

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

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

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

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

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

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

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

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

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

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

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

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