

32.0 MACT Standards Versus Effluent Guidelines

The proposed BAT and PSES effluent limitations guidelines will control volatile organic pollutants of which 22 are hazardous air pollutants (HAPs), that are released to the environment primarily in wastewater discharges and air emissions. The mass of HAPs being controlled by the effluent limitations guidelines and standards is about 40 percent of the total mass of volatile organic pollutants being controlled. 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.

Industry representatives commented that air emissions from pharmaceutical manufacturing facilities should be controlled by a NESHAP rulemaking rather than by BAT limitations and PSES. Industry representatives also commented that the Agency should integrate the development of these two rules, which now are progressing on separate schedules. Industry representatives commented further that the effluent guidelines should include the same elements of flexibility (e.g., allow for demonstration of equivalence of biological treatment to steam stripping) and format of the limitations as included in the HON (e.g., percent removal). Industry representatives also indicated that the HON will allow for emission-suppressed transport of volatile organic pollutant-containing wastewaters to central treatment facilities.

32.1 *Should the Water and Air Regulations Be Integrated*

In view of these preliminary concerns, the Agency solicits comments and data with respect to whether it is necessary or appropriate for the two rules to be integrated and, if so, how.

32.2 *List of Organic Pollutants Covered*

EPA solicits comments on whether it is necessary or appropriate for the two rules to cover the same list of volatile organic pollutants.

32.3 *Steam Stripping Design and Operating Parameters*

EPA solicits comments on whether the design and operating parameters for steam stripping technology as applied in the two rules should be the same and, if so, how (within the constraints of the governing statutes).

32.4 *Percent Removal Standard With a Base Concentration*

EPA solicits comments on whether EPA should adopt, as an alternative to the proposed concentration-based limitations and standards, effluent limitations guidelines and standards based on percent removal standards, as proposed in the HON for the Specialty Organic Chemical Manufacturing Industry (SOCMI). See solicitation numbers 14.0-14.3.

32.5 *Central Treatment for Volatiles Removal*

EPA solicits comments on whether central treatment (i.e., steam stripping or an equivalent technology prior to end-of-pipe biological treatment) is or should be an acceptable compliance approach for the effluent guidelines.

32.6 *Alternate Limitations for End-of-Pipe Biological Treatment*

EPA solicits comments on whether the effluent guidelines should include alternative limitations which would allow for end-of-pipe biological treatment of hard-piped volatile organic pollutants (in place of in-plant steam stripping or steam stripping with distillation technology).

32.7 *Control of Air Emissions Using Alternate Limitations*

EPA solicits comments on whether an alternative approach (as described in comment number 32.6) would present the same control of air emissions as achieved by in-plant steam stripping and steam stripping with distillation technology.

32.8 *Energy Use for and Air Emissions From Generation of Steam Used for Steam Stripping and Steam Stripping with Distillation*

EPA solicits comments and data on the increase in energy required to generate steam used for steam stripping and distillation, and on the increase in air emissions created by steam generation facilities (industrial boilers).

32.9 *Comments on Evaluating the Record of This Rulemaking in the Context of the MACT Rule*

The Agency requests comments on whether it is appropriate for the Office of Air and Radiation to evaluate the basis for the proposed effluent limitations and standards as part of its development of MACT standards for the pharmaceutical manufacturing industry.

33.0 Analytical Methods

A complete discussion of the new analytical methods being proposed in conjunction with these proposed

regulations may be found in section 18 of the Technical Development Document.

33.1 *Analytical Methods Proposed Today*

The methods being proposed today involve the use of isotope dilution gas chromatography/mass spectrometry (GC/MS), derivatization followed by high pressure liquid chromatography (HPLC), and GC followed by detection in an electrochemical cell optimized for nitrogen containing compounds (GC/ELCD). EPA solicits comments with respect to these techniques (see discussion in Section IX of this preamble, and the supporting compendium of analytical methods entitled "Analytical Methods for the Determination of Pollutants in Pharmaceutical Manufacturing Industry Wastewater;" see Section II of this preamble) and any suggestions regarding alternative techniques as well.

33.2 *Limitations Set at the Minimum Level of the Method*

EPA solicits comments on those limitations whose long-term average basis is equal to the minimum level established for the limited pollutant.

33.3 *Statistical Methods for Establishing Limitations*

EPA solicits alternative statistical methodologies for developing limitations based on all non-detect data which may be more appropriate than the statistical methodology employed by EPA.

33.4 *Analytical Methods for Alcohols*

EPA has proposed analytical methods for quantifying various low-molecular weight alcohols (e.g., methanol and ethanol) in wastewater. See "Analytical Methods for the Determination of Pollutants in Pharmaceutical Wastewater", EPA 821-R-95-015. EPA invites comments on the proposed methods for determining alcohols in wastewater from industrial laboratories, public sector laboratories and individual researchers familiar with similar analytical methods.

33.5 *Matrix Interferences and Analytical Methods*

EPA is interested in identifying solutions to matrix interference problems connected with the analysis of pharmaceutical manufacturing industry wastewater streams. EPA is also interested in any extraction, concentration or other analytical techniques that may offer solutions to matrix interference problems.