

Congress recognized that regulating only those sources that discharge effluent directly into the nation's waters would not be sufficient to achieve the CWA's goals. Consequently, the CWA requires EPA to promulgate nationally applicable pretreatment standards that restrict pollutant discharges for those who discharge wastewater indirectly through sewers flowing to publicly-owned treatment works (POTWs) (section 307(b) and (c), 33 U.S.C. 1317(b) and (c)). National pretreatment standards are established for those pollutants in wastewater from indirect dischargers which may pass through or interfere with POTW operations. Generally, pretreatment standards are designed to ensure that wastewater from direct and indirect industrial dischargers are subject to similar levels of treatment. In addition, POTWs are required to implement local pretreatment limits applicable to their industrial indirect dischargers to satisfy any local requirements (40 CFR 403.5).

Direct dischargers must comply with effluent limitations in National Pollutant Discharge Elimination System (NPDES) permits; indirect dischargers must comply with pretreatment standards. These limitations and standards are established by regulation for categories of industrial dischargers and are based on the degree of control that can be achieved using various levels of pollution control technology.

On November 17, 1976, (41 FR 50676) EPA promulgated "best practicable control technology currently available" (BPT) effluent limitations guidelines for the Pharmaceutical Manufacturing Point Source Category. On October 27, 1983, (48 FR 49808) the Agency revised the BPT limitations and promulgated additional limitations covering the "best available technology economically achievable" (BAT) and pretreatment and new source standards for this point source category.

On September 21, 1998, (63 FR 50388) EPA again revised the effluent limitations guidelines and standards for the Pharmaceutical Manufacturing Point Source Category. We subsequently received comments from the regulated community and after our own analysis and review, we determined that several minor amendments which are discussed below were warranted.

#### IV. Amendment to New Source Effective Dates

Section 306 of the Clean Water Act requires EPA to establish, and from time to time, revise standards of performance for categories of new sources which may discharge pollutants. Under the Act, point sources constructed to meet these

NSPS may not be subject to more stringent standards during a statutorily prescribed period following construction of such source, generally 10 years. EPA first promulgated NSPS for the Pharmaceutical Manufacturing Point Source Category in 1983 when the Agency established effluent limitations guidelines and pretreatment standards for this category. When EPA promulgated revised limitations and standards, including NSPS, for the Pharmaceuticals Manufacturing Point Source Category in 1998, 40 CFR 439.15(c), 439.25(c), 439.35(c), and 439.45(c) provided for this protection period from more stringent standards. For example, paragraph (c) of § 439.15 states:

Any new source subject to the provisions of this section that commenced discharging after November 21, 1988 and prior to November 20, 1998 must continue to achieve the standards specified in the *earlier version of this section* until the expiration of the applicable time period specified in 40 CFR 122.29(d)(1), after which the source must achieve the standards specified in §§ 439.13 and 439.14. (Emphasis supplied)

In order to remove any ambiguity about which regulations applied to dischargers constructing new facilities and commencing discharge after the 1983 regulation but before the effective date of the 1998 regulations, EPA is amending the regulation. EPA is amending paragraph (c) of each of the four sections cited above to state clearly that any new source that commenced discharging after November 21, 1988, and before November 20, 1998, must continue to achieve the standards specified for 40 CFR part 439 in the October 27, 1983, **Federal Register** (48 FR 49808) (which are contained in the 1988 edition of the CFR) until the expiration of the applicable time period specified in 40 CFR 122.29(d)(1). Thereafter, the source must comply with the applicable effluent limitations specified in the September 21, 1998, regulation (63 FR 50388). The amendments substitute for the phrase "earlier version" a specific reference to the 1988 edition of 40 CFR part 439. This will remove any uncertainty about the standards with which a point source discharger must comply.

Section 307(c) of the CWA also requires EPA to promulgate pretreatment standards for new sources simultaneously with the promulgation of NSPS for a category of sources. When EPA promulgated the PSNS for the Pharmaceutical Manufacturing Point Source Category in 1998, PSNS in §§ 439.17, 439.27, 439.37, and 439.47 failed to specify when a source constructed before the date on which

the new PSNS became effective would be subject to the more stringent standards. To correct this oversight, EPA is revising each of these four sections to read as follows:

Except as provided in 40 CFR 403.7, any new source subject to this subpart that commenced discharging after November 21, 1988, and prior to November 20, 1998, must continue to achieve the pretreatment standards specified for this section in the 1988 edition of 40 CFR part 439 during a ten-year period beginning on the date the source commenced discharge, or during the period of depreciation or amortization of the facility, whichever comes first, after which the source must achieve the same standards as specified in [insert the appropriate PSES section for the subpart].

#### V. Amendment to BOD Minimum Limitation

When EPA issued regulations for the Pharmaceutical Manufacturing Point Source Category on October 27, 1983 (49 FR 49808), the best practicable control technology (BPT) regulation in §§ 439.22 and 439.42 provided for a minimum monthly average limitation for BOD<sub>5</sub>, which was qualified by the following sentence: "However, a plant shall not be required to attain a maximum 30-day average BOD<sub>5</sub> effluent limitation of less than the equivalent of 45 mg/l." EPA included this provision because dischargers with BOD<sub>5</sub> levels up to 100 mg/L in their raw wastewater could not achieve the required 90% reduction of BOD<sub>5</sub> using biological treatment, the technological basis for the limitation. Since biological treatment could not achieve the required reduction for such dischargers, EPA established a qualified provision for a minimum BOD<sub>5</sub> concentration in the 1983 regulation.

EPA inadvertently omitted this qualified provision of the BOD<sub>5</sub> limitations from the final rule published in 1998, and this language consequently has not been included in subsequent editions of 40 CFR part 439. Today EPA is correcting this omission by adding to §§ 439.22(a) and 439.42(a) the phrase: "\* \* \*, except that no facility shall be required to attain a monthly average limitation for BOD<sub>5</sub> that is less than the equivalent of 45 mg/L."

#### VI. Amendment To Delete Methyl Cellosolve From Pretreatment Standards

EPA is amending 40 CFR part 439 by deleting the pretreatment standards for methyl Cellosolve from §§ 439.16, 439.17, 439.36 and 439.37, and from Table 2 of Appendix A. In the 1998 regulation, EPA established pretreatment standards for methyl