

methods can be found in the Methods Compendium mentioned previously.

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

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

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

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

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

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

A. Preliminary Development of Air Emissions Standards

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

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

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

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

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