

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000), requires EPA to develop an accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications." "Policies that have tribal implications" is defined in the Executive Order to include regulations that have substantial direct effects on one or more Indian tribes, on the relationship between Federal government and Indian tribes or on the distribution of power and responsibilities between the Federal government and Indian tribes.

This final rule does not have tribal implications. It will not have substantial direct effects on tribal governments, on the relationship between this Federal government and Indian tribes or on the distribution of power and responsibilities between the Federal government and Indian tribes. It merely clarifies applicable dates, corrects an inadvertent error and omission, and makes other non-substantive edits. EPA has not identified any pharmaceutical facilities covered by today's rule that are owned and/or operated by Indian tribal governments. No Indian tribes are responsible for implementing the CWA NPDES permitting program. Thus, Executive Order 13175 does not apply to this rule.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

Executive Order 13045 "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997) applies to any rule that: (1) Is determined to be "economically significant" as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This final rule is not subject to Executive Order 13045 because it is not an economically significant rule as defined under Executive Order 12866. Further, this rule does not concern an environmental health or safety risk that

EPA has reason to believe may have a disproportionate effect on children.

H. Executive Order 13211: Actions that Significantly Affect Energy Supply, Distribution, or Use

This rule is not subject to Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355; May 22, 2001) because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note), directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through the Office of Management and Budget (OMB), explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This action does not involve technical standards. Therefore, EPA did not consider the use of any voluntary consensus standards.

J. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to the publication of the rule in **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2). This rule will be effective June 11, 2003.

List of Subjects in 40 CFR Part 439

Environmental protection, Drugs, Reporting and recordingkeeping requirements, Waste treatment and disposal, Water pollution control.

Dated: February 28, 2003.

Christine Todd Whitman,
Administrator.

For reasons set out in the preamble, part 439, title 40, chapter I of the Code of Federal Regulations is amended as follows:

PART 439—PHARMACEUTICAL MANUFACTURING POINT SOURCE CATEGORY

1. The authority citation for part 439 is revised to read as follows:

Authority: 33 U.S.C. 1311, 1314, 1316, 1317, 1318, 1342 and 1361.

2. Section 439.1 is amended by revising paragraphs (b) through (n) and adding paragraphs (o) and (p) to read as follows:

§ 439.1 General definitions.

* * * * *

(b) *Bench-scale operation* means the laboratory testing of materials, methods, or processes on a small scale, such as on a laboratory worktable.

(c) *Cyanide (T)* means the parameter total cyanide.

(d) *In-plant monitoring point* means a location within a plant, where an individual process effluent can be exclusively monitored before it is diluted or mixed with other process wastewaters en route to the end-of-pipe.

(e) *Maximum daily* means the highest allowable discharge of wastewater pollutants during a calendar day or any 24 hour period that reasonably represents a calendar day for purposes of sampling.

(f) *Maximum monthly average* means the highest allowable average of daily discharges of wastewater pollutants over a calendar month, and is calculated as the sum of all daily values measured during a calendar month divided by the number of daily values measured during that month.

(g) *mg/L* means milligrams per liter or parts per million (ppm)

(h) *Minimum level* means the level at which an analytical system gives recognizable signals and an acceptable calibration point.

(i) *Nitrification capability* means the capability of a POTW treatment system to oxidize ammonia or ammonium salts initially to nitrites (via *Nitrosomonas* bacteria) and subsequently to nitrates (via *Nitrobacter* bacteria). Criteria for determining the nitrification capability of a POTW treatment system are: bioassays confirming the presence of nitrifying bacteria; and analyses of the nitrogen balance demonstrating a reduction in the concentration of ammonia or ammonium salts and an