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Part III

Environmental Protection Agency

40 CFR 439

Effluent Limitations Guidelines, Pretreatment Standards, and New Source Performance Standards for the Pharmaceutical Manufacturing Point Source Category; Direct Final Rule and Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 439

[FRL–7462–8]

Effluent Limitations Guidelines, Pretreatment Standards, and New Source Performance Standards for the Pharmaceutical Manufacturing Point Source Category

AGENCY: Environmental Protection Agency.

ACTION: Direct final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking direct final action to amend certain provisions of the effluent guidelines for the Pharmaceutical Manufacturing Point Source Category, which were published on September 21, 1998 (63 FR 50424). First, EPA is clarifying the date on which a discharger subject to the New Source Performance Standards (NSPS) and the Pretreatment Standards for New Sources (PSNS) would be subject to effluent limitations and pretreatment standards established in the 1998 regulation. Second, this rule re-establishes a minimum concentration for the maximum monthly average BOD_5 limitation that EPA inadvertently omitted from the Best Practicable Control Technology (BPT) requirements in two subcategories of the 1998 regulation. Next, the amendments correct an error in EPA's pass-through analysis prepared in support of the 1998 rule and, as a result, deletes methyl Cellosolve (2-methoxyethanol) from the pretreatment standards in two subcategories and from Appendix A, Table 2, ''Surrogate Parameters for Indirect Dischargers.'' Finally, the Agency is making other non-substantive editorial and format changes such as removing redundancies, and adding definitions.

DATES: This rule is effective on June 11, 2003 without further notice, unless EPA receives adverse comment by May 12, 2003. If we receive such comment, we will publish a timely withdrawal in the **Federal Register** informing the public that this rule will not take effect.

ADDRESSES: Comments may be submitted electronically, by mail, or through hand delivery/courier. Please mail comments to the Water Docket, Environmental Protection Agency, Mailcode: 4101T, 1200 Pennsylvania Avenue, NW., Washington, DC, 20460 or submit them electronically to *http://www.epa.gov/edocket.* Send either to the Attention of Docket ID No. OW–2003–0007. See section I.C., of the **SUPPLEMENTARY INFORMATION** section for more information on submitting comments.

FOR FURTHER INFORMATION CONTACT: Dr. Frank Hund, EPA Office of Water by phone at (202)566–1027 or by e-mail at *hund.frank@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Regulated Entities

Entities potentially regulated by this action include facilities of the following types that discharge pollutants directly or indirectly to U.S. waters.

Category	Examples of regulated entities	SIC (NAICS) code
Industry	Facilities that generate process wastewater from the manufacture of pharmaceutical products and/or pharmaceutical intermediates by fermentation, extraction, chemical synthesis and/or mixing, compounding and formulating.	2833, R834, 2836 (2834–04, 2834–98).

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. This table lists the types of entities that EPA is now aware could potentially be regulated by this action. Other types of entities not listed in the table could also be regulated. To determine whether your facility is regulated by this action, you should carefully examine the definitions and applicability criteria in §§ 439.1, 439.10, 439.20, 439.30, 439.40 and 439.50 of title 40 of the Code of Federal Regulations. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

B. How Can I Get Copies of This Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under Docket ID No. OW–2003–0007. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. The official public docket is the collection of materials that is available for public viewing at the Water Docket in the EPA Docket Center, (EPA/DC) EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the Water Docket is (202) 566–2426. For access to docket materials, please call ahead to schedule an appointment. Every user is entitled to copy 100 pages before incurring a charge. The Docket may charge 15 cents a page for each page over the 100-page limit.

2. *Electronic Access.* You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/.*

An electronic version of the public docket is available through EPA's electronic public docket and comment system, ''EPA Dockets.'' You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, select ''search,'' then key in the appropriate docket identification number.

II. Legal Authority

The U.S. Environmental Protection Agency is promulgating these regulations under the authority of 33 U.S.C. 1311, 1314, 1316, 1317, 1318, 1342 and 1361.

III. Overview of Effluent Limitations Guidelines and Standards

Congress adopted the Clean Water Act (CWA) to ''restore and maintain the chemical, physical, and biological integrity of the Nation's waters'' (section 101(a), 33 U.S.C. 1251(a)). To achieve this goal, the CWA prohibits the discharge of pollutants into navigable waters except in compliance with the statute. The Clean Water Act confronts the problem of water pollution on a number of different fronts. Its primary reliance, however, is on establishing restrictions on the types and amounts of pollutants discharged from various industrial, commercial, and public sources of wastewater.

Congress recognized that regulating only those sources that discharge effluent directly into the nation's waters would not be sufficient to achieve the CWA's goals. Consequently, the CWA requires EPA to promulgate nationally applicable pretreatment standards that restrict pollutant discharges for those who discharge wastewater indirectly through sewers flowing to publicly-owned treatment works (POTWs) (section 307(b) and (c), 33 U.S.C. 1317(b) and (c)). National pretreatment standards are established for those pollutants in wastewater from indirect dischargers which may pass through or interfere with POTW operations. Generally, pretreatment standards are designed to ensure that wastewater from direct and indirect industrial dischargers are subject to similar levels of treatment. In addition, POTWs are required to implement local pretreatment limits applicable to their industrial indirect dischargers to satisfy any local requirements (40 CFR 403.5).

Direct dischargers must comply with effluent limitations in National Pollutant Discharge Elimination System (NPDES) permits; indirect dischargers must comply with pretreatment standards. These limitations and standards are established by regulation for categories of industrial dischargers and are based on the degree of control that can be achieved using various levels of pollution control technology.

On November 17, 1976, (41 FR 50676) EPA promulgated ''best practicable control technology currently available'' (BPT) effluent limitations guidelines for the Pharmaceutical Manufacturing Point Source Category. On October 27, 1983, (48 FR 49808) the Agency revised the BPT limitations and promulgated additional limitations covering the ''best available technology economically achievable'' (BAT) and pretreatment and new source standards for this point source category.

On September 21, 1998, (63 FR 50388) EPA again revised the effluent limitations guidelines and standards for the Pharmaceutical Manufacturing Point Source Category. We subsequently received comments from the regulated community and after our own analysis and review, we determined that several minor amendments which are discussed below were warranted.

IV. Amendment to New Source Effective Dates

Section 306 of the Clean Water Act requires EPA to establish, and from time to time, revise standards of performance for categories of new sources which may discharge pollutants. Under the Act, point sources constructed to meet these NSPS may not be subject to more stringent standards during a statutorily prescribed period following construction of such source, generally 10 years. EPA first promulgated NSPS for the Pharmaceutical Manufacturing Point Source Category in 1983 when the Agency established effluent limitations guidelines and pretreatment standards for this category. When EPA promulgated revised limitations and standards, including NSPS, for the Pharmaceuticals Manufacturing Point Source Category in 1998, 40 CFR 439.15(c), 439.25(c), 439.35(c), and 439.45(c) provided for this protection period from more stringent standards. For example, paragraph (c) of § 439.15 states:

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

In order to remove any ambiguity about which regulations applied to dischargers constructing new facilities and commencing discharge after the 1983 regulation but before the effective date of the 1998 regulations, EPA is amending the regulation. EPA is amending paragraph (c) of each of the four sections cited above to state clearly that any new source that commenced discharging after November 21, 1988, and before November 20, 1998, must continue to achieve the standards specified for 40 CFR part 439 in the October 27, 1983, **Federal Register** (48 FR 49808) (which are contained in the 1988 edition of the CFR) until the expiration of the applicable time period specified in 40 CFR 122.29(d)(1). Thereafter, the source must comply with the applicable effluent limitations specified in the September 21, 1998, regulation (63 FR 50388). The amendments substitute for the phrase ''earlier version'' a specific reference to the 1988 edition of 40 CFR part 439. This will remove any uncertainty about the standards with which a point source discharger must comply.

Section 307(c) of the CWA also requires EPA to promulgate pretreatment standards for new sources simultaneously with the promulgation of NSPS for a category of sources. When EPA promulgated the PSNS for the Pharmaceutical Manufacturing Point Source Category in 1998, PSNS in §§ 439.17, 439.27, 439.37, and 439.47 failed to specify when a source constructed before the date on which the new PSNS became effective would be subject to the more stringent standards. To correct this oversight, EPA is revising each of these four sections to read as follows:

> Except as provided in 40 CFR 403.7, any new source subject to this subpart that commenced discharging after November 21, 1988, and prior to November 20, 1998, must continue to achieve the pretreatment standards specified for this section in the 1988 edition of 40 CFR part 439 during a ten-year period beginning on the date the source commenced discharge, or during the period of depreciation or amortization of the facility, which ever comes first, after which the source must achieve the same standards as specified in [insert the appropriate PSES section for the subpart].

V. Amendment to BOD Minimum Limitation

When EPA issued regulations for the Pharmaceutical Manufacturing Point Source Category on October 27, 1983 (49 FR 49808), the best practicable control technology (BPT) regulation in §§ 439.22 and 439.42 provided for a minimum monthly average limitation for BOD_5, which was qualified by the following sentence: ''However, a plant shall not be required to attain a maximum 30-day average BOD_5 effluent limitation of less than the equivalent of 45 mg/l.'' EPA included this provision because dischargers with BOD_5 levels up to 100 mg/L in their raw wastewater could not achieve the required 90% reduction of BOD_5 using biological treatment, the technological basis for the limitation. Since biological treatment could not achieve the required reduction for such dischargers, EPA established a qualified provision for a minimum BOD_5 concentration in the 1983 regulation.

EPA inadvertently omitted this qualified provision of the BOD_5 limitations from the final rule published in 1998, and this language consequently has not been included in subsequent editions of 40 CFR part 439. Today EPA is correcting this omission by adding to §§ 439.22(a) and 439.42(a) the phrase: '' * * *, except that no facility shall be required to attain a monthly average limitation for BOD_5 that is less than the equivalent of 45 mg/L.''

VI. Amendment To Delete Methyl Cellosolve From Pretreatment Standards

EPA is amending 40 CFR part 439 by deleting the pretreatment standards for methyl Cellosolve from §§ 439.16, 439.17, 439.36 and 439.37, and from Table 2 of Appendix A. In the 1998 regulation, EPA established pretreatment standards for methyl

Cellosolve and other pollutants which EPA's pass-through analysis concluded would pass through POTW treatment rather than be removed by POTW treatment. EPA based its determination on a chemical and engineering evaluation of which pollutants would not be susceptible to treatment in POTW biological treatment systems. EPA's pass-through analysis depended on a number of calculations, relying in part on a comparison of a parameter's Henry's Law Constant (H_L) with a threshold H_L value.

In a letter to EPA dated November 28, 2000, the Pharmaceutical Research and Manufacturers of America (PhRMA) indicated that EPA had used an incorrect H_L value for methyl Cellosolve in the pass-through analysis by assuming an H_L value of 2.9×10^{-3} atm/gmole/m^3. This was the same H_L value that had been used for methyl Cellosolve by EPA's Office of Air Quality Planning and Standards (OAQPS) in establishing the Maximum Air Control Technology (MACT) standards for pharmaceutical manufacturers that were promulgated in 1998, and that had been developed concomitantly with revised pretreatment standards for 40 CFR part 439. The OAQPS, however, subsequently revised its H_L value for methyl Cellosolve from 2.9×10^{-3} to 3.3×10^{-7} atm/gmole/m^3, based on a value reported by Johanson G. and Dynesius B. in ''Liquid/air partition coefficients of six commonly used glycol ethers,'' *British Journal of Industrial Medicine,* 1988, 45:561–564.

The determination of an incorrect H_L constant was reinforced when EPA also considered the analytical technique required to measure low concentrations of methyl Cellosolve in wastewater. Analytical methods to measure volatile organic analytes (VOAs) utilize an inert gas purging technique to recover VOAs from a wastewater sample. But methyl Cellosolve does not purge efficiently and so must be analyzed using a direct injection technique. This fact offered additional evidence that EPA had used an inappropriate H_L value for methyl Cellosolve in the earlier pass-through analysis of the pretreatment standards.

The revised H_L for methyl Cellosolve (3.3×10^{-7} atm/gmole/m^3) is well below the threshold H_L value (1×10^{-5} atm/gmole/m^3) that EPA used to classify a compound as a volatile organic compound (VOC) for purposes of the Agency's pass-through analysis. Thus, EPA relied on an inappropriate H_L value for methyl Cellosolve in the pass-through analysis for the 1998 rule. This caused this compound to be identified as a VOC, which the Agency's pass-through analysis determined would pass through a POTW's treatment. When EPA used the corrected lower H_L value and found that methyl Cellosolve was not a VOC, the Agency's pass-through analysis determined that this compound would not pass through a POTW's treatment.

VII. Additional Edits to 40 CFR Part 439

Today's rule also includes non-substantive edits and format changes to the rule promulgated in 1998 in order to shorten and clarify 40 CFR part 439. The ''Authority'' citation was shortened to conform with current guidance from the Federal Register Office. The text from § 439.4 was merged into § 439.2 and the heading of § 439.2 was revised to read: ''General monitoring requirements.'' Section 439.4 was re-designated under a new heading ''General limitation or standard for pH'' and the term ''Subcategory'' was removed from the heading of all subparts. EPA has also added definitions of ''Maximum daily'' and ''Maximum monthly average'' to § 439.1. These definitions are similar to those used in other effluent limitations guidelines and pretreatment standards regulations and reflect the definitions used to promulgate the limits in the existing 40 CFR part 439. Finally, the initial phrase, ''The term * * *'' was removed from all definitions, column headings and titles of all tables. Corresponding text referencing these headings and titles was also revised.

VIII. Rationale for Direct Final Rule

EPA is publishing this rule without prior proposal because we view this as a noncontroversial amendment and anticipate no adverse comment. The changes here will facilitate the implementation of part 439 and will not affect environmental impacts or compliance costs. They merely clarify applicable dates, correct an inadvertent error and omission, and make other non-substantive edits. However, in the ''Proposed Rules'' section of today's **Federal Register,** we are publishing a separate document that will serve as the proposal to amend part 439, as described herein, if adverse comments are filed. This rule will be effective on June 11, 2003 without further notice, unless we receive adverse comment by May 12, 2003. If EPA receives adverse comment on one or more distinct amendments, paragraphs, or sections of this rulemaking, we will publish a timely withdrawal in the **Federal Register** indicating which provisions will become effective and which provisions are being withdrawn due to adverse comment. Any distinct amendment, paragraph, or section of today's rulemaking for which we do not receive adverse comment will become effective on the date set out above, notwithstanding any adverse comment on any other distinct amendment, paragraph, or section of today's rule. We will address all adverse public comments in a subsequent final rule based on the proposed rule. We will not institute a second comment period on this action. Any parties interested in commenting must do so at this time.

IX. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order 12866 (58 FR 51735, (October 4, 1993)), the Agency must determine whether a regulatory action is ''significant'' and therefore subject to Office of Management and Budget (OMB) review and the requirements of the Executive Order. The Order defines ''significant regulatory action'' as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

It has been determined that this rule is not a ''significant regulatory action'' under the terms of Executive Order 12866 and is therefore not subject to OMB review.

B. Paperwork Reduction Act

This action does not impose an information collection burden under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* It merely clarifies applicable dates, corrects an inadvertent error and omission, and makes other non-substantive edits.

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology

and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

An Agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR chapter 15.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), 5 U.S.C. 601 *et seq.*, generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations and small governmental jurisdictions.

For purposes of assessing the impact of today's final rule on small entities, a small entity is defined as (1) a small business with gross revenue under $6 million (based on Small Business Administration size standards); (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of today's final rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. It merely clarifies applicable dates, corrects an inadvertent error and omission, and makes other non-substantive edits. As explained above, the change to the PSNS sections of the regulation merely removes any ambiguity about the applicability of the earlier 1983 pretreatment standards during the 10-year protection period prior to November 20, 1998, and makes them consistent with the latest NSPS sections. The PSNS revision does not establish any new requirements with respect to those subject to the regulation. The other changes similarly would have either no effect on the regulated entities, or at most an inconsequential effect. The deletion of methyl Cellosolve would reduce the economic impacts of the regulation on those entities, including small entities, subject to pretreatment standards in the two subparts which currently contain methyl Cellosolve as a regulated parameter. In addition, as noted above, the revision to re-establish the minimum concentration for BOD_5 would correct an earlier inadvertent omission and reflect the requirements of existing discharge permits.

D. Unfunded Mandates Reform Act

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

EPA has determined that this final rule does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local and tribal governments, in the aggregate, or the private sector in any one year. It merely clarifies applicable dates, corrects an inadvertent error and omission, and makes other non-substantive edits. Thus, today's rule is not subject to the requirements of sections 202 and 205 of UMRA.

For the same reason, EPA has determined that this final rule contains no regulatory requirements that might significantly affect small governments. The final rule does not uniquely affect small governments because small and large governments are affected in the same way. Thus, today's rule is not subject to the requirements of section 203 of UMRA.

E. Executive Order 13132: Federalism

Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.''

This final rule does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. Today's rule amends effluent limitations and pretreatment standards which impose requirements that apply to facilities when they discharge wastewater or introduce wastewater to a POTW. It merely clarifies applicable dates, corrects an inadvertent error, and omission, and makes other non-substantive edits. EPA has determined that there are no pharmaceutical facilities owned and/or operated by State or local governments that would be subject to today's rule. Further, the rule would only incidentally affect State and local governments in their capacity as implementers of CWA NPDES permitting programs. Thus, Executive Order 13132 does not apply to this rule.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000), requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have substantial direct effects on one or more Indian tribes, on the relationship between Federal government and Indian tribes or on the distribution of power and responsibilities between the Federal government and Indian tribes.

This final rule does not have tribal implications. It will not have substantial direct effects on tribal governments, on the relationship between this Federal government and Indian tribes or on the distribution of power and responsibilities between the Federal government and Indian tribes. It merely clarifies applicable dates, corrects an inadvertent error and omission, and makes other non-substantive edits. EPA has not identified any pharmaceutical facilities covered by today's rule that are owned and/or operated by Indian tribal governments. No Indian tribes are responsible for implementing the CWA NPDES permitting program. Thus, Executive Order 13175 does not apply to this rule.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

Executive Order 13045 ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997) applies to any rule that: (1) Is determined to be ''economically significant'' as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This final rule is not subject to Executive Order 13045 because it is not an economically significant rule as defined under Executive Order 12866. Further, this rule does not concern an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children.

H. Executive Order 13211: Actions that Significantly Affect Energy Supply, Distribution, or Use

This rule is not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355; May 22, 2001) because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note), directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.*, materials specifications, test methods, sampling procedures, business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through the Office of Management and Budget (OMB), explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This action does not involve technical standards. Therefore, EPA did not consider the use of any voluntary consensus standards.

J. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to the publication of the rule in **Federal Register.** A major rule cannot take effect until 60 days after it is published in the **Federal Register.** This action is not a ''major rule'' as defined by 5 U.S.C. 804(2). This rule will be effective June 11, 2003.

List of Subjects in 40 CFR Part 439

Environmental protection, Drugs, Reporting and recordingkeeping requirements, Waste treatment and disposal, Water pollution control.

Dated: February 28, 2003.

Christine Todd Whitman,

Administrator.

For reasons set out in the preamble, part 439, title 40, chapter I of the Code of Federal Regulations is amended as follows:

PART 439—PHARMACEUTICAL MANUFACTURING POINT SOURCE CATEGORY

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

Authority: 33 U.S.C. 1311, 1314, 1316, 1317, 1318, 1342 and 1361.

2. Section 439.1 is amended by revising paragraphs (b) through (n) and adding paragraphs (o) and (p) to read as follows:

§ 439.1 General definitions.

* * * * *

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

(c) *Cyanide (T)* means the parameter total cyanide.

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

(e) *Maximum daily* means the highest allowable discharge of wastewater pollutants during a calender day or any 24 hour period that reasonably represents a calender day for purposes of sampling.

(f) *Maximum monthly average* means the highest allowable average of daily discharges of wastewater pollutants over a calendar month, and is calculated as the sum of all daily values measured during a calendar month divided by the number of daily values measured during that month.

(g) *mg/L* means milligrams per liter or parts per million (ppm)

(h) *Minimum level* means the level at which an analytical system gives recognizable signals and an acceptable calibration point.

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

increase in the concentrations of nitrites and nitrates.

(j) *Non-detect (ND)* means a concentration value below the minimum level that can be reliably measured by the analytical method.

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

(l) *POTW* means publicly owned treatment works (40 CFR 403.3).

(m) *Process wastewater,* as defined at 40 CFR 122.2 and for the purposes of this part, does not include the following:

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

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

(n) *Non-conventional pollutants* means parameters that are neither conventional pollutants (40 CFR 401.16), nor ''toxic'' pollutants (40 CFR 401.15).

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

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

3. Section 439.2 is revised to read as follows:

§ 439.2 General monitoring requirements.

(a) Permit compliance monitoring is required for each regulated pollutant generated or used at a pharmaceutical manufacturing facility, except where the regulated pollutant is monitored as a surrogate parameter. Permit limits and compliance monitoring are not required for regulated pollutants that are neither used nor generated at the facility. Except for cyanide, for which an alternate monitoring requirement is established in subparts A and C of this part, a determination that regulated pollutants are neither used nor generated should be based on a review of all raw materials in use, and an assessment of the process chemistry, products and by-products resulting from each of the manufacturing processes. This determination along with a recommendation of any surrogate must be submitted with permit applications for approval by the permitting authority, reconfirmed by an annual chemical analysis of wastewater from each monitoring location, and measurement of a non-detect value for each regulated pollutant or its surrogate. Permits must specify that such determinations will be maintained in the facility's permit records with their discharge monitoring reports and will be available to regulatory authorities upon request.

(b) Unless noted otherwise, self-monitoring will be conducted at the point where the final effluent is discharged.

4. Section 439.4 is revised to read as follows:

§ 439.4 General limitation or standard for pH.

The pH must remain within the range 6.0 to 9.0 in any discharge subject to BPT, BCT or NSPS limitations or standards in this part.

5. Revise the heading of subpart A to read as follows:

Subpart A—Fermentation Products

6. Section 439.11 is revised to read as follows:

§ 439.11 Special definitions.

For the purpose of this subpart:

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

(b) *Product* means pharmaceutical products derived from fermentation processes.

7. Section 439.12 is amended by revising paragraphs (a) introductory text, and (b) through (e) to read as follows:

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

* * * * *

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

* * * * *

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

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

EFFLUENT LIMITATIONS (BPT)

Regulated parameter	Maximum daily [1]	Maximum monthly average [1]
COD	1675	856

[1] mg/L (ppm).

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

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

EFFLUENT LIMITATIONS (BPT)

Regulated parameter	Maximum daily [1]	Maximum monthly average [1]
Cyanide (T)	33.5	9.4

[1] mg/L (ppm).

* * * * *

8. Section 439.14 is revised to read as follows:

§ 439.14 Effluent limitations 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 application of BAT:

EFFLUENT LIMITATIONS (BAT)

Regulated parameter	Maximum daily [1]	Maximum monthly average [1]
Ammonia (as N) ...	84.1	29.4
Acetone	0.5	0.2
4-methyl-2-pentanone	0.5	0.2
Isobutyraldehyde ..	1.2	0.5
n-Amyl acetate	1.3	0.5
n-Butyl acetate	1.3	0.5
Ethyl acetate	1.3	0.5
Isopropyl acetate ..	1.3	0.5
Methyl formate	1.3	0.5
Amyl alcohol	10.0	4.1
Ethanol	10.0	4.1
Isopropanol	3.9	1.6
Methanol	10.0	4.1
Methyl Cellosolve	100.0	40.6
Dimethyl sulfoxide	91.5	37.5
Triethyl amine	250.0	102.0
Phenol	0.05	0.02
Benzene	0.05	0.02
Toluene	0.06	0.02
Xylenes	0.03	0.01
n-Hexane	0.03	0.02
n-Heptane	0.05	0.02
Methylene chloride	0.9	0.3
Chloroform	0.02	0.13
1,2-dichloroethane	0.4	0.1
Chlorobenzene	0.15	0.06
o-Dichlorobenzene	0.15	0.06
Tetrahydrofuran	8.4	2.6
Isopropyl ether	8.4	2.6
Diethyl amine	250.0	102.0
Acetonitrile	25.0	10.2

[1] mg/L (ppm).

(b) The limitations for COD are the same as specified in § 439.12(c) and (d).

(c) The limitations for cyanide are the same as specified in § 439.12(e), (f) and (g).

9. Section 439.15 is revised to read as follows:

§ 439.15 New source performance standards (NSPS).

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

PERFORMANCE STANDARDS (NSPS)

Regulated parameter	Maximum daily [1]	Maximum monthly average [1]
BOD_5	267	111
TSS	472	166
COD	1675	856
Ammonia (as N) ...	84.1	29.4
Acetone	0.5	0.2
4-methyl-2-pentanone	0.5	0.2
Isobutyraldehyde ..	1.2	0.5
n-Amyl acetate	1.3	0.5
n-Butyl acetate	1.3	0.5
Ethyl acetate	1.3	0.5
Isopropyl acetate ..	1.3	0.5
Methyl formate	1.3	0.5
Amyl alcohol	10.0	4.1
Ethanol	10.0	4.1

PERFORMANCE STANDARDS (NSPS)—Continued

Regulated parameter	Maximum daily [1]	Maximum monthly average [1]
Isopropanol	3.9	1.6
Methanol	10.0	4.1
Methyl Cellosolve	100.0	40.6
Dimethyl sulfoxide	91.5	37.5
Triethyl amine	250.0	102.0
Phenol	0.05	0.02
Benzene	0.05	0.02
Toluene	0.06	0.02
Xylenes	0.03	0.01
n-Hexane	0.03	0.02
n-Heptane	0.05	0.02
Methylene chloride	0.9	0.3
Chloroform	0.02	0.13
1,2-dichloroethane	0.4	0.1
Chlorobenzene	0.15	0.06
o-Dichlorobenzene	0.15	0.06
Tetrahydrofuran	8.4	2.6
Isopropyl ether	8.4	2.6
Diethyl amine	250.0	102.0
Acetonitrile	25.0	10.2

[1] mg/L (ppm)

(b) The limitations for cyanide are the same as specified in § 439.12(e), (f) and (g).

(c) Any new source subject to the provisions of this section that commenced discharging after November 21, 1988, and prior to November 20, 1998, must continue to achieve the standards specified for this section in the 1988 edition of 40 CFR part 439, until the expiration of the applicable time period specified in 40 CFR 122.29(d)(1), after which the source must achieve the standards specified in §§ 439.13 and 439.14.

10. Section 439.16 is revised to read as follows:

§ 439.16 Preatment standards for existing sources (PSES).

(a) Except as provided in 40 CFR 403.7 and 403.13, any existing source subject to this subpart must continue achieving the standards for cyanide specified in paragraph (c) of this section and must achieve the following standards by September 21, 2001:

PRETREATMENT STANDARDS (PSES)

Regulated parameter	Maximum daily [1]	Maximum monthly average [1]
Ammonia (as N) [2] ...	84.1	29.4
Acetone	20.7	8.2
4-methyl-2-pentanone	20.7	8.2
Isobutyraldehyde	20.7	8.2
n-Amyl acetate	20.7	8.2
n-Butyl acetate	20.7	8.2
Ethyl acetate	20.7	8.2
Isopropyl acetate	20.7	8.2
Methyl formate	20.7	8.2

PRETREATMENT STANDARDS (PSES)—Continued

Regulated parameter	Maximum daily [1]	Maximum monthly average [1]
Isopropyl ether	20.7	8.2
Tetrahydrofuran	9.2	3.4
Benzene	3.0	0.7
Toluene	0.3	0.2
Xylenes	3.0	0.7
n-Heptane	3.0	0.7
n-Hexane	3.0	0.7
Methylene chloride	3.0	0.7
Chloroform	0.1	0.03
1,2-dichloroethane ..	20.7	8.2
Chlorobenzene	3.0	0.7
o-Dichlorobenzene ..	20.7	8.2
Diethyl amine	255.0	100.0
Triethyl amine	255.0	100.0

[1] mg/L (ppm)

[2] Not applicable to sources that discharge to a POTW with nitrification capability.

(b) Sources that discharge to a POTW with nitrification capability (defined at § 439.1(i)) are not required to achieve the pretreatment standard for ammonia (as N).

(c) The limitations for cyanide are the same as specified in § 439.12(e), (f) and (g).

11. Section 439.17 is revised to read as follows:

§ 439.17 Pretreatment standards for new sources (PSNS).

(a) Except as provided in 40 CFR 403.7, any new source subject to this subpart that commenced discharge on November 20, 1998, or thereafter must achieve the same standards as specified in § 439.16.

(b) Except as provided in 40 CFR 403.7, any new source subject to this subpart that commenced discharging after November 21, 1988, and prior to November 20, 1998, must continue to achieve the pretreatment standards specified for this section in the 1988 edition of 40 CFR part 439 during a ten-year period beginning on the date the source commenced discharge, or during the period of depreciation or amortization of the facility, whichever comes first, after which the source must achieve the same standards as specified in § 439.16.

12. Revise the heading of subpart B to read as follows:

Subpart B—Extraction Products

13. Section 439.21 is revised to read as follows:

§ 439.21 Special definitions.

For the purpose of this subpart:

(a) *Extraction* means process operations that derive pharmaceutically active ingredients from natural sources

such as plant roots and leaves, animal glands, and parasitic fungi by chemical and physical extraction.

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

14. Section 439.22 is amended by revising paragraphs (a) introductory text and (b) through (d) to read as follows:

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

* * * * *

(a) The limitation for BOD_5 is the same as specified in § 439.12(a). No facility shall be required to attain a monthly average limitation for BOD_5 that is less than the equivalent of 45 mg/L.

* * * * *

(b) The limitation for TSS is the same as specified in § 439.12(b).

(c) Except for the provisions in paragraph (d) of this section, the limitations for COD are as follows:

EFFLUENT LIMITATIONS (BPT)

Regulated parameter	Maximum daily [1]	Maximum monthly average [1]
COD	228	86

[1] mg/L (ppm)

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

15. Section 439.25 is revised to read as follows:

§ 439.25 New source performance standards (NSPS).

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

PERFORMANCE STANDARDS (NSPS)

Regulated parameter	Maximum daily [1]	Maximum monthly average [1]
BOD_5	35	18
TSS	58	31

PERFORMANCE STANDARDS (NSPS)—Continued

Regulated parameter	Maximum daily [1]	Maximum monthly average [1]
COD	228	86

[1] mg/L (ppm)

(b) Any new source subject to the provisions of this section that commenced discharging after November 21, 1988, and prior to November 20, 1998, must continue to achieve the standards specified for this section in the 1988 edition of 40 CFR part 439, until the expiration of the applicable time period specified in 40 CFR 122.29(d)(1), after which the source must achieve the standards specified in §§ 439.23 and 439.24.

16. Section 439.26 is revised to read as follows:

§ 439.26 Pretreatment standards for existing sources (PSES).

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

PRETREATMENT STANDARDS (PSES)

Regulated parameter	Maximum daily [1]	Maximum monthly average [1]
Acetone	20.7	8.2
n-Amyl acetate	20.7	8.2
Ethyl acetate	20.7	8.2
Isopropyl acetate	20.7	8.2
Methylene chloride	3.0	0.7

[1] mg/L (ppm).

17. Section 439.27 is revised to read as follows:

§ 439.27 Pretreatment standards for new sources (PSNS).

(a) Except as provided in 40 CFR 403.7, any new source subject to this subpart that commenced discharge on November 20, 1998, or thereafter must achieve the same standards as specified in § 439.26.

(b) Except as provided in 40 CFR 403.7, any new source subject to this subpart that commenced discharging after November 21, 1988, and prior to November 20, 1998, must continue to achieve the pretreatment standards specified for this section in the 1988 edition of 40 CFR part 439 during a ten-year period beginning on the date the source commenced discharge, or during the period of depreciation or amortization of the facility, whichever comes first, after which the source must achieve the same standards as specified in § 439.26.

18. Revise the heading of Subpart C to read as follows:

Subpart C—Chemical Synthesis Products

19. Section 439.31 is revised, including the section heading, to read as follows:

§ 439.31 Special definitions.

For the purpose of this subpart:

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

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

20. Section 439.32 is amended by revising paragraphs (a) through (d) and removing paragraphs (e) through (g) to read as follows:

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

* * * * *

(a)The limitation for BOD_5 is the same as specified in § 439.12(a).

(b) The limitation for TSS is the same as specified in § 439.12(b).

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

(d) The limitations for cyanide are the same as specified in § 439.12(e), (f) and (g).

* * * * *

21. Section 439.34 is revised to read as follows:

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

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

(a) The limitations are the same as specified in § 439.14(a).

(b) The limitations for COD are the same as specified in § 439.12(c) and (d).

(c) The limitations for cyanide are the same as specified in § 439.12(e), (f) and (g).

22. Section 439.35 is revised to read as follows:

§ 439.35 New source performance standards (NSPS).

(a) Any new source subject to this subpart must achieve the same standards as specified in § 439.15(a).

(b) The limitations for cyanide are the same as specified in § 439.12(e), (f) and (g).

(c) Any new source subject to the provisions of this section that commenced discharging after November 21, 1988, and prior to November 20, 1998, must continue to achieve the standards specified for this section in the 1988 edition of 40 CFR part 439, until the expiration of the applicable time period specified in 40 CFR 122.29(d)(1), after which the source must achieve the standards specified in § 439.33 and § 439.34.

23. Section 439.36 is revised to read as follows:

§ 439.36 Pretreatment standards for existing sources (PSES).

Except as provided in 40 CFR 403.7 and 403.13, any existing source subject to this subpart must continue achieving the standards for cyanide specified in paragraph (b) of this section and must achieve the standards specified in § 439.16(a) by September 21, 2001.

(a) Sources that discharge to a POTW with nitrification capability (defined at § 439.1(i)) are not required to achieve the standards for ammonia (as N).

(b) The standards for cyanide are the same as specified in § 439.12(e), (f) and (g).

24. Section 439.37 is revised to read as follows:

§ 439.37 Pretreatment standards for new sources (PSNS).

(a) Except as provided in 40 CFR 403.7, any new source subject to this subpart that commenced discharge on November 20, 1998, or thereafter must achieve the same standards as specified in § 439.36.

(b) Except as provided in 40 CFR 403.7, any new source subject to this subpart that commenced discharging after November 21, 1988, and prior to November 20, 1998, must continue to achieve the pretreatment standards specified for this section in the 1988 edition of 40 CFR part 439 during a ten-year period beginning on the date the source commenced discharge, or during the period of depreciation or amortization of the facility, whichever comes first, after which the source must achieve the same standards as specified in § 439.36.

25. Revise the heading of Subpart D to read as follows:

Subpart D—Mixing/Compounding and Formulation

26. Section 439.41 is revised to read as follows:

§ 439.41 Special definitions.

For the purpose of this subpart:

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

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

27. Section 439.42 is amended by revising paragraphs (a) through (c) and removing paragraph (d) to read as follows:

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

* * * * *

(a) The limitation for BOD_5 is the same as specified in § 439.12(a). No facility shall be required to attain a monthly average limitation for BOD_5 that is less than the equivalent of 45 mg/L.

(b) The limitation for TSS is the same as specified in § 439.12(b).

(c) The limitations for COD are the same as specified in § 439.22(c) and (d).

* * * * *

28. Section 439.44 is revised to read as follows:

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

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

29. Section 439.45 is revised to read as follows:

§ 439.45 New source performance standards (NSPS).

(a) Any new source subject to this subpart must achieve the same standards as specified in § 439.25(a).

(b) Any new source subject to the provisions of this section that commenced discharging after November 21, 1988, and prior to November 20, 1998, must continue to achieve the standards specified for this section in the 1988 edition of 40 CFR part 439, until the expiration of the applicable time period specified in 40 CFR 122.29(d)(1), after which the source must achieve the standards specified in § 439.43 and § 439.44.

30. Section 439.46 is revised to read as follows:

§ 439.46 Pretreatment standards for existing sources (PSES).

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

PRETREATMENT STANDARDS (PSES)

Regulated parameter	Maximum daily[1]	Maximum monthly average[1]
Acetone	20.7	8.2
n-Amyl acetate	20.7	8.2
Ethyl acetate	20.7	8.2
Isopropyl acetate	20.7	8.2
Methylene chloride	3.0	0.7

[1] mg/L (ppm).

31. Section 439.47 is revised to read as follows:

§ 439.47 Pretreatment standards for new sources (PSNS).

(a) Except as provided in 40 CFR 403.7, any new source subject to this subpart that commenced discharge on November 20, 1998, or thereafter must achieve the same standards as specified in § 439.46.

(b) Except as provided in 40 CFR 403.7, any new source subject to this subpart that commenced discharging after November 21, 1988, and prior to November 20, 1998, must continue to achieve the pretreatment standards specified for this section in the 1988 edition of 40 CFR part 439 during a ten-year period beginning on the date the source commenced discharge, or during the period of depreciation or amortization of the facility, whichever comes first, after which the source must achieve the same standards as specified in § 439.46.

32. Revise the heading of subpart E to read as follows:

Subpart E—Research

33. Section 439.51 is revised to read as follows:

§ 439.51 Special definitions.

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

34. Section 439.52 is amended by revising paragraphs (a) through (d) to read as follows:

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

* * * * *

(a) The limitation for BOD_5 is the same as specified in § 439.12(a). No

facility shall be required to attain a monthly average limitation for BOD_5 that is less than the equivalent of 45 mg/L.

(b) The limitation for TSS is the same as specified in § 439.12(b).

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

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

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

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

* * * * *

35. Table 2 of Appendix A is revised to read as follows:

Appendix A to Part 439—Tables

* * * * *

TABLE 2.—SURROGATE PARAMETERS FOR INDIRECT DISCHARGERS (UTILIZING STEAM STRIPPING TREATMENT TECHNOLOGY)

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

[1] These parameters may be used as a surrogate to represent other parameters in the same treatability class.

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