

## SECTION 12

### NONWATER QUALITY ENVIRONMENTAL IMPACTS

#### 12.1 Introduction

Sections 304(b) and 306 of the CWA require EPA to consider the nonwater quality environmental impacts associated with effluent limitations guidelines and standards. In accordance with these requirements, EPA has considered the potential effect of the final regulatory options for the pharmaceutical manufacturing industry on energy consumption, air emissions, and solid waste generation. Sections 12.2, 12.3, and 12.4, respectively, discuss these nonwater quality environmental impacts. The Agency's development of air emission standards is discussed in 12.5.

#### 12.2 Energy Impacts

Energy impacts to the pharmaceutical manufacturing industry from the final regulatory options will include increased electrical usage and increased energy usage in the generation of steam for steam stripping. These energy impacts are discussed below in Sections 12.2.1 and 12.2.2.

##### 12.2.1 Electrical Usage

According to the Department of Energy, the pharmaceutical manufacturing industry purchased approximately  $5,404 \times 10^6$  kWh of electrical energy in 1990, accounting for 0.7% of the total U.S. industrial electrical energy purchase ( $756,646 \times 10^6$  kWh) in 1990.(1) The Agency evaluated the annual incremental increase in electrical power consumption expected under each regulatory option for direct dischargers. These estimated annual incremental increases (in kWh) are shown in Table 12-1.

For Subcategory A and C operations, the Agency is promulgating the second BPT Option (clarify CN and revise COD only) and the third BAT Option (Add Organics and Ammonia). Taken

together, these options would increase the electrical power consumption by less than 0.1 percent of the total electrical power purchased in 1990 by the pharmaceutical manufacturing industry.

For Subcategory B and D operations, the Agency is promulgating the second BPT Option (clarify CN and revise COD only) and the first BAT Option (No revision). Taken together these options would increase the electrical power consumption by less than 0.02 percent of the total electrical power purchased in 1990 by the industry.

For indirect dischargers regulated under PSES, changes in electrical energy consumption are shown in Table 12-2.

For Subcategory A and C operations, the Agency is promulgating the third PSES Option (add Organics and Ammonia, and clarify CN) and would increase the electrical power consumption by less than 0.1 percent of the total electrical power purchased in 1990 by the industry. For Subcategory B and D operations, the Agency is promulgating the second PSES Option (add Organics and withdraw CN) and would increase the electrical power consumption by less than 0.01 percent of the total electrical power purchased in 1990 by the industry.

### **12.2.2 Energy Usage in the Generation of Steam**

Of greater impact is the energy usage required to generate steam under the regulatory options that include steam stripping. Steam stripping is part of PSES options considered for Subcategory A and C indirect dischargers and Subcategory B and D indirect dischargers. The impacts of steam usage under BAT and BPT options are negligible. The Agency evaluated the annual incremental increase in energy usage from steam generation expected under each of the PSES options. These estimated annual incremental increases (in kWh/yr) are shown in Table 12-3.

According to the Department of Energy (1), the pharmaceutical manufacturing industry purchased approximately  $6,953 \times 10^6$  kWh of fuel and electric energy in 1990. For Subcategory A and/or C operations at indirect dischargers, the Agency is promulgating the third PSES Option (Add Organics and Ammonia, and clarify CN) which would increase the energy consumption for steam

generation by about 7 percent of the total fuel and electrical power purchased in 1990. For Subcategory B and/or D operations at indirect dischargers, the Agency is promulgating the second PSES Option (Add Organics and withdraw CN) which would increase the energy consumption for steam generation by an amount less than one percent of the total fuel and electrical power purchased in 1990.

It should be noted that since proposal, EPA has modified its steam stripping module to incorporate a revised approach for determining stream characteristics, resulting in a better estimation of the energy consumption for steam generation associated with steam stripping options. At proposal, EPA assumed from the detailed questionnaire responses that wastewater streams containing high concentrations of volatile organic pollutants could not be segregated from streams containing minimal or no concentrations of these pollutants. The Agency has since revised its methodology to distribute the process wastewater flow and load according to the disaggregation approach used in the MACT Standards, which assumes that pharmaceutical process wastewaters can be represented by four streams. Using this disaggregation approach has provided a better estimate of the volume of wastewater that is subject to steam stripping, and, therefore, a better estimate of the energy demand related to steam usage.

Table 12-4 summarizes the estimated increase in energy usage (including electrical power and steam generation) associated with the final regulations. Compliance with the final regulations is estimated to increase the industry's energy usage by approximately 7.6 percent. While the steam generation required under the final regulations requires increased energy consumption, the Agency notes that the potential for solvent recovery and reuse will help to offset these energy expenditures. The Agency concludes that the effluent reduction benefits from the final regulation exceed the potential adverse impacts from the increase in energy consumption that is projected.

### **12.3            Air Emission Impacts**

Pharmaceutical manufacturing facilities generate wastewaters that contain varying concentrations of organic compounds, some of which are listed as Hazardous Air Pollutants (HAPs) in Title 3 of the Clean Air Act Amendments (CAAA) of 1990. Table 12-5 lists the HAPs and volatile organic

pollutants present in pharmaceutical manufacturing wastewaters, as reported by facilities responding to the Detailed Questionnaire (volatile organic pollutants were identified as those constituents that could be analyzed by standard EPA methods for volatile organics such as gas chromatography mass spectrometry (GCMS) by analytical method 1624 (40 CFR Part 136) or GC by analytical method 8015.(2)). Prior to discharge, pharmaceutical manufacturing wastewaters typically pass through a series of collection and treatment units that are open to the atmosphere. Atmospheric exposure of organic-containing wastewaters can result in significant volatilization of HAPs, volatile organic pollutants, and other organic pollutants to the air.

Air emissions of HAPs, volatile organic pollutants, and other organic pollutants may occur from wastewater collection units such as process drains, manholes, trenches, sumps, and junction boxes, and from wastewater treatment units such as neutralization and equalization basins, settling basins, clarifiers, biological treatment units, air and steam strippers lacking air pollution control devices, and other units that expose wastewater to the air.

To determine the impact of the final regulation on air emissions, the Agency had to first determine the current amount of organic constituents emitted into the air from pharmaceutical manufacturing wastewaters. 12.3.1 describes the air emissions estimated by facilities responding to the Detailed Questionnaire. 12.3.2 discusses the regulatory impact on air emissions based on a comparison of current air emissions from pharmaceutical manufacturing wastewaters to projected air emissions from pharmaceutical manufacturing wastewaters of facilities complying with the final regulation.

This also discusses the estimated impact on criteria pollutant emissions in the generation of steam for regulatory options which include steam stripping.

### **12.3.1 Current Air Emissions Based on Detailed Questionnaire Responses**

In response to 3a of the Detailed Questionnaire, entitled "Compound or Chemical Usage and Disposition," facilities estimated the quantities of virgin chemicals used and disposed of during manufacturing of pharmaceutical products in calendar year 1990. As part of the chemical usage

and disposition reporting, facilities were asked to estimate the amount of virgin chemicals used in pharmaceutical manufacturing operations that were: 1) emitted into the air from wastewater prior to discharge, 2) degraded and/or destroyed, and 3) discharged to a surface water and/or a POTW. These three disposition methods summarize the fate, or disposal pathways, of organic constituents present in pharmaceutical manufacturing wastewaters. Overall, a total of 8.5 million pounds of organic pollutants were reported as emitted into the air in 1990 from pharmaceutical manufacturing wastewaters based on summarized Detailed Questionnaire responses.

Upon examining responses to the Detailed Questionnaire regarding the fate of wastewater organic constituents, the Agency suspected that a greater percentage of wastewater organic constituents are emitted to the air than most facilities reported. The Agency noted that several indirect dischargers that had no on-site wastewater treatment systems reported a large percentage of wastewater organic constituents degraded and/or destroyed on site. It is improbable that such high rates of degradation and/or destruction could be achieved in the absence of any wastewater treatment system, such as biological treatment or incineration. In addition, some plants with open impoundments or basins with mechanical agitators or aerators, reported relatively small percentages of air emissions from wastewater in Table 3-2 of the Detailed Questionnaire. The responses to the Detailed Questionnaire also lacked in most cases an indication of the estimation method used in determining the load discharged as air emissions from wastewater.

Because of these deficiencies in the Detailed Questionnaire responses, EPA believes that the industry reported data provides a minimum estimate of air emissions. The Agency believes that the actual amount of air emissions from pharmaceutical manufacturing wastewaters is greater than the total described above.

### **12.3.2 Regulatory Impact on Air Emissions**

Air emissions from pharmaceutical manufacturing facilities will be controlled by the MACT Standards and the effluent limitations guidelines and standards described in this document. For indirect dischargers, these regulations share the common technology basis of in-plant steam stripping.

The use of in-plant steam stripping as part of the Agency's promulgated regulatory options will impact air emissions in two ways. First, priority and nonconventional pollutants that are currently released as air emissions from wastewater at pharmaceutical manufacturing facilities will be removed and condensed by in-plant steam stripping for recycle, reuse, or disposal. Second, the generation of steam for steam stripping will result in increased emissions of criteria pollutants (CO, NO<sub>x</sub>, VOC, SO<sub>2</sub>, and particulate matter). A brief description of the regulatory impact of the MACT standards is provided in 12.3.2.1, and EPA's evaluation of these air emission impacts are described in Sections 12.3.2.2 and 12.3.2.3 below.

#### **12.3.2.1 Regulatory Impact of the MACT Standards on Air Emissions**

The MACT Standards that are being promulgated in conjunction with these effluent standards will control HAP emissions from wastewater treatment and wastewater collection devices at major source pharmaceutical plants using steam stripping as the reference control technology. The final MACT Standards for the pharmaceutical industry will reduce emissions of many of the HAPs listed in 112(b)(1) of the CAAA. The alternatives considered in the development of this regulation, including those alternatives selected as standards for new and existing sources, are based on process and emissions data received from the existing facilities known by EPA to be in operation. The major HAPs emitted by facilities covered by the MACT standards include methylene chloride, methanol, toluene, and hydrogen chloride. The significant reductions in HAP emissions required by the final MACT standards will also result in incidental reductions in nonHAP air emissions because many nonHAPs are found in the same wastewater streams as the HAPs, and thus will be steam stripped along with the HAPs. Further description of the reduction in air emissions resulting from the promulgated MACT Standards is provided in the next section.

#### **12.3.2.2 Reduction in Air Emissions Due to Promulgated Effluent Standards**

As discussed in 11, the Agency is promulgating effluent limitations guidelines and standards for ammonia and organic pollutants based on the following in-plant and end-of-pipe treatment technologies, as shown in Table 12-6.

For Subcategory A and/or C direct and indirect dischargers, there are significant air emissions which the MACT controls are designed to address. As a result of the application of these MACT controls, the load of VOCs to POTWs from pharmaceutical manufacturing plants would be reduced by approximately 48 percent. The Agency estimates that these MACT strippers will provide HAP and nonHAP load removals, as shown in Table 12-7.

For Subcategory A and/or C direct dischargers, the BAT treatment technology (advanced biological treatment plus ammonia nitrification) applied at the end-of-pipe location will result in the removal of some additional HAP and nonHAP load. In addition, for Subcategory A and/or C and Subcategory B and/or D indirect dischargers, the PSES treatment technology (in-plant steam stripping) applied to streams that are not already controlled by the application of MACT wastewater strippers will also result in the removal of additional HAP and nonHAP load. Some of this load may also have been air emissions from wastewater. The Agency estimates that the wastewater strippers costed to achieve compliance with the options beyond no revision put forward by the Office of Water will provide HAP and nonHAP load removals, as shown in Table 12-8.

### **12.3.2.3 Criteria Pollutant Air Emissions**

EPA evaluated the impact of steam generation requirements, under regulatory options that include in-plant steam stripping, on criteria pollutant emissions. To develop this estimate, total steam generation requirements were estimated using the pharmaceutical cost model and it was assumed that the steam would be generated in industrial boilers with no emission controls. Ninety-five percent of the required boiler fuel is assumed to be natural gas and the remaining 5% supplied by low sulfur Number 6 fuel oil.(3) The calculation of criteria pollutant air emissions is presented in the calculation package entitled Calculation of Air Emissions Related to Steam Generation, dated May 19, 1998.(4) Table 12-9 presents an estimate of the resultant criteria pollutant emissions.

For those PSES options selected as the basis of regulation (organics and ammonia, clarify cyanide for A/C indirects; organics only, withdraw cyanide for B/D indirects), the resultant criteria

pollutant emission total is 308 tons/yr or  $0.62 \times 10^6$  lbs/yr. The Agency concludes that the air emission and effluent reduction benefits of hazardous air pollutants, priority, nonconventional, and conventional pollutants outweigh the potential negative impacts of increased emissions of criteria air pollutants.

## **12.4            Solid Waste Impacts**

The Agency has evaluated the following solid waste impacts which would be expected due to the application of the final BPT, BCT, BAT, and PSES effluent limitations guidelines and standards:

- The increase in dry sludge generation due to the application of advanced biological treatment;
- The increase in waste solvent generation due to the application of in-plant steam stripping; and
- The increase in waste hydrogen chloride (HCl) due to scrubber liquor generated by facilities with wastewaters containing ammonia.

These impacts are discussed below in Sections 12.4.1, 12.4.2, and 12.4.4, respectively. 12.4.3 presents an overview of EPA's waste minimization and combustion strategy including EPA's approach for clean fuels.

### **12.4.1            Dry Sludge Generation**

Based on the responses to the Detailed Questionnaire, pharmaceutical manufacturers generated approximately 112,000 tons of dry sludge in 1990. Table 12-10 presents the amount of sludge (dry basis) generated in 1990 by Subcategory A and/or C and Subcategory B and/or D direct and indirect dischargers as well as the estimated amount of additional dry sludge that would be generated by Subcategory A and/or C and Subcategory B and/or D direct and indirect dischargers facilities complying with the final effluent limitations guidelines. On an industry-wide basis, some sludge generated may be hazardous because it may contain hazardous constituents. For purposes of estimating compliance costs, all sludge generated was assumed to require disposal as hazardous

waste, so that the cost of such disposal was accounted for where it was required. Not all facilities actually generate sludge that is considered hazardous, so the cost of sludge disposal may be overestimated for these facilities.

Compliance with BPT/BCT is expected to increase the mass of wastewater treatment sludge generated by Subcategory A and/or C direct dischargers by 343 tons/yr, a result of increased solids generation and removal at facilities upgrading to advanced biological treatment systems. This represents approximately a 1% increase in the current sludge generation rate of 36,400 tons/yr for Subcategory A and/or C direct dischargers.

Compliance with BPT/BCT is expected to increase the mass of wastewater treatment sludge generated by Subcategory B and/or D direct dischargers by 194 tons/yr, a result of increased solids generation and removal at facilities upgrading to advanced biological treatment systems. This represents less than a 7% increase in the current sludge generation rate of 2,760 tons/yr for Subcategory B and/or D direct dischargers.

Compliance with BAT is expected to increase the mass of wastewater treatment sludge generated by Subcategory A and/or C direct dischargers by 308 tons/yr, a result of increased solids generation and removal at facilities upgrading to advanced biological treatment systems including nitrification. This represents approximately a one percent increase in the current sludge generation rate of 36,400 tons/yr for Subcategory A and/or C direct dischargers.

BAT is not being revised for Subcategory B and/or D direct dischargers and therefore will not increase the mass of wastewater treatment sludge generated.

Compliance with BAT/BPT/BCT is anticipated to improve the quality of wastewater treatment sludge by reducing mass loadings of pollutants exported in sludge through conversion to organic material. The Agency concludes that there will be no adverse non-water quality environment impacts regarding sludge management.

No additional sludge is expected to be generated by facilities that discharge indirectly as a result of the final regulations.

#### **12.4.2 Waste Solvent Generation**

Compliance with PSES for Subcategory A and/or C and Subcategory B and/or D indirect dischargers is expected to increase the amount of waste solvents generated by pharmaceutical manufacturing facilities as a result of in-plant steam stripping. The amount of waste solvents recovered as a result of steam stripping by Subcategory A and/or C and Subcategory B and/or D indirect dischargers would be approximately 10,600 and 3,310 tons/yr, respectively. As discussed previously, the use of in-plant steam stripping would remove a significant amount of organic pollutants from the wastewater prior to atmospheric exposure of the wastewater and the subsequent emission of pollutants into the air.

Organic solvent overheads generated under the promulgated PSES options will create the opportunity for additional solvent recovery or reuse in the pharmaceutical manufacturing industry. For example, the Agency is aware of at least one pharmaceutical manufacturer that is currently distilling methanol from a process wastewater stream and recycling the concentrated methanol overheads back into their process operation. The Agency is also aware of at least two other pharmaceutical manufacturers that steam strip their process wastewaters and sell the solvent overheads for profit. Where possible, facilities would be expected to recover solvents for reuse within the process or for use in other industrial processes.

The solvent overheads will also have a value associated with their energy content. The Agency has estimated that the energy value of the solvent overheads generated under the promulgated options will be 14.3 million kWh/yr for Subcategory A and/or C indirect dischargers and 4.4 million kWh/yr for Subcategory B and/or D indirect dischargers.

### **12.4.3 Waste Minimization and Combustion Strategy**

In May 1994, the EPA Administrator announced a Draft Hazardous Waste Minimization and Combustion Strategy that is pertinent to the pharmaceutical manufacturing industry. The Draft Strategy provides the central framework for EPA's federal effort to maximize the source reduction and recycling of hazardous wastes under RCRA. The Draft Strategy focuses on a number of specific goals, including reducing the amount and toxicity of hazardous waste that is generated, particularly when such reductions would benefit more than one environmental medium. The Draft Strategy also encompasses a number of other features, including public outreach, public involvement and environmental justice, permitting, enforcement, risk assessments, and good science.(5)

In April 1996, EPA proposed Revised Standards for Hazardous Waste Combustors (61 FR 17358). In June 1998, the Revised Standards for Hazardous Waste Combustors Final Rule - Part 1 was published. This final rule addresses four elements of the April 1996 proposal: RCRA comparable fuel exclusion; permit modifications for hazardous waste combustion units; notification of intent to comply; and waste minimization and pollution prevention criteria for compliance extensions.

#### **12.4.3.1 Waste Minimization**

The Draft Strategy has both short-term and a longer-term phases. In the short-term, EPA will address the source reduction and environmentally sound recycling of halogenated (and metal-bearing) combustible wastes. The longer-term effort will encompass all RCRA hazardous wastes, taking a more comprehensive approach to how wastes are generated and managed, and the role waste minimization can play as a preferred "mode of management" over other forms of waste management (e.g., treatment, storage, and disposal). This source reduction (waste minimization) strategy should reduce the long-term demand for combustion and other waste management facilities.(6) 7.2 presents EPA's efforts toward increasing opportunities for source reduction (e.g., process changes) in the pharmaceutical manufacturing industry.

The Agency also has released a draft report by the EPA Office of Solid Waste's Definition of Solid Waste Task Force. This report, Reengineering RCRA for Recycling(6), presents recommendations of the Task Force to improve the regulation of hazardous waste recycling under RCRA. One of the recommendations of the Task Force was that provision should be made to exempt "clean" waste-derived fuels from the regulatory requirements of RCRA for hazardous wastes. "Clean fuels" are fuels with "*de minimis*" levels of halogens (primarily chlorine in this case) or toxic metals, especially fuels that are characteristically hazardous only because of ignitability.

Under the final rule, EPA is excluding from the regulatory definition of solid waste, hazardous waste-derived fuels that meet specification levels comparable to fossil fuels for concentrations of hazardous constituents and for physical properties that affect burning. Specific waste codes that EPA expects to contain only those constituents for which the final rule sets maximum allowable concentrations include ignitable solvent wastes (F003 and F005). All wastes consisting primarily of alcohols, petroleum distillates, oils, or other ignitable organic liquids are the most likely candidates for applying to this rule.

In the case of the pharmaceutical manufacturing industry, the volatile organic pollutants that are generated in the largest quantities are non-halogenated volatile organic pollutants, including methanol, toluene, xylene, and acetone. In the final rule methanol, xylene, and acetone are listed V wastes with no corresponding constituent limit in regards to the RCRA comparable fuel exclusion. Implementation of in-plant steam stripping technology affords the opportunity to recover these pollutants and reuse them for their solvent properties. In situations where reuse of solvents is not practical, these non-halogenated pollutants can potentially be used as comparable fuel as defined in the Final Revised Standards for Hazardous Waste Combusters.

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

### **12.4.3.2 Combustion**

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

EPA estimates that approximately 13,900 tons per year or 12,600 metric tons per year of solvent waste (halogenated and nonhalogenated) would be recovered from in-plant steam stripping at pharmaceutical manufacturing facilities. Currently there is RCRA-permitted capacity at commercially available facilities to incinerate in excess of 1 million metric tons per year of solvents. Therefore, there is adequate capacity at commercial incinerators to combust the entire mass of solvents assuming that none would be recovered and recycled. Again, however, it is the Agency's policy that the most appropriate mode of management for solvents removed from pharmaceutical manufacturing wastewaters by steam stripping is recycle in the process, recycle at other facilities, or use as comparable fuels.

### **12.4.4 Waste Hydrogen Chloride Scrubber Liquor**

Compliance with PSES for Subcategory A and/or C indirect dischargers is expected to increase the amount of waste hydrogen chloride (HCl) scrubber liquor recovered by pharmaceutical manufacturing facilities that generate wastewaters containing ammonia. HCl wet scrubbers are used to control air emissions from steam strippers used to remove ammonia from the wastewater. The amount of waste scrubber liquor generated by Subcategory A and/or C indirect dischargers from the regulation of ammonia and organics, would be approximately 283 tons/yr.

## **12.5            Development of Air Emission Standards**

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

112(b) lists the 189 chemicals, compounds, or groups of chemicals deemed by Congress to be hazardous air pollutants (HAPs). These toxic air pollutants are to be regulated by national emission standards for hazardous air pollutants (NESHAP). 112(c) requires the Administrator to use this list of HAPs to develop and publish a list of source categories for which NESHAP will be developed. EPA must list all known categories and subcategories of "major sources."

The term major source is defined in paragraph 112(a)(1) to mean any stationary source or group of stationary sources located within a contiguous area and under common control that emits or has the potential to emit, considering controls, in the aggregate 10 tons per year (tons/yr) or more of any HAP or 25 tons/yr or more of any combination of HAPs. The term stationary source, from 111 of the CAA, means any building, structure, facility, or installation that emits or may emit any air pollutant. The term area source, as defined in 112(a)(2), means any stationary source of HAPs that is not a major source.

Notice of the initial list of categories of major and area sources of HAPs was published on July 16, 1992 (57 FR 31576), under authority of 112(c). This notice listed pharmaceutical manufacturing as a category of major sources of HAPs. Notice of the schedule for the promulgation of emission standards for the listed categories, under authority of 112(e), was given on December 3, 1993 (58 FR 63941). Under this notice, emission standards for the pharmaceutical production industry would be promulgated no later than November 15, 1997. This promulgation deadline has been extended to July 1998.

112(d) of the CAA directs the Administrator to promulgate emission standards for each category of HAP sources listed under 112(c). Such standards are applicable to both new and existing sources and must require the maximum degree of reduction in emissions of the hazardous air

pollutants subject to this (including a prohibition on such emissions, where achievable) that the Administrator, taking into consideration the cost of achieving such emission reduction, and any non-air quality health and environmental impacts and energy requirements, determines is achievable for new and existing sources in the category or subcategory to which such emission standard applies. See 42 U.S.C. 7412(d)(2).

112(d)(3) provides that the maximum degree of reduction in emissions that is deemed achievable for new sources shall not be any less stringent than the emission control that is achieved in practice by the best controlled similar source. For existing sources, the standards may not be less stringent than the average emission limitation achieved by the best performing 12 percent of existing sources in each category of 30 or more sources.

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

EPA is finalizing the MACT standard for pharmaceutical facilities concurrently with the effluent limitations guidelines and standards for this industry. The MACT standards will require the control of several different emission points, including storage tanks, equipment leaks, vents, and organic air emissions from wastewater operations. The area of overlap between the OAQPS Pharmaceutical MACT and the pharmaceutical effluent guidelines is process wastewater from manufacturing operations.

The control approach that EPA OAQPS is promulgating for the pharmaceutical manufacturing industry wastewater emissions source consists first of identifying a subset of wastewater streams that require control through a combination of wastewater flow rate and concentration action levels, and second, the control requirements for these affected streams. Table 12-11 summarizes the wastewater flow rate and concentration action levels and the control requirements for these

affected streams. The flow rate and concentration of each wastewater stream are then determined to reflect the characteristics at the point of determination (POD) of the wastewater stream.

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

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

The control requirements for affected wastewater streams include managing the identified wastewater streams in controlled units during collection and treatment to remove or destroy the organics. This control approach includes: 1) suppression or control of air emissions from the point of wastewater determination to the treatment device by installing controls on the sewer system, tanks, and containers used to transport the wastewater; 2) treatment of the wastewater to remove or destroy the organics; 3) control of air emissions from the treatment device (e.g., the non-condensable air emissions from the stripper condenser); and 4) control or recycling of the

organics removed by the treatment device (e.g., the condensed residuals collected by the stripper condenser).

The treatment device used as the basis for control of air emissions from the pharmaceutical manufacturing industry is the steam stripper. The pharmaceutical manufacturing industry requirements are performance standards, so that any device that achieves the desired performance can be used. In addition, the regulation allows several compliance alternatives including the use of open biological treatment units to treat the wastewater if a controlled (*i.e.*, covered) collection and treatment system is used up to the unit and the biological treatment (*e.g.*, aeration basin) unit can be demonstrated to achieve the required level of biological degradation. The regulation requires the use of the procedures outlined in Appendix C of 40 CFR Part 63 to demonstrate that the organics are being degraded by the biological treatment unit and not emitted to the air.

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

**Table 12-1**

**Estimated Annual Electrical Energy Consumption  
for Direct Increase Dischargers**

Option	Increase in Electrical Energy Consumption (kWh/yr)	
	Subcategory A and C Direct Dischargers	Subcategory B and D Direct Dischargers
BPT No Revision and Clarify CN	NA	NA
BPT Clarify CN, Revise COD Only	2,110,000	1,070,000
BPT Clarify CN, Revise BOD <sub>5</sub> and TSS Only	274,000	4,090,000
BPT Clarify CN and Revise BOD <sub>5</sub> , TSS and COD	2,150,000	261,000
BAT Revise COD to BPT Limits and Clarify CN	NA	NA
BAT Add Organics Only, Revise COD to BPT Limits, and Clarify CN	1,100,000	242,000
BAT Add Organics and Ammonia, Revise COD to BPT Limits, and Clarify CN	3,770,000	NA

**Table 12-2**

**Estimated Annual Electrical Energy Consumption  
Increase for Indirect Dischargers**

PSES Options	Increase in Electrical Energy Consumption (kWh/yr)	
	Subcategory A and C Indirect Dischargers	Subcategory B and D Indirect Dischargers
No Revision and Clarify CN	NA	NA
Add Organics and Withdraw CN	NA	0.459x10 <sup>6</sup>
Add Organics and Ammonia, and Clarify CN	5.94x10 <sup>6</sup>	NA
Add Organics and Ammonia, and Revise CN	5.94x10 <sup>6</sup>	NA

**Table 12-3**

**Estimated Annual Energy Demand Related to  
Steam Usage Increase for Indirect Dischargers**

<b>PSES Options</b>	<b>Increase in Energy Demand Related to Steam Usage (kWh/yr)</b>	
	<b>Subcategory A and C Indirect Dischargers</b>	<b>Subcategory B and D Indirect Dischargers</b>
No Revision and Clarify CN	NA	NA
Add Organics and Withdraw CN	NA	58.8 x 10 <sup>6</sup>
Add Organics and Ammonia, and Clarify CN	454 x 10 <sup>6</sup>	NA
Add Organics and Ammonia, and Revise CN	454 x 10 <sup>6</sup>	NA

**Table 12-4**

**Regulatory Impact on Energy Usage**

<b>Facility Subcategories</b>	<b>Regulation</b>	<b>Source of Increased Energy Usage</b>	<b>Amount of Increase in Energy Usage (1 x 10<sup>6</sup> kWh)</b>
Subcategory A and C Direct Dischargers	BPT	Advanced Biological Treatment	2.11
Subcategory B and D Direct Dischargers	BPT	Advanced Biological Treatment	1.07
Subcategory A and C Direct Dischargers	BAT	Advanced Biological Treatment with nitrification	3.77
Subcategory A and C Indirect Dischargers	PSES	In-plant Steam Stripping + Steam Usage	460
Subcategory B and D Indirect Dischargers	PSES	In-plant Steam Stripping + Steam Usage	59
Total			526

**Table 12-5**

**HAPs and Volatile Organic Pollutants Present in Pharmaceutical Manufacturing Wastewaters**

HAPs		Volatile Organic Pollutants	
Const. Code	Chemical Name	Const. Code	Chemical Name
3	Acetonitrile	3	Acetonitrile
12	Aniline	10	n-Amyl acetate
15	Benzene	11	Amyl alcohol
22	Bis(chloromethyl)ether	15	Benzene
25	2-Butanone (MEK)	25	2-Butanone (MEK)
35	Chlorobenzene	26	n-Butyl acetate
37	Chloroform	27	n-Butyl alcohol
39	Chloromethane	29	tert-Butyl alcohol
62	N,N-Dimethylaniline	35	Chlorobenzene
64	N,N-Dimethylformamide	37	Chloroform
67	1,4-Dioxane	39	Chloromethane
77	Ethylene glycol	43	Cyclohexane
79	Formaldehyde	51	1,2-Dichloroethane
83	Glycol ethers	58	Diethyl ether
87	n-Hexane	66	Dimethyl sulfoxide
97	Methanol (Methyl alcohol)	67	1,4-Dioxane
102	Methylene chloride	70	Ethanol
105	Methyl isobutyl ketone (MIBK)	71	Ethyl acetate
114	Phenol	77	Ethylene glycol
130	Toluene	84	n-Heptane
136	Triethylamine	87	n-Hexane
139	Xylenes	94	Isopropanol
		97	Methanol
		101	Methyl cellosolve
		102	Methylene chloride
		103	Methyl formate

**Table 12-5 (Continued)**

HAPs		Volatile Organic Pollutants	
Const. Code	Chemical Name	Const. Code	Chemical Name
		105	Methyl isobutyl ketone (MIBK)
		117	n-Propanol
		118	Acetone
		130	Toluene
		134	Trichlorofluoromethane
		139	Xylenes

**Table 12-6**

**Treatment Technologies Selected as the Bases of Regulations**

Subcategory	BAT Treatment Technologies for Organic Pollutants	PSES Treatment Technologies for Organic Pollutants
A and C	End-of-pipe advanced biological treatment with Nitrification	Compliance with MACT Standards and In-Plant steam stripping for organic compounds and Ammonia.
B and D	No additional control required	Compliance with MACT Standards and In-Plant steam stripping for organic compounds.

**Table 12-7**

**Estimated HAP and nonHAP Load Removals  
for MACT Wastewater Strippers**

<b>Subcategory</b>	<b>Discharge Status</b>	<b>HAP and nonHAP Load Removals for MACT Wastewater Strippers (lbs/yr)</b>
A and C	Direct	$14.1 \times 10^6$
A and C	Indirect	$41.4 \times 10^6$
B and D	Direct	0
B and D	Indirect	0

**Table 12-8**

**Estimated HAP and nonHAP Load Removals for PSES Options  
Based on Steam Stripping**

<b>Subcategory</b>	<b>Discharge Status</b>	<b>HAP and NonHAP Load Removals for PSES Options Based on Steam Stripping</b>
A and C (a)	Indirect	$10.7 \times 10^6$
B and D	Indirect	$3.3 \times 10^6$

(a) For Subcategories A and C the PSES option includes regulation of ammonia.

**Table 12-9**

**Increase in Criteria Pollutant Emissions from Steam Generation (tons/year)**

Criteria Pollutant	Subcategory A and C Indirects	Subcategory B and D Indirects
	Add Organics and Ammonia	Add Organics
CO	38	5
NO <sub>x</sub>	164	21
VOC	6	1
SO <sub>2</sub>	47	6
PM	18	2
Total	273	35

Source: Reference 4.

**Table 12-10**

**Regulatory Impact on Solid Waste Generation**

	Subcategory A and C Direct Dischargers	Subcategory B and D Direct Dischargers	Subcategory A and C Indirect Dischargers	Subcategory B and D Indirect Dischargers
Current dry sludge generated (tons/yr)	36,400	2,760	68,500	4,630
BPT/BCT Increase in dry sludge generation (tons/yr)	343	194	--	--
BAT Increase in dry sludge generation (tons/yr)	308	--	--	--
PSES Increase in waste solvent generation (tons/yr)	--	--	10,600	3,310
PSES Increase in waste HCl generation (tons/yr)	--	--	283	--

-- = No impact on solid waste generation

**Table 12-11**

**Summary of MACT Standards for New and Existing Sources of Process Wastewater**

<b>Emission Source</b>	<b>New or Existing?</b>	<b>Applicability Requirement</b>	<b>Cutoff</b>	<b>Control Efficiency</b>
Wastewater	New and Existing	>1 Mg/yr total HAP load from all POD within a process or any single POD	1,300 ppmw at POD of partially soluble HAPs	99% reduction of partially soluble HAPs
			5,200 ppmw at POD of total HAP load	99% reduction of partially soluble HAPs  90% reduction of soluble HAPs  95% reduction of total HAP using biotreatment
		>1 Mg/yr total HAP load from facility	10,000 ppmw at POD of total HAP load	99% reduction of partially soluble HAPs  90% reduction of soluble HAPs  95% reduction of total HAP using biotreatment
	New	>1 Mg/yr total HAP load from all POD within a process or any single POD	110,000 ppmw at POD of soluble HAPs	99% reduction of soluble HAPs

POD: Point of determination

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