

EPA is directed to take into consideration the cost of achieving the effluent reduction and any non-water quality environmental impacts and energy requirements.

*e. Pretreatment Standards for Existing Sources (PSES)—section 307(b) of the CWA.* PSES are designed to prevent the discharge of pollutants that pass through, interfere with, or are otherwise incompatible with the operation of publicly owned treatment works (POTWs). The CWA authorizes EPA to establish pretreatment standards for pollutants that pass through POTWs or interfere with treatment processes or sludge disposal methods at POTWs. Pretreatment standards are technology-based and are analogous to BAT effluent limitations guidelines. See Section IX.E.5. (ii) for discussion of EPA's pass-through methodology.

The General Pretreatment Regulations, which set forth the framework for the implementation of categorical pretreatment standards, are found at 40 CFR part 403. Those regulations contain a definition of pass-through that addresses localized rather than national instances of pass-through and establish pretreatment standards that apply to all nondomestic dischargers. For national instances of pass-through, EPA performs an analysis based on the procedures set forth at 52 FR 1586 (January 14, 1987).

*f. Pretreatment Standards for New Sources (PSNS)—section 307(b) of the CWA.* Like PSES, PSNS are designed to prevent the discharge of pollutants that pass through, interfere with, or are otherwise incompatible with the operation of a POTW. PSNS are to be issued at the same time as NSPS. New indirect dischargers have the opportunity to incorporate into their plants the best available demonstrated technologies. The Agency considers the same factors in promulgating PSNS as it considers in promulgating NSPS.

*g. Best Management Practices (BMPs).* Section 304(e) of the CWA gives the Administrator the authority to publish regulations, in addition to the effluent limitations guidelines and standards listed above, to control plant site runoff, spillage or leaks, sludge or waste disposal, and drainage from raw material storage that the Administrator determines are associated with or ancillary to the industrial manufacturing or treatment process of the regulated point source category and that she (he) determines may contribute significant amounts of pollutants to waters of the United States.

## 2. Prior Regulations

EPA promulgated interim final BPT regulations for the pharmaceutical manufacturing point source category on November 17, 1976 (41 FR 50676; 40 CFR part 439, Subparts A–E). The five subcategories of the pharmaceutical manufacturing industry (40 CFR 439) are:

- Subpart A—Fermentation Products Subcategory.
- Subpart B—Extraction Products Subcategory.
- Subpart C—Chemical Synthesis Subcategory.
- Subpart D—Mixing, Compounding, and Formulating Subcategory.
- Subpart E—Research Subcategory.

The 1976 BPT regulations set monthly limitations for BOD<sub>5</sub> and COD based on percent removal for all subcategories. No daily maximum effluent limitations were established for these parameters. The pH was set within the range of 6.0 to 9.0 standard units. The regulations also set maximum 30 day average total suspended solids (TSS) limitations for subcategories B, D, and E. No TSS limitations were established for subcategories A and C. Subpart A was amended (42 FR 6813) on February 4, 1977, to improve the language referring to separable mycelia and solvent recovery. The amendment also allowed the inclusion of spent beers (broths) in the calculation of raw waste loads for Subpart A in those instances where the spent beer is actually treated in the wastewater treatment system.

On October 27, 1983, at 48 FR 49808, EPA promulgated revised BPT and BAT, PSES, and PSNS regulations for Subparts A–D covering the toxic pollutant cyanide and the conventional pollutants BOD<sub>5</sub>, TSS and pH and the nonconventional pollutant COD. The 1983 regulations kept intact the percent reduction regulations for BOD<sub>5</sub> and COD established in 1976 but added floor concentration-based limitations for these parameters applicable to subcategories B and D. In addition, limitations for TSS based on each plant's BOD<sub>5</sub> discharge were promulgated for subcategories A–D. EPA also promulgated BPT, BAT, PSES and PSNS for pH (6.0–9.0) and BAT concentration-based limitations controlling the discharge of cyanide from subcategory A–D plants. The Agency also proposed NSPS for BOD<sub>5</sub>, TSS and pH in the October 1983 notice, but did not publish NSPS for these parameters. That proposal is being replaced by today's NSPS proposal.

On December 16, 1986, at 51 FR 45094, EPA promulgated BCT effluent limitations for BOD<sub>5</sub>, TSS and pH for

subcategories A–D. That final rule set BCT effluent limitations equal to the existing BPT effluent limitations for BOD<sub>5</sub>, TSS, and pH.

## 3. Litigation History

The effluent limitations guidelines and standards for the pharmaceutical manufacturing industry have never been the subject of litigation.

## 4. Section 304(m) Requirements

Section 304(m) of the Clean Water Act (33 U.S.C. 1314(m)), added by the Water Quality Act of 1987, requires EPA to establish schedules for (i) reviewing and revising existing effluent limitations guidelines and standards and (ii) promulgating new effluent guidelines. On January 2, 1990, EPA published an Effluent Guidelines Plan (55 FR 80), in which schedules were established for developing new and revised effluent guidelines for several industry categories. One of the industries for which the Agency established a schedule was the pharmaceutical manufacturing point source category.

Natural Resources Defense Council, Inc. (NRDC) and Public Citizen, Inc. challenged the Effluent Guidelines Plan in a suit filed in U.S. District Court for the District of Columbia (*NRDC et al. v. Reilly*, Civ. No. 89–2980 (D.D.C.)). (The suit originally challenged EPA's failure to publish the plan by the statutory deadline.) The plaintiffs charged that EPA's plan did not meet the requirements of section 304(m). On January 31, 1992, EPA entered into a consent decree (the "304(m) Decree"), which established schedules for, among other things, EPA's proposal and promulgation of approximately 20 effluent guidelines including those for the pharmaceutical manufacturing point source category.

On May 18, 1994, the Agency published a second plan (see 59 FR 25859). The plan projected proposal and promulgation dates for several industrial categories including the pharmaceutical manufacturing category.

## B. Clean Air Act

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 section 112 of the Clean Air Act (CAA).

Section 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). Section 112(c) requires the