operation of law and, hence, do not impose any Federal intergovernmental mandate, as defined in section 101 of the Unfunded Mandates Act.

List of Subjects in 40 CFR Part 81

Environmental protection, Air pollution control, Intergovernmental relations, Carbon monoxide.

Authority: 42 U.S.C. 7401–7671q.

Dated: August 1, 1997.

Chuck Findley,

Acting Regional Administrator.

[FR Doc. 97–20969 Filed 8–7–97; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 439

[FRL 5872–6]

Notice of Availability; Effluent Limitations Guidelines, Pretreatment Standards, and New Source Performance Standards: Pharmaceutical Manufacturing Category

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability.

SUMMARY: On May 2, 1995, EPA proposed Clean Water Act (CWA) effluent limitations guidelines, new source performance standards, and pretreatment standards for the introduction of pollutants into publicly owned treatment works to reduce the discharge of pollutants from the pharmaceutical manufacturing industry (60 FR 21592). This document describes new information the Agency has obtained since the proposal, provides detailed information concerning regulatory options under the CWA which were identified in the April 2, 1997 (62 FR 15753) Maximum Achievable Control Technology (MACT) Standard Clean Air Act (CAA) proposal, and presents the results of analyses of old and newly acquired data and suggested modifications to the proposal. This document also solicits public comments regarding any of the information presented in this document and the record supporting this notice of data availability.

DATES: Comments on this document are solicited and will be accepted until September 22, 1997. Comments are to be submitted in triplicate, and also in electronic format (diskettes) if possible.

ADDRESSES: Comments are to be submitted to Dr. Frank H. Hund at the following address: Engineering and Analysis Division (4303), EPA, 401 M Street, S.W., Washington, D.C. 20460.

The data and analyses being announced today are available for review in the EPA Water Docket at EPA Headquarters at Waterside Mall, room M2616, 401 M Street, SW, Washington, DC 20460. For access to the Docket materials, call (202) 260–3027 between 9:00 a.m. and 3:30 p.m. for an appointment. A reasonable fee may be charged for copying.

FOR FURTHER INFORMATION CONTACT: For additional technical information, contact Dr. Frank H. Hund at the following address: Engineering and Analysis Division (4303), EPA, 401 M Street, S.W., Washington, D.C. 20460, telephone number (202) 260–7182. For information on economic impacts, contact Mr. William Anderson at the same address, telephone number (202) 260–5131.

SUPPLEMENTARY INFORMATION:

Contents of this Document

I. Summary of the CWA Regulatory Options Identified in the Maximum Achievable Control Technology (MACT) Standard Proposal and Purpose of This Notice

On May 2, 1995 (60 FR 21592), EPA proposed regulations to reduce discharges to navigable waters of toxic, conventional, and nonconventional pollutants in treated wastewater from the Pharmaceutical Manufacturing Category. In that proposed rule the Agency indicated that it would be proposing a Maximum Achievable Control Technology (MACT) standard for the Pharmaceutical Manufacturing Industry. Under the CAA on April 2, 1997 at 62 FR 15753, EPA proposed MACT Standards to control emissions of Hazardous Air Pollutants (HAPs) from storage tanks, process vents, equipment leaks and wastewater (the MACT proposal). In the preamble to the MACT proposal (62 FR 15760), EPA also indicated it was considering modifications to its effluent guidelines proposal of May 2, 1995 in order to avoid duplicative regulations.

For direct discharging fermentation (subcategory A) and chemical synthesis (subcategory C) facilities, EPA discussed changing its model BAT technology basis for Volatile Organic Pollutants (VOCs), which include many of the HAPs intended for control by the MACT Standards, from in-plant steam stripping followed by advanced biological treatment to advanced biological treatment. This change was based on the

fact that the MACT Standards control many of the wastestreams containing VOCs. Since the MACT Standards use steam stripping as the technology basis, certain costs previously associated with steam stripping in the effluent guidelines proposal are now being considered as part of the costs of the MACT Standards. However, for a small number of the wastewater streams that are not controlled by the MACT Standards, additional costs associated with steam stripping will be identified as costs resulting from compliance with the effluent limitations guidelines and standards.

For PSES, three modifications to the 1995 proposal were discussed. Option 1 would be compliance with the wastewater MACT Standards with the addition of some effluent monitoring. Options 2 and 3 were intended to control the additional discharge of VOCs not controlled by the MACT Standards. Option 2 would require compliance with the wastewater MACT Standards as well as compliance with additional pretreatment standards for volatile HAPs and non-HAPs not covered by the MACT Standards and basing the pretreatment standards on the MACT percent reduction approach. Option 3 would require the same compliance as Option 2 except that the additional pretreatment standards would be based on the performance database for the same control technology as the 1995 proposed PSES for VOCs. For the purpose of this notice, EPA has dropped Option 2 since it considers the data supporting Option 3 to be adequate for developing pretreatment standards, and has incorporated several scenarios into Option 3. Hereafter, the options being discussed include option 1 as discussed above and the option scenarios derived using Option 3.

Thus, the new PSES/PSNS option designations and descriptions are: Option 1—compliance with the MACT Standards plus some regular monitoring, Option 2—compliance with the MACT Standards plus additional PSES based on the performance database for the 1995 proposed PSES for all VOCs except alcohols and related pollutants, and Option 3—same as option 2 except the additional pollutants include alcohols and related pollutants. EPA has received numerous comments and data submissions concerning the 1995 proposal and in this notice, EPA is making these new data submissions available for comment and is providing a discussion of the results of analyses performed relating to specific issues raised by commenters. EPA will also solicit information and comments on a variety of other issues or questions.

II. Data Acquired Since the May 2, 1995 Proposal

Since the proposal, EPA has acquired a significant amount of data and information from the industry, and the Agency has included these new data and information in Section 13.1 of the supporting record of this Notice in order that the new data can be reviewed by interested parties. The Agency solicits comments based on reviews of these data. The new data submitted include: (1) Technology performance data for Biochemical Oxygen Demand (BOD_5), Chemical Oxygen Demand (COD), and Total Suspended Solids (TSS) for advanced biological treatment systems; (2) nitrification in biological treatment systems data for ammonia; (3) advanced biological treatment systems data for organic pollutants; (4) steam stripping performance data for volatile organic pollutants; and (5) technology performance data for treatment of cyanide. Below are summaries of each type of new data and the results of additional analysis of these data by the Agency.

A. Individual Plant Submissions

1. Biological and Advanced Biological Treatment Data (Biochemical Oxygen Demand (BOD_5), Chemical Oxygen Demand (COD), Total Suspended Solids (TSS) and Ammonia)

Additional BOD_5, COD, and TSS data were submitted with comments on the proposed CWA effluent limitations guidelines and standards from five facilities. The data from three of the facilities represent additional years of data that supplement the 1990 year data that were previously part of the best CWA technology performance database. Data from one other facility represent a new source of BOD_5, COD, and TSS performance data, while data from the fifth facility included only one data pair and were not included in the long-term means determination.

Performance data on ammonia nitrification from one facility were used as the basis of ammonia limitations at proposal. This facility has provided additional multi-year effluent ammonia data. Also since proposal, EPA has collected additional ammonia nitrification data from three other facilities. One facility did not show a period of consistent nitrification and data from this facility were therefore not included. The other new ammonia data from biological treatment have been added to the existing ammonia database.

In response to the various CWA proposal comments related to BOD_5, COD, TSS, and ammonia, EPA has incorporated the newly submitted data with the data used for the proposal and revised its proposed limitations for the various parameters. These revised limitations and, in some cases, alternate control levels are discussed further in Section II.B.1 below. EPA requests comments on the newly submitted data (see Notice Record Section 13.1.1).

2. Biological and Advanced Biological Treatment Organics Data

New organics biological treatment performance data were submitted with CWA proposal comments from six facilities. Four of these facilities represented performance of advanced biological treatment. Advanced biological treatment was defined in the CWA proposal as, ''treatment systems that consistently surpass, on a long-term basis, 90% BOD_5 reduction and 74% COD reduction in pharmaceutical manufacturing wastewater, as required by the existing BPT effluent limitations guidelines (40 CFR Part 439)''. The additional data include some information on 45 organic pollutants and describe the removal performance with respect to 16 of the pollutants for which limitations were proposed. Removal performance for the remaining 29 organic pollutants was not provided, however. In response to the various CWA proposal comments related to the proposed organics limitations, EPA has incorporated the newly submitted data with the data used for the proposal and has revised its proposal limitations for the various parameters. Those revised limitations and, in some cases, alternative control levels are discussed further in Section II.B.2 below. EPA requests comments on the newly submitted data (see Notice Record Section 13.1.2) and their use.

3. Steam Stripping Performance Data

New data representing the performance of steam stripping technology in removing volatile organic pollutants were submitted with CWA proposal comments by three facilities. The additional data reflect treatment by four stream strippers of 23 of the pollutants for which standards were proposed. In response to the CWA proposal comments related to steam stripping of volatile organics, EPA has incorporated the newly submitted data with the data used at proposal and revised its proposal pretreatment standards for the various parameters. These revised standards and, in some cases, alternate control levels are discussed in Section II.B.3. below. EPA

requests comments on the newly submitted data (see Notice Record Section 13.1.3) and their use.

4. Technology Performance Data for Cyanide

EPA received additional cyanide treatment performance data from three facilities. Two of these facilities use alkaline chlorination treatment and one of these facilities uses hydrolysis treatment. For one facility, the new data include the individual effluent data points corresponding to the facility's Section 308 Questionnaire average 1990 effluent cyanide concentration. For the second facility, the new data include (1) part of the raw 1990 data used in developing the facility's Section 308 Questionnaire average effluent cyanide concentration (the other part of the raw 1990 data used in the reported averages could not be located by the plant) and (2) additional 1994 cyanide destruction data. For the third facility, the new data include 1994 cyanide destruction data. In response to the CWA comments related to cyanide, EPA has incorporated the newly submitted data with the data used at proposal and revised its proposed limitations and standards for cyanide. These revised standards and, in some cases, alternate control levels are discussed in Section II.B.4. below. EPA requests comments on the newly submitted data (see Notice Record Section 13.1.4) and their use.

B. Data Editing Criteria and Limitations

After considering comments on the proposed CWA effluent limitations guidelines and standards, EPA has developed data editing criteria and methodologies for developing alternative limitations. The new data editing criteria and methodologies address comments on the proposed limitations; these comments and the approach(s) to respond to them are discussed below.

1. Biological and Advanced Biological Treatment Data (Biochemical Oxygen Demand (BOD_5), Chemical Oxygen Demand (COD), Total Suspended Solids (TSS) and Ammonia)

The data used in determining limitations for BOD_5, COD and TSS, were selected based on the following criteria which were discussed in the proposal. First, the treatment at the facility must qualify as advanced biological treatment as defined in section II.A.2. Next, the facilities must treat a majority (49% or more by volume) of pharmaceutical process wastewater in relation to other process wastewater. Finally, the treatment facilities must be representative of conventional treatment technologies. Using these criteria facilities were selected to provide data used in determining limitations for BOD_5, COD and TSS.

The data used in determining limitations for ammonia were selected based on biological nitrification. Facility input and nitrate levels helped to determine which facilities nitrified. Some of these facilities only experienced occasional nitrification. For these cases, the data representing nitrification were extracted from the data which did not. These data sets were used in determining limitations for ammonia.

EPA received several comments indicating that in developing the proposed BPT limitations on BOD_5, COD, and TSS, EPA did not take into account significant amounts of non-process water present in the effluent of some best performing facilities. In evaluating this comment, EPA has recalculated long-term means, limitations, and facility effluent concentrations for BOD_5, COD, and TSS from biological treatment using the following methodology. If 25% or more of the treated plant flow was non-process wastewater, then the non-process wastewater flow was assumed to be dilution water and the plant performance data were then reaveraged using the corrected parameter concentrations. The 25% or more non-process wastewater cutoff was chosen because dilution above this level would cause any concentration data reported to reflect too much uncertainty for the data to determine the performance of the technology used as a basis of effluent numerical limits. This is the same cutoff of acceptable dilution relied on in the Organic Chemicals, Plastics, and Synthetic Fibers (OCPSF) regulation.

In applying this methodology to best performers in the BPT database, EPA revised the performance from three facilities. The resulting limitations are less stringent than the proposed limitations and are presented in Table 1. These limitations would be converted to mass standards by the permit authority using the pharmaceutical process wastewater flow of the facility and not the end-of-pipe treatment flow. EPA requests comments on the newly calculated BPT limitations for BOD_5 and TSS, the newly calculated BAT limitations for COD and ammonia, and the methodology used to calculate them (see Notice Record Section 14.6.1).

TABLE 1.—LONG-TERM MEAN CONCENTRATIONS AND BPT AND BAT EFFLUENT LIMITATIONS

Pollutant parameter	Long-term mean concentration(mg/l)	BPT/BAT effluent limitations	
		Maximum for any one day (mg/l)	Monthly average (mg/l)
Subcategory A/C:			
BOD_5	125.0	647.0	202.0
COD*	951.0	2,150.0	1,210.0
TSS	347.0	1,980.0	594.0
Ammonia*	2.1	9.2	3.8
Subcategory B/D:			
BOD_5	13.7	64.4	21.1
COD*	72.4	282.0	110.0
TSS	33.8	164.0	52.4

*BAT Limitations.

2. Biological and Advanced Biological Treatment Organics Data

The data used in determining the BAT limitations for organic pollutants were selected based on the following criteria which were discussed in the proposal. First, the treatment at the facility must qualify as advanced biological treatment as defined in section II.A.2. Next, the facilities must treat a majority (49% or more by volume) of pharmaceutical process wastewater in relation to other process wastewater. Then, pollutant data sets must contain detected influent values which are greater than ten times the detection level of the pollutant in the effluent. In the proposal, data sets that showed influent levels of pollutants 10 times effluent levels were considered to show evidence of treatment. EPA excluded pollutant data sets which did not show pollutant removal through treatment or which had pollutant effluent values greater than influent values. Additionally, EPA excluded data sets which consisted of average pollutant influent values which were low (i.e., less than 10 times the long term mean of the effluent value for that pollutant), thus, did not represent technology performance. Finally, EPA received several comments stating that data sets with a small number of data points should not be used in limitations and standards development. Therefore, EPA excluded data sets with less than three data points. From these criteria, data were selected to be used in determining limitations for organic pollutants.

Several commenters on the CWA proposal indicate that in developing the proposed BAT limitations on nonconventionals, EPA did not take into

account significant amounts of non-process water present in the effluent of some best performing facilities. In evaluating this comment, EPA has recalculated long-term means, limitations, and facility effluent concentrations for nonconventionals from biological treatment using the following methodology. If 25% or more of the treated plant flow was non-process wastewater, then the non-process wastewater flow was assumed to be dilution water and the plant performance data were then reaveraged using the corrected pollutant concentrations.

The new candidate BAT limitations based on advanced biological treatment were developed using the data editing criteria listed above and incorporating the dilution water corrections. They are in Table 2. These limitations would be converted to mass standards by the permit authority using the pharmaceutical process wastewater flow of the facility and not necessarily the total end-of-pipe treatment facility discharge flow. EPA requests comments on the newly calculated candidate BAT limitations and the methodology used to calculate them (see Notice Record Section 14.6.2).

TABLE 2.—LONG-TERM MEAN CONCENTRATIONS AND BAT EFFLUENT LIMITATIONS

Pollutant code and pollutant name	Long-term mean concentration (mg/L)	BAT effluent limitations	
		Maximum for any one day (mg/L)	Monthly average (mg/L)
003—Acetonitrile	0.05	0.2	0.09
010—n-Amyl Acetate	0.3	1.1	0.5
011—Amyl Alcohol	1.1	3.7	1.8
012—Aniline	0.03	0.1	0.05
015—Benzene	0.002	0.009	0.004
025—2-Butanone (MEK)	0.04	0.2	0.08
026—n-Butyl Acetate	0.3	1.1	0.5
027—n-Butyl Alcohol	1.1	3.7	1.8
029—tert-Butyl Alcohol	1.1	3.7	1.8
035—Chlorobenzene	0.03	0.1	0.05
037—Chloroform	0.01	0.02	0.01
048—o-Dichlorobenzene	0.03	0.1	0.05
051—1,2-Dichloroethane	0.05	0.4	0.1
055—Diethylamine	0.01	0.05	0.02
060—N,N-Dimethylacetamide	0.01	0.05	0.02
062—N,N-Dimethylaniline	0.03	0.1	0.05
064—N,N-Dimethylformamide	0.01	0.05	0.02
066—Dimethyl Sulfoxide	0.05	0.2	0.1
067—1,4-Dioxane	0.8	8.4	2.6
070—Ethanol	1.1	3.7	1.8
071—Ethyl Acetate	0.3	1.1	0.5
077—Ethylene Glycol	1.1	3.7	1.8
079—Formaldehyde	0.3	1.2	0.5
080—Formamide	0.01	0.05	0.02
084—n-Heptane	0.005	0.02	0.009
087—n-Hexane	0.01	0.03	0.02
093—Isobutyraldehyde	0.3	1.2	0.5
094—Isopropanol	0.8	3.3	1.4
095—Isopropyl Acetate	0.3	1.1	0.5
096—Isopropyl Ether	0.8	8.4	2.6
097—Methanol	1.7	5.0	2.6
101—Methyl Cellosolve	1.1	3.7	1.8
102—Methylene Chloride	0.1	0.9	0.3
103—Methyl Formate	0.3	1.1	0.5
105—4-Methyl-2-Pentanone (MIBK)	0.1	0.4	0.2
113—Petroleum Naphtha	0.01	0.06	0.02
114—Phenol	0.01	0.05	0.02
115—Polyethylene Glycol 600	0.8	8.4	2.6
117—n-Propanol	1.1	3.7	1.8
118—Acetone	0.1	0.4	0.2
124—Pyridine	0.03	0.1	0.05
129—Tetrahydrofuran	0.8	8.4	2.6
130—Toluene	0.01	0.06	0.02
136—Triethylamine	0.01	0.05	0.02
139—Xylenes	0.005	0.02	0.01

3. Steam Stripping Performance Data

The steam stripping data used in determining the new candidate PSES limitations for volatile organic pollutants shown in Table 3 were selected based on the following criteria which also were discussed in the CWA proposal:

- All data point pairs with influent concentrations below detection limit were deleted;
- All data points that were collected from a flash tank or distillation pot were deleted;
- All data point pairs with a negative percent removal or that showed no removal after treatment were deleted;

- All data point pairs with an influent lower than the long term means shown in Table 3 were deleted;
- All data point pairs collected from a steam stripper with inadequate steam to feed ratios or an inadequate number of equilibrium stages in the stripper were deleted;
- Effluent concentrations that were reported below the detection limit were assumed to have a concentration equal to the detection limit; and
- Data which came from a single wastewater stream at one facility that was deemed to have an atypical matrix, i.e., did not lend itself to BAT performance, were not used. Similarly, other data points which were not considered representative of BAT technology performance were not used.

The data sets used in the development of the limitations are included in the record for this notice. The new candidate PSES (Table 3) are based on air stripping for ammonia and steam stripping for VOCs, and were developed using the data editing criteria listed above. EPA requests comments on the newly calculated candidate PSES and the methodology used to calculate them (see Notice Record Section 14.6.3).

TABLE 3.—LONG-TERM MEAN CONCENTRATIONS AND PSES EFFLUENT STANDARDS

Pollutant code and pollutant name	Long-term mean concentration (mg/L)	PSES effluent standards	
		Maximum for any one day (mg/L)	Monthly average (mg/L)
009—Ammonia as N	9.9	12.9	10.9
010—n-Amyl Acetate	4.1	20.7	8.2
011—Amyl Alcohol	11.8	47.4	20.6
012—Aniline	1,240	3,160	1,760
015—Benzene	0.2	3.0	0.6
025—2-Butanone (MEK)	121	1,440	430
026—n-Butyl Acetate	4.1	20.7	8.2
027—n-Butyl Alcohol	1,240	3,160	1,760
029—tert-Butyl Alcohol	11.8	47.4	20.6
035—Chlorobenzene	0.2	3.0	0.6
037—Chloroform	0.01	0.1	0.03
048—o-Dichlorobenzene	4.1	20.7	8.2
051—1,2-Dichloroethane	4.1	20.7	8.2
055—Diethylamine	4.1	20.7	8.2
062—N,N-Dimethylaniline	11.8	47.4	20.6
067—1,4-Dioxane	1,240	3,160	1,760
070—Ethanol	355	1,900	724
071—Ethyl Acetate	4.1	20.7	8.2
080—Formamide	11.8	47.4	20.6
084—n-Heptane	0.2	3.0	0.6
087—n-Hexane	0.2	3.0	0.6
093—Isobutyraldehyde	4.1	20.7	8.2
094—Isopropanol	11.8	47.4	20.6
095—Isopropyl Acetate	4.1	20.7	8.2
096—Isopropyl Ether	4.1	20.7	8.2
097—Methanol	1,240	3,160	1,760
101—Methyl Cellosolve	0.2	3.0	0.6
102—Methylene Chloride	0.2	3.0	0.6
103—Methyl Formate	4.1	20.7	8.2
105—4-Methyl-2-Pentanone (MIBK)	4.1	20.7	8.2
113—Petroleum Naphtha	1,240	3,160	1,760
117—n-Propanol	355	1,900	724
118—Acetone	4.1	20.7	8.2
124—Pyridine	43.1	569	163
129—Tetrahydrofuran	1.5	9.2	3.4
130—Toluene	0.1	0.3	0.1
136—Triethylamine	4.1	20.7	8.2
139—Xylenes	0.2	3.0	0.6

4. Technology Performance Data for Cyanide

Commenters indicated that the hydrogen peroxide technology basis used to determine the CWA proposal limitations and standards for cyanide when used to oxidize cyanide in certain mixtures containing organic synthesis waste products, could cause equipment explosions and accordingly raised plant safety concerns. Other commenters have indicated that the technology basis for cyanide limitations and standards should not be limited to hydrogen peroxide oxidation technology since it may not be appropriate to all cyanide treatment situations. In addressing these comments, EPA has reevaluated all of the cyanide destruction data in its data base. Data representing the performance of hydrogen peroxide, alkaline chlorination, and hydrolysis technologies were reevaluated from a performance standpoint. EPA has excluded from consideration those data sets that consist of only one data point pair and those datasets for which the influent or effluent cyanide concentrations are unknown. The Agency is developing two sets of possible limitations, the one based on hydrogen peroxide oxidation technology, and the other based on alkaline chlorination technology. EPA is considering promulgating two sets of limitations, one of these based on hydrogen peroxide technology would be used by the great majority of facilities.

Facilities with a potential safety hazard would be required to comply with limitations based on alkaline chlorination. We invite comments on parameters to define which cyanide limits would apply. Some commenters have suggested that cyanide wastestreams with high organic content as evidenced by high COD and TOC (total organic carbon) would be more appropriately controlled by limitations based on alkaline chlorination. EPA requests data to define these levels and any other data persons believe relevant to determining the performance and safety aspects of these technologies (see Notice Record Section 14.6.4).

Technology	Long-term mean concentration (mg/L)	Maximum for any one day (mg/L)	Monthly average (mg/L)
Hydrogen peroxide oxidation	0.24	0.8	0.4
Alkaline chlorination	4.8	22.9	9.8

C. EPA and PhRMA Sampling Results

In August of 1996, EPA and the Pharmaceutical Research and Manufacturers Association (PhRMA) conducted sampling at the Barceloneta POTW in Barceloneta, Puerto Rico. The purpose of the sampling visit was to obtain data on the removal of alcohols (methanol, ethanol and isopropanol) and other oxygenates in the primary treatment works of a POTW. Specifically, EPA was attempting to determine the extent to which these compounds volatilize in the grit chambers and primary clarifiers of a POTW prior to the secondary (biodegradation) treatment process. The Barceloneta POTW was selected for sampling because the influent of this POTW was known to contain measurable quantities of alcohols and other pollutants for which pretreatment standards were proposed in May, 1995. In addition to the wastewater sampling for the alcohols and other pollutants, EPA conducted a separate biodegradation study to determine the extent to which the alcohol pollutants were being aerobically biodegraded in the aerated grit chambers. Split samples were obtained by PhRMA representatives for some of the wastewater samples as well as the biodegradation samples. The data from this sampling episode are being considered by EPA in its pass-through determination for alcohols.

The results of the sampling study are summarized in Table 4 below. EPA sampling results indicate that most of the methanol is lost in the grit chambers through volatilization while most of the ethanol and isopropanol are lost through aerobic biodegradation. Based on an evaluation of the results of the sampling episode, EPA believes that the losses of the methanol, ethanol, and isopropanol in the primary treatment units are due to volatilization. In a follow-up study, PhRMA conducted an anaerobic biodegradation study on primary clarifier influent and has suggested that the losses of the alcohols in the primary clarifier may be due to anaerobic degradation either chemical or biochemical. In this study, PhRMA attempted to measure the decrease in alcohol concentration under anoxic (anaerobic conditions). EPA's analysis of these data indicates that the level of uncertainty connected with the analytical measurements is much greater than the differences in concentration of alcohol over time. EPA has included both study reports in the supporting documentation for this notice (see Notice Record Section 13.2.4) and solicits comments on both study reports.

TABLE 4.—PERCENT LOSSES OF ALCOHOLS IN PRIMARY TREATMENT

Pollutant	Average influent Mass, lbs	Average grit chamber effluent mass, lbs	Average primary clarifier effluent mass, lbs	Overall percent loss, primary treatment	Volatization loss, range EPA	Volatization loss, range PhRMA
Methanol	9,046	7,964	7,314	19.1	14.2–16.1	12.5–15.9
Ethanol	10,593	9,325	7,908	25.3	4.1–8.8	3.9–8.9
Isopropanol	5,054	4,756	4,476	11.4	0.0–5.1	0.0–3.9

Based on the results shown above, EPA believes that there is general agreement between the EPA results and the results measured by analyzing the samples obtained by PhRMA on the overall percentage losses through volatization of the three pollutants, methanol, ethanol, and isopropanol. The general ranges of volatization losses of these three pollutants are 12.5–16.1% for methanol, 3.9–8.9% for ethanol, and 0.0–5.1% for isopropanol. Results of the estimates of volatization for these three pollutants, along with those for four other VOCs (acetone, chloroform, methylene chloride, and toluene) were used to develop an alternative method of evaluating pass-through. The use of these results are discussed in Section II. B. below.

II. Analysis of Best Available Technology (BAT) and Pretreatment Standards for Existing Sources (PSES) Options Identified in the Maximum Achievable Control Technology (MACT) Proposal

In section seven of the preamble to the proposal (62 FR 15760), EPA identified options for controlling the load of VOCs not controlled by the proposed MACT wastewater standards. EPA outlined options for controlling the remaining load generated by direct and indirect dischargers. In Section I options were identified and modifications to them based on analysis subsequent to the MACT Standards proposal were described. In the sections that follow, the Agency will discuss in more detail the current status of these options, discuss the reasoning behind any modifications and provide preliminary information on annual cost estimate and loading removal results.

A. BAT Option

In the MACT proposal preamble, EPA indicated that in view of the MACT proposed wastewater standards, it was considering changing the BAT technology basis for subcategories A and C to advanced biological treatment only from in-plant steam stripping plus

advanced biological treatment. EPA believes that this revised approach is still appropriate and has estimated the annual costs to meet CWA requirements to be $3.8 million (1990 dollars). These costs represent a significant difference from the VOC control costs ($30.6 million, 1990 dollars) for the May 1995 proposed BAT option which included in-plant steam stripping costs. This decrease in costs is due simply to the fact that the main responsibility for VOC control and its costs at these facilities will be incurred under the CAA MACT rule. EPA has estimated that the removal of VOCs achieved by the proposed MACT wastewater standards and the BAT option currently being considered is of the same degree or greater than that achieved by the original proposed CWA option, alone.

The costs cited above (3.8 million 1990 dollars) associated with the effluent guidelines compliance with BAT for direct dischargers are mainly to achieve compliance with end-of-pipe organic limitations, but also contain some costs for cyanide, ammonia and COD control. These costs also include costs for two steam strippers for VOC control not controlled by the MACT Standards. The end-of-pipe long-term means used in the compliance cost estimation were developed after consideration of comments and newly received data and were discussed in greater detail in section B.2. of this notice.

B. PSES Analysis

EPA has received a significant number of comments on its pass-through analysis and its decision to propose regulations for water soluble organic compounds such as methanol and ethanol. In the 1995 CWA proposal, EPA performed a pass-through analysis on all pollutants for which regulations were proposed including the alcohols and other water soluble organic compounds using the BAT and POTW removal data available then. Since the proposal additional information has been obtained, including the Barceloneta sampling episode analysis results discussed above, and an alternative pass-through analysis has been conducted; these are discussed below.

1. Pass-Through

In performing its pass-through analysis for water soluble volatiles (e.g., methanol) and other pollutants prior to the proposal of the CWA pharmaceutical effluent limitations guidelines and standards, EPA compared the average pollutant removal achieved by well operated POTWs achieving secondary treatment (based on data available then) to the pollutant removal achieved by application of the proposed BAT technology. For the VOCs, including water soluble volatiles, the percent removal analysis did not use numerical percent removals since there were no data on actual treatment (biodegradation versus volatization). However, since volatization occurs in both BAT and POTW biological treatment systems, and since no data concerning the relative amounts of volatization in these systems were available, volatilization was assumed to be equal between the two for the purposes of the pass-through analysis done in 1995 to support the proposed CWA requirements. Some commenters on that proposal have indicated that EPA underestimated the amount of biodegradation of methanol and other water soluble pollutants, and overestimated the extent to which the pollutants volatilize in sewers, POTW headworks, and secondary treatment works. In order to address these and other comments concerning water soluble organic pollutants, EPA sampled the Barceloneta, Puerto Rico POTW which was discussed above in Section II.C. Additionally, EPA has received some data concerning the issue of volatization of water soluble organics and will be discussing these data below.

a. New Data Related to Pass-Through. Since proposal EPA has received and reviewed the results of computer-based modeling which attempted to simulate the behavior of water soluble organics in sewer systems, and has conducted modeling on the water soluble and other pollutants using data from the Barceloneta POTW study. The latter modeling efforts were conducted in order to obtain a realistic estimate of how much volatization of volatile organic pollutants occurs throughout the entire POTW system. The computer modeling study report entitled ''Emissions of High-Solubility VOCs from Municipal Sewers'' is part of the supporting record for this notice (see Notice Record Section 13.1.5). The results of this study indicate that volatilization of methanol and ethanol in closed sewers is expected to be minimal with maximum emission rates of 0.03 and 0.19% being projected under most sewer conditions. However, under open sewer conditions, volatilization percentages of methanol and ethanol could be as high as 6.5 and 20%, respectively.

Using the influent concentration data obtained from the Barceloneta, PR sampling visit, EPA has modeled the relative degrees of volatilization and biodegradation in the overall treatment works of this plant. EPA's modeling results using the WATER8 model program and its biodegradation and volatization rate constants are shown below in Table 5.

TABLE 5.—WATER 8 MODELING RESULTS FOR PRIMARY AND SECONDARY TREATMENT

[In percent]

Pollutant	Volatization in primary	Biodegradation in primary	Volatization in secondary	Biodegradation in secondary	Overall volatization	Overall biodegradation
Methanol	2.1	0.0	2.0	90.8	4.0	90.5
Ethanol	2.2	0.0	0.5	97.7	2.7	92.9
Isopropanol	4.2	0.0	10.8	74.0	14.3	77.0
Acetone	8.0	0.0	3.2	94.9	10.7	84.8
Chloroform	40.9	0.0	58.7	40.5	71.2	23.9
Methylene Chloride	38.9	0.0	70.4	28.6	78.2	17.8
Toluene	46.1	0.0	36.9	62.7	60.4	32.4

Note: Volatilization and biodegradation percentages may not add up to 100% since some of the compound remains in the effluent and some goes out with the sludge.

Results of this modeling for methanol, ethanol, and isopropanol shows less volatization in the primary treatment portion than the empirical data from the Barceloneta POTW sampling shown in Table 4.

b. Possible Alternative Pass-Through Analysis. EPA has conducted a pass-through analysis for all pollutants which are considered to be candidates for regulation at this time by comparing well operated secondary treatment POTW median percent removals with the BAT percent removals. This method of conducting the pass-through analysis includes the volatization in the percent removals and assumes that they are equal for both POTW and BAT removal processes. The results of this analysis, using a strict comparison of removal percentages, indicate that 33 pollutants pass through POTWs. Nonetheless, while this analysis may be appropriate for moderately soluble volatile organics such as chloroform, methylene chloride, and toluene, where volatization rates at POTWs are higher (see Table 5 results), the analysis may not be appropriate for biodegradable water soluble volatile organics mentioned earlier in the previous section. The assumption that the BAT and POTW volatization percentages are equal may not be accurate for these pollutants. It is possible that the BAT volatization could be greater than POTW volatization due to higher influent concentrations at pharmaceutical facility treatment works, and, as a result, some or all of these compounds may not be determined to pass through the POTW. However, given the higher biodegradability of the water soluble volatile compounds, its expected that the biodegradation will be the predominant removal pathway in biological and advanced systems at both POTWs and direct discharger BAT plants and, thus, one could conclude that these compounds do not pass-through. Additionally, EPA has identified other pollutants for which it has proposed pretreatment standards that have lower Henry's law constants (less tendency to volatilize than acetone) which along with the alcohols in question may or may not pass through POTWs. These pollutants are formamide, N,N-dimethylaniline, pyridine, 1,4 dioxane, aniline and petroleum naphtha. Consequently, the Agency is contemplating incorporation of the alcohol pass-through scenarios into the options selection for the final rule. EPA requests data from any BAT level direct dischargers regarding volatization of these compounds in their biological treatment system, especially in the primary portion of their facility. EPA also solicits comment on the differences between the Water8 model results and the empirical data in estimating volatization and biodegradation in the primary portion of biological treatment works and on the use of these results in the pass-through analysis (Section 14.14).

2. Preliminary Costs and Loading Removals Assuming Two Different Pass-Through Scenarios for Modified Options

Based on the use of the alternate pass-through analysis approaches, EPA has developed compliance cost and pollutant removal estimates for two categorical pretreatment options, one involving regulation of alcohols and related pollutants and the other with no regulation of alcohols and related pollutants via categorical pretreatment standards. The alcohols and related pollutants in question are methanol, ethanol, n-propanol, isopropanol, n-butyl alcohol, tert-butyl alcohol, amyl alcohol, formamide, N,N-dimethylaniline, pyridine, 1,4-dioxane, aniline, and petroleum naphtha. For Option 2, under which alcohols and related pollutants would not be regulated under PSES, EPA estimates annual compliance costs of $40.0 million (1990 dollars) for A/C subcategory facilities and organic pollutant removals of 6.9 million pounds per year. For B/D subcategory facilities EPA estimates annual compliance costs of $8.4 million and organic pollutant removals of 3.3 million pounds per year. For Option 3, where alcohols and related pollutants would be regulated, EPA estimates annual compliance costs of $44.6 million for A/C subcategory facilities and organic pollutant removals of 11.9 million pounds per year. For B/D subcategory facilities, EPA estimates annual compliance costs of $10.8 million per year and organic pollutant removals of 5.4 million pounds per year.

Several commenters suggested that EPA exclude small facilities based on their flow and concentration from categorical pretreatment standards. While EPA has not decided whether it is appropriate to exclude small facilities from these categorical pretreatment standards, because the economic analysis for the final rule will be redone and may show increased economic impacts on small facilities when completed, EPA has conducted two alternative cost scenarios under which small facilities would be excluded from PSES for VOCs. If small facilities (those that discharge less than 10,000 lbs per year of regulated pollutants) are excluded from these pretreatment standards, the Option 2 annual compliance costs are $36.5 million and 6.5 million pounds per year for A/C subcategory facilities and $5.0 million and 2.6 million pounds per year for subcategory B/D facilities. The Option 3 costs and removals for non-excluded A/C facilities are $40.7 million and 11.5 million pounds per year while the costs and removals for non-excluded B/D facilities are $6.6 million and 4.1 million pounds per year. EPA estimates that assuming the 10,000 pound per year cut-off, 34 A/C facilities and 67 B/D facilities would be excluded from pretreatment standards for organic pollutants. The cost and removal information is summarized in Table 6 below.

TABLE 6.—PSES COSTS AND REMOVALS

Option/subcategory	Scenario	Total annual costs (million/yr)	Total annual organics removal million lbs/yr
2/A/C	No small plant exclusion	$40.0	6.9
2/A/C	34 small plants excluded	36.5	6.5
3/A/C	No small plant exclusion	44.6	11.9
3/A/C	34 small plants excluded	40.7	11.5
2/B/D	No small plants exclusion	8.4	3.3
2/B/D	67 small plants excluded	5.0	2.6
3/B/D	No small plants exclusion	10.8	5.4
3/B/D	67 small plants excluded	6.6	4.1

The costing methodology used as well as the individual plant cost estimates may be found in Section 14.8 of the supporting documentation for this notice. The long-term mean concentrations used to calculate

pollutant removals may also be found in the supporting documentation. Individual facilities are encouraged to examine the input data used to make cost and loadings estimates for their facility and verify their accuracy based on 1990 Questionnaire responses.

IV. Results of Analyses of Pre-Proposal and Newly Acquired Data With Respect to Various Comment Issues

Since proposal the Agency has been evaluating comments made with respect to various regulatory issues and analyzing existing and newly submitted data in the context of the proposal comments. As a result of these analyses, EPA is considering approaches on specific issues that differ from the positions taken by EPA at proposal. The issues and new approaches to them are discussed below. A more complete discussion of the analyses performed with respect to each issue may be found in the supporting documentation for this notice.

A. New Source Performance Basis

EPA received comments on its subcategory A/C new source performance standards for the pollutant parameters BOD^5, COD and TSS which are based on the performance data from one facility. The commenters indicated that the production range of this facility is too narrow to adequately represent new source A/C facilities. In response to this comment, EPA is reassessing the Subcategory A/C NSPS for BOD_5, COD, and TSS using data from two best performer facilities (Facility 30701 and Facility 31121). EPA is also reassessing the Subcategory C NSPS for BOD_5, COD, and TSS that would be based on activated carbon pretreatment of Subcategory C wastewaters only, followed by advanced biological treatment. EPA requests comment on the appropriateness of using the additional plant data.

B. Ammonia Limitations and Standards

EPA has received additional ammonia treatment performance data representative of steam stripping and biological nitrification technologies. With respect to the proposed BAT ammonia limitations, EPA is evaluating revised limitations based on an expanded nitrification database. The Agency is costing two stage nitrification for those facilities with 1990 Questionnaire response data which indicate an end-of-pipe ammonia as N (Nitrogen) concentration above the long-term mean developed from the expanded database. EPA has converted the ammonium hydroxide loadings data from the 1990 Questionnaire into an ammonia as N end-of-pipe concentration for this purpose.

At proposal, EPA developed a PSES for ammonia for indirect A/C facilities based on air stripping performance data. In the proposal preamble, the Agency indicated that they believed that steam stripper treatability performance would be as good as or better than the demonstrated air stripping performance. Newly submitted steam stripping performance data for ammonia as N (Nitrogen) supports this belief and shows better performance and lower effluent concentrations than the air stripping data used to develop the proposed PSES (see Section 13.1.3 of the Record). Therefore, EPA does not currently intend to revise the proposal. EPA solicits comment on the new BAT nitrification data.

The BAT technology basis for controlling ammonia is nitrification at biological or advanced biological treatment systems and some POTWs with biological or advanced biological treatment have nitrification. Accordingly, EPA is requesting comments on its intention to allow the pass-through analysis to consider whether nitrification is part of the POTW technology in determining whether ammonia discharges from pharmaceutical industrial users pass-through POTWs. Additionally, EPA is requesting information from pharmaceutical facilities with higher current ammonia loadings than were shown in their 1990 questionnaire responses and information from facilities on the availability of land for two-stage nitrification treatment. (See Sections VI C and D.)

C. Pollutant Exclusions

EPA received several comments questioning the reasoning behind the regulation of certain pollutants as well as the overall rationale for selecting pollutants for regulation. Other commenters indicated that EPA was regulating too many pollutants. In response, EPA has reviewed the loadings bases for all of the pollutants selected for regulation and has determined that in the case of eight pollutants, insufficient amounts of the pollutants are being discharged to justify national regulation. These pollutants are diethyl ether, cyclohexane, chloromethane, dimethylamine, methylamine, furfural, 2-methylpyridine and trichlorofluoromethane. EPA's revised pollutants to regulate analysis is presented in Section 14.4 of the record for this rule.

D. Use of Surrogate Pollutants

In an effort to respond to comments concerning excessive monitoring for regulated organic pollutants, EPA is considering permitting facilities that discharge more than one regulated organic pollutant be allowed to monitor for surrogate pollutants. Plants would be allowed to monitor for a surrogate pollutant(s) only if they certify that the other pollutants are receiving the same degree of treatment as the surrogate pollutant(s) and all of the pollutants discharged are in the same treatability class(s) as the surrogate pollutant(s). Treatability classes have been identified for both steam stripping and biological treatment technologies, the PSES and BAT technology bases for limitations controlling the organics. Individual plants may choose to certify by selecting a pollutant for monitoring in a given treatability class and providing documentation for approval by the permit or pretreatment authorities that the other pollutants in that treatability class are treated to the same extent as the monitored pollutant. This documentation should include appropriate engineering documentation that demonstrates that all of the regulated pollutants in a given treatability class are being treated using identical treatment. The permit or pretreatment authorities may require the surrogate pollutant to be the pollutant present in the highest concentration. EPA has also developed a list of surrogate pollutants for guidance for the permit or pretreatment authority based on the following criteria: (1) the number of facilities discharging the pollutant, i.e., the larger the number of facilities discharging the pollutant, the more appropriate would be its use as a surrogate; (2) the total quantity of a pollutant discharged, i.e., the more a pollutant is discharged the more suitable it is for use as a surrogate, and (3) the number of streams containing a pollutant, i.e., the more streams containing a pollutant, the more suitable for use as a surrogate. Both the treatability classes and the suggested surrogate pollutants are presented in Tables 7 and 8.

TABLE 7.—POTENTIAL SURROGATES FOR DIRECT DISCHARGERS (BIOTREATMENT)

Compound	Number of facilities reporting constituent	Quantity discharged (lbs/yr)
Alcohols		
Ethanol	**97**	**6,802,384**
Isopropanol	**85**	**4,565,370**
Methanol	**82**	**15,388,273**
n-Butyl alcohol	18	675,189
Phenol	12	10,974
Ethylene glycol	10	225,188
Amyl alcohol	6	197,635
tert-Butyl alcohol	5	121,408
n-Propanol	5	12,238
Aldehydes		
Formaldehyde	**27**	**334,527**
Isobutyraldehyde	2	35,659
Alkanes		
n-Heptane	**12**	**28,044**
n-Hexane	**9**	**11,265**
Petroleum naphtha	3	261,137
Amides & Amines		
N,N-Dimethylformamide	**22**	**494,837**
Triethylamine	**15**	**633,225**
N,N-Dimethylacetamide	7	1,046,333
Diethylamine	7	219,374
Formamide	4	7,544
Aromatics		
Toluene	**43**	**783,364**
Xylenes	**14**	**53,724**
Pyridine	10	212,581
Chlorobenzene	4	5,616
Aniline	4	4,603
o-Dichlorobenzene	2	21,499
N,N-Dimethylaniline	2	19,155
Benzene	1	121,400
Chlorinated Alkanes		
Methylene chloride	**47**	**3,590,640**
Chloroform	**17**	**409,317**
1,2-Dichloroethane	**6**	**27,559**
Esters & Ethers		
Ethyl acetate	**27**	**390,584**
Tetrahydrofuran	**17**	**478,669**
Isopropyl acetate	9	184,550
Polyethylene glycol 600	8	31,219
1,4-Dioxane	6	24,927
n-Amyl acetate	5	293,408
Isopropyl ether	5	12,387
n-Butyl acetate	3	512,926
Methyl formate	3	157,727
Ketones		
Acetone	**55**	**4,573,766**
MIBK	9	635,677
2-Butanone (MEK)	**4**	**17,426**
Miscellaneous		
Ammonia (aqueous)	**32**	**1,365,741**
Acetonitrile	**16**	**433,041**
Dimethyl sulfoxide	**14**	**753,157**
Methyl cellosolve	**4**	**758,637**

Notes: Compounds in bold represent the surrogate parameters for each individual category. Miscellaneous compounds have no particular surrogate compound identified. Compounds sorted in order of # of facilities reporting constituent, in each individual category.

TABLE 8.—POTENTIAL SURROGATES FOR INDIRECT DISCHARGERS (STEAM STRIPPING)

Compound	Number of facilities reporting constituent	Quantity discharged (lbs/yr)	Henry's law constant (atm/gmole/m^3)
High Strippability			
Methylene chloride	**47**	**3,590,640**	**2.68E–03**
Toluene	**43**	**783,637**	**5.93E–03**
Chloroform	**17**	**409,317**	**3.39E–03**
Xylenes	14	53,724	5.10E–03
n-Heptane	12	28,044	2.8E+00
n-Hexane	9	11,265	1.55E+00
Methyl cellosolve	**4**	**758,637**	**2.90E–03**
Chlorobenzene	4	5,616	3.93E–03
Benzene	1	121,400	5.55E–03
Medium Strippability			
Acetone	**55**	**4,573,766**	**3.67E–05**
Ammonia (aqueous)	**32**	**1,365,741**	**3.28E–04**
Ethyl Acetate	**27**	**390,584**	**1.20E–04**
Tetrahydrofuran	**17**	**478,669**	**1.10E–04**
Triethylamine	**15**	**633,225**	**1.38E–04**
MIBK	9	635,677	9.40E–05
Isopropyl acetate	9	184,550	3.17E–04
Diethylamine	7	219,374	1.10E–04
1,2-Dichloroethane	6	27,559	1.10E–03
n-Amyl acetate	5	293,408	3.91E–04
Isopropyl ether	5	12,387	2.24E–03

TABLE 8.—POTENTIAL SURROGATES FOR INDIRECT DISCHARGERS (STEAM STRIPPING)—Continued

Compound	Number of facilities reporting constituent	Quantity discharged (lbs/yr)	Henry's law constant (atm/gmole/m^3)
2-Butanone (MEK)	4	17,426	4.36E–05
n-Butyl acetate	3	512,926	4.68E–04
Methyl formate	3	157,727	8.10E–05
Isobutyraldehyde	2	35,659	1.47E–04
o-Dichlorobenzene	2	21,499	1.94E–03
Low Strippability			
Ethanol	**97**	**6,802,384**	**6.26E–06**
Isopropanol	**85**	**4,565,370**	**8.07E–06**
Methanol	**82**	**15,388,273**	**2.70E–06**
N-Butyl alcohol	18	675,189	5.57E–06
Pyridine	10	212,581	5.30E–06
Amyl alcohol	6	197,635	2.23E–05
1,4-Dioxane	6	24,927	4.88E–06
tert-Butyl alcohol	5	121,408	1.17E–05
n-Propanol	5	12,238	6.85E–06
Methylamine	4	23,717	1.11E–05
Formamide	4	7,544	1.92E–05
Aniline	4	4,603	2.90E–06
Petroleum naphtha	3	261,137	2.70E–06
N,N-Dimethylaniline	2	19,155	1.75E–05

Notes: Compounds in bold represent the surrogate parameters for each individual category. Compounds sorted in order of number of facilities reporting constituents, in each individual category.

EPA solicits comment on these surrogate pollutant approaches, the suggested surrogate pollutants, the biotreatment and steam stripping treatability classes presented in Tables 7 and 8, what type of POTW and permit approval process is necessary and an estimate of the amount of burden hours (costs) the suggested approach would take in developing and certifying the necessary documentation and for POTW/permit authority approval.

E. Small Facility Exclusion

As noted in the preceding section, based on comments on the CWA proposal and the potential for some economic impact from the costs associated with the combination of the MACT Standards and Effluent Limitations Guidelines and Standards, EPA has identified two groups of facilities in the A (Fermentation) and C (Chemical Synthesis) subcategories and B (Natural Extraction) and D (Formulation) subcategories which are smaller waste load dischargers. These facilities discharge less than 10,000 pounds of organic pollutants per year. In the options presented in the preceding section, EPA has presented PSES approaches which exclude 34 Subcategory A/C and 67 Subcategory B/D facilities from PSES.

F. Changes in Engineering Cost and Load Removal Estimates

The Agency has made several changes to the cost model used to calculate costs and loading removals for the pharmaceutical manufacturing effluent guidelines based on proposal comments and new data. These changes are detailed in the ''Post-proposal Documentation Report for the Pharmaceutical Manufacturing Industry Engineering Cost Model'' which is located in Section 14.8 of the record for this notice. A summary of the major cost model changes follow.

EPA has re-evaluated the unit costs used in the cost model at proposal. EPA has incorporated additional unit cost data related to steam, electrical, labor, and steam stripper overheads disposal costs submitted with proposal comments. EPA has also incorporated separate steam and electrical costs for domestic plants and plants in Puerto Rico.

EPA has modified the biological treatment module to change the sequence of design to design BAT first, and BPT, second. EPA has also modified this module to account for MACT Standards removals for the CWA pollutants of concern. For those facilities that were identified during the development of the MACT Standards proposal as requiring control, pollutant load removals from the MACT Standards have been subtracted out prior to assessing the costs and removals for facilities subject to the effluent guidelines and standards. EPA has also modified the biological treatment cost module to assess facility end-of-pipe concentrations after correcting for non-process dilution wastewaters. In addition, EPA has modified the biological treatment module to cost for two-stage nitrification where ammonia treatment is deemed necessary.

EPA has modified the steam stripping module to incorporate a revised approach for determining stream characteristics. At proposal, the cost model utilized data from the 1990 Detailed Questionnaire from Table 3–2 (pollutant loadings) and from Table 4–8 (process area stream data). EPA has revised the steam stripping module to incorporate the Table 3–2 pollutant loadings data and distribute the process wastewater flow and load according to the disaggregation approach used in the MACT Standards. Under this approach, it is assumed that pharmaceutical process wastewaters can be represented by four streams with the following breakdown in percent flow and load:

[In percent]

	Pollutant load	Process wastewater flow
Stream 1	1	44
Stream 2	2	9
Stream 3	6	19
Stream 4	91	28

For those facilities that were identified in the work on the MACT proposal as requiring control, pollutant load removals associated with the MACT Standards and costs for steam stripping at these facilities have been subtracted out prior to assessing the facility need for control of any remaining VOCs by effluent guidelines and standards. After application of the MACT Standards, EPA determined that additional control is required under the effluent guidelines. Steam strippers are costed starting with control of the most concentrated streams, until end-of-pipe concentrations meet the long-term means developed from EPA's steam stripping performance database. In addition, based on proposal comments, EPA has re-evaluated the steam stripper component pieces that should be costed and is including costs for the following additional steam stripping equipment: an overheads distillate pump, a distillate receiver tank, and a bottoms pump.

EPA has revised the cyanide destruction cost module to allow for

alkaline chlorination treatment for those facilities where hydrogen peroxide treatment cannot be used due to safety considerations. For facilities whose 1990 Detailed Questionnaire data indicate that the facility is not in compliance with the cyanide treatment long-term means, EPA costed a treatment system upgrade, wastewater storage, and monitoring costs. For facilities whose 1990 Detailed Questionnaire data indicate that the facility is in compliance with the cyanide treatment long-term means, treatment system upgrades are not required but wastewater storage and analysis costs were developed to make certain that compliance is met by the approved cyanide method.

EPA has revised the wastewater compliance monitoring cost module to reflect the change from in-plant standards to end-of-pipe standards for all pollutants (except cyanide). In addition, EPA has gathered updated analysis costs for the proposed analytical methods.

V. Discussion of Pollution Prevention Approach

EPA discussed pollution prevention in the preamble of the proposed CWA effluent guidelines and standards and in the proposed technical development document. EPA is interested in incorporating pollution prevention into this regulation wherever possible and welcomes pollution prevention suggestions. Since proposal, the Agency has received suggestions regarding relief from or waivers of effluent limitations and standards in connection with pollution prevention programs which result in the reduction or elimination of pollutant use at a facility. One suggestion presented to the Agency was that Subcategory B/D dischargers that incorporate best management practices (BMPs), which reduce their discharge of any of the regulated pollutants should not have to monitor for the specific regulated pollutants, and possibly only monitor for the conventional pollutants and COD. This pollution prevention approach is similar to the one adopted in the Pesticide Formulators, Packagers and Repackagers (PFPR) final regulation which was published in the **Federal Register** on November 6, 1996 at 61 FR 57518. It should be noted that PFPR facilities that use the promulgated pollution prevention option will have to assess their wastewater and put in appropriate treatment before any wastewater can be discharged.

Another pollution prevention approach suggested to EPA was that Subcategory A/C facilities that can demonstrate a reduction in the use of a regulated pollutant and resultant lowered emissions/discharges to all media (i.e., less non-water quality environmental impacts) should receive a higher effluent discharge limitation. As suggested, the higher effluent discharge limitation would be directly proportional to the amount of reduction achieved in the use of the regulated pollutant.

More detailed discussion about each approach may be found in the supporting documentation for this notice (see Notice Record Section 19.2). Although EPA is interested in incorporating pollution prevention into regulations wherever possible, the Agency has concerns about the identification of benchmarks or reward criteria for the above suggested approaches. EPA invites comments on both suggested approaches, as well as information on any additional pollution prevention-based suggestions.

VI. Solicitation of Data and Comments

In addition to soliciting comments and data relating to any of the material presented in this notice, EPA is specifically interested in receiving comments and data regarding a number of specific issues which are discussed below. In commenting or providing data with respect to a specific issue, commenters should refer to the specific issue which the comments address.

A. Determination of the Pass Through for Water Soluble Pollutants for POTWs With Covered Headworks and Primary Tanks or Demonstrating Less Than 5% Volatilization

EPA is considering providing in the categorical pretreatment standards that if a POTW covers or encloses its headworks and primary tanks or the POTW can demonstrate that less than 5% volatilization of water soluble organics such as methanol occurs during the treatment process that no pass-through of water soluble organics occurs for their pharmaceutical industrial users. In order to be able to determine that pass-through does not occur for a water soluble pollutant, the POTW must have its primary treatment works covered or enclosed or must demonstrate through appropriate sampling and analyses that volatilization of less than 5% of a specific water soluble pollutant is occurring. This sampling and analysis must follow the sampling protocols used in the EPA Barceloneta POTW study discussed previously in this notice and use 40 CFR part 126 approved analytical methods. EPA requests comments and data regarding the use of specific POTW criteria for the pass-through determination for water soluble organics.

B. Determination of Pass-through at POTWs with Nitrification

EPA is aware that certain POTWs which treat pharmaceutical discharges possess nitrification capability. New data from a POTW with nitrification were received as part of comments on the CWA proposal and are included in the record (Section 13.1.5.) In order to more accurately determine whether pass-through occurs, the Agency is considering providing in the categorical pretreatment standards that ammonia does not pass-through at POTWs with nitrification. EPA requests comments on this POTW specific pass-through determination for ammonia.

C. Information From Facilities With Higher Ammonia Loadings Than Were Shown in Their 1990 Questionnaire Responses

In the 1990 Detailed Questionnaire, facilities supplied ammonium hydroxide (aqueous ammonia) loadings data in Table 3–2. EPA has converted these loadings data to an ammonia as N effluent load and concentration to assess facility compliance with the proposed ammonia long-term means. EPA is specifically requesting effluent ammonia as N concentration data (including the supporting analytical reports) from those facilities whose effluent ammonia as N loadings are higher than those calculated from the reported ammonium hydroxide loads in the 1990 questionnaire in Table 3.2. The data may be for any time period after 1989 including 1990 if these data indicate higher loadings than were reported in the facilities questionnaire response.

D. Information on Land Availability for Two-Stage Nitrification Treatment

EPA is requesting information from direct discharging facilities that would be subject to ammonia limitations about the availability of land on site for the construction of two-stage nitrification treatment. Plants that claim that land for two-stage nitrification is not available should provide sufficient documentation in the form of plant property plans and other information with their comments. Plants for which land for two stage nitrification is available should provide information concerning any difficulties or problems they expect to encounter with the installation of two-stage nitrification at their facilities.

E. Information From Subcategory B/D Facilities on Number of Operating Days per Week

EPA is requesting information from Subcategory B/D facilities concerning the number of days per week of operation at these facilities (does the facility operate five days per week or seven days per week.) The Agency needs this information in order to perform accurate compliance cost estimates and economic impact analyses. Subcategory B/D facilities should supply this information as well as facilities whose hours of operation have changed since 1990.

F. Proposed Exclusion for Organic Chemicals, Plastics, and Synthetic Fibers (OCPSF) Manufacturers of Bulk Pharmaceutical Intermediates and Active Ingredients With Less Than 50% Pharmaceutical Wastewater

EPA requests comment on the exclusion of organic chemical manufacturers covered by the OCPSF regulation (40 CFR 414) that manufacture pharmaceutical intermediates and active ingredients from the final pharmaceutical regulation provided that the pharmaceutical portion of the process wastewater is less than 50 percent of the total process wastewater. The Agency believes it may not be necessary to cover the pharmaceutical wastewater at these facilities because most of the pollutants that would be controlled by pharmaceutical limitations and standards are already being controlled by the OCPSF limitations and standards. The pollutants found in pharmaceutical facility discharges and not specifically regulated such as some of the water soluble organics by the OCPSF regulations are either not present in wastewaters being discharged from the type of pharmaceutical operations occurring at these facilities or are well treated by the biological treatment systems found at these facilities or their POTWs. The Agency emphasizes that any process wastewater covered by such an exclusion must be covered by OCPSF effluent limitations guidelines and standards. EPA requests comments concerning such an exclusion and any information regarding the bases that EPA has suggested to justify an exclusion for these facilities.

G. Wastewater From Pilot Plant Operations

EPA has received a number of comments on its proposal to consider wastewater from pilot plant operations as production wastewater and not as subcategory E (Research) wastewater. The Agency solicits comments specifically from facilities that will experience difficulty with having to treat pilot plant wastewater with their normal production wastewater. EPA is specifically interested in learning details of the problems that might be encountered in complying with the proposal definition of pilot plant wastewater.

H. Basis for Determining Which Cyanide Standards Apply

EPA has developed two sets of cyanide limitations and standards based on hydrogen peroxide oxidation and alkaline chlorination technologies. The Agency is requesting suggestions from commenters concerning what parameter levels describing cyanide wastestreams should be used to determine which standards are appropriate. Individual commenters have suggested that cyanide wastestreams with high organic content as evidenced by high COD and TOC (total organic carbon) would be more appropriately controlled by standards based on alkaline chlorination. EPA invites information and comments concerning the parameters and levels which could determine which set of standards will be appropriate for individual facilities.

Dated: August 1, 1997.

Robert Perciasepe,

Assistant Administrator for Water.

[FR Doc. 97–20979 Filed 8–7–97; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 721

[OPPTS–50620C; FRL–5735–3]

RIN 2070–AB27

Butanamide, 2,2′-[3′dichloro[1,1′-biphenyl]-4,4′-diyl) bisazobis N-2,3-dihydro-2-oxo-1H-benximdazol-5-yl)-3-oxo-; Proposed Significant New Use Rule; Extension of Comment Period

AGENCY: Environmental Protection Agency (EPA).

ACTION: Extension of comment period.

SUMMARY: EPA is extending the comment period for the proposed significant new use rule (SNUR) for butanamide, 2,2′-[3′,dichloro[1,1′-biphenyl]-4,4′-diyl)bisazobis *N*-2,3-dihydro-2-oxo-1H-benximdazol-5-yl)-3-oxo-. As initially published in the **Federal Register** of June 26, 1997 (62 FR 34424) (FRL–5723–4), the comments were to be received on or before July 28, 1997. One commenter requested additional time to research and submit comments. EPA is therefore extending the comment period 30 days in order to give all interested persons the opportunity to comment fully.

DATES: Written comments must be submitted to EPA by August 27, 1997.

ADDRESSES: Each comment must bear the appropriate docket control number OPPTS–50620B. All comments should be sent in triplicate to: OPPT Document Control Officer (7407), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Rm. G–099, East Tower, Washington, DC 20460.

Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: oppt-ncic@epamail.epa.gov. Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comments and data will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by (OPPTS–50620B). No confidential business information (CBI) should be submitted through e-mail. Electronic comment on this document may be filed online at many Federal Depository Libraries.

All comments which are claimed confidential must be clearly marked as such. Three additional sanitized copies of any comments containing CBI must also be submitted. Nonconfidential versions of comments on the proposed rule will be placed in the rulemaking record and will be available for public inspection.

FOR FURTHER INFORMATION CONTACT: Susan B. Hazen, Director, Environmental Assistance Division (7408), Office of Pollution Prevention and Toxics, Environmental Protection Agency, Rm. E–543B, 401 M St., SW., Washington, DC 20460, telephone: (202) 554–1404, TDD: (202) 554–0551; e-mail: TSCA-Hotline@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: This extension of the comment period will allow interested parties who intend to comment on the proposed rule additional time to consider their response.

List of Subjects in 40 CFR Part 721

Environmental protection, Chemicals, Hazardous materials, Recordkeeping and reporting requirements.