulatory Flexibility Act

The Regulatory Flexibility Act, 5 U.S.C. 601 *et. seq.*, requires EPA and other agencies to prepare an initial regulatory flexibility analysis for regulations that have a significant impact on a substantial number of small entities. EPA projects that today's proposed rule, if promulgated, could affect small businesses. The initial regulatory flexibility analysis for these proposed rules is incorporated into the economic impact analysis and is discussed in section XI.B. Reporting and other compliance requirements are summarized in sections IX.I and detailed in the TDD. While the Agency has not identified any duplicative, overlapping, or conflicting Federal rules, a discussion of other related rulemakings is presented in sections V.B, V.C, V.D, X.A, X.B, XII.A, and XII.B.

### F. Reduction of Unfunded Mandates and Consultation with State, Local, and Tribal Governments

Executive Order No. 12875 supplements Executive Order No. 12866 [Sec. 1(b)(9)], and is intended "to reduce the imposition of unfunded mandates upon State, local, and tribal governments." Facilities in the pharmaceutical manufacturing industry are not associated with tribal governments, and the burden to states and local authorities is expected to be minimal, if not decreased, by the implementation of this rule.

These proposed requirements, when promulgated, will be implemented via the existing regulatory structure and no additional burden is expected beyond that previously estimated by EPA for the NPDES and general pretreatment programs. In the absence of effluent limitations guidelines and pretreatment standards, establishing BAT, BCT, NSPS, PSES, and PSNS permit limitations are to be developed on a case-by-case "Best Professional Judgment" (BPJ) basis. In addition, NPDES permits for all direct dischargers

and POTWs must incorporate state water quality standards where necessary. Once these revised pharmaceutical effluent guidelines and standards are in place, regulatory burdens on the states and local POTWs in developing pollutant control requirements that heretofore have not been addressed for this industry, particularly for volatile organic pollutants and other wastewater discharge characteristics, will be reduced. For example, the Agency is aware that certain POTWs have expended considerable resources for outside contractors (e.g., engineering consultants) to secure technical support in developing the basis for local limits or other special requirements, for POTW maintenance and equipment replacement, and for special treatment systems. These requirements were needed to prevent pollutant pass through, interference, or sludge contamination attributable to pharmaceutical facility discharges.

In compliance with E.O. 12875, EPA has involved state and local governments in the process of developing this rule. Since the inception of the project in 1986, there have been periodic meetings with the industry and its trade association, the Pharmaceutical Research and Manufacturers of America (PhRMA), to discuss progress on the rulemaking. The Agency also has met with the Natural Resources Defense Council (NRDC) to discuss progress on this rulemaking. Because most of the facilities affected by this proposal are indirect dischargers, the Agency conducted an outreach survey to a limited number of POTWs substantially affected by one or more pharmaceutical manufacturing facilities to solicit their input on the need for this proposed rule and pertinent technical issues. The Agency has worked with the Food and Drug Administration (FDA) to explore pollution prevention opportunities to the maximum extent feasible. As described previously in this preamble, EPA shared with FDA information and data gathered from the industry in responses to EPA's detailed Section 308 questionnaire. This was done to assist FDA in evaluating the environmental impacts of revised drug manufacturing processes (as described in "supplement" applications) and of new drug manufacturing processes. These reviews will ensure that opportunities for solvent use minimization/elimination and water-based manufacturing processes (e.g., water-based tablet coating) are considered and adopted within the constraints of maintaining the efficacy

of both existing and new pharmaceutical products.

The Agency also held a public meeting on May 23, 1994. EPA representatives of the Office of Water and the Office of Air and Radiation outlined the underlying technical basis and options being considered for this proposal, the efforts to coordinate the future air rule and this proposed water rule, and took comments and questions from the audience. The Agency also consulted with representatives of selected POTWs regarding underlying technical aspects of this proposal.

The Agency will continue this process of consulting with state, local, and other affected parties after proposal in order to further minimize the potential for unfunded mandates that may result from this rule.

#### *G. Paperwork Reduction Act*

The proposed effluent guidelines and standards for the pharmaceutical manufacturing industry contain no information collection activities beyond those required for the NPDES permit program and the general pretreatment program. Therefore, an information collection request (ICR) has not been submitted to the Office of Management and Budget (OMB) for review and approval under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*

OMB has approved the existing information collection requirements associated with NPDES discharge permit applications and the general pretreatment program under the provisions of the Paperwork Reduction Act.

The collection of information required for NPDES discharge permit applications has an estimated reporting burden averaging 12 hours per response and an estimated annual recordkeeping burden averaging two hours per respondent. These estimates include time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

### **XIV. Solicitation of Data and Comments**

#### *A. Introduction and General Solicitation*

EPA invites and encourages public participation in this rulemaking. The Agency asks that comments address any perceived deficiencies in the record of this proposal and that suggested revisions or corrections be supported by data.

The Agency invites all parties to coordinate their data collection activities with EPA to facilitate

mutually beneficial and cost-effective data submissions. EPA is interested in participating in study plans, data collection and documentation. Please refer to the "For Further Information" section at the beginning of this preamble for technical contacts at EPA.

When responding to these comment solicitations, please identify for each comment or data submission the comment solicitation number or numbers that the comment or data submission addresses. Commenters should also submit an electronic version on diskette if possible.

#### *B. Specific Data and Comment Solicitations*

EPA has solicited comments and data on many individual topics throughout this preamble. The Agency incorporates each of these solicitations here, and reiterates its interest in receiving data and comments on the issues addressed by those solicitations. EPA particularly requests comments and data on the following issues:

#### **1.0 General**

##### *1.1 Comments on Options and Technologies Evaluated*

The Agency solicits comments on all of the technologies and technology options identified in today's proposal.

##### *1.2 Comments on Options/Technologies Selected for Proposal*

The Agency solicits comments on the options and technologies and compliance monitoring points selected for proposal today, and the technical, policy, and legal bases expressed by EPA in support of such selections.

##### *1.3 Comments on Proposed Effluent Limitations and Standards*

The Agency solicits comments on the effluent limitations and standards proposed today.

##### *1.4 Comments on the Methodology Used to Develop Steam Stripper- and Steam Stripper With Distillation-Based Limitations and Standards*

The Agency solicits comment regarding its methodology for developing the proposed limitations and standards based on available steam stripper and steam stripper/distillation performance data.

#### **2.0 Adequacy of the 308 Questionnaire Database**

The Agency has collected a significant amount of technical and economic data from pharmaceutical manufacturing facilities. Nonetheless, the Agency is open to suggestions regarding any additional data collections that may be

required. The Agency also solicits information, comments, and data on the following technical areas:

a. Data characterizing in-facility process wastewater streams bearing pollutants proposed to be regulated, including ammonia concentration in the wastewater stream, stream pH, stream TDS and TSS, and information on the ionic species in the stream.

b. Information on new steam strippers installed since 1990 for the treatment of pharmaceutical process wastewater.

c. Information on the storage capacity used by facilities prior to steam stripping.

d. Information on steam generation and cost, including how much steam is generated on-site and at what cost, how much steam is purchased from off-site sources and at what cost, steam condition, and steam pressure used by the facility.

e. Information on scaling in steam strippers including information concerning the issues, problems, and solutions to scaling.

f. Information on the operation and maintenance costs for running steam strippers at pharmaceutical manufacturing facilities.

### 3.0 Basis for Pollutant Loading Estimates

EPA requests information from plants that completed Table 3-2 of the "1990 Pharmaceutical Manufacturing Survey" but did not indicate a technical basis for their loadings estimates (*i.e.*, air emissions from wastewater, discharges to surface waters/sewers etc.). The Agency requests that facilities specify the method and underlying assumptions used in making air emission and water discharge estimates for individual pollutants, the loading estimate values either estimated or measured, and the uncertainty associated with the method used to estimate these quantities.

### 4.0 Subcategorization

EPA is proposing to maintain the existing subcategorization scheme. The rationale for maintaining this scheme is discussed in Section IX.A.3 of this preamble.

#### 4.1 Comments on Maintaining the Existing Subcategorization Scheme

EPA solicits comments regarding the decision to maintain the existing scheme.

#### 4.2 Alternative Regulatory Schemes

The Agency also solicits suggestions for alternative regulatory schemes.

## 5.0 Definition of Research Operations

### 5.1 Definition

Research operations are defined and discussed in section IX.A.4 of this preamble. EPA solicits comments regarding the definition of research operations for the pharmaceutical manufacturing category.

### 5.2 Research Operation Wastewater in Combination With Other Subcategory Wastewater

EPA solicits comment on whether wastewaters generated from bench-scale pharmaceutical research operations at facilities with other pharmaceutical subcategory wastewaters (A, B, C, D) should be subject to the proposed subcategory A, B, C, and/or D standards and limitations rather than the existing BPT limitations for subcategory E.

## 6.0 Characterization of Individual Process Wastewater Streams

The Agency anticipates that at most facilities, a greater mass of volatile organic pollutants will be concentrated in specific wastewater streams rather than being evenly distributed in all wastewater streams. Nonetheless, EPA has assumed for purposes of this proposal that wastewater streams with volatile organic pollutants at concentrations above the distillation treatability target concentrations would require steam stripping. Because of a lack of detailed and consistent flow and pollutant characterization data in the plant responses to the section 308 questionnaire, EPA assumed, when estimating costs associated with the steam stripping and steam stripping with distillation options, that facilities would be treating all or most of the process wastewater generated by their individual plants. EPA believes that this is not a realistic assumption and that the costs developed for in-plant steam stripping and steam stripping with distillation are substantially overstated. As a practical matter, EPA anticipates that plants will attempt to segregate and treat the most concentrated volatile pollutant-bearing wastewater streams from those not requiring treatment, thus reducing the amount of wastewater that will be treated. Since amount of flow entering a steam stripper or steam stripper with distillation unit is a significant cost component in the design of these units (*i.e.*, the greater the flow the greater the cost), reductions in input flows should result in significant cost reductions.

### 6.1 Data on Flow and Organic Pollutant Distribution

In order to obtain better estimates of the volume and pollutant characterization of wastewaters requiring treatment, EPA solicits data from plants in the industry on the distribution of volatile organic pollutants in process wastewater streams. These data should specify: (1) The number and measured or estimated volume of *individual* process wastewater streams; (2) the types of organics in these waste streams and the ranges of organic pollutant concentrations either measured or estimated in these streams (*e.g.*, <1 mg/l, 1-10 mg/l, 10-100 mg/l, 100-1,000 mg/l, >1,000 mg/l); and (3) the ten organic pollutants found or expected to be found in these streams in the highest concentrations. In any cases where these data are estimates, the underlying assumptions for these estimates will need to be specified. In cases where plants undertake to generate data from process wastewater flow measurements and pollutant analyses, the measurement and analytical methods used to generate these data also will need to be specified. The Agency strongly suggests that any such plants which choose to generate these data should contact EPA staff (please refer to the **FOR FURTHER INFORMATION** section of this preamble) for guidance on details of the scope and methods of data collection and supporting documentation.

### 6.2 Wastewater Stream Segregation

EPA anticipates that plants would segregate volatile bearing wastewater from non-volatile bearing wastewater. EPA solicits comments supported by data concerning whether stream segregation of volatile bearing streams from non-volatile bearing streams is feasible and/or practical.

## 7.0 BAT Limitations for Direct Discharging Facilities With Subcategory B and D Operations Based on Steam Stripping or Steam Stripping With Distillation

In section IX.E.3.c(2) of this preamble, EPA speculated that pollutant loading data from years other than 1990 may indicate that in-plant steam stripping technology or in-plant steam stripping with distillation technology is an appropriate basis for BAT regulations for facilities with subcategory B and/or D operations. Accordingly, EPA solicits volatile pollutant loading data from direct discharging facilities with subcategory B and D operations for

years other than 1990 (i.e., 1991–1994, or any later period if available).

### 7.1 Feasibility and Appropriateness of Such Limits

EPA also solicits comment concerning the feasibility and appropriateness of setting BAT limitations on volatile organic pollutants for facilities with subcategory B and/or D operations based on steam stripping or steam stripping with distillation.

### 7.2 Point of Regulation for BAT Limitations and NSPS Standards Based on In-Plant Technologies

EPA also solicits comment on the point of regulation for any BAT limitations and NSPS standards based on in-plant technologies.

### 7.3 Limitations if Facilities Change Their Mode of Discharge

EPA also solicits comment on the issue of whether it should promulgate separate BAT limitations, based on in-plant technologies, for facilities with subcategory B and/or D operations that change their mode of discharge from indirect to direct (in view of EPA's proposal today to base PSES on steam stripping for these subcategories).

## 8.0 Definition of Process Wastewater

The Agency is proposing a definition of process wastewater for the effluent limitations guidelines regulation set out at 40 CFR section 122.2. The definition specifically includes any water which, during manufacturing or processing, comes into direct contact with or results from the production or use of any raw material, intermediate product, finished product, by-product, or waste product. The types of wastewaters considered to be process wastewater are set out in the proposed regulation at § 439.01(m), and discussed in detail in section 5 of the TDD. EPA solicits comment on the wastewaters being defined as process wastewater.

## 9.0 Prohibited Discharges

The Agency is proposing to prohibit the discharge of certain materials to POTWs or waters of the United States without an NPDES permit or individual control mechanism authorizing such discharge. See proposed regulation at §§ 439.10, 439.20, 439.30 and 439.40. A list of these materials is set forth at § 439.01(m)(1) of the proposed regulation. The Agency believes that discharge and loss of these materials is inappropriate from the standpoint of productivity loss, pollution prevention, adverse impacts on wastewater treatment (i.e., in POTWs) and worker safety and health.

### 9.1 List of Prohibited Materials

EPA solicits comment on the specific proposed list of materials prohibited for discharge. EPA is separately soliciting comment on whether BMPs are appropriate for application to control the discharge of these materials through leaks, spills, and intentional diversions (see solicitation number 31 in this section of the preamble).

### 9.2 Non-Process Wastewaters

EPA solicits comment on the following waters and wastewaters proposed to be 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 nonprocess water generated on site. EPA also solicits comment on the proposal that the discharge of such waters and wastewaters be regulated separately.

### 9.3 Costs of Complying With the Prohibitions

EPA solicits comment on the potential costs of complying with the proposed prohibition of the discharge of materials used in or generated by pharmaceutical manufacturing processes.

## 10.0 TOC Limits as Alternative to COD Limits

EPA is aware of suggestions that, in some instances, the TOC (Total Organic Carbon) test may be an appropriate substitute for the COD test and that, therefore, TOC limits should be promulgated instead of or as an alternative to COD limits. Industrial commenters on analytical methods have indicated that the approved method for determining COD in wastewater does not completely correct for abnormally high chloride (a direct interferent) concentrations found in some wastewaters.

EPA solicits all influent and effluent TOC and COD concentration data points that are descriptive of the same wastewater stream but the Agency is especially interested in those concentration data that are descriptive of wastewaters with high chloride concentrations.

## 11.0 Wastewaters From Bioengineered Materials

The Agency recognizes that there has been considerable development of bioengineered materials that may be incorporated in pharmaceutical products. The Agency is concerned about the release of these bioengineered materials in pharmaceutical

wastewaters. EPA solicits comment and data that characterize wastewater from the development of bioengineered materials.

## 12.0 Source Reduction Activities

The Agency solicits information and data on any efforts (ongoing or planned) concerning source reduction activities at pharmaceutical manufacturing facilities, as discussed in Section IX of this preamble.

### 12.1 Pollution Prevention and Combustion Strategy

EPA solicits comments on the waste minimization and combustion strategy discussed in Section XII.B of this preamble as it may be applied in this industry. See also solicitation number 22 below.

## 13.0 Water-Based Tablet Coating Processes

EPA is aware that certain facilities engaging in subcategory D operations (compounding/mixing/formulating) have opportunities to make process changes that can result in lower wastewater discharges and air emissions of volatile pollutants. Specifically, facilities may utilize an aqueous-based tablet coating process as opposed to a volatile organic solvent-based tablet coating process. EPA realizes that this substitution is not feasible for all coating processes. Nonetheless, EPA solicits data from plants in the industry on any changes or substitutions made to solvent-based tablet coating processes.

## 14.0 Concentration Versus Percent Reduction and Mass-Based Limitations

The Agency today is proposing concentration-based effluent limitations and standards as the most appropriate basis for controlling the discharge of conventional, priority, and nonconventional pollutants from the pharmaceutical manufacturing industry. Industry representatives have commented that alternative formats for these limitations and standards controlling volatile pollutants may be appropriate, including percent removal with base concentrations as provided for in the HON.

### 14.1 Concentration-Based Format

The Agency solicits comment on the concentration-based format for limitations being proposed today.

### 14.2 Implementation of an Alternative Percent Reduction Limitation

The Agency solicits comment on alternative percent reduction-based limitations, as used for some of the existing effluent limitations and the

HON, and how this approach would be implemented. See solicitation number 32.4.

#### 14.3 Implementation of a Mass-Based Limitation

The Agency solicits comment on alternative mass-based limitations and how this approach would be implemented.

#### 15.0 In-Plant Limitations for Volatile Organic Pollutant Control

For PSES and PSNS, the Agency is proposing to require compliance monitoring in-plant for certain pollutants (e.g., chloroform, methylene chloride, and toluene) that due to dilution would be found at the end-of-pipe at levels below the current analytical limits of detection. The long-term average concentrations upon which the applicable standards are based are, for many pollutants, near the analytical limits of detection established for these pollutants in wastewater. The Agency is concerned that measurements made at end-of-pipe, after dilution with process and non-process wastewaters, will not adequately reflect the performance of the PSES or PSNS level treatment due to uncertainty associated with pollutant concentration measurements near established limits of detection. EPA has a similar concern for the proposed BAT technology for facilities with subcategory A and/or C operations and the NSPS technology for all manufacturing subcategories.

During development of these proposed regulations, industry representatives asserted that requiring compliance monitoring in-plant on internal streams may reduce their flexibility in compliance and require installation of specific in-plant treatment technologies. Based upon available data, the Agency believes that even if in-plant monitoring is required, pharmaceutical facilities will retain considerable flexibility in choosing specific compliance strategies that may be implemented at individual facilities, including available in-plant treatment technologies. EPA also believes in-plant limitations will enhance opportunities for recovery and reuse of solvents and may allow for the generation of "clean fuels," as described in section XI.C of this preamble.

#### 15.1 Feasibility of End-of-Pipe Limits in Measuring Compliance

EPA solicits comments and data on whether requiring compliance monitoring at the end-of-pipe could practically or feasibly be used to determine whether the proposed BAT,

PSES, NSPS and PSNS limitations and standards are being met.

#### 15.2 Feasibility of End-of-Pipe Limits in Measuring Technology Performance

EPA solicits comments and data on whether requiring compliance monitoring at the end-of-pipe could practically or feasibly be used to measure the performance of the process technologies that form the basis of EPA's proposed BAT, PSES, NSPS and PSNS regulation.

#### 15.3 Extent That In-Plant Control Enhances Recovery/Reuse

The Agency solicits comments and specific supporting data on the extent to which recovery and reuse opportunities may be enhanced by in-plant control.

#### 15.4 Compliance Strategy With In-Plant Monitoring Points

The Agency solicits comments on whether compliance strategies are either enhanced or limited by the use of in-plant monitoring points.

#### 15.5 Air Emissions

The Agency solicits comment on the extent to which air emissions may be controlled by in-plant limits and standards for volatile organic pollutants based on steam stripping or steam stripping with distillation.

#### 15.6 Minimum Concentration and Flow Thresholds

EPA is aware that it may not be efficient or cost effective for plants to steam strip or distill wastewater streams containing low concentrations of volatile organic pollutants. Consequently, EPA solicits suggestions for concentration and flow thresholds for identifying wastewater streams containing volatile organic pollutants which would be subject to in-plant steam stripping or steam stripping with distillation.

#### 15.7 Setting In-Plant Limitations on Case-by-Case Basis

The Agency solicits comment on the burden imposed on permit writers to establish in-plant BAT limitations and NSPS on a case-by-case basis for the 45 volatile organic pollutants for which EPA is proposing to specify end-of-pipe limitations and standards. EPA also seeks comment on its proposal that the end-of-pipe BAT limitations and NSPS standards for particular pollutants would not apply if a permit writer finds in-plant limitations or standards to be necessary for those pollutants; EPA also seeks comment on the recommendation that the permit writer consult the appropriate PSES or PSNS table in

setting the necessary in-plant limitations and standards on a best professional judgment basis. EPA also seeks comment on the utility of relying on EPA's existing NPDES permit regulations to address issues associated with pollutants that are not detectable at the end of the pipe.

#### 15.8 Deference to Clean Air Act Rulemaking

The Agency seeks comment on all aspects of EPA's policy determination in this proposal to defer to the Clean Air Act rulemaking for the pharmaceutical industry with respect to the control of volatile air emissions from certain pharmaceutical wastestreams.

#### 15.9 Comments on Steam Stripping With Distillation

The Agency requests comments and data on whether steam stripping with distillation should be the technology basis for effluent limitations and standards for volatile organic pollutants, particularly those that are difficult to strip, such as methanol and ethanol.

#### 15.10 Comments on the Proposed End-of-Pipe Limits for Highly Strippable Volatile Organic Pollutants

The Agency solicits comments supported by data regarding whether it is appropriate to develop limitations requiring compliance monitoring at the end of the pipe for highly strippable volatile organic pollutants such as methylene chloride and chloroform.

#### 16.0 WATER7 Model

In analyzing responses to the mass balance question (section 3-2 of the 308 questionnaire), EPA has determined that many of the loading estimates (i.e., to air, to water etc.) provided for individual pollutants were not accompanied with explanations of how the estimates were made. The Agency is concerned that the 308 mass balance responses may underestimate the amount of pollutant air emissions from wastewater and overestimate the amount of pollutant biodegradation and/or destruction. Consequently, EPA has used the WATER7 computer model in conjunction with other 308 response data to develop pollutant-by-pollutant air emission estimates. The WATER7 program was used previously to estimate air emissions from wastewater for the SOCOMI HON (see 59 FR 19402).

#### 16.1 Technical Validity of the WATER7 Model

EPA solicits comments on the technical validity of the WATER7 model and its use in estimating pollutant releases at pharmaceutical facilities.

### 16.2 Other Models for Estimating Air and Water Loadings

The Agency also welcomes suggestions regarding the use of other computer models for estimating air and water loadings at pharmaceutical plants.

#### 17.1 Alternative Technologies to Steam Stripping or Steam Stripping With Distillation Technology

For volatile organic pollutants, EPA is proposing to base its BAT limitations for facilities with subcategory A and/or C operations and PSES limitations for all manufacturing subcategories on steam stripping technology. EPA also proposed to base NSPS and PSNS regulations for all manufacturing subcategories for those pollutants on in-plant steam stripping with distillation technology. The Agency believes that steam stripping technology is the best available technology and that steam stripping with distillation technology is the best demonstrated technology for removing volatile pollutants from wastewater that also offer the opportunity for recovery and recycle of solvents.

EPA solicits comments accompanied by data regarding other technologies designed to remove volatile organic pollutants from wastewater. Information on alternative technologies should be accompanied by influent and effluent data that demonstrate removal.

### 18.0 Materials of Construction for Steam Stripper and Distillation Columns

EPA has used stainless steel as its construction material in steam stripper and distillation column capital cost estimates. Nonetheless, the Agency recognizes that certain corrosive (low pH) streams may require the use of construction materials made of corrosion resistant alloys such as Hastalloy to allow long-term operation of steam strippers and distillation columns.

#### 18.1 Process Wastewater Characteristics Requiring Special Alloys

The Agency solicits comments and data on the characteristics of any process wastewater streams that may require that steam strippers and/or distillation columns be constructed of highly specialized alloys such as Hastalloy.

#### 18.2 Existing Materials of Construction

The Agency requests information regarding the construction materials used to build all the steam strippers and distillation units currently in-place within the industry.

### 19.0 Streams Containing Volatile Organic Pollutants That Also Contain Significant Amounts of Dissolved Solids

EPA wants to ensure that the final limitations and standards for volatile organics based on steam stripping or steam stripping with distillation technology adequately reflect the dissolved solids content of representative industry wastestreams. The Agency is aware that certain waste streams that contain large concentrations of certain inorganic salts may cause scaling problems within packed columns that may reduce column performance. Consequently, EPA solicits comments supported by data concerning the strippability of wastestreams containing high concentrations of inorganic salts (dissolved solids).

### 20.0 COD Removal Through Steam Stripping and Steam Stripping With Distillation

As indicated earlier in this preamble, the Agency does not have removal data for COD achievable through steam stripping and steam stripping with distillation technology.

#### 20.1 COD Removal Data

EPA solicits any influent and effluent COD data across a steam stripper and/or distillation unit for any available time period. The COD influent and effluent data should also include influent stream characteristics data (i.e., organic constituent concentrations) if possible. EPA also solicits COD data for any facilities that also have a biological treatment system following a steam stripper or distillation unit for which COD data are available or may be gathered.

#### 20.2 COD Regulation Beyond BPT

EPA is proposing BAT limitations and NSPS for COD for all manufacturing subcategories based on advanced biological treatment (the BPT-level technology). EPA is not proposing COD limitations and standards based on steam stripping or steam stripping with distillation because EPA is unable at this time to quantify the COD loading reductions attainable through those technologies in addition to advanced biological treatment. EPA solicits comments and data concerning whether BAT limitations and NSPS for COD based on in-plant steam stripping or steam stripping with distillation in addition to advanced biological treatment are necessary or appropriate for facilities with subcategory A and/or C operations. EPA also solicits comments and data on the advisability of adding granular activated carbon

adsorption technology to the steam stripping-based technologies for additional removal of COD. EPA also solicits comments and data concerning BAT limitations and NSPS for COD for facilities with subcategory B and D operations.

### 21.0 Clean Up of Steam Stripping and Distillation Overheads, i.e., Condensates

#### 21.1 Additional Treatment Required for Clean Up

EPA is aware that the overhead materials recovered from steam stripping and distillation may need to be "cleaned up" prior to reuse. EPA solicits information on the technologies that are currently being used to purify overheads from steam stripping and distillation.

#### 21.2 Costs of Overhead Recovery for Reuse

EPA solicits information and data regarding the costs of cleaning up or purifying overheads for reuse in manufacturing operations along with information on the cost of virgin solvent materials.

#### 22.0 Clean Fuels

EPA is aware that some facilities use distillation/steam stripping overheads as boiler feed. The Agency solicits data and comment concerning the use of such overheads as "clean fuels" from plants which are using overheads as boiler feed and from plants which plan to do so in the future.

### 23.0 Regulation of Ammonia at BAT and PSES

EPA is proposing effluent limitations and standards controlling the discharge of the pollutant ammonia for facilities with subcategory A and/or C operations because it is a pollutant of concern and is discharged at treatable concentration levels. Data are available demonstrating that ammonia passes through POTWs, and that ammonia is not adequately treated at direct dischargers. The control technology basis for BAT ammonia limitations is incidental removal through in-plant steam stripping and advanced biological treatment upgraded for nitrification. The control technology basis for PSES ammonia limitations is removal through in-plant steam stripping. Industry representatives have commented that ammonia discharges from direct dischargers should be controlled through water quality standards. Industry representatives have also commented that the adoption of technology-based limitations and standards for ammonia would result in

significant cross-media transfers and energy use.

### 23.1 Degree to Which Ammonia Passes Through POTWs

EPA solicits comments and data on the degree to which ammonia generated by pharmaceutical manufacturing facilities passes through POTWs.

### 23.2 Degree to Which Ammonia is Treated at Direct Dischargers

EPA solicits comments and data on the degree to which ammonia is adequately treated at direct discharging facilities.

### 23.3 Achievability of the Proposed Ammonia Limitations

EPA solicits comments and data on the achievability of the Agency's proposed ammonia limitations.

### 23.4 Proposed Ammonia Control Technologies

EPA solicits comments on the underlying control technologies proposed for ammonia treatment.

### 23.5 Nutrient Balance of Downstream Biotreatment

EPA solicits comments on the extent to which ammonia removal may adversely affect the nutrient balance of process wastewaters treated in biological treatment systems.

### 23.6 Other Factors

EPA solicits comments on the costs, effluent reduction benefits, water quality benefits, and any other factors that may be related to the proposed ammonia limitations and standards.

## 24.0 Impact of Pharmaceutical Wastewaters on POTW Operations

EPA has received information and data indicating that pharmaceutical manufacturing process wastewaters discharged to POTWs contain significant concentrations of volatile organic pollutants. These concentrations can result in slug loads of volatile organic pollutants and other wastewater constituents that, in turn, may cause significant air emissions in the headworks of these POTWs and may be a threat to worker safety and health. The Agency's proposed PSES are intended to reduce the concentration of volatile organic pollutants in pharmaceutical discharges. EPA solicits comments and supporting data on these findings and on the question whether these objectives can be satisfied by assuring that discharges to the POTW sewer are near or at the level of detection.

### 24.1 PSES Removal of Volatile Organic Pollutants

The Agency solicits comments and data that address the extent to which EPA's proposed PSES may reduce the concentration of volatile organic pollutants in pharmaceutical plant discharges to POTWs.

### 24.2 Regulatory Approach

The Agency solicits comment on the appropriate regulatory approach for facilities that discharge pharmaceutical manufacturing wastewater to privately owned treatment works. The Agency specifically requests comment on whether such discharges are best regulated under today's proposed regulations, are best regulated under effluent limitations guidelines and standards for centralized waste treatment facilities, 40 CFR Part 437, or are best regulated on a case-by-case basis using best professional judgment.

### 24.3 Comments on the Finding of No Pass-Through for 33 Volatile Organic Pollutants Under PSES Co-Proposal (2)

The Agency solicits comments and data regarding its finding under PSES co-proposal (2) that the specified 33 volatile organic pollutants do not pass through.

### 24.4 Need for Pretreatment Standards for 33 Less Strippable Volatile Organic Pollutants

The Agency proposes as PSES and PSNS pass-through co-proposal (1) to establish PSES and PSNS for 33 less strippable volatile organic pollutants. Co-proposal (1) is supported by the Association of Metropolitan Sewerage Agencies, which in letter to EPA dated February 14, 1995, asserted that the promulgation of national pretreatment standards for these pollutants would be the most environmentally sound, timely and cost-effective method of addressing those pollutants. See Section IX.E.5.a. EPA solicits comments on EPA's two pass-through co-proposals and on the asserted benefits to POTWs associated with co-proposal (1).

Industry data supplied to the Agency indicate preliminarily that only 10 percent of the indirect sources account for 80 to 90 percent of the total discharge of these pollutants to POTWs and that problems associated with discharges to POTWs are specific and local. EPA solicits comments and supporting data on the extent to which indirect discharges present a national problem warranting regulation at the national, as opposed to local, level and whether mechanisms other than those considered as the technology basis for

PSES and PSNS are possible alternatives for addressing the problem.

### 24.5 Effect of Forthcoming Clean Air Rule

EPA is developing a separate rulemaking (under the requirements of Section 112 of the Clean Air Act) to address the air emissions from pharmaceutical plants, including the emissions of most of these 12 volatile organic pollutants. EPA's air rulemaking may complement this proposal so that standards set at the point of discharge to the POTW sewer may satisfy EPA's objectives in this rulemaking. EPA expects to propose these air emission standards next year. As a result, EPA is also considering whether to establish the limits for the 12 highly strippable organic pollutants at the point of discharge to the POTW sewer and solicits comments and supporting data on this question.

## 25.0 Pretreatment of Methanol

### 25.1 Biodegradation of Non-Halogenated Volatile Organic Pollutants Without Causing Air Emissions

Industry representatives have stated that EPA's pretreatment standards requiring removal of methanol and other non-halogenated volatile organic pollutants (e.g., acetone, ethanol, and isopropanol) are not necessary because these pollutants are adequately biodegraded by POTWs. Industry maintains that these pollutants have low predicted air emissions from industrial direct discharge systems and, at the lower temperatures and concentrations found in POTW systems, would have even lower potential to be emitted from POTWs.

EPA solicits comments and supporting data regarding the ability of POTWs to biodegrade non-halogenated volatile organic pollutants without significant air emissions.

### 25.2 BOD<sub>5</sub> Removal Efficiency at POTWs

Industry also asserts that removal of these non-halogenated volatile organic pollutants (a portion of which are measured as BOD<sub>5</sub>) may have adverse impacts on the BOD<sub>5</sub> removal efficiency of biological treatment systems at POTWs receiving pharmaceutical manufacturing process wastewaters. EPA solicits comments and supporting data on whether pretreatment of these pollutants will adversely affect the BOD<sub>5</sub> removal efficiency of POTWs.

### 25.3 Financial Impact on POTWs

The industry has asserted that pretreatment of methanol and other non-halogenated volatile organic

pollutants by pharmaceutical manufacturing facilities will have an adverse financial impact on POTWs.

EPA solicits comments and supporting data on whether pretreatment for removal of these pollutants, and thereby reduced BOD<sub>5</sub> raw waste loads to POTWs, will have adverse financial impacts on POTW revenues.

### **26.0 Pass-Through of COD at POTWs**

EPA will be conducting a POTW pass-through analysis for the pollutant COD because EPA is concerned that certain refractory organic waste materials from subcategory A and C operations measured as COD may pass-through the treatment afforded by POTWs.

#### *26.1 Data on COD Pass-Through*

EPA is soliciting data on COD removal (influent and effluent data) from POTWs that treat wastewater from pharmaceutical plants engaging in subcategory A and C operations.

#### *26.2 Appropriate Procedure for Conducting the COD Pass-Through Analysis*

EPA also solicits comments on the appropriate procedure for conducting a pass-through analysis for the pollutant COD.

### **27.0 Pretreatment Standards for Nonstrippable Organic Pollutants**

#### *27.1 Package Biotreatment for Five Nonstrippable Organic Pollutants*

As noted in Section IX.E.5.a of this preamble, EPA has determined that five nonstrippable biodegradable organic pollutants (N,N dimethyl formamide, dimethyl sulfoxide, N,N-dimethyl acetamide, formaldehyde and ethylene glycol) pass through POTWs. EPA is considering developing pretreatment standards for these pollutants based on package biological treatment. EPA solicits comments and data regarding whether pretreatment standards based on package biological treatment for the five nonstrippable organic pollutants should be promulgated.

#### *27.2 Other Treatment Technologies for Nonstrippable Organic Pollutants*

EPA solicits data and information regarding the ability of other technologies to reduce wastewater concentrations of the five nonstrippable organic pollutants identified in the comment solicitation above.

#### *27.3 POTW Pass Through for Acetonitrile and PEG 600*

EPA solicits data and information concerning whether acetonitrile and

polyethylene glycol 600 pass through POTWs.

### **28.0 PSES for Additional Pollutants**

Although today's proposed PSES would control 45 volatile organic pollutants (as well as cyanide and ammonia for subcategories A and C), the Agency is concerned that additional pollutants currently being discharged by pharmaceutical plants may either pass through POTWs or interfere with their operation.

Consequently, EPA solicits comments and data concerning other pollutants discharged by pharmaceutical plants in all manufacturing subcategories that may pass through and/or interfere with POTWs, such as sulfates and sulfide (hydrogen sulfide) which are capable of causing significant worker safety problems and corrosion.

### **29.0 Revision of BPT**

EPA is proposing to revise the existing BPT effluent limitations, which are outdated and no longer represent the average of the best performers in the pharmaceutical manufacturing industry. In developing the proposed revised BPT effluent limitations, EPA has identified the average of the best performers with advanced biological treatment.

#### *29.1 Advanced Biological Treatment*

EPA solicits comments and data with respect to whether EPA has appropriately selected advanced biological treatment as the technology basis for the proposed BPT conventional pollutant limitations.

#### *29.2 Methodology Used to Select Best Performers*

EPA solicits comments on the methodology used to select the best performing facilities with advanced biological treatment and to develop the limitations based on performance data from these facilities.

#### *29.3 Statutory Authority and Other Factors*

EPA solicits comments and data with respect to the authority under the Clean Water Act to revise BPT, and on costs, effluent reduction benefits, water quality benefits, and any other factors that may be related to the proposed BPT revisions.

### **30.0 Revision of BCT**

EPA is proposing to revise the existing BCT effluent limitations that were promulgated in July 1986 (51 FR 24974). EPA identified no technologies that achieve greater removals of conventional pollutants than those associated with the proposed revised

BPT limitations that are also cost-reasonable.

#### *30.1 Proposed Baseline for BCT Cost Test*

EPA solicits comments on the baseline used for this proposal (i.e., revised BPT limits being proposed today) beyond which candidate technologies were identified, and the alternative baseline identified (i.e., existing BPT limitations).

#### *30.2 Candidate Technologies for BCT*

EPA solicits comments on the candidate technologies considered for BCT in this analysis and any others not identified that may be appropriate.

#### *30.3 BCT Results*

EPA solicits comments on the finding that none of the candidate BCT technologies beyond BPT were cost-reasonable.

#### *30.4 Other Factors*

EPA solicits comments with respect to costs, effluent reduction benefits, and any other factors that may be related to the proposed BCT revisions.

### **31.0 Applicability and Scope of Best Management Practices**

Section 304(e) of the CWA gives the Administrator the authority to publish regulations to control plant site runoff, spillage or leaks, sludge or waste disposal, and drainage from raw material storage that the Administrator determines are associated with or ancillary to the industrial manufacturing or treatment processes of the regulated point source category and that she (he) determines may contribute significant amounts of pollutants to waters of the United States. Examples of BMP regulations include the requirement that dikes be constructed in process areas and required employee training in spill prevention and control.

#### *31.1 Establishment of BMPs*

EPA solicits comments regarding whether BMP regulations should be established for the pharmaceutical manufacturing industry.

#### *31.2 BMPs and Costs*

The Agency also solicits suggestions on possible BMPs to be prescribed by regulation, accompanied by facility implementation cost estimates that may be appropriate for this industrial category.

#### *31.3 Suggested Specific BMPs*

The Agency solicits comments on the suggested specific BMPs presented in Appendix B of the Technical Development Document.

### 32.0 MACT Standards Versus Effluent Guidelines

The proposed BAT and PSES effluent limitations guidelines will control volatile organic pollutants of which 22 are hazardous air pollutants (HAPs), that are released to the environment primarily in wastewater discharges and air emissions. The mass of HAPs being controlled by the effluent limitations guidelines and standards is about 40 percent of the total mass of volatile organic pollutants being controlled. It is the Agency's intent for both the effluent guidelines being proposed today and the MACT standards to be proposed at a later date that upon promulgation the in-plant technology basis of both rules will be applicable to essentially the same high concentration low volume process wastewater streams in which the bulk of the volatile organic pollutants are contained.

Industry representatives commented that air emissions from pharmaceutical manufacturing facilities should be controlled by a NESHAP rulemaking rather than by BAT limitations and PSES. Industry representatives also commented that the Agency should integrate the development of these two rules, which now are progressing on separate schedules. Industry representatives commented further that the effluent guidelines should include the same elements of flexibility (e.g., allow for demonstration of equivalence of biological treatment to steam stripping) and format of the limitations as included in the HON (e.g., percent removal). Industry representatives also indicated that the HON will allow for emission-suppressed transport of volatile organic pollutant-containing wastewaters to central treatment facilities.

#### 32.1 *Should the Water and Air Regulations Be Integrated*

In view of these preliminary concerns, the Agency solicits comments and data with respect to whether it is necessary or appropriate for the two rules to be integrated and, if so, how.

#### 32.2 *List of Organic Pollutants Covered*

EPA solicits comments on whether it is necessary or appropriate for the two rules to cover the same list of volatile organic pollutants.

#### 32.3 *Steam Stripping Design and Operating Parameters*

EPA solicits comments on whether the design and operating parameters for steam stripping technology as applied in the two rules should be the same and, if so, how (within the constraints of the governing statutes).

#### 32.4 *Percent Removal Standard With a Base Concentration*

EPA solicits comments on whether EPA should adopt, as an alternative to the proposed concentration-based limitations and standards, effluent limitations guidelines and standards based on percent removal standards, as proposed in the HON for the Specialty Organic Chemical Manufacturing Industry (SOCMI). See solicitation numbers 14.0-14.3.

#### 32.5 *Central Treatment for Volatiles Removal*

EPA solicits comments on whether central treatment (i.e., steam stripping or an equivalent technology prior to end-of-pipe biological treatment) is or should be an acceptable compliance approach for the effluent guidelines.

#### 32.6 *Alternate Limitations for End-of-Pipe Biological Treatment*

EPA solicits comments on whether the effluent guidelines should include alternative limitations which would allow for end-of-pipe biological treatment of hard-piped volatile organic pollutants (in place of in-plant steam stripping or steam stripping with distillation technology).

#### 32.7 *Control of Air Emissions Using Alternate Limitations*

EPA solicits comments on whether an alternative approach (as described in comment number 32.6) would present the same control of air emissions as achieved by in-plant steam stripping and steam stripping with distillation technology.

#### 32.8 *Energy Use for and Air Emissions From Generation of Steam Used for Steam Stripping and Steam Stripping with Distillation*

EPA solicits comments and data on the increase in energy required to generate steam used for steam stripping and distillation, and on the increase in air emissions created by steam generation facilities (industrial boilers).

#### 32.9 *Comments on Evaluating the Record of This Rulemaking in the Context of the MACT Rule*

The Agency requests comments on whether it is appropriate for the Office of Air and Radiation to evaluate the basis for the proposed effluent limitations and standards as part of its development of MACT standards for the pharmaceutical manufacturing industry.

### 33.0 Analytical Methods

A complete discussion of the new analytical methods being proposed in conjunction with these proposed

regulations may be found in section 18 of the Technical Development Document.

#### 33.1 *Analytical Methods Proposed Today*

The methods being proposed today involve the use of isotope dilution gas chromatography/mass spectrometry (GC/MS), derivatization followed by high pressure liquid chromatography (HPLC), and GC followed by detection in an electrochemical cell optimized for nitrogen containing compounds (GC/ELCD). EPA solicits comments with respect to these techniques (see discussion in Section IX of this preamble, and the supporting compendium of analytical methods entitled "Analytical Methods for the Determination of Pollutants in Pharmaceutical Manufacturing Industry Wastewater;" see Section II of this preamble) and any suggestions regarding alternative techniques as well.

#### 33.2 *Limitations Set at the Minimum Level of the Method*

EPA solicits comments on those limitations whose long-term average basis is equal to the minimum level established for the limited pollutant.

#### 33.3 *Statistical Methods for Establishing Limitations*

EPA solicits alternative statistical methodologies for developing limitations based on all non-detect data which may be more appropriate than the statistical methodology employed by EPA.

#### 33.4 *Analytical Methods for Alcohols*

EPA has proposed analytical methods for quantifying various low-molecular weight alcohols (e.g., methanol and ethanol) in wastewater. See "Analytical Methods for the Determination of Pollutants in Pharmaceutical Wastewater", EPA 821-R-95-015. EPA invites comments on the proposed methods for determining alcohols in wastewater from industrial laboratories, public sector laboratories and individual researchers familiar with similar analytical methods.

#### 33.5 *Matrix Interferences and Analytical Methods*

EPA is interested in identifying solutions to matrix interference problems connected with the analysis of pharmaceutical manufacturing industry wastewater streams. EPA is also interested in any extraction, concentration or other analytical techniques that may offer solutions to matrix interference problems.

### 33.6 Analytical Method for the Determination of Polyethylene Glycol 600 in Wastewater

EPA has determined that GC/MS methods have not been found to be useful in the determination of polyethylene glycol 600 in wastewater. EPA invites suggestions concerning the analysis of this pollutant in wastewater.

### 33.7 COD Determinations in Samples With High Chloride Content

EPA is aware that the standard method determinations of COD in samples with high chloride content (e.g., brackish wastewater) need to be pretreated to remove chloride prior to the oxidation step in the COD determination. EPA requests comments regarding the techniques used to remove chlorides prior to the oxidation step and their adequacy in preventing interference with the COD determinations. EPA also solicits data and information with respect to any analytical method studies involving COD determinations in wastewaters with high chloride concentrations.

### 34.0 Surface Impoundments

EPA is concerned about the transfer of volatile organic pollutants from surface impoundments located at pharmaceutical manufacturing facilities to groundwater and air. EPA solicits comment and data on the monitoring of surface impoundments, including leachate data and air emissions data.

### 35.0 Regulatory Impact Analysis

EPA solicits comments concerning the methodology employed to estimate costs and benefits in the Regulatory Impact Analysis developed for these regulations and the conclusions EPA reached by applying those methodologies.

### 36.0 Economic Impact Analysis

EPA solicits comments on the methodology employed to measure the economic impacts of the proposed regulations.

#### 36.1 Definition of Small Entities

The Agency solicits comment on the definition of small entity used in this analysis, the analytical procedures for assessing impacts on small entities, and the opportunities to minimize the impacts on small entities, as described in the Economic Impact Analysis and Regulatory Flexibility Analysis of Proposed Effluent Guidelines for the Pharmaceutical Manufacturing Industry.

### 37.0 Use of Bulk Parameters to Represent Pollutants of Concern

EPA solicits comments and data on the use of bulk parameters such as COD

to represent the presence and treatability of pollutants of concern, such as the broad range of organic compounds present in pharmaceutical manufacturing process wastewaters, particularly chemical synthesis process wastewaters. See also solicitation numbers 10.0, 20.0, 26.0, 27.0, and 28.0.

### 38.0 Reducing Monitoring Requirements

The Agency solicits comment on ways to reduce the monitoring requirements associated with the proposed rulemaking.

#### 38.1 Subcategory D Facilities

The Agency is aware that many facilities with subcategory D operations do not use or generate the pollutants for which regulations are being proposed today. Consequently, these facilities should not be required to monitor for these pollutants. EPA solicits comment on any appropriate mechanism for reducing monitoring requirements for these facilities.

#### 38.2 Pollutants Not Used or Generated

Similarly, facilities with operations in other subcategories may not use or generate specific pollutants for which regulations are being proposed. EPA solicits comment on any appropriate mechanism for reducing monitoring requirements for these pollutants at such facilities.

#### 38.3 Use of Alternate Analytical Methods

EPA also solicits comments on whether circumstances may exist under which it may be appropriate to allow facilities to use analytical methods for organic pollutants other than those used to generate data upon which this proposal is based. Such circumstances may include "screening" to confirm the absence of pollutants where solvents are not used in pharmaceutical manufacturing processes (i.e., subcategory D, mixing/ compounding/ formulating). These alternate methods might include Methods 624 and 625 as alternatives to Methods 1624 and 1625.

### 39.0 Privately Owned Treatment Plants

EPA solicits comment on the issue whether part 439 should apply to process wastewater pollutants introduced into privately owned treatment works.

#### List of Subjects in 40 CFR Part 439

Environmental Protection Air pollution control, pharmaceutical manufacturing Pollution prevention, Wastewater treatment.

Dated: February 28, 1995.

**Carol M. Browner,**  
Administrator.

For the reasons set out in the preamble, title 40, chapter I, part 439 of the Code of Federal Regulations is proposed to be amended as follows:

### PART 439—PHARMACEUTICAL MANUFACTURING POINT SOURCE CATEGORY

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

**Authority:** Sections 301, 304, 306, 307, and 501 of the Clean Water Act, (33 U.S.C. 1311, 1314, 1316, 1317, and 1361).

2. The Table of Contents for part 439 is amended by adding §§ 439.3 and 439.4 and the entire table of contents is published for the convenience of the reader.

Sec.	
439.0	Applicability.
439.1	General definitions.
439.2	Monitoring requirements.
439.3	Dilution prohibition.
439.4	[Reserved]

#### Subpart A—Fermentation Subcategory

439.10	Applicability; description of the fermentation products subcategory.
439.11	Specialized definitions.
439.12	Effluent limitations representing the degree of effluent reduction attainable by the application of best practicable control technology currently available (BPT).
439.13	Effluent limitations representing the degree of effluent reduction attainable by the best conventional pollutant control technology (BCT).
439.14	Effluent limitations representing the degree of effluent reduction attainable by the application of best available technology economically achievable (BAT).
439.15	New source performance standards (NSPS).
439.16	Pretreatment standards for existing sources (PSES).
439.17	Pretreatment standards for new sources (PSNS).
439.18	[Reserved]

#### Subpart B—Extraction Subcategory

439.20	Applicability; description of the extraction products subcategory.
439.21	Specialized definitions.
439.22	Effluent limitations representing the degree of effluent reduction attainable by the application of best practicable control technology currently available (BPT).
439.23	Effluent limitations representing the degree of effluent reduction attainable by the best conventional pollutant control technology (BCT).
439.24	Effluent limitations representing the degree of effluent reduction attainable by the application of best available technology economically achievable (BAT).

- 439.25 New source performance standards (NSPS).
- 439.26 Pretreatment standards for existing sources (PSES).
- 439.27 Pretreatment standards for new sources (PSNS).
- 439.28 [Reserved]

**Subpart C—Chemical Synthesis Subcategory**

- 439.30 Applicability; description of the chemical synthesis products subcategory.
- 439.31 Specialized definitions.
- 439.32 Effluent limitations representing the degree of effluent reduction attainable by the application of best practicable control technology currently available (BPT).
- 439.33 Effluent limitations representing the degree of effluent reduction attainable by the best conventional pollutant control technology (BCT).
- 439.34 Effluent limitations representing the degree of effluent reduction attainable by the application of best available technology economically achievable (BAT).
- 439.35 New source performance standards (NSPS).
- 439.36 Pretreatment standards for existing sources (PSES).
- 439.37 Pretreatment standards for new sources (PSNS).
- 439.38 [Reserved]

**Subpart D—Mixing, Compounding and Formulating Subcategory**

- 439.40 Applicability; description of the mixing, compounding and formulating subcategory.
- 439.41 Specialized definitions.
- 439.42 Effluent limitations representing the degree of effluent reduction attainable by the application of best practicable control technology currently available (BPT).
- 439.43 Effluent limitations representing the degree of effluent reduction attainable by the best conventional pollutant control technology (BCT).
- 439.44 Effluent limitations representing the degree of effluent reduction attainable by the application of best available technology economically achievable (BAT).
- 439.45 New source performance standards (NSPS).
- 439.46 Pretreatment standards for existing sources (PSES).

- 439.47 Pretreatment standards for new sources (PSNS).
- 439.48 [Reserved]

**Subpart E—Research Subcategory**

- 439.50 Applicability; description of the research subcategory.
- 439.51 Specialized definitions.
- 439.52 Effluent limitations representing the degree of effluent reduction attainable by the application of best practicable control technology currently available (BPT).
- 439.53 Effluent limitations representing the degree of effluent reduction attainable by the best conventional pollutant control technology (BCT). [Reserved]
- 439.54 Effluent limitations representing the degree of effluent reduction attainable by the application of best available technology economically achievable (BAT). [Reserved]
- 439.55 New source performance standards (NSPS). [Reserved]
- 439.56 Pretreatment standards for existing sources (PSES). [Reserved]
- 439.57 Pretreatment standards for new sources (PSNS). [Reserved]
- 439.58 [Reserved]

3. Sections 439.0 through 439.2 are revised and §§ 439.3 and 439.4 are added to read as follows:

**General Provisions**

**§ 439.0 Applicability.**

This part applies to any pharmaceutical manufacturing facility that discharges or may discharge process wastewater pollutants to the waters of the United States, or that introduces or may introduce process wastewater pollutants into a publicly owned treatment works. This part does not apply to process wastewater pollutants introduced into privately owned treatment works.

**§ 439.1 General definitions.**

In addition to the definitions set forth in 40 CFR part 401, the following definitions shall apply to this part:

(a) *Annual average.* The mean concentration, mass loading or production-normalized mass loading of a pollutant over a period of 365 consecutive days (or such other period of time determined by the permitting

authority to be sufficiently long to encompass expected variability of the concentration, mass loading, or production-normalized mass loading at the relevant point of measurement).

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

(c) *Chemical oxygen demand (COD).* A 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 adverse effects, either singly or in combination. It is expressed as the amount of oxygen consumed by a chemical oxidant in a specific test.

(d) *Conventional pollutants.* The pollutants identified in Section 304(a)(4) of the CWA and the regulations thereunder, 40 CFR 401.16 (i.e., biochemical oxygen demand (BOD<sub>5</sub>), total suspended solids (TSS), oil and grease, pH, and fecal coliform).

(e) *End-of-pipe effluent.* Final plan effluent discharged to waters of the United States or to a POTW.

(f) *In-plant monitoring points.* (1) For regulated organic pollutants, monitoring point(s) prior to dilution by non-process wastewater, commingling with other process wastewaters not containing the regulated organic pollutants at treatable levels, and any conveyance, equalization, or other wastewater treatment units that are open to the atmosphere.

(2) For cyanide, monitoring point(s) prior to dilution or mixing with any noncyanide-bearing wastewater.

(g) *Minimum level.* The level at which an analytical system gives recognizable signals and an acceptable calibration point. The following minimum levels (for water samples only) and analytical methods apply to pollutants in this part:

Pollutant	Method	Minimum level micrograms per liter (µg/L)
Acetone .....	1624B	50
Acetonitrile .....	1666, 1671	5,000
Ammonia (aqueous) .....	350.1, 350.2, 350.3	30
n-Amyl Acetate .....	1666	5
Amyl Alcohol .....	1666	500
Aniline .....	1665	2
Benzene .....	1624B	10
BOD <sub>5</sub> .....	405.1	(a)
2-Butanone .....	1624B	50
n-Butyl Acetate .....	1666	5
n-Butyl Alcohol .....	1666	500

Pollutant	Method	Minimum level micrograms per liter (µg/L)
<i>tert</i> -Butyl Alcohol .....	1666	100
Chemical Oxygen Demand (COD) .....	410.1, 410.2, 410.3, 410.4	( <sup>a</sup> )
Chlorobenzene .....	1624B	10
Chloroform .....	1624B	10
Chloromethane .....	1624B	50
Cyanide (Total) .....	335.1, 335.2, 335.3	( <sup>a</sup> )
Cyclohexane .....	1666	5
1,2-Dichlorobenzene .....	1625B	10
1,2-Dichloroethane .....	1624B	10
Diethylamine .....	1666, 1671	50,000
Diethyl Ether .....	1624B	50
N,N-Diethylacetamide .....	1665	50
N,N-Dimethylaniline .....	1665	10
Dimethylamine .....	1666, 1671	50,000
N,N-Dimethylformamide .....	1665	5
Dimethylsulfoxide .....	1666, 1671	20,000
1,4-Dioxane .....	1624B	50
Ethanol .....	1666, 1671( <sup>b</sup> )	3,180
Ethyl Acetate .....	1666	10
Ethylene Glycol .....	1666, 1671	100,000
Formaldehyde .....	1667	50
Formamide .....	1666, 1671	100,000
Furfural .....	1666, 1677	50
n-Heptane .....	1666	10
n-Hexane .....	1666	10
Isobutyraldehyde .....	1666, 1667	10
Isopropanol .....	1666	200
Isopropyl Acetate .....	1666	10
Isopropyl Ether .....	1666	5
Methanol .....	1666, 1671( <sup>a</sup> )	3,180
Methylamine .....	1666, 1671	50,000
Methyl Cellosolve .....	1666, 1671	20,000
Methylene Chloride .....	1624B	10
Methyl Formate .....	1666	100
Methyl Isobutyl Ketone (MIBK) .....	1666	10
2-Methylpyridine .....	1624B, 1665	5
Petroleum Naptha (as n-pentane) .....	1666	10
Phenol .....	1625	10
Polyethylene Glucol 600 .....	1673	1,000
n-Propanol .....	1666, 1671( <sup>b</sup> )	3,180
Pyridine .....	1665	5
Tetrahydrofuran .....	1666	20
Toluene .....	1624	10
Trichlorofluoromethane .....	1666	10
Triethylamine .....	1666, 1671	50,000
TSS .....	160.2	( <sup>a</sup> )
m,p-Xylene .....	1666	10
o-Xylene .....	1666	5

(<sup>a</sup>)—As specified in 40 CFR Part 136.

(<sup>b</sup>)—Method 1671 is modified ASTM Method D3695–88.

(h) *New source.* As defined in EPA's regulations at 40 CFR 122.2 and 122.29.

(i) *Nonconventional pollutants.* Pollutants that are neither conventional pollutants nor toxic pollutants.

(j) *Non-detect (ND) value.* A concentration-based measurement reported below the minimum level (see paragraph (g) of this section) that can be reliably measured by the analytical method for the pollutant.

(k) *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.

(l) *POTW.* Publicly owned treatment works, as defined at 40 CFR 403.3(o).

(m) *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 the purposes of this part, the following materials are excluded from the definition of process wastewater, and the discharge of such materials must be regulated separately.

(i) Trimethyl silanol;

(ii) Any active anti-microbial materials;

(iii) Wastewater from imperfect fermentation batches; and

(iv) 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 nonprocess water generated on site. The discharge of such waters and

wastewaters must be regulated separately.

(n) *Toxic pollutants*. The pollutants designated by EPA as toxic in 40 CFR 401.15.

(o) *Xylenes*. The sum of o-xylene, p-xylene, and m-xylene.

**§ 439.2 Monitoring requirements.**

Permit compliance monitoring is required for each regulated pollutant generated or used at a pharmaceutical manufacturing facility. Routine

compliance monitoring is not required for regulated pollutants not generated or used at the facility. Except for cyanide, for which a separate procedure is established in subparts A and C, determination that regulated pollutants are not generated or used should be based on a review of all raw materials used, and an assessment of all chemical processes used, considering resulting products and by-products. The determination that a regulated pollutant

is not generated or used must be confirmed by annual chemical analyses of wastewater from each monitoring location. Such confirmation is provided by an analytical measurement of a non-detect value. Compliance monitoring for all regulated pollutants generated or used is required at each of the monitoring locations specified in this part for those pollutants or at such locations specified pursuant to 40 CFR 122.45.

CAS No.	Pollutant	Monitoring frequency (frequency per week)
67-64-1	Acetone	1
75-05-8	Acetonitrile	1
1336-21-6	Ammonia	1
628-63-7	n-Amyl Acetate	1
71-41-0	Amyl Alcohol	1
62-53-3	Aniline	1
71-43-2	Benzene	1
78-93-3	2-Butanone	1
123-86-4	n-Butyl Acetate	1
71-36-3	n-Butyl Alcohol	1
75-65-0	tert-Butyl Alcohol	1
C-004-(r)	Chemical Oxygen Demand (COD)	7
108-90-7	Chloabenzene	1
67-66-3	Chloroform	1
74-87-3	Chloromethane	1
57-12-5	Cyanide, Total	(b)1
110-82-7	Cyclohexane	1
95-50-1	1,2-Dichlorobenzene	1
107-06-2	1,2-Dichloroethane	1
109-89-7	Diethylamine	1
60-29-7	Diethyl ether	1
127-19-5	N,N-Dimethylacetamide	1
121-69-7	N,N-Dimethylaniline	1
124-40-3	Dimethylamine	1
68-12-2	N,N-Dimethylformamide	1
67-68-5	Dimethylsulfoxide	1
123-91-1	1,4-Dioxane	1
64-17-5	Ethanol	1
141-78-6	Ethyl acetate	1
107-21-1	Ethylene glycol	1
50-00-1	Formaldehyde	1
75-12-7	Formamide	1
98-01-1	Furfural	1
142-82-5	n-Heptane	1
110-54-3	n-Hexane	1
78-84-2	Isobutyraldehyde	1
67-63-0	Isopropanol	1
108-21-4	Isopropyl acetate	1
108-20-3	Isopropyl ether	1
67-56-1	Methanol	1
74-89-5	Methylamine	1
109-86-4	Methyl Cellosolve	1
75-09-2	Methylene Chloride	1
107-31-3	Methyl formate	1
108-10-1	Methyl Isobutyl Ketone	1
109-06-8	2-Methylpyridine	1
8030-30-6	Petroleum Naphtha	1
108-95-2	Phenol	1
25322-68-3	Polyethylene Glycol 600	1
71-23-8	n-Propanol	1
110-86-1	Pyridine	1
109-99-9	Tetrahydrofuran	1
108-88-3	Toluene	1
75-69-4	Trichlorodluoromethane	1
121-44-8	Triethylamine	1
(c)	Xylenes	1
C-002-(a)	BOD <sub>5</sub>	7

CAS No.	Pollutant	Monitoring frequency (frequency per week)
C-009-(a) .....	TSS .....	7

- (a) These are synthetic CASRN's designed for use with the Environmental Monitoring Methods Index (EMMI).
- (b) Monitoring frequency for cyanide is once per treated batch.
- (c) M-Xylene 108-38-3, o-Xylene 95-47-6, p-Xylene 106-42-3.

**§ 439.3 Dilution prohibition.**

Dilution may not be practiced to meet the effluent limitations and standards specified in this part.

**§ 439.4 [Reserved]**

**Subpart A—Fermentation Subcategory**

4. Sections 439.10 through 439.14 are revised to read as follows:

**§ 439.10 Applicability; description of the fermentation subcategory; prohibition.**

(a) The provisions of this subpart are applicable to discharges resulting from the manufacture of pharmaceuticals by fermentation. Fermentation operations are defined as 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. Fermentation operations include pilot-scale research operations not covered by the provisions of subpart E, Research Subcategory.

(b) The discharge of nonprocess wastewater and materials excluded from the definition of process wastewater at § 439.1 is not covered by this subpart. Discharge of such nonprocess wastewater and excluded materials into publicly owned treatment works or waters of the United States by a source subject to this subpart without an NPDES permit or individual control mechanism authorizing such discharge is prohibited.

**§ 439.11 Specialized definitions.**

For the purpose of this subpart:

- (a) Except as provided in paragraph (b) of this section, the general definitions, abbreviations, and methods of analysis set forth in 40 CFR part 401 and § 439.1 shall apply to this subpart.
- (b) The term "product" shall mean pharmaceutical products derived from fermentation processes.

**§ 439.12 Effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).**

(a) 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 degree of effluent reduction attainable by the application of the best practicable control technology currently available.

(1) Subpart A (For In-Plant Monitoring Points).

Pollutant or pollutant property	BPT effluent limitations micrograms per liter (µg/L)	
	Maximum for any one day	Monthly average
Cyanide (Total) .....	766	406

(2) Subpart A (For End-of-Pipe Effluent).

Pollutant or pollutant property	BPT effluent limitations milligrams per liter (mg/L)	
	Maximum for any one day	Monthly average
BOD <sub>5</sub> .....	137	58
TSS .....	318	110
COD .....	1100	628

(3) The pH shall be within the range of 6.0-9.0 standard units.

(b) Permittees not using or generating cyanide are deemed to comply with the monitoring requirements specified in paragraph (a) of this section for cyanide if they certify to the permit issuing authority that they are not using or generating this pollutant.

**§ 439.13 Effluent limitations representing the degree of effluent reduction 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 degree of effluent reduction attainable by the application of the best conventional pollutant control technology: The limitations shall be the same as those specified for the conventional pollutants BOD<sub>5</sub> and TSS in § 439.12 for the best practicable control technology currently available.

**§ 439.14 Effluent limitations representing the degree of effluent reduction attainable by the application of best available technology economically achievable (BAT).**

(a) 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 degree of effluent reduction attainable by the application of the best available technology economically achievable.

(1) Subpart A (For In-Plant Monitoring Points).

Pollutant or pollutant property	BAT effluent limitations micrograms per liter (µg/L)	
	Maximum for any one day	Monthly average
Cyanide (Total) .....	766	406

(2) Subpart A (For End-of-Pipe Effluent). The limitations in the following table do not apply for any pollutant(s) for which the permit writer finds it necessary to specify in-plant monitoring requirements pursuant to 40 CFR 122.44(i) and 122.45(h). Limitations for those pollutant(s) would be established on a best professional judgment basis pursuant to 40 CFR 125.3.

Pollutant or pollutant property	BAT effluent limitations micrograms per liter (µNDg/L)	
	Maximum for any one day	Monthly average
Acetone	ND	ND
Acetonitrile	ND	ND
Ammonia	4,850	3,230
n-Amyl Acetate	105	45
Amyl Alcohol	668	ND
Aniline	10	10
Benzene	ND	ND
2-Butanone (MEK)	202	86
n-Butyl Acetate	87	37
n-Butyl Alcohol	ND	ND
tert-Butyl Alcohol	668	284
Chemical Oxygen Demand (COD)	1,100,000	628,000
Chlorobenzene	ND	ND
Chloroform	ND	ND
Chloromethane	ND	ND
Cyclohexane	ND	ND
o-Dichlorobenzene	ND	ND
1,2-Dichloroethane	100	35
Diethylamine	ND	ND
Diethyl Ether	574	244
Dimethylamine	ND	ND
N,N-Dimethylacetamide	ND	ND
N,N-Dimethylaniline	50	50
N,N-Dimethylformamide	45	19
Dimethyl Sulfoxide	ND	ND
1,4-Dioxane	220	94
Ethanol	ND	ND
Ethyl Acetate	105	45
Ethylene Glycol	ND	ND
Formaldehyde	1,480	623
Formamide	ND	ND
Furfural	2,670	1,140
n-Heptane	ND	ND
n-Hexane	ND	ND
Isobutyraldehyde	1,370	581
Isopropanol	ND	ND
Isopropyl Acetate	87	37
Isopropyl Ether	574	244
Methanol	ND	ND
Methylamine	ND	ND
Methyl Cellosolve	ND	ND
Methyl Formate	105	ND
Methylene Chloride	ND	ND
Methyl Isobutyl Ketone (MIBK)	ND	ND
2-Methylpyridine	50	50
Petroleum Naphtha	ND	ND
Phenol	25	14
Polyethylene Glycol 600	4,870	2,070
n-Propanol	ND	ND
Pyridine	10	10
Tetrahydrofuran	910	264
Toluene	ND	ND
Trichlorofluoromethane	ND	ND
Triethylamine	ND	ND
Xylenes	ND	ND

(b) Permittees not using or generating cyanide are deemed to comply with the monitoring requirements specified in paragraph (a) of this section for cyanide if they certify to the permit issuing authority that they are not using or generating this pollutant.

5. Section 439.15 is amended by revising paragraph (a) introductory text and paragraph (b) and by adding paragraph (c) to read as follows:

**§ 439.15 New source performance standards (NSPS).**

(a) Any new source subject to this subpart that was a "new source" under 40 CFR 122.29 prior to [promulgation date of the final rule] must achieve the following new source performance standards until the expiration of the applicable time period specified in 40 CFR 122.29(d)(1), after which the source must achieve the effluent limitations

specified in §§ 439.12, 439.13, and 439.14.

\* \* \* \* \*

(b) Except as provided in paragraph (a) of this section, any new source subject to this subpart must achieve the following new source performance standards.

(1) Subpart A (For In-Plant Monitoring Points).

Pollutant or pollutant property	New source performance standards micrograms per liter (µg/L)	
	Maximum for any one day	Monthly average
Cyanide (Total) .....	766	406

(2) Subpart A (For End-of Pipe Effluent). The standards in the following table do not apply for any pollutant(s) for which the permit writer finds it necessary to specify in-plant monitoring requirements pursuant to 40 CFR 122.44(i) and 122.45(h). Standards for those pollutant(s) would be established on a best professional judgment basis pursuant to 40 CFR 125.3.

Pollutant or pollutant property	New source performance standards micrograms per liter (µg/L)	
	Maximum for any one day	Monthly average
Acetone .....	ND	ND
Acetonitrile .....	ND	ND
Ammonia .....	4,850	3,230
n-Amyl Acetate .....	14	6
Amyl Alcohol .....	ND	ND
Aniline .....	10	4
Benzene .....	ND	ND
2-Butanone (MEK) .....	144	61
n-Butyl Acetate .....	11	ND
n-Butyl Alcohol .....	ND	ND
tert-Butyl Alcohol .....	ND	ND
Chlorobenzene .....	ND	ND
Chloroform .....	ND	ND
Chloromethane .....	ND	ND
Cyclohexane .....	ND	ND
o-Dichlorobenzene .....	ND	ND
1,2-Dichloroethane .....	13	ND
Diethylamine .....	ND	ND
Diethyl Ether .....	74	ND
Dimethylamine .....	ND	ND
N,N-Dimethylacetamide .....	ND	ND
N,N-Dimethylaniline .....	50	45
N,N-Dimethylformamide .....	45	19
Dimethyl Sulfoxide .....	ND	ND
1,4-Dioxane .....	ND	ND
Ethanol .....	ND	ND
Ethyl Acetate .....	14	ND
Ethylene Glycol .....	ND	ND
Formaldehyde .....	1,480	623
Formamide .....	ND	ND
Furfural .....	53	ND
n-Heptane .....	ND	ND
n-Hexane .....	ND	ND
Isobutyraldehyde .....	304	129
Isopropanol .....	ND	ND
Isopropyl Acetate .....	11	ND
Isopropyl Ether .....	74	32
Methanol .....	ND	ND
Methylamine .....	ND	ND
Methyl Cellosolve .....	ND	ND
Methyl Formate .....	ND	ND
Methylene Chloride .....	ND	ND
Methyl Isobutyl Ketone (MIBK) .....	ND	ND
2-Methylpyridine .....	50	45
Petroleum Naphtha .....	ND	ND
Phenol .....	25	14
Polyethylene Glycol 600 .....	4,870	2,070
n-Propanol .....	ND	ND
Pyridine .....	10	10
Tetrahydrofuran .....	910	264
Toluene .....	ND	ND
Trichlorofluoromethane .....	ND	ND
Triethylamine .....	ND	ND
Xylenes .....	ND	ND

(3) Subpart A For End-of-Pipe Effluent).

Pollutant or pollutant property	New source performance standards milligrams per liter (mg/L)	
	Maximum for any one day	Monthly average
BOD <sub>5</sub> .....	62	29
COD .....	781	538
TSS .....	87	43
pH .....	( <sup>a</sup> )	( <sup>a</sup> )

(<sup>a</sup>) Within the range of 6.0 to 9.0 standard units.

(c) Permittees not using or generating cyanide are deemed to comply with the monitoring requirements specified in paragraph (a) of this section for cyanide if they certify to the permit issuing authority that they are not using or generating this pollutant.

6. Section 439.16 is revised to read as follows:

**§ 439.16 Pretreatment standards for existing sources (PSES).**

(a) Except as provided in 40 CFR 403.7 and 403.13, any existing source subject to this subpart that introduces

pollutants into a publicly owned treatment works must comply with 40 CFR part 403 by [date 3 years from the promulgation date of the final rule] and achieve the following pretreatment standards for existing sources.

(1) Subpart A (For In-Plant Monitoring Points).

Pollutant or pollutant property	Pretreatment standards for existing sources micrograms per liter (µg/L)	
	Maximum for any one day	Monthly average
Benzene .....	796	268
Chlorobenzene .....	796	268
Chloroform .....	ND	ND
Chloromethane .....	796	268
Cyanide .....	766	406
Cyclohexane .....	796	268
n-Heptane .....	796	268
n-Hexane .....	796	268
Methyl Cellosolve .....	ND	ND
Methylene Chloride .....	809	279
Toluene .....	198	148
Trichlorofluoromethane .....	796	268
Xylenes .....	796	268

(2) Subpart A (For End-of-Pipe Monitoring Points).

[Note: With respect to pollutants in this table, EPA proposes pretreatment standards for existing sources only for ammonia under co-proposal (2).]

Pollutant or pollutant property	Pretreatment standards for existing sources micrograms per liter (µg/L)	
	Maximum for any one day	Monthly average
Acetone .....	31,400	9,690
Ammonia .....	12,900	10,900
n-Amyl Acetate .....	23,900	8,050
Amyl Alcohol .....	607,000	205,000
Aniline .....	10,900,000	3,690,000
2-Butanone (MEK) .....	1,440,000	430,000
n-Butyl Acetate .....	23,900	8,050
n-Butyl Alcohol .....	10,900,000	3,690,000
tert-Butyl Alcohol .....	607,000	205,000
o-Dichlorobenzene .....	23,900	8,050
1,2-Dichloroethane .....	23,900	8,050
Diethylamine .....	ND	ND
Diethyl Ether .....	23,900	8,050
Dimethylamine .....	607,000	205,000
N,N-Dimethylaniline .....	607,000	205,000
1,4-Dioxane .....	10,900,000	3,690,000
Ethanol .....	2,200,000	784,000
Ethyl Acetate .....	23,900	8,050
Formamide .....	607,000	205,000
Furfural .....	607,000	205,000
Isobutyraldehyde .....	23,900	8,050

Pollutant or pollutant property	Pretreatment standards for existing sources micrograms per liter (µg/L)	
	Maximum for any one day	Monthly average
Isopropanol .....	597,000	198,000
Isopropyl Acetate .....	23,900	8,050
Isopropyl Ether .....	23,900	8,050
Methanol .....	11,700,000	3,800,000
Methylamine .....	607,000	205,000
Methyl Formate .....	23,900	8,050
Methyl Isobutyl Ketone (MIBK) .....	23,900	8,050
2-Methylpyridine .....	607,000	205,000
Petroleum Naphtha .....	10,900,000	3,690,000
n-Propanol .....	2,790,000	941,000
Pyridine .....	1,000	1,000
Tetrahydrofuran .....	9,210	3,360
Triethylamine .....	ND	ND

(b) Indirect dischargers not using or generating cyanide are deemed to comply with the monitoring requirements specified in paragraph (a) of this section for cyanide if they certify to the control authority that they are not using or generating this pollutant.

7. Section 439.17 is amended by revising paragraph (a) introductory text and paragraph (b) and by adding paragraph (c) to read as follows:

**§ 439.17 Pretreatment standards for new sources (PSNS).**

(a) Any new source subject to this subpart that was a "new source" under 40 CFR 122.29 prior to [promulgation date of the final rule] must achieve the following pretreatment standards for new sources 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.

\* \* \* \* \*

(b) Except as provided in 40 CFR 403.7 and paragraph (a) of this section, any new source subject to this subpart that introduces pollutants into a publicly owned treatment works must comply with 40 CFR part 403 and achieve the following pretreatment standards for new sources.

(1) Subpart A (For In-Plant Monitoring).

[Note: With respect to pollutants in this table, EPA does not propose pretreatment standards for new sources for pollutants with an asterisk (\*) under co-proposal (2).]

Pollutant or pollutant property	Pretreatment standards for new sources micrograms per liter (µg/L)	
	Maximum for any one day	Monthly average
Acetone * .....	1,190	600
Amyl Alcohol * .....	8,690	3,220
Benzene .....	573	212
n-Butyl Alcohol * .....	8,690	3,220
tert-Butyl Alcohol * .....	8,690	3,220
Chlorobenzene .....	573	212
Chloroform .....	ND	ND
Chloromethane .....	573	212
Cyanide .....	766	406
Cyclohexane .....	573	212
Diethylamine * .....	ND	ND
Diethyl Ether * .....	2,230	826
Dimethylamine * .....	ND	ND
Ethanol * .....	8,690	3,220
Formamide * .....	ND	ND
n-Heptane .....	573	212
n-Hexane .....	573	212
Isopropanol * .....	8,690	3,220
Methanol * .....	8,320	ND
Methylamine * .....	ND	ND
Methyl Cellosolve .....	ND	ND
Methylene Chloride .....	809	279
Methyl Formate * .....	2,230	826
n-Propanol * .....	8,690	3,220
Toluene .....	184	135
Trichlorofluoromethane .....	573	212
Triethylamine * .....	ND	ND
Xylenes .....	573	212

(2) Subpart A (For End-of-Pipe Monitoring Points).

[Note: With respect to pollutants in this table, EPA does not propose pretreatment standards for new sources for pollutants with an asterisk (\*) under co-proposal (2).]

Pollutant or pollutant property	Pretreatment standards for new sources micrograms per liter (µg/L)	
	Maximum for any one day	Monthly average
Ammonia .....	12,900	10,900
n-Amyl Acetate* .....	2,230	826
Aniline* .....	8,690	3,220
2-Butanone (MEK)* .....	161,000	57,900
n-Butyl Acetate* .....	2,230	826
o-Dichlorobenzene* .....	2,230	826
1,2-Dichloroethane* .....	2,230	826
N,N-Dimethylaniline* .....	8,690	3,220
1,4-Dioxane* .....	8,690	3,220
Ethyl Acetate* .....	2,230	826
Furfural* .....	8,690	3,220
Isobutyraldehyde* .....	2,230	826
Isopropyl Acetate* .....	2,230	826
Isopropyl Ether* .....	2,230	826
Methyl Isobutyl Ketone (MIBK)* .....	2,230	826
2-Methylpyridine* .....	8,690	3,220
Petroleum Naphtha* .....	8,690	3,220
Pyridine* .....	1,000	1,000
Tetrahydrofuran* .....	9,210	3,360

(c) Indirect dischargers not using or generating cyanide are deemed to comply with the monitoring requirements specified in paragraph (a) of this section for cyanide if they certify to the control authority that they are not using or generating this pollutant.

**§ 439.18 [Reserved]**

**Subpart B—Extraction Subcategory**

8. Sections 439.20 through 439.24 are revised to read as follows:

**§ 439.20 Applicability; description of the extraction subcategory; prohibition.**

(a) The provisions of this subpart are applicable to discharges resulting from the manufacture of pharmaceutical products by biological and natural extraction operations. Biological and natural extraction operations are defined as process operations that utilize the chemical and physical extraction of pharmaceutically active ingredients from natural sources such as plant roots and leaves, animal glands, and parasitic fungi. Biological and natural extraction operations include pilot-scale research operations not covered by the provisions of subpart E, Research Subcategory.

(b) The discharge of nonprocess wastewater and materials excluded from the definition of process wastewater at § 439.1 is not covered by this subpart. Discharge of such nonprocess wastewater and excluded materials into publicly owned treatment works or waters of the United States by a source subject to this subpart without an

NPDES permit or individual control mechanism authorizing such discharge is prohibited.

**§ 439.21 Specialized definitions.**

(a) Except as provided paragraph (b) of this section, the general definitions, abbreviations, and methods of analysis set forth in 40 CFR part 401 and § 439.1 shall apply to this subpart.

(b) The term “product” shall mean any biological and natural extraction product. This subcategory shall include blood fractions, vaccines, serums, animal bile derivatives, endocrine products, and isolation of medicinal products, such as alkaloids, from botanical drugs and herbs.

**§ 439.22 Effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).**

(a) 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 degree of effluent reduction attainable by the application of the best practicable control technology currently available.

(1) Subpart B (For End-of-Pipe Effluent).

Pollutant or pollutant parameter	BPT effluent limitations milligrams per liter (mg/L)	
	Maximum for any one day	Monthly average
BOD <sub>5</sub> .....	37	11
TSS .....	80	27
COD .....	145	60

(2) The pH shall be within the range of 6.0–9.0 standard units.

(b) [Reserved]

**§ 439.23 Effluent limitations representing the degree of effluent reduction 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 degree of effluent reduction attainable by the application of the best conventional pollutant control technology: The limitations shall be the same as those specified for conventional pollutants BOD<sub>5</sub> and TSS in § 439.22 for the best practicable control technology currently available.

**§ 439.24 Effluent limitations representing the degree of effluent reduction attainable by the application of best available technology economically achievable (BAT).**

(a) 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 degree of

effluent reduction attainable by the application of the best available technology economically achievable.

(1) Subpart B (For End-of-Pipe Effluent).

Pollutant or pollutant property	BAT effluent limitations micrograms per Liter (µg/L)	
	Maximum for any one day	Monthly average
Acetone	413	178
Acetonitrile	ND	ND
n-Amyl Acetate	3,000	1,280
Amyl Alcohol	3,980	1,690
Aniline	10	10
Benzene	40	17
2-Butanone (MEK)	202	86
n-Butyl Acetate	500	500
n-Butyl Alcohol	ND	ND
tert-Butyl Alcohol	3,980	1,690
Chemical Oxygen Demand (COD)	145,000	59,900
Chlorobenzene	ND	ND
Chloroform	22	13
Chloromethane	206	87
Cyclohexane	ND	ND
o-Dichlorobenzene	ND	ND
1,2-Dichloroethane	438	152
Diethylamine	ND	ND
Diethyl Ether	4,870	2,070
N,N-Dimethylacetamide	ND	ND
Dimethylamine	ND	ND
N,N-Dimethylaniline	50	50
N,N-Dimethylformamide	45	19
Dimethyl Sulfoxide	ND	ND
1,4-Dioxane	220	94
Ethanol	ND	ND
Ethyl Acetate	3,000	1,280
Ethylene Glycol	ND	ND
Formaldehyde	1,480	623
Formamide	ND	ND
Furfural	3,000	1,280
n-Heptane	ND	ND
n-Hexane	ND	ND
Isobutyraldehyde	1,370	581
Isopropanol	1,120	476
Isopropyl Acetate	500	500
Isopropyl Ether	4,870	2,070
Methanol	6,660	ND
Methylamine	ND	ND
Methyl Cellosolve	ND	ND
Methylene Chloride	1,420	357
Methyl Formate	3,000	1,280
Methyl Isobutyl Ketone (MIBK)	119	51
2-Methylpyridine	50	50
Petroleum Naphtha	40	17
Phenol	25	14
Polyethylene Glycol 600	4,870	2,070
n-Propanol	3,980	ND
Pyridine	10	10
Tetrahydrofuran	15,000	4,350
Toluene	40	17
Trichlorofluoromethane	599	322
Triethylamine	ND	ND
Xylenes	ND	ND

(2) [Reserved]

(b) [Reserved]

9. Section 439.25 is amended by revising paragraph (a) introductory text and paragraph (b) to read as follows:

**§ 439.25 New source performance standards (NSPS).**

(a) Any new source subject to this subpart that was a "new source" under 40 CFR 122.29 prior to [promulgation date of the final rule] must achieve the

following new source performance standards until the expiration of the applicable time period specified in 40 CFR 122.29(d)(1), after which the source must achieve the effluent limitations

specified in §§ 439.22, 439.23, and 439.24.

\* \* \* \* \*

(b) Except as provided in paragraph (a) of this section any new source subject to this subpart must achieve the

following new source performance standards.

(1) Subpart B (For End-of-Pipe Effluent) The standards in the following table do not apply for any pollutant(s) for which the permit writer finds it

necessary to specify in-plant monitoring requirements pursuant to 40 CFR 122.44(i) and 122.45(h). Standards for those pollutant(s) would be established on a best professional judgment basis pursuant to 40 CFR 125.3.

Pollutant or pollutant property	New source performance standards micrograms per liter (µg/L)	
	Maximum for any one day	Monthly average
Acetone	ND	ND
Acetonitrile	ND	ND
Ammonia	4,850	3,230
n-Amyl Acetate	14	6
Amyl Alcohol	ND	ND
Aniline	ND	10/4
2-Butanone (MEK)	144	61
n-Butyl Acetate	11	ND
n-Butyl Alcohol	ND	ND
tert-Butyl Alcohol	ND	ND
Chlorobenzene	ND	ND
Chloroform	ND	ND
Chloromethane	ND	ND
Cyclohexane	ND	ND
o-Dichlorobenzene	ND	ND
1,2-Dichloroethane	13	ND
Diethylamine	ND	ND
Diethyl Ether	74	ND
Dimethylamine	ND	ND
N,N-Dimethylacetamide	ND	ND
N,N-Dimethylaniline	50	45
N,N-Dimethylformamide	45	19
Dimethyl Sulfoxide	ND	ND
1,4-Dioxane	ND	ND
Ethanol	ND	ND
Ethyl Acetate	14	ND
Ethylene Glycol	ND	ND
Formaldehyde	1,480	623
Formamide	ND	ND
Furfural	53	ND
n-Heptane	ND	ND
n-Hexane	ND	ND
Isobutyraldehyde	304	129
Isopropanol	ND	ND
Isopropyl Acetate	11	ND
Isopropyl Ether	74	32
Methanol	ND	ND
Methylamine	ND	ND
Methyl Cellosolve	ND	ND
Methyl Formate	ND	ND
Methylene Chloride	ND	ND
Methyl Isobutyl Ketone (MIBK)	ND	ND
2-Methylpyridine	50	45
Petroleum Naphtha	ND	ND
Phenol	25	14
Polyethylene Glycol 600	4,870	2,070
n-Propanol	ND	ND
Pyridine	10	10
Tetrahydrofuran	910	264
Toluene	ND	ND
Trichlorofluoromethane	ND	ND
Triethylamine	ND	ND
Xylenes	ND	ND

(2) Subpart B (For End-of-Pipe Effluent).

Pollutant or pollutant parameter	New source performance standards milligrams per liter (mg/L)	
	Maximum for any one day	Monthly average
BOD <sub>5</sub> .....	34	10
COD .....	60	24
TSS .....	40	12

Pollutant or pollutant parameter	New source performance standards milligrams per liter (mg/L)	
	Maximum for any one day	Monthly average
pH .....	(a)	(a)

(a) Within the range of 6.0 to 9.0 standard units.

10. Section 439.26 is revised to read as follows:

**§ 439.26 Pretreatment standards for existing sources (PSES).**

(a) Except as provided in 40 CFR 403.7 and 403.13, any existing source subject to this subpart that introduces pollutants into a publicly owned treatment works must comply with 40 CFR part 403 and by [date 3 years from the promulgation date of the final rule] achieve the following pretreatment standards for existing sources.

(1) Subpart B (For In-Plant Monitoring Points).

Pollutant or pollutant property	Pretreatment standards for existing sources micrograms per liter (µg/L)	
	Maximum for any one day	Monthly average
Benzene .....	796	268
Chlorobenzene .....	796	268
Chloroform .....	ND	ND
Chloromethane .....	796	268
Cyclohexane .....	796	268
n-Heptane .....	796	268
n-Hexane .....	796	268
Methyl Cellosolve .....	ND	ND
Methylene Chloride .....	809	279
Toluene .....	198	148
Trichlorofluoromethane .....	796	268
Xylenes .....	796	268

(2) Subpart B (For End-of-Pipe Monitoring Points).

(Note: Under co-proposal (2), EPA does not propose pretreatment standards for existing sources for these pollutants.)

Pollutant or pollutant property	Pretreatment standards for existing sources micrograms per liter (µg/L)	
	Maximum for any one day	Monthly average
Acetone .....	31,400	9,690
n-Amyl Acetate .....	23,900	8,050
Amyl Alcohol .....	607,000	205,000
Aniline .....	10,900,000	3,690,000
2-Butanone (MEK) .....	1,440,000	430,000
n-Butyl Acetate .....	23,900	8,050
n-Butyl Alcohol .....	10,900,000	3,690,000
tert-Butyl Alcohol .....	607,000	205,000
o-Dichlorobenzene .....	23,900	8,050
1,2-Dichloroethane .....	23,900	8,050
Diethylamine .....	ND	ND
Diethyl Ether .....	23,900	8,050
Dimethylamine .....	607,000	205,000
N,N-Dimethylaniline .....	607,000	205,000
1,4-Dioxane .....	10,900,000	3,690,000
Ethanol .....	2,200,000	784,000
Ethyl Acetate .....	23,900	8,050
Formamide .....	607,000	205,000
Furfural .....	607,000	205,000
Isobutyraldehyde .....	23,900	8,050
Isopropanol .....	597,000	198,000
Isopropyl Acetate .....	23,900	8,050
Isopropyl Ether .....	23,900	8,050
Methanol .....	11,700,000	3,800,000
Methylamine .....	607,000	205,000
Methyl Formate .....	23,900	8,050
Methyl Isobutyl Ketone (MIBK) .....	23,900	8,050
2-Methylpyridine .....	607,000	205,000
Petroleum Naphtha .....	10,900,000	3,690,000
n-Propanol .....	2,790,000	941,000
Pyridine .....	1,000	1,000

Pollutant or pollutant property	Pretreatment standards for existing sources micrograms per liter (µg/L)	
	Maximum for any one day	Monthly average
Tetrahydrofuran .....	9,210	3,360
Triethylamine .....	ND	ND

(b) [Reserved]  
 11. Section 439.27 is amended by revising paragraph (a) introductory text and paragraph (b) to read as follows:

**§ 439.27 Pretreatment standards for new sources (PSNS).**

(a) Any new source subject to this subpart that was a "new source" under 40 CFR 122.29 prior to [promulgation date of the final rule] must achieve the

following pretreatment standards for new sources 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.

\* \* \* \* \*

(b) Except as provided in 40 CFR 403.7 and paragraph (a) of this section, any new source subject to this subpart

that introduces pollutants into a publicly owned treatment works must comply with 40 CFR part 403 and achieve the following pretreatment standards for new sources.

(1) Subpart B (For In-Plant Monitoring Points).

**[Note:** With respect to pollutants in this table, EPA does not propose pretreatment standards for new sources for pollutants with an asterisk (\*) under co-proposal (2).]

Pollutant or pollutant property	Pretreatment standards for new sources micrograms per liter (µg/L)	
	Maximum for any one day	Monthly average
Acetone* .....	1,190	600
Amyl Alcohol* .....	8,690	3,220
Benzene .....	573	212
n-Butyl Alcohol* .....	8,690	3,220
tert-Butyl Alcohol* .....	8,690	3,220
Chlorobenzene .....	573	212
Chloroform .....	ND	ND
Chloromethane .....	573	212
Cyclohexane .....	573	212
Diethylamine* .....	ND	ND
Diethyl Ether* .....	2,230	826
Dimethylamine* .....	ND	ND
Ethanol* .....	8,690	3,220
Formamide* .....	ND	ND
n-Heptane .....	573	212
n-Hexane .....	573	212
Isopropanol* .....	8,690	3,220
Methanol* .....	8,320	ND
Methylamine* .....	ND	ND
Methyl Cellosolve .....	ND	ND
Methylene Chloride .....	809	279
Methyl Formate* .....	2,230	826
n-Propanol* .....	8,690	3,220
Toluene .....	184	135
Trichlorofluoromethane .....	573	212
Triethylamine* .....	ND	ND
Xylenes .....	573	212

(2) Subpart B (For End-of-Pipe Monitoring Points).

**[Note:** With respect to pollutants in this table, EPA does not propose pretreatment standards for new sources for pollutants with an asterisk (\*) under co-proposal (2).]

Pollutant or pollutant property	Pretreatment standards for new sources micrograms per liter (µg/L)	
	Maximum for any one day	Monthly average
n-Amyl Acetate* .....	2,230	826
Aniline* .....	8,690	3,220
2-Butanone (MEK)* .....	161,000	57,900
n-Butyl Acetate* .....	2,230	826
o-Dichlorobenzene* .....	2,230	826
1,2-Dichloroethane* .....	2,230	826

Pollutant or pollutant property	Pretreatment standards for new sources micrograms per liter (µg/L)	
	Maximum for any one day	Monthly average
N,N-Dimethylaniline*	8,690	3,220
1,4-Dioxane*	8,690	3,220
Ethyl Acetate*	2,230	826
Furfural*	8,690	3,220
Isobutyraldehyde*	2,230	826
Isopropyl Acetate*	2,230	826
Isopropyl Ether*	2,230	826
Methyl Isobutyl Ketone (MIBK)*	2,230	826
2-Methylpyridine*	8,690	3,220
Petroleum Naphtha*	8,690	3,220
Pyridine*	1,000	1,000
Tetrahydrofuran*	9,210	3,360

§ 439.28 [Reserved]

Subpart C—Chemical Synthesis Subcategory

12. Sections 439.30 through 439.34 are revised to read as follows:

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

(a) The provisions of this subpart are applicable to discharges resulting from the manufacture of pharmaceutical products by chemical synthesis operations. Chemical synthesis is defined as the process(es) of using a chemical reaction or series of chemical reactions to produce a specified product. Chemical synthesis operations include pilot-scale research operations not covered by the provisions of subpart E, Research Subcategory.

(b) The discharge of non-process wastewater and materials excluded from the definition of process wastewater at § 439.1 is not covered by this subpart. Discharge of such non-process wastewater and excluded materials into publicly owned treatment works or waters of the United States by a source subject to this subpart without an NPDES permit or individual control mechanism authorizing such discharge is prohibited.

§ 439.31 Specialized definitions.

For the purpose of this subpart:

(a) Except as provided in paragraph (b) of this section, the general definitions, abbreviations, and methods of analysis set forth in 40 CFR part 401 and § 439.1 shall apply to this subpart.

(b) The term “product” shall mean any pharmaceutical product derived from chemical synthesis processes.

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

(a) 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 degree of effluent reduction attainable by the application of the best practicable control technology currently available.

(1) Subpart C (For In-Plant Monitoring Points).

Pollutant or pollutant property	BPT effluent limitations micrograms per liter (µg/L)	
	Maximum for any one day	Monthly average
Cyanide (Total) .....	766	406

(2) Subpart C (For End-of-Pipe Effluent).

Pollutant or pollutant property	BPT effluent limitations micrograms per liter (mg/L)	
	Maximum for any one day	Monthly average
BOD <sub>5</sub> .....	137	58
TSS .....	318	110
COD .....	1100	628

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

(b) Permittees not using or generating cyanide are deemed to comply with the monitoring requirements specified in paragraph (a) of this section for cyanide if they certify to the permit issuing authority that they are not using or generating this pollutant.

§ 439.33 Effluent limitations representing the degree of effluent reduction 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 degree of effluent reduction attainable by the application of the best conventional pollutant control technology: The limitations shall be the same as those specified for conventional pollutants BOD<sub>5</sub> and TSS in § 439.32 for the best practicable control technology currently available.

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

(a) 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 degree of effluent reduction attainable by the application of the best available technology economically achievable.

(1) Subpart C (For In-Plant Monitoring Points)

Pollutant or pollutant property	BAT effluent limitations micrograms per liter (µg/L)	
	Maximum for any one day	Monthly average
Cyanide (Total) .....	766	406

(2) Subpart C (For End-of-Pipe Effluent). The limitations in the following table do not apply for any pollutant(s) for which the permit writer finds it necessary to specify in-plant monitoring requirements pursuant to 40 CFR 122.44(i) and 122.45(h). Limitations for those pollutant(s) would be established on a best professional

judgment basis pursuant to 40 CFR  
125.3.

Pollutant or pollutant property	BAT effluent limitations micrograms per liter (µg/L)	
	Maximum for any one day	Monthly average
Acetone .....	ND	ND
Acetonitrile .....	ND	ND
Ammonia .....	4,850	3,230
n-Amyl Acetate .....	105	45
Amyl Alcohol .....	668	ND
Aniline .....	10	10
Benzene .....	ND	ND
2-Butanone (MEK) .....	202	86
n-Butyl Acetate .....	87	37
n-Butyl Alcohol .....	ND	ND
tert-Butyl Alcohol .....	668	284
Chemical Oxygen Demand (COD) .....	1,100,000	628,000
Chlorobenzene .....	ND	ND
Chloroform .....	ND	ND
Chloromethane .....	ND	ND
Cyclohexane .....	ND	ND
o-Dichlorobenzene .....	ND	ND
1,2-Dichloroethane .....	100	35
Diethylamine .....	ND	ND
Diethyl Ether .....	574	244
Dimethylamine .....	ND	ND
N,N-Dimethylacetamide .....	ND	ND
N,N-Dimethylaniline .....	50	50
N,N-Dimethylformamide .....	45	19
Dimethyl Sulfoxide .....	ND	ND
1,4-Dioxane .....	220	94
Ethanol .....	ND	ND
Ethyl Acetate .....	105	45
Ethylene Glycol .....	ND	ND
Formaldehyde .....	1,480	623
Formamide .....	ND	ND
Furfural .....	2,670	1,140
n-Heptane .....	ND	ND
n-Hexane .....	ND	ND
Isobutyraldehyde .....	1,370	581
Isopropanol .....	ND	ND
Isopropyl Acetate .....	87	37
Isopropyl Ether .....	574	244
Methanol .....	ND	ND
Methylamine .....	ND	ND
Methyl Cellosolve .....	ND	ND
Methyl Formate .....	105	ND
Methylene Chloride .....	ND	ND
Methyl Isobutyl Ketone (MIBK) .....	ND	ND
2-Methylpyridine .....	50	50
Petroleum Naphtha .....	ND	ND
Phenol .....	25	14
Polyethylene glycol 600 .....	4,870	2,070
n-Propanol .....	ND	ND
Pyridine .....	10	10
Tetrahydrofuran .....	910	264
Toluene .....	ND	ND
Trichlorofluoromethane .....	ND	ND
Triethylamine .....	ND	ND
Xylenes .....	ND	ND

(b) Permittees not using or generating cyanide are deemed to comply with the monitoring requirements specified in paragraph (a) of this section for cyanide if they certify to the permit issuing authority that they are not using or generating this pollutant.

13. Section 439.35 is amended by revising paragraph (a) introductory text and paragraph (b) and by adding paragraph (c) to read as follows:

**§ 439.35 New source performance standards (NSPS).**

(a) Any new source subject to this subpart that was a "new source" under

40 CFR 122.29 prior to [promulgation date of the final rule] must achieve the following new source performance standards until the expiration of the applicable time period specified in 40 CFR 122.29(d)(1), after which the source must achieve the effluent limitations

specified in §§ 439.32, 439.33, and 439.34.

\* \* \* \* \*

(b) Except as provided in paragraph (a) of this section, any new source subject to this subpart must achieve the following new source performance standards.

(1) Subpart C (For In-Plant Monitoring Points).

Pollutant or pollutant property	New source performance standards micrograms per liter (µg/L)	
	Maximum for any one day	Monthly average
Cyanide (Total) .....	766	406

(2) Subpart C (For End-of-Pipe Effluent). The standards in the following table do not apply for any pollutant(s) for which the permit writer finds it necessary to specify in-plant monitoring requirements pursuant to 40 CFR 122.44(i) and 122.45(h). Standards for those pollutant(s) would be established on a best professional judgment basis pursuant to 40 CFR 125.3.

Pollutant or pollutant property	New source performance standards micrograms per liter (µg/L)	
	Maximum for any one day	Monthly average
Acetone .....	ND	ND
Acetonitrile .....	ND	ND
Ammonia .....	4,850	3,230
n-Amyl Acetate .....	14	6
Amyl Alcohol .....	ND	ND
Aniline .....	10	4
Benzene .....	ND	ND
2-Butanone (MEK) .....	144	61
n-Butyl Acetate .....	11	ND
n-Butyl Alcohol .....	ND	ND
tert-Butyl Alcohol .....	ND	ND
Chlorobenzene .....	ND	ND
Chloroform .....	ND	ND
Chloromethane .....	ND	ND
Cyclohexane .....	ND	ND
o-Dichlorobenzene .....	ND	ND
1,2-Dichloroethane .....	13	ND
Diethylamine .....	ND	ND
Diethyl Ether .....	74	ND
Dimethylamine .....	ND	ND
N,N-Dimethylacetamide .....	ND	ND
N,N-Dimethylaniline .....	50	45
N,N-Dimethylformamide .....	45	19
Dimethyl Sulfoxide .....	ND	ND
1,4-Dioxane .....	ND	ND
Ethanol .....	ND	ND
Ethyl Acetate .....	14	ND
Ethylene Glycol .....	ND	ND
Formaldehyde .....	1,480	623
Formamide .....	ND	ND
Furfural .....	53	ND
n-Heptane .....	ND	ND
n-Hexane .....	ND	ND
Isobutyraldehyde .....	304	129
Isopropanol .....	ND	ND
Isopropyl Acetate .....	11	ND
Isopropyl Ether .....	74	32
Methanol .....	ND	ND
Methylamine .....	ND	ND
Methyl Cellosolve .....	ND	ND
Methyl Formate .....	ND	ND
Methylene Chloride .....	ND	ND
Methyl Isobutyl Ketone (MIBK) .....	ND	ND
2-Methylpyridine .....	50	45
Petroleum Naphtha .....	ND	ND
Phenol .....	25	14
Polyethylene Glycol 600 .....	4,870	2,070
n-Propanol .....	ND	ND
Pyridine .....	10	10
Tetrahydrofuran .....	910	264
Toluene .....	ND	ND
Trichlorofluoromethane .....	ND	ND
Triethylamine .....	ND	ND
Xylenes .....	ND	ND

(3) Subpart C (For End-of-Pipe Effluent).

Pollutant or pollutant property	New source performance standards milligrams per liter (mg/L)	
	Maximum for any one day	Monthly average
BOD <sub>5</sub> .....	62	29
COD .....	781	538
TSS .....	87	43
pH .....	( <sup>a</sup> )	( <sup>a</sup> )

(<sup>a</sup>) Within the range of 6.0 to 9.0 standard units.

(c) Permittees not using or generating cyanide are deemed to comply with the monitoring requirements specified in paragraph (a) of this section for cyanide if they certify to the permit issuing authority that they are not using or generating this pollutant.

14. Section 439.36 is revised to read as follows:

**§ 439.36 Pretreatment standards for existing sources (PSES).**

(a) Except as provided in 40 CFR 403.7 and 403.13, any existing source subject to this subpart that introduces pollutants into a publicly owned

treatment works must comply with 40 CFR part 403 and by [date 3 years from the promulgation date of the final rule] achieve the following pretreatment standards for existing sources.

(1) Subpart C (For In-Plant Monitoring Points).

Pollutant or pollutant property	Pretreatment standards for existing sources micrograms per liter (µg/L)	
	Maximum for any one day	Monthly average
Benzene .....	796	268
Chlorobenzene .....	796	268
Chloroform .....	ND	ND
Chloromethane .....	796	268
Cyanide .....	766	406
Cyclohexane .....	796	268
n-Heptane .....	796	268
n-Hexane .....	796	268
Methyl Cellosolve .....	ND	ND
Methylene Chloride .....	809	279
Toluene .....	198	148
Trichlorofluoromethane .....	796	268
Xylenes .....	796	268

(2) Subpart C (For End-of-Pipe Monitoring Points).

[Note: With respect to the pollutants in this table, EPA proposes pretreatment standards for existing sources only for ammonia under co-proposal (2).]

Pollutant or pollutant property	Pretreatment standards for existing sources micrograms per liter (µg/L)	
	Maximum for any one day	Monthly average
Acetone .....	31,400	9,690
Ammonia .....	12,900	10,900
n-Amyl Acetate .....	23,900	8,050
Amyl Alcohol .....	607,000	205,000
Aniline .....	10,900,000	3,690,000
2-Butanone (MEK) .....	1,440,000	430,000
n-Butyl Acetate .....	23,900	8,050
n-Butyl Alcohol .....	10,900,000	3,690,000
tert-Butyl Alcohol .....	607,000	205,000
o-Dichlorobenzene .....	23,900	8,050
1,2-Dichloroethane .....	23,900	8,050
Diethylamine .....	ND	ND
Diethyl Ether .....	23,900	8,050
Dimethylamine .....	607,000	205,000
N,N-Dimethylaniline .....	607,000	205,000
1,4-Dioxane .....	10,900,000	3,690,000
Ethanol .....	2,200,000	784,000
Ethyl Acetate .....	23,900	8,050
Formamide .....	607,000	205,000
Furfural .....	607,000	205,000
Isobutyraldehyde .....	23,900	8,050
Isopropanol .....	597,000	198,000
Isopropyl Acetate .....	23,900	8,050

Pollutant or pollutant property	Pretreatment standards for existing sources micrograms per liter (µg/L)	
	Maximum for any one day	Monthly average
Isopropyl Ether .....	23,900	8,050
Methanol .....	11,700,000	3,800,000
Methylamine .....	607,000	205,000
Methyl Formate .....	23,900	8,050
Methyl Isobutyl Ketone (MIBK) .....	23,900	8,050
2-Methylpyridine .....	607,000	205,000
Petroleum Naphtha .....	10,900,000	3,690,000
n-Propanol .....	2,790,000	941,000
Pyridine .....	1,000	1,000
Tetrahydrofuran .....	9,210	3,360
Triethylamine .....	ND	ND

(b) Indirect dischargers not using or generating cyanide are deemed to comply with the monitoring requirements specified in paragraph (a) of this section for cyanide if they certify to the control authority that they are not using or generating this pollutant.

15. Section 439.37 is amended by revising paragraph (a) introductory text and paragraph (b) and by adding paragraph (c) to read as follows:

**§ 439.37 Pretreatment standards for new sources (PSNS).**

(a) Any new source subject to this subpart that was a "new source" under 40 CFR 122.29 prior to [promulgation date of the final rule] must achieve the following pretreatment standards for new sources 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.

\* \* \* \* \*

(b) Except as provided in 40 CFR 403.7 and paragraph (a) of this section, any new source subject to this subpart that introduces pollutants into a publicly owned treatment works must comply with 40 CFR part 403 and achieve the following pretreatment standards for new sources.

(1) Subpart C (For In-Plant Monitoring Points).

[Note: With respect to pollutants in this table, EPA does not propose pretreatment standards for new sources for pollutants with an asterisk (\*) under co-proposal (2).]

Pollutant or pollutant property	Pretreatment standards for new sources micrograms per liter (µg/L)	
	Maximum for any one day	Monthly average
Acetone* .....	1,190	600
Amyl Alcohol* .....	8,690	3,220
Benzene .....	573	212
n-Butyl Alcohol* .....	8,690	3,220
tert-Butyl Alcohol* .....	8,690	3,220
Chlorobenzene .....	573	212
Chloroform .....	ND	ND
Chloromethane .....	573	212
Cyanide .....	766	406
Cyclohexane .....	573	212
Diethylamine* .....	ND	ND
Diethyl Ether* .....	2,230	826
Dimethylamine* .....	ND	ND
Ethanol* .....	8,690	3,220
Formamide* .....	ND	ND
n-Heptane .....	573	212
n-Hexane .....	573	212
Isopropanol* .....	8,690	3,220
Methanol* .....	8,320	ND
Methylamine* .....	ND	ND
Methyl Cellosolve .....	ND	ND
Methylene Chloride .....	809	279
Methyl Formate* .....	2,230	826
n-Propanol* .....	8,690	3,220
Toluene .....	184	135
Trichlorofluoromethane .....	573	212
Triethylamine* .....	ND	ND
Xylenes .....	573	212

(2) Subpart C (For End-of-Pipe Monitoring Points).

[Note: With respect to pollutants in this table, EPA does not propose pretreatment standards for new sources for pollutants with an asterisk (\*) under co-proposal (2).]

Pollutant or pollutant property	Pretreatment standards for new sources micrograms per liter (µg/L)	
	Maximum for any one day	Monthly average
Ammonia .....	12,900	10,900
n-Amyl Acetate* .....	2,230	826
Aniline* .....	8,690	3,220
2-Butanone (MEK)* .....	161,000	57,900
n-Butyl Acetate* .....	2,230	826
o-Dichlorobenzene* .....	2,230	826
1,2-Dichloroethane* .....	2,230	826
N,N-Dimethylaniline* .....	8,690	3,220
1,4-Dioxane* .....	8,690	3,220
Ethyl Acetate* .....	2,230	826
Furfural* .....	8,690	3,220
Isobutyraldehyde* .....	2,230	826
Isopropyl Acetate* .....	2,230	826
Isopropyl Ether* .....	2,230	826
Methyl Isobutyl Ketone (MIBK)* .....	2,230	826
2-Methylpyridine* .....	8,690	3,220
Petroleum Naphtha* .....	8,690	3,220
Pyridine* .....	1,000	1,000
Tetrahydrofuran* .....	9,210	3,360

(c) Indirect dischargers not using or generating cyanide are deemed to comply with the monitoring requirements specified in paragraph (a) of this section for cyanide if they certify to the control authority that they are not using or generating this pollutant.

**§ 439.38 [Reserved]**

**Subpart D—Mixing, Compounding and Formulating Subcategory**

16. Sections 439.40 through 439.44 are revised to read as follows:

**§ 439.40 Applicability; description of the mixing, compounding and formulating subcategory; prohibition.**

(a) The provisions of this subpart are applicable to discharges resulting from the mixing, compounding and formulating operations of pharmaceutical products. Mixing, compounding, and formulating operations are defined as processes through which pharmaceutical products are put in dosage forms. Mixing, compounding, and formulating operations include pilot-scale research operations not covered by the provisions of subpart E, Research Subcategory.

(b) The discharge of non-process wastewaters and materials excluded from the definition of process wastewater at § 439.1 is not covered by this subpart. Discharge of such non-process wastewater and excluded materials into publicly owned treatment works or waters of the United States, by a source subject to this subpart, without

an NPDES permit or individual control mechanism authorizing such discharge is prohibited.

**§ 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 40 CFR part 401 and § 439.1 shall apply to this subpart.

(b) The term “product” shall mean products from plants that 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 representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).**

(a) 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 degree of effluent reduction attainable by the application of the best practicable control technology currently available.

(1) Subpart D (For End-of-Pipe Effluent).

Pollutant or pollutant parameter	BPT effluent limitations milligrams per liter (mg/L)	
	Maximum for any one day	Monthly average
BOD <sub>5</sub> .....	37	11
TSS .....	80	27
COD .....	145	60

(2) The pH shall be within the range of 6.0–9.0 standard units.

(b) [Reserved]

**§ 439.43 Effluent limitations representing the degree of effluent reduction 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 degree of effluent reduction attainable by the application of the best conventional pollutant control technology. The limitations shall be the same as those specified for conventional pollutants BOD<sub>5</sub> and TSS in § 439.42 for the best practicable control technology currently available.

**§ 439.44 Effluent limitations representing the degree of effluent reduction attainable by the application of best available technology economically achievable (BAT).**

(a) 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 degree of

effluent reduction attainable by the

application of the best available technology economically achievable.

(1) Subpart D (For End-of-Pipe Effluent).

Pollutant or pollutant property	BAT effluent limitations micrograms per liter (µg/L)	
	Maximum for any one day	Monthly average
Acetone	413	178
Acetonitrile	ND	ND
n-Amyl Acetate	3,000	1,280
Amyl Alcohol	3,980	1,690
Aniline	10	10
Benzene	40	17
2-Butanone (MEK)	202	86
n-Butyl Acetate	500	500
n-Butyl Alcohol	ND	ND
tert-Butyl Alcohol	3,980	1,690
Chemical Oxygen Demand (COD)	145,000	59,900
Chlorobenzene	ND	ND
Chloroform	22	13
Chloromethane	206	87
Cyclohexane	ND	ND
o-Dichlorobenzene	ND	ND
1,2-Dichloroethane	438	152
Diethylamine	ND	ND
Diethyl Ether	4,870	2,070
N,N-Dimethylacetamide	ND	ND
Dimethylamine	ND	ND
N,N-Dimethylaniline	50	50
N,N-Dimethylformamide	45	19
Dimethyl Sulfoxide	ND	ND
1,4-Dioxane	220	94
Ethanol	ND	ND
Ethyl Acetate	3,000	1,280
Ethylene Glycol	ND	ND
Formaldehyde	1,480	623
Formamide	ND	ND
Furfural	3,000	1,280
n-Heptane	ND	ND
n-Hexane	ND	ND
Isobutyraldehyde	1,370	581
Isopropanol	1,120	476
Isopropyl Acetate	500	500
Isopropyl Ether	4,870	2,070
Methanol	6,660	ND
Methylamine	ND	ND
Methyl Cellosolve	ND	ND
Methylene Chloride	1,420	357
Methyl Formate	3,000	1,280
Methyl Isobutyl Ketone (MIBK)	119	51
2-Methylpyridine	50	50
Petroleum Naphtha	40	17
Phenol	25	14
Polyethylene Glycol 600	4,870	2,070
n-Propanol	3,980	ND
Pyridine	10	10
Tetrahydrofuran	15,000	4,350
Toluene	40	17
Trichlorofluoromethane	599	322
Triethylamine	ND	ND
Xylenes	ND	ND

(2) [Reserved]

(b) [Reserved]

17. Section 439.45 is amended by revising paragraph (a) introductory text and paragraph (b) to read as follows:

**§ 439.45 New source performance standards (NSPS).**

(a) Any new source subject to this subpart that was a "new source" under

40 CFR 122.29 prior to [promulgation date of the final rule] must achieve the following new source performance standards until the expiration of the applicable time period specified in 40 CFR 122.29(d)(1), after which the source must achieve the effluent limitations

specified in §§ 439.42, 439.43, and 439.44.

\* \* \* \* \*

(b) Except as provided in paragraph (a) of this section, any new source subject to this subpart must achieve the following new source performance standards.

(1) Subpart D (For End-of-Pipe Monitoring Points). The standards in the following table do not apply for any pollutant(s) for which the permit writer finds it necessary to specify in-plant monitoring requirements pursuant to 40 CFR 122.44(i) and 122.45(h). Standards for those pollutant(s) would be established on a best professional judgment basis pursuant to 40 CFR 125.3.

Pollutant or pollutant property	New source performance standards micrograms per liter (µg/L)	
	Maximum for any one day	Monthly average
Acetone	ND	ND
Acetonitrile	ND	ND
Ammonia	4,850	3,230
n-Amyl Acetate	14	6
Amyl Alcohol	ND	ND
Aniline	10	4
Benzene	ND	ND
2-Butanone (MEK)	144	61
n-Butyl Acetate	11	ND
n-Butyl Alcohol	ND	ND
tert-Butyl Alcohol	ND	ND
Chlorobenzene	ND	ND
Chloroform	ND	ND
Chloromethane	ND	ND
Cyclohexane	ND	ND
o-Dichlorobenzene	ND	ND
1,2-Dichloroethane	13	ND
Diethylamine	ND	ND
Diethyl Ether	74	ND
Dimethylamine	ND	ND
N,N-Dimethylacetamide	ND	ND
N,N-Dimethylaniline	50	45
N,N-Dimethylformamide	45	19
Dimethyl Sulfoxide	ND	ND
1,4-Dioxane	ND	ND
Ethanol	ND	ND
Ethyl Acetate	14	ND
Ethylene Glycol	ND	ND
Formaldehyde	1,480	623
Formamide	ND	ND
Furfural	53	ND
n-Heptane	ND	ND
n-Hexane	ND	ND
Isobutyraldehyde	304	129
Isopropanol	ND	ND
Isopropyl Acetate	11	ND
Isopropyl Ether	74	32
Methanol	ND	ND
Methylamine	ND	ND
Methyl Cellosolve	ND	ND
Methyl Formate	ND	ND
Methylene Chloride	ND	ND
Methyl Isobutyl Ketone (MIBK)	ND	ND
2-Methylpyridine	50	45
Petroleum Naphtha	ND	ND
Phenol	25	14
Polyethylene Glycol 600	4,870	2,070
n-Propanol	ND	ND
Pyridine	10	10
Tetrahydrofuran	910	264
Toluene	ND	ND
Trichlorofluoromethane	ND	ND
Triethylamine	ND	ND
Xylenes	ND	ND

(2) Subpart D (For End-of-Pipe Effluent).

Pollutant or pollutant property	New source performance standards milligrams per liter (mg/L)	
	Maximum for any one day	Monthly average
BOD <sub>5</sub>	34	10

Pollutant or pollutant property	New source performance standards milligrams per liter (mg/L)	
	Maximum for any one day	Monthly average
COD .....	60	24
TSS .....	40	12
pH .....	( <sup>a</sup> )	( <sup>a</sup> )

(<sup>a</sup>) Within the range of 6.0–9.0 standard units.

18. Section 439.46 is revised to read as follows:

**§ 439.46 Pretreatment standards for existing sources (PSES).**

(a) Except as provided in 40 CFR 403.7 and 403.13, any existing source subject to this subpart that introduces pollutants into a publicly owned treatment works must comply with 40 CFR part 403 and by [date 3 years from the promulgation date of the final rule] achieve the following pretreatment standards for existing sources.

(1) Subpart D (For In-Plant Monitoring Points).

Pollutant or pollutant property	Pretreatment standards for existing sources micrograms per liter (µg/L)	
	Maximum for any one day	Monthly average
Benzene .....	796	268
Chlorobenzene .....	796	268
Chloroform .....	ND	ND
Chloromethane .....	796	268
Cyclohexane .....	796	268
n-Heptane .....	796	268
n-Hexane .....	796	268
Methyl Cellosolve .....	ND	ND
Methylene Chloride .....	809	279
Toluene .....	198	148
Trichlorofluoromethane .....	796	268
Xylenes .....	796	268

(2) Subpart D (For End-of-Pipe Monitoring Points).

[Note: Under co-proposal (2), EPA does not propose pretreatment standards for existing sources for these pollutants.]

Pollutant or pollutant property	Pretreatment standards for existing sources micrograms per liter (µg/L)	
	Maximum for any one day	Monthly average
Acetone .....	31,400	9,690
n-Amyl Acetate .....	23,900	8,050
Amyl Alcohol .....	607,000	205,000
Aniline .....	10,900,000	3,690,000
2-Butanone (MEK) .....	1,440,000	430,000
n-Butyl Acetate .....	23,900	8,050
n-Butyl Alcohol .....	10,900,000	3,690,000
tert-Butyl Alcohol .....	607,000	205,000
o-Dichlorobenzene .....	23,900	8,050
1,2-Dichloroethane .....	23,900	8,050
Diethylamine .....	ND	ND
Diethyl Ether .....	23,900	8,050
Dimethylamine .....	607,000	205,000
N,N-Dimethylaniline .....	607,000	205,000
1,4-Dioxane .....	10,900,000	3,690,000
Ethanol .....	2,200,000	784,000
Ethyl Acetate .....	23,900	8,050
Formamide .....	607,000	205,000
Furfural .....	607,000	205,000
Isobutyraldehyde .....	23,900	8,050
Isopropanol .....	597,000	198,000
Isopropyl Acetate .....	23,900	8,050
Isopropyl Ether .....	23,900	8,050
Methanol .....	11,700,000	3,800,000
Methylamine .....	607,000	205,000
Methyl Formate .....	23,900	8,050

Pollutant or pollutant property	Pretreatment standards for existing sources micrograms per liter (µg/L)	
	Maximum for any one day	Monthly average
Methyl Isobutyl Ketone (MIBK) .....	23,900	8,050
2-Methylpyridine .....	607,000	205,000
Petroleum Naphtha .....	10,900,000	3,690,000
n-Propanol .....	2,790,000	941,000
Pyridine .....	1,000	1,000
Tetrahydrofuran .....	9,210	3,360
Triethylamine .....	ND	ND

(b) [Reserved]  
 19. Section 439.47 is amended by revising paragraph (a) introductory text and paragraph (b) to read as follows:

**§ 439.47 Pretreatment standards for new sources (PSNS).**

(a) Any new source subject to this subpart that was a "new source" under 40 CFR 122.29 prior to [promulgation date of the final rule] must achieve the

following pretreatment standards for new sources 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.

\* \* \* \* \*

(b) Except as provided in 40 CFR 403.7 and paragraph (a) of this section, any new source subject to this subpart

that introduces pollutants into a publicly owned treatment works must comply with 40 CFR part 403 and achieve the following pretreatment standards for new sources.

(1) Subpart D (For In-Plant Monitoring Points).

[Note: With respect to pollutants in this table, EPA does not propose pretreatment standards for new sources for pollutants with an asterisk (\*) under co-proposal (2).]

Pollutant or pollutant property	Pretreatment standards for new sources micrograms per liter (µg/L)	
	Maximum for any one day	Monthly average
Acetone* .....	1,190	600
Amyl Alcohol* .....	8,690	3,220
Benzene .....	573	212
n-Butyl Alcohol* .....	8,690	3,220
tert-Butyl Alcohol* .....	8,690	3,220
Chlorobenzene .....	573	212
Chloroform .....	ND	ND
Chloromethane .....	573	212
Cyclohexane .....	573	212
Diethylamine* .....	ND	ND
Diethyl Ether* .....	2,230	826
Dimethylamine* .....	ND	ND
Ethanol* .....	8,690	3,220
Formamide* .....	ND	ND
n-Heptane .....	573	212
n-Hexane .....	573	212
Isopropanol* .....	8,690	3,220
Methanol* .....	8,320	ND
Methylamine* .....	ND	ND
Methyl Cellosolve .....	ND	ND
Methylene Chloride .....	809	279
Methyl Formate* .....	2,230	826
n-Propanol* .....	8,690	3,220
Toluene .....	184	135
Trichlorofluoromethane .....	573	212
Triethylamine* .....	ND	ND
Xylenes .....	573	212

(2) Subpart D (For End-of-Pipe Monitoring Points).

[Note: With respect to pollutants in this table, EPA does not propose pretreatment standards for new sources for pollutants with an asterisk (\*) under co-proposal (2).]

Pollutant or pollutant property	Pretreatment standards for new sources micrograms per liter (µg/L)	
	Maximum for any one day	Monthly average
n-Amyl Acetate* .....	2,230	826

Pollutant or pollutant property	Pretreatment standards for new sources micrograms per liter (µg/L)	
	Maximum for any one day	Monthly average
Aniline*	8,690	3,220
2-Butanone (MEK)*	161,000	57,900
n-Butyl Acetate*	2,230	826
o-Dichlorobenzene*	2,230	826
1,2-Dichloroethane*	2,230	826
N,N-Dimethylaniline*	8,690	3,220
1,4-Dioxane*	8,690	3,220
Ethyl Acetate*	2,230	826
Furfural*	8,690	3,220
Isobutyraldehyde*	2,230	826
Isopropyl Acetate*	2,230	826
Isopropyl Ether*	2,230	826
Methyl Isobutyl Ketone (MIBK)*	2,230	826
2-Methylpyridine*	8,690	3,220
Petroleum Naphtha*	8,690	3,220
Pyridine*	1,000	1,000
Tetrahydrofuran*	9,210	3,360

**§ 439.48 [Reserved]**

**Subpart E—Research Subcategory**

20. Sections 439.50 through 439.52 are revised to read as follows:

**§ 439.50 Applicability; description of the research subcategory; prohibition.**

(a) The provisions of this subpart are applicable to discharges resulting from bench-scale pharmaceutical research operations and product development activities. This subpart does not apply to pilot- or full-scale operations that generate wastewaters using fermentation, extraction, chemical synthesis, or mixing, compounding and formulating. Such operations are covered under subparts A, B, C, and D, respectively.

(b) The discharge of non-process wastewaters and materials excluded from the definition of process wastewater at § 439.1 is not covered by this subpart. Discharges of such non-process wastewater and excluded materials into publicly owned treatment works or waters of the United States, by a source subject to this subpart without an NPDES permit or individual control mechanism authorizing such discharge is prohibited.

**§ 439.51 Specialized definitions.**

For the purpose of this subpart:

(a) Except as provided below, the general definitions, abbreviations, and methods of analysis set forth in 40 CFR part 401 and § 439.1 shall apply to this subpart.

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

**§ 439.52 Effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).**

(a) 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 degree of effluent reduction attainable by the application of the best practicable control technology currently available.

(1) The allowable discharge for the pollutant parameters BOD<sub>5</sub> 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 waste treatment plant corresponding to the maximum production period for a given pharmaceutical plant as defined in paragraph (a)(4) of this section.

(2) The allowable effluent discharge limitation for the daily average mass of BOD<sub>5</sub> in any calendar month shall specifically not reflect not less than 90 percent reduction in the long term daily average raw waste content of BOD<sub>5</sub> multiplied by a variability factor of 3.0. However, a plant shall not be required to attain a 30-day average BOD<sub>5</sub> effluent limitation of less than the equivalent of 45 mg/L.

(3) The allowable effluent discharge limitation for the daily average mass of COD in any calendar month shall specifically not 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. However, a plant shall not be required to attain a 30-day average COD effluent

limitation of less than the equivalent of 220 mg/L.

(4) The long term daily average raw waste load for the pollutant parameters BOD<sub>5</sub> 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.

(5) To assure equity in regulation of discharges from sources covered by this subpart of the point source category, calculation of raw waste loads of BOD<sub>5</sub> 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, except the residual amounts of solvents remaining after the practice of solvent recovery and/or separate disposal or reuse. 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 subpart 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 permit conditions. These limits may be achieved by any one of several programs and practices or a combination thereof.

(6) The allowable effluent discharge limitation for the daily average mass of TSS in any calendar month shall be 1.7 times the BOD<sub>5</sub> limitation determined in paragraph (a)(2) of this section.

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

(b) [Reserved]

439.53 Effluent limitations representing the degree of effluent reduction attainable by the best conventional pollutant control technology (BCT). [Reserved]

439.54 Effluent limitations representing the degree of effluent reduction attainable by the application of best available technology economically achievable (BAT). [Reserved]

439.55 New source performance standards (NSPS). [Reserved]

439.56 Pretreatment standards for existing sources (PSES). [Reserved]

439.57 Pretreatment standards for new sources (PSNS). [Reserved]

439.58 [Reserved]

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