

- 4. Mixing/Compounding/Formulating
- VIII. Summary of Data Gathering Efforts
 - A. Technical and Economic Data
 - 1. 1989 Screener Survey of the Pharmaceutical Industry
 - 2. 1990 Pharmaceutical Manufacturing Industry Survey
 - 3. Sampling and Analytical Program
 - B. Air Emission Data
- IX. Development of Effluent Limitations Guidelines and Standards
 - A. Industry Subcategorization
 - 1. Introduction
 - 2. Current Subcategorization
 - 3. Rationale for Maintaining the Current Subcategorization
 - 4. Subcategory Regulation Not Revised
 - B. Water Use, Wastewater Discharge and Characterization
 - 1. Water Use and Wastewater Generation
 - 2. Wastewater Discharge
 - 3. Wastewater Characterization
 - C. Selection of Pollutant Parameters
 - 1. Pollutants Regulated
 - 2. Pollutants Not Regulated
 - D. Available Technologies
 - 1. Pollution Prevention Technologies Considered
 - 2. In-plant Technologies Considered
 - 3. End-of-Pipe Technologies Considered
 - E. Rationale for Selection of Technology Bases for Proposed Regulations
 - 1. BPT
 - 2. BCT
 - 3. BAT
 - 4. NSPS
 - 5. PSES
 - 6. PSNS
 - 7. BMPs
 - F. Determination of Long-Term Averages, Variability Factors, and Limitations
 - G. Costs
 - 1. BPT
 - 2. BAT
 - 3. PSES
 - H. Pollutant Reductions
 - 1. Conventional Pollutants
 - 2. Priority Pollutants
 - 3. Nonconventional Pollutants
 - I. Regulatory Implementation
 - 1. Applicability
 - 2. Upset and Bypass Provisions
 - 3. Variances and Modifications
 - 4. Relationship of Effluent Limitations to NPDES Permits and Monitoring Requirements
 - 5. Best Management Practices
 - 6. Analytical Methods
- X. Regulation of the Pharmaceutical Manufacturing Industry Under the Clean Air Act Amendments of 1990
 - A. Preliminary Development of Air Emissions Standards
 - B. Potential Interaction of Proposed Effluent Limitations Guidelines and Future Air Emissions Standards
- XI. Impacts of Regulatory Options Considered in this Rulemaking
 - A. Regulatory Options
 - B. Economic Impact Considerations
 - 1. Introduction
 - 2. Projected Facility Economic Impacts
 - 3. Projected Owner Company-Level Economic Impacts
 - 4. Projected Employment Losses and Gains and Community-Level Economic Impacts

- 5. Projected Foreign Trade Impacts
- 6. Regulatory Flexibility Analysis
- 7. Projected Distributional Impacts
- 8. Projected Impacts on New Sources
- 9. Regulatory Impact Assessment
- XII. Relationship of Proposed Effluent Guidelines to EPA's Hazardous Waste Initiatives
 - A. Relationship to Rulemaking Activities Under RCRA
 - 1. Introduction and Overview of Land Ban Regulations
 - 2. The Land Disposal Restrictions Program
 - 3. Phase 3 and the Pharmaceutical Effluent Guidelines
 - B. Coordination With Waste Minimization and Combustion Strategy
 - 1. Waste Minimization
 - 2. Combustion
- XIII. Administrative Requirements
 - A. Changes in Format and Name
 - B. Docket and Public Record
 - C. Clean Water Act Procedural Requirements
 - D. Executive Order 12866
 - E. Regulatory Flexibility Act
 - F. Reduction of Unfunded Mandates and Consultation with State Local, and Tribal Governments
 - G. Paperwork Reduction Act
- XIV. Solicitation of Data and Comments
 - A. Introduction and General Solicitation
 - B. Specific Data and Comment Solicitations

I. Definitions, Acronyms, and Abbreviations

1989 Pharmaceutical Screener Questionnaire—A short questionnaire distributed by EPA to all known pharmaceutical facilities in June 1989 in order to identify plants which manufacture pharmaceutical products.

1990 Detailed Questionnaire—The 1990 Pharmaceutical Manufacturing Survey. A questionnaire sent by EPA to certain facilities in the pharmaceutical manufacturing industry in September 1991 to gather technical and financial information. The questionnaire was sent to those facilities likely to be affected by promulgation of revised effluent limitations guidelines, pretreatment standards, and new source performance standards for this industry.

Administrator—The Administrator of the U.S. Environmental Protection Agency.

Agency—The U.S. Environmental Protection Agency.

Annual average—The mean concentration, mass loading or production-normalized mass loading of a pollutant over a period of 365 consecutive days (or such other period of time determined by the permitting authority to be sufficiently long to encompass expected variability of the concentration, mass loading or production-normalized mass loading at the relevant point of measurement).

Average monthly discharge limitation—The highest allowable

average of "daily discharges" over a calendar month, calculated as the sum of all "daily discharges" measured during a calendar month divided by the number of "daily discharges" measured during that month.

BAT—The best available technology economically achievable, as described in Section 304(b)(2) of the Clean Water Act.

Bench-scale operation—Laboratory testing of materials, methods, or processes on a small scale, such as on a laboratory worktable.

BCT—The best conventional pollutant control technology, as described in section 304(b)(4) of the Clean Water Act.

BID—Background Information Document, which presents the technical basis for air pollution controls under the Clean Air Act.

Biological and Natural Extraction—The chemical and physical extraction of pharmaceutically active ingredients from natural sources such as plant roots and leaves, animal glands, and parasitic fungi. The process operations involving biological and natural extraction define subcategory B (40 CFR 439, subpart B).

BMP or BMPs—Best management practices, as described in section 304(e) of the Clean Water Act.

BOD₅—Five-Day Biochemical Oxygen Demand. A measure of biochemical decomposition of organic matter in a water sample. It is determined by measuring the dissolved oxygen consumed by microorganisms to oxidize the organic contaminants in a water sample under standard laboratory conditions of five days and 20 °C. BOD₅ is not related to the oxygen requirements in chemical combustion.

Boiler—Any enclosed combustion device that extracts useful energy in the form of steam and is not an incinerator.

BPT—The best practicable control technology currently available, as described in section 304(b)(1) of the Clean Water Act.

CAA—Clean Air Act. The Air Pollution Prevention and Control Act (42 U.S.C. 7401 et seq.), as amended, *inter alia*, by the Clean Air Act Amendments of 1990 (Pub. L. 101-549, 104 Stat. 2399).

Chemical Synthesis—The process(es) of using a chemical reaction or a series of chemical reactions to manufacture pharmaceutically active ingredients. The chemical synthesis process operations define subcategory C (40 CFR 439, subpart C).

Clarifier—A treatment unit designed to remove suspended materials from wastewater, typically by sedimentation.

Closed vent system—A system that is not open to the atmosphere and is composed of piping, ductwork,