

HON, and how this approach would be implemented. See solicitation number 32.4.

14.3 Implementation of a Mass-Based Limitation

The Agency solicits comment on alternative mass-based limitations and how this approach would be implemented.

15.0 In-Plant Limitations for Volatile Organic Pollutant Control

For PSES and PSNS, the Agency is proposing to require compliance monitoring in-plant for certain pollutants (e.g., chloroform, methylene chloride, and toluene) that due to dilution would be found at the end-of-pipe at levels below the current analytical limits of detection. The long-term average concentrations upon which the applicable standards are based are, for many pollutants, near the analytical limits of detection established for these pollutants in wastewater. The Agency is concerned that measurements made at end-of-pipe, after dilution with process and non-process wastewaters, will not adequately reflect the performance of the PSES or PSNS level treatment due to uncertainty associated with pollutant concentration measurements near established limits of detection. EPA has a similar concern for the proposed BAT technology for facilities with subcategory A and/or C operations and the NSPS technology for all manufacturing subcategories.

During development of these proposed regulations, industry representatives asserted that requiring compliance monitoring in-plant on internal streams may reduce their flexibility in compliance and require installation of specific in-plant treatment technologies. Based upon available data, the Agency believes that even if in-plant monitoring is required, pharmaceutical facilities will retain considerable flexibility in choosing specific compliance strategies that may be implemented at individual facilities, including available in-plant treatment technologies. EPA also believes in-plant limitations will enhance opportunities for recovery and reuse of solvents and may allow for the generation of "clean fuels," as described in section XI.C of this preamble.

15.1 Feasibility of End-of-Pipe Limits in Measuring Compliance

EPA solicits comments and data on whether requiring compliance monitoring at the end-of-pipe could practically or feasibly be used to determine whether the proposed BAT,

PSES, NSPS and PSNS limitations and standards are being met.

15.2 Feasibility of End-of-Pipe Limits in Measuring Technology Performance

EPA solicits comments and data on whether requiring compliance monitoring at the end-of-pipe could practically or feasibly be used to measure the performance of the process technologies that form the basis of EPA's proposed BAT, PSES, NSPS and PSNS regulation.

15.3 Extent That In-Plant Control Enhances Recovery/Reuse

The Agency solicits comments and specific supporting data on the extent to which recovery and reuse opportunities may be enhanced by in-plant control.

15.4 Compliance Strategy With In-Plant Monitoring Points

The Agency solicits comments on whether compliance strategies are either enhanced or limited by the use of in-plant monitoring points.

15.5 Air Emissions

The Agency solicits comment on the extent to which air emissions may be controlled by in-plant limits and standards for volatile organic pollutants based on steam stripping or steam stripping with distillation.

15.6 Minimum Concentration and Flow Thresholds

EPA is aware that it may not be efficient or cost effective for plants to steam strip or distill wastewater streams containing low concentrations of volatile organic pollutants. Consequently, EPA solicits suggestions for concentration and flow thresholds for identifying wastewater streams containing volatile organic pollutants which would be subject to in-plant steam stripping or steam stripping with distillation.

15.7 Setting In-Plant Limitations on Case-by-Case Basis

The Agency solicits comment on the burden imposed on permit writers to establish in-plant BAT limitations and NSPS on a case-by-case basis for the 45 volatile organic pollutants for which EPA is proposing to specify end-of-pipe limitations and standards. EPA also seeks comment on its proposal that the end-of-pipe BAT limitations and NSPS standards for particular pollutants would not apply if a permit writer finds in-plant limitations or standards to be necessary for those pollutants; EPA also seeks comment on the recommendation that the permit writer consult the appropriate PSES or PSNS table in

setting the necessary in-plant limitations and standards on a best professional judgment basis. EPA also seeks comment on the utility of relying on EPA's existing NPDES permit regulations to address issues associated with pollutants that are not detectable at the end of the pipe.

15.8 Deference to Clean Air Act Rulemaking

The Agency seeks comment on all aspects of EPA's policy determination in this proposal to defer to the Clean Air Act rulemaking for the pharmaceutical industry with respect to the control of volatile air emissions from certain pharmaceutical wastestreams.

15.9 Comments on Steam Stripping With Distillation

The Agency requests comments and data on whether steam stripping with distillation should be the technology basis for effluent limitations and standards for volatile organic pollutants, particularly those that are difficult to strip, such as methanol and ethanol.

15.10 Comments on the Proposed End-of-Pipe Limits for Highly Strippable Volatile Organic Pollutants

The Agency solicits comments supported by data regarding whether it is appropriate to develop limitations requiring compliance monitoring at the end of the pipe for highly strippable volatile organic pollutants such as methylene chloride and chloroform.

16.0 WATER7 Model

In analyzing responses to the mass balance question (section 3-2 of the 308 questionnaire), EPA has determined that many of the loading estimates (i.e., to air, to water etc.) provided for individual pollutants were not accompanied with explanations of how the estimates were made. The Agency is concerned that the 308 mass balance responses may underestimate the amount of pollutant air emissions from wastewater and overestimate the amount of pollutant biodegradation and/or destruction. Consequently, EPA has used the WATER7 computer model in conjunction with other 308 response data to develop pollutant-by-pollutant air emission estimates. The WATER7 program was used previously to estimate air emissions from wastewater for the SOCOMI HON (see 59 FR 19402).

16.1 Technical Validity of the WATER7 Model

EPA solicits comments on the technical validity of the WATER7 model and its use in estimating pollutant releases at pharmaceutical facilities.