ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 451

[OW–2002–0026; FRL–7783–6]

RIN 2040–AD55

Effluent Limitations Guidelines and New Source Performance Standards for the Concentrated Aquatic Animal Production Point Source Category

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: Today's final rule establishes Clean Water Act effluent limitations guidelines and new source performance standards for concentrated aquatic animal production facilities. The animals produced range from species produced for human consumption as food to species raised to stock streams for fishing. The animals are raised in a variety of production systems. The production of aquatic animals contributes pollutants such as suspended solids, biochemical oxygen demand, and nutrients to the aquatic environment. The regulation establishes technology-based narrative limitations and standards for wastewater discharges from new and existing concentrated aquatic animal production facilities that discharge directly to U.S. waters. EPA estimates that compliance with this regulation will affect 242 facilities. The rule is projected to reduce the discharge of total suspended solids by about 0.5 million pounds per year and reduce the discharge of biochemical oxygen demand (BOD) and nutrients by about 0.3 million pounds per year. The estimated annual cost for commercial facilities is $0.3 million. The estimated annual cost to Federal and State hatcheries is $1.1 million. EPA estimates that the annual monetized environmental benefits of the rule will be in the range of $66,000 to $99,000.

DATES: This regulation is effective September 22, 2004. For judicial review purposes, this final rule is promulgated as of 1 p.m. (Eastern time) on September 7, 2004 as provided at 40 CFR 23.2.

ADDRESSES: EPA has established a docket for this action under Docket ID No. OW–2002–0026. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although not listed in the index, some information is not publicly available, *i.e.*, confidential business information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Water docket in the EPA Docket Center (EPA/DC) EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the Water Docket is (202) 566–2426.

FOR FURTHER INFORMATION CONTACT: For additional information contact Marta Jordan at (202) 566–1049.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does This Action Apply To Me?

Entities that directly discharge to waters of the U.S. potentially regulated by this action include:

Category	Examples of regulated entities and SIC Codes	Examples of regulated entities and NAICS codes
Facilities engaged in concentrated aquatic animal production, which may include the following sectors: Commercial (for profit) and Non-commercial (public) facilities.	0273—Animal Aquaculture. 0921—Fish Hatcheries and Preserves.	112511—Finfish Farming and Fish Hatcheries. 112519—Other Animal Aquaculture.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. This table lists the types of entities that EPA is now aware could potentially be regulated by this action. Other types of entities not listed in the table could also be regulated. To determine whether your facility is regulated by this action, you should carefully examine the applicability criteria listed at 40 CFR part 451 of today's rule. If you have questions regarding the applicability of this action to a particular entity, consult the person listed for information in the preceding **FOR FURTHER INFORMATION CONTACT** section.

B. How Can I Get Copies of This Document and Other Related Information?

1. Docket. EPA has established an official public docket for this action under Docket ID No. OW–2002–0026. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Water Docket in the EPA Docket Center (EPA/DC), EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the Water Docket is (202) 566–2426. Every user is entitled to copy 266 pages per day before incurring a charge. The Docket may charge 15 cents a page for each page over the page limit plus an administrative fee of $25.00.

2. Electronic Access. You may access this Federal Register document electronically through the EPA Internet under the ''Federal Register'' listings at *http://www.epa.gov/fedrgstr/.*

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, select ''search,'' then key in the appropriate docket identification number. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in section B.1.

C. What Other Information Is Available To Support This Final Rule?

The major documents supporting the final regulations are the following:

• ''Technical Development Document for the Final Effluent Limitations Guidelines and New Source Performance Standards for the Concentrated Aquatic Animal Production Point Source Category'' [EPA–821–R–04–012] referred to in the preamble as the Technical Development Document (TDD). The TDD presents the technical information that formed the basis for EPA's decisions in today's final rule. The TDD describes, among other things, the data collection activities, the wastewater treatment technology options considered by the Agency as the basis for effluent limitations guidelines and standards, the pollutants found in wastewaters from concentrated aquatic animal production facilities, the estimates of pollutant removals associated with certain pollutant control options, and the cost estimates related to reducing the pollutants with those technology options.

• ''Economic and Environmental Benefit Analysis of the Final Effluent Limitations Guidelines and Standards for the Concentrated Aquatic Animal Production Point Source Category [EPA–821–R–04–013] referred to in this preamble as the Economic and Environmental Benefit Analysis or EEBA. This document presents the methodology used to assess economic impacts, environmental impacts and benefits of the final rule. The document also provides the results of the analyses conducted to estimate the projected impacts and benefits.

Major supporting documents are available in hard copy from the National Service Center for Environmental Publications (NSCEP), U.S. EPA/NSCEP, P.O. Box 42419, Cincinnati, Ohio, USA 45242–2419, (800) 490–9198, *www.epa.gov/ncepihom.* You can obtain electronic copies of this preamble and rule as well as major supporting documents at EPA Dockets at *www.epa.gov/edocket* and at *www.epa.gov/guide/aquaculture.*

D. What Process Governs Judicial Review for Today's Final Rule?

Under Section 509(b)(1) of the Clean Water Act (CWA), judicial review of today's effluent limitations guidelines and standards may be obtained by filing a petition for review in the United States Circuit Court of Appeals within 120 days from the date of promulgation of these guidelines and standards. For judicial review purposes, this final rule is promulgated as of 1 pm (Eastern time) on September 7, 2004 as provided at 40 CFR 23.2. Under section 509(b)(2) of the CWA, the requirements of this regulation may not be challenged later in civil or criminal proceedings brought by EPA to enforce these requirements.

E. What Are the Compliance Dates for Today's Final Rule?

Existing direct dischargers must comply with today's limitations based on the best practicable control technology currently available (BPT), the best conventional pollutant control technology (BCT), and the best available technology economically achievable (BAT) as soon as their National Pollutant Discharge Elimination System (NPDES) permits include such limitations. Generally, this occurs when existing permits are reissued. New direct discharging sources must obtain an NPDES permit for the discharge and comply with applicable new source performance standards (NSPS) on the date the new sources begin discharging. For purposes of NSPS, a source is a new source if it commences construction after September 22, 2004.

F. How Does EPA Protect Confidential Business Information (CBI)?

Certain information and data in the record supporting the final rule have been claimed as CBI and, therefore, EPA has not included these materials in the record that is available to the public in the Water Docket. Further, the Agency has withheld from disclosure some data not claimed as CBI because release of this information could indirectly reveal information claimed to be confidential. To support the rulemaking while preserving confidentiality claims, EPA is presenting in the public record certain information in aggregated form, masking facility identities, or using other strategies.

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II. Definitions, Acronyms, and Abbreviations Used in This Document

Act—The Clean Water Act.

Agency—U.S. Environmental Protection Agency.

AWQC—Ambient water quality criteria.

BAT—Best available technology economically achievable, as defined by section 304(b)(2)(B) of the Act.

BCT—Best conventional pollutant control technology, as defined by section 304(b)(4) of the Act.

BMP—Best management practice, as defined by section 304(e) of the Act.

BOD_5—Biochemical oxygen demand measured over a five day period.

BPJ—Best professional judgment.

BPT—Best practicable control technology currently available, as defined by section 304(b)(1) of the Act.

CAAP—Concentrated aquatic animal production.

CBI—Confidential business information.

CFR—Code of Federal Regulations.

CWA—33 U.S.C. §§ 1251 *et seq.*, as amended.

Conventional Pollutants—Constituents of wastewater as determined by Section 304(a)(4) of the CWA (and EPA regulations), *i.e.*, pollutants classified as biochemical oxygen demand, total suspended solids, oil and grease, fecal coliform, and pH.

Daily Discharge—The discharge of a pollutant measured during any calendar day or any 24-hour period that reasonably represents a calendar day.

Daily Maximum Limit—the highest allowable ''daily discharge''.

Direct Discharger—A facility that discharges or may discharge treated or untreated wastewaters into waters of the United States.

DMR—Discharge monitoring report; consists of the reports filed with the permitting authority by permitted dischargers to demonstrate compliance with permit limits.

DO—Dissolved oxygen.

ELG—Effluent limitations guidelines.

EQIP—Environmental Quality Incentives Program.

Existing source—For this rule, any facility from which there is or may be a discharge of pollutants, the construction of which is commenced before September 22, 2004.

Extralabel drug use—Actual use or intended use of a drug in an animal in a manner that is not in accordance with the approved label. The Federal Food, Drug, and Cosmetic Act allows veterinarians to prescribe extralabel uses of certain approved animal drugs and approved human drugs for animals under certain conditions. These conditions are spelled out in Food and Drug Administration regulations at 21 CFR Part 530. Among these requirements are that any extralabel use must be by or on the order of a veterinarian within the context of a veterinarian-client-patient relationship, must not result in violative residues in food-producing animals, and the use must be in conformance with the regulations. A list of drugs specifically prohibited from extralabel use appears at 21 CFR 530.41.

Facility—All contiguous property and equipment owned, operated, leased, or under the control of the same person or entity.

FAO—United Nations Food and Agriculture Organization.

FCR—Feed conversion ratio.

FDF—Fundamentally different factor.

FFDCA—Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301, *et seq.*, as amended.

FIFRA—Federal Insecticide, Fungicide and Rodenticide Act.

FR—Federal Register.

FTE—Full Time Equivalent Employee.

FWS—U.S. Fish and Wildlife Service.

INAD—Investigational new animal drug. A new animal drug (or animal feed containing a new animal drug) intended for testing or clinical investigational use in animals. Food and Drug Administration regulations limit the conditions under which such drugs may be used. 21 CFR 511, 514.

Indirect Discharger-A facility that discharges or may discharge wastewaters into a publicly-owned treatment works.

JSA/AETF—Joint Subcommittee on Aquaculture, Aquaculture Effluents Task Force.

lb(s)/yr—pound(s) per year.

NAICS—North American Industry Classification System. NAICS was developed jointly by the U.S., Canada, and Mexico to provide new comparability in statistics about business activity across North America.

NEPA—National Environmental Policy Act, 33 U.S.C. 4321, *et seq.*

NMFS—National Marine Fisheries Service.

NPDES Permit—A permit to discharge wastewater into waters of the United States issued under the National Pollutant Discharge Elimination System, authorized by Section 402 of the CWA.

NRCS—Natural Resources Conservation Service.

Nonconventional Pollutants—Pollutants that are neither conventional pollutants listed at 40 CFR 401 nor toxic pollutants listed at 40 CFR 401.15 and Part 423 Appendix A.

Non-water quality environmental impact—Deleterious aspects of control and treatment technologies applicable to point source category wastes, including, but not limited to air pollution, noise, radiation, sludge and solid waste generation, and energy used.

NRDC—Natural Resources Defense Council.

NSPS—New Source Performance Standards.

NTTAA—National Technology Transfer and Advancement Act, 15 U.S.C. 272 note.

OMB—Office of Management and Budget

Outfall—The mouth of conduit drains and other conduits from which a facility discharges effluent into receiving waters.

Pass through—a discharge that exits a POTW into waters of the United States in quantities or concentrations that alone or in conjunction with discharges from other sources, causes a violation of any requirement of the POTW's NPDES permit (including an increase in the magnitude or duration of a violation).

PCB—Polychlorinated biphenyls.

POC—Pollutants of Concern. Pollutants commonly found in aquatic animal production wastewaters. Generally, a chemical is considered as a POC if it was detected in untreated process wastewater at 5 times a baseline value in more than 10% of the samples.

Point Source—Any discernable, confined, and discrete conveyance from which pollutants are or may be discharged. See CWA Section 502(14).

POTW(s)—Publicly owned treatment works. It is a treatment works as defined by Section 212 of the Clean Water Act that is owned by a State or municipality (as defined by Section 502(4) of the Clean Water Act). This definition includes any devices and systems used in the storage, treatment, recycling and reclamation of municipal sewage or industrial wastes of a liquid nature. It also includes sewers, pipes and other conveyances only if they convey wastewater to a POTW Treatment Plant. The term also means the municipality as defined in Section 502(4) of the Clean Water Act, which has jurisdiction over the Indirect Discharges to and the discharges from such a treatment works.

Priority Pollutant—One hundred twenty-six compounds that are a subset of the 65 toxic pollutants and classes of pollutants outlined pursuant to Section 307 of the CWA. 40 CFR Part 423, Appendix A.

PSES—Pretreatment standards for existing sources of indirect discharges, under Section 307(b) of the CWA, applicable to indirect dischargers that commenced construction prior to the effective date of a final rule.

PSNS—Pretreatment standards for new sources under Section 307(c) of the CWA.

QUAL2E—Enhanced Stream Water Quality Model.

RFA—Regulatory Flexibility Act, 5 U.S.C. 601, *et. seq.*

SBREFA—Small Business Regulatory Enforcement Fairness Act of 1996, Public Law 104–121.

SIC—Standard Industrial Classification, a numerical categorization system used by the U.S. Department of Commerce to catalogue economic activity. SIC codes refer to the products or groups of products that are produced or distributed, or to services that are provided, by an operating establishment. SIC codes are used to group establishments by the economic activities in which they are engaged. SIC codes often denote a facility's primary, secondary, tertiary, etc. economic activities.

TDD—Technical Development Document.

TSS—Total Suspended Solids.

U.S.C.—United States Code.

UMRA—Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1501.

USDA—United States Department of Agriculture.

III. Under What Legal Authority Is This Final Rule Issued?

The U.S. Environmental Protection Agency is promulgating these regulations under the authority of Sections 301, 304, 306, 307, 308, 402, and 501 of the Clean Water Act, 33 U.S.C. 1311, 1314, 1316, 1318, 1342, and 1361.

IV. What Is the Statutory and Regulatory Background to This Rule?

A. Clean Water Act

Congress passed the Federal Water Pollution Control Act (1972), also known as the Clean Water Act (CWA),

to ''restore and maintain the chemical, physical, and biological integrity of the Nation's waters.'' (33 U.S.C. 1251(a)). The CWA establishes a comprehensive program for protecting our nation's waters. Among its core provisions, the CWA prohibits the discharge of pollutants from a point source to waters of the U.S. except as authorized by a National Pollutant Discharge Elimination System (NPDES) permit. The CWA also requires EPA to establish national technology-based effluent limitations guidelines and standards (effluent guidelines or ELG) for different categories of sources, such as industrial, commercial and public sources of waters. Effluent guidelines are implemented when incorporated into an NPDES permit. Effluent guidelines can include numeric and narrative limitations, including Best Management Practices, to control the discharge of pollutants from categories of point sources.

Congress recognized that regulating only those sources that discharge effluent directly into the nation's waters may not be sufficient to achieve the CWA's goals. Consequently, the CWA requires EPA to promulgate nationally applicable pretreatment standards that restrict pollutant discharges from facilities that discharge wastewater indirectly through sewers flowing to publicly-owned treatment works (POTWs). (See Section 307(b) and (c), 33 U.S.C. 1317(b) & (c)). National pretreatment standards are established only for those pollutants in wastewater from indirect dischargers that may pass through, interfere with, or are otherwise incompatible with POTW operations. Generally, pretreatment standards are designed to ensure that wastewaters from direct and indirect industrial dischargers are subject to similar levels of treatment. In addition, POTWs must develop local treatment limits applicable to their industrial indirect dischargers. Any POTWs required to develop a pretreatment program must develop local limits to implement the general and specific national pretreatment standards. Other POTWs must develop local limits to ensure compliance with their NPDES permit for pollutants that result in pass through or interference at the POTW. (See 40 CFR 403.5). Today's rule does not establish national pretreatment standards for this category, which contains very few indirect dischargers, because the indirect dischargers would be discharging mainly TSS and BOD, which the POTWs are designed to treat and which consequently, do not pass through. In addition, nutrients discharged from CAAP facilities are in concentrations lower, in full flow discharges, and similar in off-line settling basin discharges, to nutrient concentrations in human wastes discharged to POTWs. The options EPA considered do not directly treat nutrients, but some nutrient removal is achieved incidentally through the control of TSS. EPA concluded POTWs would achieve removals of TSS and associated nutrients equivalent to those achievable by the options considered for this rulemaking and therefore there would be no pass through of pollutants in amounts needing regulation. In the event of pass through that causes a violation of a POTW's NPDES limit, the POTW must develop local limits for its users to ensure compliance with its permit.

Direct dischargers must comply with effluent limitations in NPDES permits. Technology-based effluent limitations in NPDES permits are derived from effluent limitations guidelines and new source performance standards promulgated by EPA, as well as occasionally from best professional judgment analyses. Effluent limitations are also derived from water quality standards. The effluent limitations guidelines 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.

EPA promulgates national effluent limitations guidelines and standards for major industrial categories generally for three classes of pollutants: (1) Conventional pollutants (*i.e.*, total suspended solids, oil and grease, biochemical oxygen demand, fecal coliform, and pH); (2) toxic pollutants (*e.g.*, toxic metals such as chromium, lead, nickel, and zinc; toxic organic pollutants such as benzene, benzo-*a*-pyrene, phenol, and naphthalene); and (3) Nonconventional pollutants (*e.g.*, ammonia-N, formaldehyde, and phosphorus). EPA considered the discharge of these classes of pollutants in the development of this rule. EPA is establishing BMP requirements for the control of conventional, toxic and Nonconventional pollutants. EPA considers development of four types of effluent limitations guidelines and standards for direct dischargers. The paragraphs below describe those pertinent to today's rule.

1. Best Practicable Control Technology Currently Available (BPT)—Section 304(b)(1) of the CWA

EPA may promulgate BPT effluent limits for conventional, toxic, and nonconventional pollutants. For toxic pollutants, EPA typically regulates priority pollutants, which consist of a specified list of toxic pollutants. In specifying BPT, EPA looks at a number of factors. EPA first considers the cost of achieving effluent reductions in relation to the effluent reduction benefits. The Agency also considers the age of the equipment and facilities, the processes employed, engineering aspects of the control technologies, any required process changes, non-water quality environmental impacts (including energy requirements), and such other factors as the Administrator deems appropriate. (See CWA 304(b)(1)(B)). Traditionally, EPA establishes BPT effluent limitations based on the average of the best performance of facilities within the industry, grouped to reflect various ages, sizes, processes, or other common characteristics. Where existing performance is uniformly inadequate, EPA may establish limitations based on higher levels of control than currently in place in an industrial category, if the Agency determines that the technology is available in another category or subcategory and can be practically applied.

2. Best Conventional Pollutant Control Technology (BCT)—Section 304(b)(4) of the CWA

The 1977 amendments to the CWA required EPA to identify additional levels of effluent reduction for conventional pollutants associated with BCT technology for discharges from existing industrial point sources. In addition to other factors specified in Section 304(b)(4)(B), the CWA requires that EPA establish BCT limitations after consideration of a two-part ''cost-reasonableness'' test. EPA explained its methodology for the development of BCT limitations in July 1986 (51 FR 24974).

Section 304(a)(4) designates the following as conventional pollutants: Biochemical oxygen demand measured over five days (BOD_5), total suspended solids (TSS), fecal coliform, pH, and any additional pollutants defined by the Administrator as conventional. The Administrator designated oil and grease as an additional conventional pollutant on July 30, 1979 (44 FR 44501).

3. Best Available Technology Economically Achievable (BAT)—Section 304(b)(2) of the CWA

In general, BAT effluent limitations guidelines represent the best economically achievable performance of facilities in the industrial subcategory or category. The CWA establishes BAT as

a principal national means of controlling the direct discharge of toxic and nonconventional pollutants. The factors considered in assessing BAT include the cost of achieving BAT effluent reductions, the age of equipment and facilities involved, the process employed, potential process changes, non-water quality environmental impacts including energy requirements, economic achievability, and such other factors as the Administrator deems appropriate. The Agency retains considerable discretion in assigning the weight to be accorded these factors. Generally, EPA determines economic achievability on the basis of total costs to the industry and the effect of compliance with BAT limitations on overall industry and subcategory financial conditions. As with BPT, where existing performance is uniformly inadequate, BAT may reflect a higher level of performance than is currently being achieved based on technology transferred from a different subcategory or category. BAT may be based upon process changes or internal controls, even when these technologies are not common industry practice.

4. New Source Performance Standards (NSPS)—Section 306 of the CWA

New Source Performance Standards reflect effluent reductions that are achievable based on the best available demonstrated control technology. New facilities have the opportunity to install the best and most efficient production processes and wastewater treatment technologies. As a result, NSPS should represent the most stringent controls attainable through the application of the best available demonstrated control technology for all pollutants (*i.e.*, conventional, nonconventional, and priority pollutants). In establishing NSPS, EPA is directed to take into consideration the cost of achieving the effluent reduction, any non-water quality environmental impacts, and energy requirements.

B. Section 304(m) Consent Decree

Section 304(m) of the CWA requires EPA every two years to publish a plan for reviewing and revising existing effluent limitations guidelines and standards and for promulgating new effluent guidelines. On January 2, 1990, EPA published an Effluent Guidelines Plan (see 55 FR 80) in which the Agency established schedules for developing new and revised effluent guidelines for several industry categories. Natural Resources Defense Council, Inc., and Public Citizen, Inc., challenged the Effluent Guidelines Plan in a suit filed in the U.S. District Court for the District of Columbia, (*NRDC et al* v. *Leavitt*, Civ. No. 89–2980). On January 31, 1992, the court entered a consent decree which, among other things, established schedules for EPA to propose and take final action on effluent limitations guidelines and standards for several point source categories. The amended consent decree requires EPA to take final action on the Concentrated Aquatic Animal Production (CAAP) effluent guidelines by June 30, 2004.

C. Clean Water Act Requirements Applicable to CAAP Facilities

EPA's existing National Pollutant Discharge Elimination System (NPDES) regulations define when a hatchery, fish farm, or other facility is a concentrated aquatic animal production facility and, therefore, a point source subject to the NPDES permit program. See 40 CFR 122.24. In defining ''concentrated aquatic animal production (CAAP) facility,'' the NPDES regulations distinguish between warmwater and coldwater species of fish and define a CAAP facility by, among other things, the size of the operation and frequency of discharge.

A facility is a CAAP facility if it meets the criteria in 40 CFR 122 appendix C or if it is designated as a CAAP facility by the NPDES program director on a case-by-case basis. The criteria described in appendix C are as follows. A hatchery, fish farm, or other facility is a concentrated aquatic animal production facility if it grows, contains, or holds aquatic animals in either of two categories: cold water species or warm water species. The cold water species category includes facilities where animals are produced in ponds, raceways, or other similar structures that discharge at least 30 days per year but does not include facilities that produce less than approximately 20,000 pounds per year or facilities that feed less than approximately 5,000 pounds during the calendar month of maximum feeding. The warm water species category includes facilities where animals are produced in ponds, raceways, or other similar structures that discharge at least 30 days per year, but does not include closed ponds that discharge only during periods of excess runoff or facilities that produce less than approximately 100,000 pounds per year. 40 CFR part 122, appendix C. Today's action does not revise the NPDES regulation that defines CAAP facilities.

Most facilities falling under the definition of CAAP are either flow-through, recirculating or net pen systems. These systems discharge continuously or discharge 30 days or more per year as defined in 40 CFR part 122 and are subject to permitting depending on the production level at the facility. Most pond facilities do not require permits because ponds generally discharge fewer than 30 days per year and therefore generally are not CAAP facilities unless designated by the NPDES program director. The NPDES program director can designate a facility on a case-by-case basis if the director determines that the facility is a significant contributor of pollution to waters of the U.S.

V. How Was This Final Rule Developed?

This section describes the background to development of the proposal, the proposed rule, EPA's data collection effort, and changes to the proposal EPA considered based on new information and comments on the proposal.

A. September 2002 Proposed Rule

EPA started work on these effluent guidelines in January 2000. EPA relied on a federal interagency group known as the Joint Subcommittee on Aquaculture as a primary contact for information about the industry. The Joint Subcommittee on Aquaculture, authorized by the National Aquaculture Act of 1980, 94 Stat. 1198, 16 U.S.C. 2801, *et seq*, operates under the National Science and Technology Council of the Office of Science and Technology in the Office of the Science Advisor to the President. The National Aquaculture Act's purpose is to promote aquaculture in the United States to help meet its future food needs and contribute to solving world resource problems. The Act provides for the identification of regulatory constraints on the development of commercial aquaculture, and for development of a plan identifying specific steps the Federal Government can take to remove unnecessarily burdensome regulatory barriers to the initiation and operation of commercial aquaculture ventures. It also directs Federal agencies with functions or responsibilities that may affect aquaculture to perform such functions or responsibilities, to the maximum extent practicable, in a manner that is consistent with the purpose and policy of the Act. The Joint Subcommittee on Aquaculture established the Aquaculture Effluents Task Force (AETF) to work with EPA to provide information and expertise for the development of this rule. The AETF became an instrumental group providing input and comments to EPA. The AETF consists of members from various Federal agencies, State governments, industry, academia, and

non-governmental (environmental) organizations.

EPA used the information provided by the AETF and conducted its own research for this rulemaking effort. EPA also relied on the 1998 Census of Aquaculture conducted by the Department of Agriculture (USDA) to provide information on the size and distribution of facilities in the industry. The Census also provided some basic information on the revenues and prices realized by aquatic animal producers. This information became a primary resource for describing the industry.

Because of limitations in the Census data, EPA conducted its own survey of the aquatic animal production industry. EPA adopted a two-phase approach to collecting data from aquatic animal producers. In the first phase, EPA distributed a ''screener'' survey. EPA designed this survey to collect very basic information from all known aquatic animal producers including public facilities regardless of size, ownership, or production system. EPA mailed the survey to approximately 6,000 potential aquatic animal producers in August 2001. The survey consisted of 11 questions asking for general facility information. EPA used the information collected to refine the profiles of the industry with respect to the production systems in use and the type of effluent controls in use. The screener survey, AETF information, and Census data became the primary sources for the proposed rule.

EPA based the limitations and standards for the proposed rule on the analysis of technologies to achieve effluent reductions using model aquatic animal production facilities. Each of these model facilities represented a different segment of the population corresponding to a particular production system type, size range (in terms of annual pounds of aquatic animals produced), and species produced.

EPA evaluated the economic impact of each regulatory option it considered for the proposed effluent limitations and new source performance standards based on the revenues and production cost information available from the USDA Census of Aquaculture along with EPA's own engineering cost estimates for the pollution control technologies being considered. After determining revenues and compliance costs for each model facility, EPA used a compliance cost-to-revenue ratio as a predictor of potential economic impacts for the different model facilities. EPA used this economic analysis in its evaluation of whether it should limit the application of the national limitations and standards by size of production.

On September 12, 2002, EPA published the proposed rule (*see* 67 FR 57872). The proposed limitations and standards applied only to new and existing CAAP facilities that discharge directly to waters of the United States. EPA proposed requirements for three subcategories for this industry: flow-through, recirculating, and net pen systems. Flow-through and recirculating production systems are land-based. Net pens, by contrast, are located in open water.

EPA based the proposed requirements for the recirculating and flow-through subcategories on effluent control technologies that remove suspended solids from the animal production water prior to discharge. The technologies considered include quiescent zones, settling basins (including off-line settling basins, full flow settling basins, and polishing settling basins) and filtration technology. EPA proposed to establish limitations on the concentration of Total Suspended Solids (TSS) in the discharges from these facilities based on its preliminary assessment of the performance achieved by the various control technologies. In the case of recirculating systems, EPA based the proposed TSS limitations on solids polishing or secondary solids removal technology. For flow-through systems, EPA based the proposed TSS limitations on primary or secondary solids settling technologies depending on the production level of the facility (*i.e.*, primary for 100,000–475,000 lbs/yr and secondary for >475,000 lbs/yr). In addition to numeric limits, EPA also proposed to require these facilities to implement operational measures so-called—Best Management Practices (BMPs)—to reduce the discharge of pollutants and develop a BMP plan to document these practices. Depending on the type and size of the facility, the plan would have required a facility to identify and implement practices that controlled, for example, the discharge of solids and ensured the proper storage and disposal of drugs and chemicals.

EPA based the proposed requirements for net pen facilities on requirements to reduce the amount of solids, mainly feed, being added directly into waters of the U.S. The proposal required net pen facilities to develop and implement BMPs to address the discharge of solids including the requirement to conduct active feed monitoring to minimize the amount of feed not eaten and thus discharged to the aquatic environment. Other proposed requirements included adoption of practices to ensure proper storage and disposal of drugs and chemicals. In addition, EPA proposed that net pen facilities prevent the discharge of solid wastes such as feed bags, trash, net cleaning debris, and dead fish; chemicals used to clean the nets, boats or gear; and materials containing or treated with tributyltin compounds. Further requirements were designed to minimize the discharge of blood, viscera, fish carcasses or transport water containing blood associated with the transport or harvesting of fish.

B. December 2003 Notice of Data Availability

On December 29, 2003, EPA published a Notice of Data Availability (NODA) at 68 FR 75068. In the NODA, EPA summarized the data received since the proposed rule and described how the Agency might use the data for the final rule. The NODA also discussed the second phase of data collection, a detailed survey, which EPA conducted in 2002. The detailed survey was mailed to a stratified sample population of facilities identified from the screener survey. EPA received responses from 203 facilities. The surveyed population included a statistically representative sample of facilities that reported producing aquatic animals with flow-through, recirculating and net pen systems. EPA also surveyed a small number of facilities that would not have been subject to the proposed requirements. EPA's objective was to further verify the assumptions on which it had based its preliminary decision to exclude these facilities from the scope of the final rule.

The detailed data collected through this survey allowed EPA to revise the methods used for the proposed rule to estimate costs and economic impacts. EPA developed facility-specific costs and economic impact assessments for each surveyed facility based on the detailed information provided in the survey responses. The detailed information included production systems, annual production, and control practices and technologies in place at the facility.

The detailed responses to the second survey provided EPA with better information on the baseline level of control technologies and operational measures in use at CAAP facilities. Based on this understanding, EPA described two modified options in the NODA that EPA was considering for the final rule. These options reflected the same technologies and practices considered for the proposed regulation, but reconfigured the combinations of treatment technologies and practices into revised regulatory options.

EPA visited 17 additional sites and sampled at one facility in response to issues raised in the comments. The NODA discussed the post-proposal data including site visits and additional sampling. The results of EPA's analyses of the data were also presented in the NODA. EPA solicited comment on the new data and the conclusions being drawn from them.

C. Public Comments

EPA has prepared a ''Comment Response Document'' that includes the Agency's responses to comments submitted on the proposed rule and the notice of data availability. All of the public comments, including supporting documents, are available for public review in the administrative record for this final rule, filed under docket number OW–2002–0026.

The comment period on the proposed rule closed on January 27, 2003. EPA received approximately 300 comments, including form letters. EPA received comments from sources including the Joint Subcommittee on Aquaculture—Aquaculture Effluents Task Force (JSA/AETF), industry trade associations, Federal and State agencies, environmental organizations, and private citizens. For the NODA, EPA received 20 comments between December 29, 2003 and February 12, 2004.

D. Public Outreach

As part of the development of the proposed rule and today's final rule, EPA has conducted outreach activities. EPA met with affected and interested stakeholders through site visits and sampling trips to obtain information on operating and waste management practices at CAAP facilities. EPA met numerous times with members of the JSA/AETF and conducted outreach with small businesses during the SBREFA process.

EPA conducted three public meetings to discuss the proposed rule during the public comment period for the proposed rule. EPA has participated in the industry's conferences to update participants on the progress and status of the rule. EPA also held several meetings with other federal agencies to discuss issues that potentially affect their mission, programs, or responsibilities.

Moreover, EPA maintains a website that posts information relating to the regulation. EPA provided supporting documents for the proposed rule on the site. The documents included the Technical Development Document, the Draft Guidance for Aquatic Animal Production Facilities to Assist in Reducing the Discharge of Pollutants, and the Economic and Environmental Impact Analysis. These documents used to support the proposed rule and the final supporting documents are available at *www.epa.gov/guide/aquaculture*.

VI. What Are Some of the Significant Changes in the Content of the Final Rule and the Methodology Used To Develop It?

This section describes some of the major changes that EPA made to the final rule from that it proposed. This section also describes differences in the methodology EPA used in evaluating its options for the final rule.

A. Subcategorization

The proposed regulation included limitations and standards for three subcategories: Flow-through systems, recirculating systems and net pens. The final rule establishes limitations and standards for the same systems but for only two subcategories: A flow-through and recirculating systems subcategory and a net pens subcategory. The recirculating and flow-through systems are combined into one subcategory instead of two separate subcategories.

As previously noted, flow-through and recirculating systems are both land based systems that typically discharge continuously, but can occasionally discontinue discharges for short periods of time. The principal distinguishing characteristic between these two systems is the degree to which water is reused prior to its discharge, with recirculating systems typically discharging lower volumes of wastewater. In the proposal, EPA distinguished recirculating systems from flow-through systems by describing a recirculating system as one that typically filters with biological or mechanically supported filtration and reuses the water in which the aquatic animals are raised. Net pen systems, by contrast, are located in open water and have distinctly different characteristics from either recirculating or flow-through systems.

EPA received a number of comments on the distinction between flow-through and recirculating systems described in the proposed rule. Because some flow-through systems also reuse their production water, commenters did not believe EPA had adequately distinguished recirculating systems from flow-through systems. Some commenters encouraged EPA to use hydraulic retention time as a basis for distinguishing between flow-through and recirculating systems. However, EPA's review of available data showed that there is no clear dividing line between the hydraulic retention time in a system that was considered a recirculating system and one that was considered a flow-through system. EPA examined the aquatic animal production literature for alternatives for distinguishing recirculating systems and flow-through systems. Given the difficulty in distinguishing certain flow-through facilities from recirculating ones, EPA considered whether it should combine the two subcategories into one subcategory. EPA discussed this in the NODA and solicited comment on this option.

While some commenters opposed combining these two subcategories, EPA has decided to combine flow-through and recirculating systems for the purpose of establishing effluent limitations guidelines for the following reasons. First, as some commenters recognized, both flow-through and recirculating systems may reuse water and employ similar measures to maintain water quality including mechanical filtration. Second, the characteristic of wastewater discharged from facilities that are identified as recirculating systems that are similar to the wastewater from the off-line or solids treatment units at flow-through systems. Both waste streams are characterized by high levels of suspended solids, which can be effectively treated through properly designed and operated treatment systems employing either settling technology combined with effective feed management or a carefully controlled feed management system alone. Therefore, EPA decided that the same requirements should apply both to wastewater discharged from recirculating production systems and wastewater discharged from off-line solids treatment units at flow-through facilities. Moreover, EPA had based the proposed limits for both of these waste streams on the same data set. For the foregoing reasons, EPA has concluded that this change in the organization of the final rule does not substantively change the requirements.

Commenters also pointed to differences in BMPs employed at the different production systems. EPA recognizes that there are differences between recirculating systems and flow-through systems. EPA has concluded, however, that the control technology selected as the basis for the final narrative limitations will effectively remove pollutants from both systems to the same degree. Further, the BMP requirements in the final rule for this subcategory are flexible enough to accommodate differences in the specific

practices appropriate for the two types of production systems. Finally, commenters were concerned that collapsing these two systems into one subcategory could be interpreted as indicating that EPA favors recirculating systems over flow-through systems and implying that flow-through systems should be modified to become recirculating systems. This certainly is not EPA's intention and the Agency is not suggesting that recirculating systems should replace existing flow-through systems or be given a preference in the construction of new systems. The primary reason to collapse these two systems into one subcategory is to eliminate redundancy in the CFR.

B. Regulated Pollutants

There are a number of pollutants associated with discharges from CAAP facilities. CAAP facilities can have high concentrations of suspended solids and nutrients, high BOD and low dissolved oxygen levels. Organic matter is discharged primarily from feces and uneaten feed. Metals, present in feed additives or from the deterioration of production equipment, may also be present in CAAP wastewater. Effluents with high levels of suspended solids, when discharged into receiving waters, can have a detrimental effect on the environment. Suspended solids can degrade aquatic ecosystems by increasing turbidity and reducing the depth to which sunlight can penetrate, thus reducing photosynthetic activity. Suspended particles can damage fish gills, increasing the risk of infection and disease. Nutrients are discharged mainly in the form of nitrate, ammonia and organic nitrogen. Ammonia causes two main problems in water. First, it is toxic to aquatic life. Second, it is easily converted to nitrate which may increase plant and algae growth.

Some substances, like drugs and pesticides, that may be present in the wastewater may be introduced directly as part of the aquatic animal production process. An important source of the pollutants potentially present in CAAP wastewater is, as the above discussion suggests, the feed used in aquatic animal production. Feed used at CAAP facilities contributes to pollutant discharges in a number of ways: by-product feces, ammonia excretions and, most directly, as uneaten feed (in dissolved and particulate forms). Moreover, the feed may be the vehicle for introducing other substances into the wastewater, like drugs. For example, medicated feed may introduce antibiotics into the wastewater.

In the proposed rule, EPA proposed to establish numeric limitations for only a single pollutant—total suspended solids (TSS)—while controlling the discharge of other pollutants through narrative requirements. Following proposal, EPA reevaluated the technological basis for the numerical limits for TSS and determined that it would be more appropriate to promulgate qualitative TSS limits, in the form of solids control BMP requirements, that could better respond to regional and site-specific conditions and accommodate existing state programs in cases where these appear to be working well (see Section VIII.B. for further discussion). EPA is thus not promulgating numerical limitations for TSS or other pollutants.

EPA is instead establishing narrative effluent limitations requiring implementation of effective operational measures to achieve reduced discharges of solids and other materials. For the final rule, as it did at proposal, EPA has also developed narrative limitations that will address a number of other pollutants potentially present in CAAP wastewater. These narrative limitations address spilled materials (drugs, pesticides and feed), fish carcasses, viscera and other waste, excess feed, feed bags, packaging material and netting.

EPA's decision to not establish national numeric limits for TSS will not restrict a permit writer's authority to impose site-specific permit numeric effluent limits on the discharge of TSS or other pollutants in appropriate circumstances. For example, a permit writer may establish water quality-based effluent limits for TSS (see 40 CFR 122.44(d) or regulate TSS (by establishing numeric limits) as a surrogate for the control of toxic pollutants (see 40 CFR 122.44(e)(2)(ii)) where site-specific circumstances warrant. The permit writer may also issue numeric limits in general permits applicable to classes of facilities. In fact, one of the bases for EPA's decision not to establish uniform national TSS limits is the recognition that a number of states, particularly those with significant numbers of CAAP facilities, already have general permits with numeric limits tailored to the specific production systems, species raised, and environmental conditions in the state, and these permits seem to be working well to minimize discharges of suspended solids (see DCN 63056). EPA believes there would be minimal environmental gain from requiring these states to redo their General Permits to conform to a set of uniform national concentration-based limits that in most cases would not produce significant changes in control technologies and practices at CAAP facilities.

In the final rule, EPA is also not establishing numeric limits for any drug or pesticide, but is requiring CAAP facilities to ensure proper storage of drugs, pesticides and feed to prevent spills and any resulting discharges of drugs and pesticides. EPA is also establishing a requirement to implement procedures for responding to spills of these materials to minimize their discharge from the facility. EPA's survey of this industry indicated that many CAAP facilities currently employ a number of different measures to prevent spills and have established in-place systems to address spills in the event they occur. EPA is thus establishing a requirement for all facilities to develop and implement BMPs that avoid inadvertent spills of drugs, pesticides, and feed and to implement procedures for properly containing, cleaning and disposing of any spilled materials to minimize their discharge from the facility. The effect of these requirements will be to promote increased care in the handling of these materials.

Some commenters suggested that EPA regulate certain other pollutants or substances that may be discharged from these production systems. For this rule, EPA evaluated control of some of these. For example, EPA evaluated the application of activated carbon treatment to remove compounds such as antibiotic active ingredients from wastewater prior to discharge. For the reasons discussed in Section IX.A, however, EPA is not basing any pollutant limitations on the application of this technology.

C. Treatment Options Considered

EPA evaluated three treatment options as the basis for BPT/BCT/BAT proposed limitations for the flow-through and recirculating subcategories and three options for the net pen subcategory. For flow-through and recirculating systems, EPA proposed a numeric limitation for TSS. For Option 1, the least stringent option, EPA considered TSS limitations based on primary settling as well as the use of BMPs to control the discharge of solids from the production system. The second treatment option (Option 2) considered by EPA for establishing TSS limitations was based on Option 1 technologies plus the addition of reporting requirements if INAD or extralabel drug use were used in the production systems, plus the implementation of BMPs to ensure proper storage, handling and disposal of drugs and chemicals and the prevention of escapes when non-native species are produced. EPA based limitations for the most stringent option (Option 3) on primary settling

and the addition of secondary solids settling, in conjunction with BMPs, to control the discharge of solids from the production system. This option also included BMPs to control drugs, chemicals and non-native species and the reporting of drugs. For New Source Performance Standards (NSPS), EPA considered the same three options.

EPA evaluated three treatment options for the net pen subcategory. The least stringent option, Option 1, required feed management and operational BMPs for solids control. Option 2 consisted of the same practices and technology as Option 1 plus a BMP plan to address drugs, chemicals, pathogens, and non-native species and general reporting requirements for the use of certain drugs and chemicals. Option 3, the most stringent option, included the requirements of the first two options as well as active feed monitoring to control the supply of feed in the production units. Many existing facilities use active feed or real time monitoring to track the rate of feed consumption and detect uneaten feed passing through the nets. These systems may include the use of devices such as video cameras, digital scanning sonar detection, or upwellers, in addition to good husbandry and feed management practices. These systems and practices allow facilities to cease feeding the aquatic animals when a build-up of feed or over-feeding is observed. EPA considered the same treatment options for NSPS.

The NODA described two additional options that EPA was considering for flow-through and recirculating systems, but did not identify any new options for net pens. These two options contained the same treatment technologies and practices described in the three options considered for the proposed rule but in slightly different combinations.

The NODA Option A included primary solids treatment, a reporting requirement for the INAD and extralabel drug uses, and the implementation of BMPs to control drugs and chemicals. In addition to Option A requirements, Option B included secondary solids removal treatment or, alternatively, the implementation of BMPs for feed management, and solids handling to control the discharge of solids.

As previously explained, for flow-through or recirculating systems, today's final rule does not establish numeric limitations for total suspended solids (TSS) but does include narrative limitations requiring the solids control measures and operational practices described as part of Option B for BPT/BCT/BAT limitations and NSPS. These include requirements to minimize the discharge of solids. It also requires facilities to develop and implement practices designed to prevent the discharge of spilled drugs and pesticides, inspection and maintenance protocols designed to prevent the discharge of pollutants as a result of structural failure, training of personnel, various recordkeeping requirements, and documentation of the implementation of these requirements in a BMP plan which is maintained on site and available to the permitting authority upon request.

For net pens, the final rule establishes non-numeric, narrative limitations that are similar to those adopted for flow-through and recirculating systems. Thus, the limitations require minimization of feed input, proper storage of drugs, pesticides and feed, routine inspection and maintenance of the production and wastewater treatment systems, training of personnel, and appropriate recordkeeping. Compliance with these requirements must be documented in a BMP plan which describes how the facility is minimizing solids discharges through feed management and how it is complying with prohibitions on the discharge of feed bags and other solid waste materials. Further, net pens must minimize the accumulation of uneaten feed beneath the pens through active feed monitoring and management strategies.

D. Reporting Requirements

EPA's proposed rule would have required permittees to report the use of INADs and extralabel use of both drugs and chemicals. In the final rule, EPA is modifying the proposed requirement, by deleting the reporting requirements for chemicals, including pesticides, and by further limiting the reporting requirement for drugs, as described below. EPA used the term ''chemicals'' in the proposed rule to refer to registered pesticides.

EPA's decision not to include pesticides in the final reporting requirements is based on the language in the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the regulations that implement the statute. FIFRA Section 5 authorizes EPA to allow field testing of pesticides under development through the issuance of Experimental Use Permits. Further, FIFRA Section 18 authorizes EPA to allow States to use a pesticide for an unregistered use for a limited time if EPA determines that emergency conditions exist. Under both of these provisions the applicant is required to submit information concerning the environmental risk associated with the pesticide use as part of the application for the permit or exemption. Also in both cases the permittee or the State or Federal authority must report immediately to EPA any adverse effects from the use. Prior to issuing an emergency exemption, EPA is required to determine that the exemption will not cause unreasonable adverse effects on the environment (*see* 40 CFR 166.25(b)(1)(ii)) and that the pesticide is likely to be used in compliance with the requirements imposed under the exemption (*see* 40 CFR 166.25(b)(1)(iii)). EPA's regulation further specifies that the applicant for an emergency exemption must coordinate with other affected State or Federal agencies to which the requested exemption is likely to be of concern. The application must indicate that the coordination has occurred, and any comments provided by the other agencies must be submitted to EPA with the application (*see* 40 CFR 166.20(a)(8)).

In contrast, the FDA's regulations for Investigative New Animal Drugs (INADs) exempt INADs from the requirement to conduct an Environmental Assessment (*see* 21 CFR 25.20 and 25.33). As a policy matter, FDA encourages INAD sponsors to notify permitting authorities of the use of an INAD. There is, however, no requirement that the sponsors comply. Therefore, EPA considers the reporting of INADs in today's regulation necessary to ensure that permit writers are aware of the potential for discharge of the INAD and can take action as necessary in authorized circumstances.

EPA is providing an exception to the requirement to report INAD use. When an INAD has already been approved for use in another species or to treat another disease and is applied at a dosage that does not exceed the approved dosage, reporting is not required if it will be used under similar conditions. The requirement that the use be under similar conditions is intended to limit the exception to cases where the INAD use would not be expected to produce significantly different environmental impacts from the previously approved use. For example, use of a drug that had been previously approved for a freshwater application as an INAD in a marine setting would not be considered a similar condition of use, since marine ecosystems may have markedly different vulnerabilities than freshwater ecosystems. Similarly, the use of a drug approved to treat terrestrial animals as an INAD to treat aquatic animals would not be considered a similar condition of use. In contrast, the use of a drug to treat fish in a freshwater system that was previously approved for a different

freshwater species would be considered use under similar conditions. EPA has concluded that when a drug is used under similar conditions it is unlikely that the environmental impacts would be different than those that were already considered in the prior approval of the drug.

CAAP facilities must also report the use of extralabel drugs. However, as with INADs, reporting is not required if the extralabel use does not exceed the approved dosage and is used under similar conditions. EPA anticipates that most extralabel drug use will not require reporting, but wants to ensure that permitting authorities are aware of situations in which a higher dose of a drug is used or the drug is used under significantly different conditions from the approved use. It is also possible that drugs approved for terrestrial animals could be used to treat aquatic animals as extralabel use drugs.

For the final rule, the timing and content of reporting requirements related to the use of INADs and extralabel drugs are similar to the proposed requirements. EPA requires both oral and written reporting. The final rule has an added requirement that the CAAP facility report the method of drug application in both the oral report and the written report. EPA has concluded that both oral and written reports are reasonable requirements because the oral report lets the permitting authority know of the drug use sooner than the written report, thus facilitating site-specific action if warranted. The written report provides confirmation of the use of the drug and more complete information for future data analysis and control measures. Today's regulation also adds a requirement that CAAP facilities notify the permitting authority in writing within seven days after signing up to participate in INAD testing. Advance notice prior to the use of the INAD allows the permitting authority to determine whether additional controls on the discharge of the INAD during its use may be warranted.

Finally, today's regulation includes a requirement to report any spill of drugs, pesticides or feed that results in a discharge to waters of the U.S. Facilities are expected to implement proper storage for these products and implement procedures for the containing, cleaning and disposing of spilled material. If the spilled material enters the production system or wastewater treatment system it can be assumed that the material will reach waters of the U.S. EPA considers reporting of these events necessary to alert the permitting authority to potential impacts in the receiving stream. Facilities are expected to make an oral report to the permitting authority within 24 hours of the spill's occurrence followed by a written report within 7 days. The report shall include the identity of the material spilled and an estimated amount.

EPA has concluded that today's reporting requirements are appropriate because they make it easier for the permitting authority to evaluate what additional control measures on INADs and extralabel drug use may be necessary to prevent or minimize harm to waters of the U.S. and to respond more effectively to any unanticipated environmental impacts that may occur. Because neither of these classes of drugs has undergone an environmental assessment for the use being made of them, EPA is ensuring that the permitting authority is aware of their use and if warranted can take site specific action.

Today's reporting requirements are authorized under several sections of the CWA. Section 308 of the CWA authorizes EPA to require point sources to make such reports and ''provide such other information as [the Administrator] may reasonably require.'' 33 U.S.C. 1318(a)(A). Section 402(a) of the Act authorizes EPA to impose permit conditions as to ''data and information collection, reporting and such other requirements as [the Administrator] deems appropriate.'' 33 U.S.C. 1342(a)(2). It is well established that these provisions justify EPA's establishing a range of information disclosure requirements. Thus, for example, the United States Court of Appeals for the District of Columbia Circuit concluded that the Agency's data gathering authority was not limited to information on toxic pollutants already identified by the Agency in a permittee's discharge. EPA regulations required permit applications to include information on toxic pollutants that an applicant used or manufactured as an intermediate or final product or byproduct. In the court's view, EPA could reasonably determine that it could not regulate effectively without information on such pollutants because they could end up present in the permittee's discharge. *Natural Resources Defense Council, Inc.* v. *U.S. Environmental Protection Agency,* 822 F.2d 104, 119 (DC Cir. 1987). The same is true for certain INADs and extralabel drug use that may end up as pollutants discharged to waters of the U.S.

Under the proposed rule, the operators of facilities subject to the rule were to certify that they had developed a BMP plan that met the requirements in the regulation. EPA continues to view BMPs as effective tools to control the discharge of pollutants from CAAP facilities and is establishing narrative requirements based on the use of BMPs as the basis of today's regulation. EPA has also retained the requirement for a BMP plan. The BMP plan is a tool in which the facility must describe the operational measures it will use to meet the non-numeric effluent limitations in the regulation. Upon incorporation of today's requirements into an NPDES permit, the CAAP facility owner or operator will be expected to develop site-specific operational measures that satisfy the requirements. The final rule requires CAAP facilities to develop a BMP plan that describes how the CAAP facility will comply with the narrative requirements and that is maintained at the CAAP facility. The CAAP facility owner or operator must certify in writing to the permitting authority that the plan has been developed. In EPA's view, a BMP plan, as a practical matter, can assist facilities in achieving compliance with the non-numeric limitations. It can also assist regulatory authorities in verifying compliance with the requirements and modifying specific permit conditions where warranted. As explained earlier in this section, EPA has concluded Section 308 clearly authorizes it to require this information. Of course, irrespective of the content of the plan, a facility must still comply with the narrative limitations.

In conjunction with the requirement to inspect and provide regular maintenance of CAAP production and treatment systems to prevent structural damage, EPA is including a reporting requirement associated with failure of the CAAP containment structure and any resulting discharges. EPA is requiring CAAP facilities to report any failure of or damage to the structural integrity of the containment system that results in a material discharge of pollutants to waters of the U.S. For net pen systems, for example, failures might include physical damage to the predator control nets or the nets containing the aquatic animals, that may result in a discharge of the contents of the nets. Physical damage might include abrasion, cutting or tearing of the nets and breakdown of the netting due to rot or ultra violet exposure. For flow-through and recirculating systems, a failure might include the collapse of, or damage to, a rearing unit or wastewater treatment structure; damage to pipes, valves, and other plumbing fixtures; and damage or malfunction to screens or physical barriers in the system, which would prevent the unit from containing

water, sediment, and the aquatic animals. The permitting authority may further specify in the permit what constitutes a material discharge of pollutants that would trigger the reporting requirements. The permittee must report the failure of the containment system within 24 hours of discovery of the failure. The permittee must notify the permitting authority orally and describe the cause of the failure in the containment system and identify materials that were discharged as a result of this failure. Further, the facility must provide a written report within seven days of discovery of the failure documenting the cause, the estimated time elapsed until the failure was repaired, an estimate of the material released as a result of the failure, and steps being taken to prevent a reoccurrence.

E. Costs

At proposal, EPA used a model facility approach to estimate the cost of installing or upgrading wastewater treatment to achieve the proposed requirements. As described in the preamble to the proposed regulation (67 FR 57872), EPA developed 21 model facilities (based on the USDA's Census of Aquaculture and EPA's screener survey) characterized by different combinations of production systems, size categories, species and ownership types. EPA developed regulatory technology options based on screener survey responses, site visits, industry and other stakeholder input, and existing permit requirements.

EPA estimated the cost for each option component for each model facility. We then calculated costs for each regulatory option at each model facility based on model facility characteristics and the costs of the option's technologies or practices corresponding to the option.

EPA estimated frequency factors for treatment technologies and existing BMPs based on screener survey responses, site visits, and sampling visits. Baseline frequency factors represented the portion of the facilities represented by a particular model facility that would not incur costs to comply with the proposed requirements because they were already using the technology or practice. EPA adjusted the component cost for each model facility to account for those facilities that already have the component in-place. Subsequently, EPA derived national estimates of costs by aggregating the component costs applicable to each model facility across all model facilities.

EPA's detailed surveys captured information on the treatment in-place at the facility and other site-specific information (such as labor rates). EPA obtained additional cost information from data supplied from public comments and site visits. With the new data, EPA revised the method to estimate compliance costs. Instead of a model facility approach, EPA used a facility-level cost analysis based on the available facility-specific data contained in the detailed survey responses. We applied statistically-derived survey weights instead of the frequency factors used at proposal to estimate costs to the CAAP industry as a whole.

For proposal, EPA used national averages for many of the cost elements, such as labor rates and land costs. In its analysis for the final regulation, EPA used facility specific cost information, such as labor rates, to determine the costs associated with implementing the regulatory options. When facility specific rates were not available, EPA used national averages for similar ownership types of facilities (*i.e.*, non-commercial and commercial ownership) to determine managerial and staff labor rates. EPA revised estimates for all labor costs using the employee and wage information supplied in the detailed surveys. For those facilities indicating they use unpaid labor for part of the facility operation, we used wages for similar categories (*i.e.*, managerial or staff) supplied by that facility to estimate costs associated with implementing the regulatory options.

Comments also suggested that EPA's assumed land costs were too low at proposal; EPA assumed national average land values for agricultural land. EPA revised its estimates for land costs when determining the opportunity costs of using land at a facility if structural improvements were evaluated that required use of facility land that was not currently in use by the CAAP operation's infrastructure (*e.g.*, occupied by tanks, raceways, buildings, settling basins, *etc.*). When evaluating the cost of land for the revised analyses, EPA used land costs of $5,000/acre, which is twice the median value for land associated with aquaculture facilities surveyed in the U.S. (*see* DCN 63066). EPA used this conservative estimate because the only facilities that required structural improvements in the options evaluated were non-commercial facilities, for which land value estimates were not available.

EPA considered several technology-based options to determine the technical and economic feasibility of requiring numeric TSS limits for in-scope CAAP facilities. EPA's analysis of the detailed survey revealed that over 90% of the flow-through and recirculating system facilities currently had at least primary settling technologies in-place. EPA performed a cost analysis for the facilities without primary settling using the facility-specific configuration information provided in the detailed survey. EPA also evaluated facilities with primary settling in-place by comparing actual (*i.e.*, DMR data) or estimated TSS effluent concentrations to the proposed limits. For those facilities not meeting the proposed TSS limits, EPA also evaluated the implementation of additional solids controls, including secondary solids polishing and feed management.

For facilities with no solids control equipment, we estimated the costs for primary solids control. EPA evaluated each facility to identify the configuration of the existing treatment units and what upgrades would be required.

EPA also used industry cost information provided through public comment and the detailed survey to estimate costs for design and installation of primary settling equipment for effective settling of suspended solids. For example, we used the facility-level data included in the detailed survey responses to place and size the off-line settling basins on the facility site.

EPA classified each facility's wastewater treatment system based on the description provided in its survey response and available monitoring data, including DMR data. We assumed that treatment technologies indicated by a facility on the detailed survey are properly sized, installed, and maintained. EPA estimated facility-specific costs for each of the responding direct dischargers and used these estimates as the basis for national estimates. Because the survey did not collect information about many specific parameters used in individual facilities' production processes and treatment systems, EPA supplemented the facility-specific information with typical specifications or parameters from literature, survey results, and industry comments. For example, EPA assumed that facilities have pipes of typical sizes for their operations.

As a consequence of such assumptions, a particular facility might need a different engineering configuration from those modeled if it installed equipment that varies from the equipment or specifications we used to estimate costs. EPA nonetheless considers that costs for these facilities are generally accurate and representative, especially industry-wide. EPA applied typical specifications and parameters representative of the

industry to a range of processes and treatment systems. We contacted facilities to get site-specific configuration information where possible.

In revising cost estimates, EPA paid particular attention to:

1. Size of tanks, raceways, and culture units;
2. Labor rates;
3. Treatment components in place;
4. BMPs and plans in place;
5. Daily operations at the facility.

Site visits and analysis of the detailed surveys indicated that raceways and quiescent zones are cleaned as necessary to maintain system process water quality.

In evaluating facilities for the need to use additional solids controls, EPA first checked for evidence of a good feed management program. If the facility reported they practice feed management, EPA looked for evidence of solids management and good operation of the physical plant, including regular cleaning and maintenance of feed equipment and solids collection devices (*e.g.*, quiescent zones, sedimentation basins, screens, *etc.*). To evaluate the effectiveness of a facility's solids control practices, we calculated feed conversion ratios (FCRs) using pounds of feed per pound of live product (as reported in the detailed survey) and considered existing solids control equipment. We assumed facilities lacking evidence of good feed management or solids control programs would incur additional costs to improve or establish them.

EPA estimated FCRs from data in the detailed survey and follow-up with some facilities and compared FCRs for groups of facilities (*i.e.*, combinations of ownership, species and production system types such as commercial trout flow-through facilities or government salmon flow-through facilities). We found a wide range of FCRs (reported by facilities in their detailed surveys, which were validated by call backs to the facility) among apparently similar facilities within ownership-species-production system groupings.

For example, we had good data for 24 of 60 government trout producers using flow-through systems. They reported a range of FCRs of 0.79 to 1.80 with a median FCR of 1.30. If an individual facility's reported FCR was significantly greater than the median, EPA further evaluated the facility to ascertain the reason for the higher FCR. Facilities that produce larger fish, such as broodstock, might have higher FCRs because the larger fish produce less flesh per unit of food. Facilities with fluctuating water temperatures could also be less efficient than facilities with constant water temperatures. We did not apply costs for solids control BMPs for facilities with reasonable explanations for the higher FCRs. We evaluated facilities that did not report FCRs or provide enough data for an estimate by using a randomly selected FCR, which is described in Chapter 10 of the Technical Development Document (DCN 63009).

For those facilities that required additional solids controls, EPA evaluated both feed management and the installation of secondary solids polishing technologies. EPA received comments on the use of microscreen filters and EPA agrees with concerns raised in comments that the cost associated with enclosing the filter in a heated structure would be prohibitive. EPA found that the effective operation of microscreen filters requires that they be enclosed in heated buildings to prevent freezing when located in cold climates. EPA's revised estimates of costs for secondary solids polishing are not based on the application of microscreen filters unless the detailed survey response indicated that such a structure existed at the site. When the detailed survey did not indicate a structure at the site, EPA estimated costs for a second stage settling structure rather than a microscreen filter. Based on data from two of EPA's sampling episodes at CAAP facilities, this technology will achieve the proposed limits for TSS.

We also considered the use of activated carbon filtration to treat effluent containing drug or pesticide active ingredients from wastewater, but rejected controls for these materials. Research indicates that this technology is effective at treating these compounds, and at least one aquatic animal production facility installed this technology for water quality reasons. EPA estimated the costs for activated carbon treatment as a stand-alone technology. We estimated costs on a site-specific basis for facilities which reported using drugs and then added these costs for the different regulatory options considered to assess the economic achievability of this technology. A detailed discussion of how EPA estimated costs is available from the public record (DCN 62451). EPA considers these costs to be economically unachievable or not affordable on a national scale. However, EPA is aware of at least one facility currently using this technology, and notes that it is an effective technology for removing drug compounds from wastewater.

EPA estimated the costs to develop and implement escape management practices at facilities where (1) the cultured species was not commonly produced or regarded as native in the State, (2) the facility was a direct discharger, and (3) the species was expected to survive if released. (In contrast, producers of a warm water species in a cold climate, such as tilapia producers in Minnesota or Idaho, would not incur costs for this practice.) Costs for escape prevention include staff time for production unit and discharge point inspections and maintenance of escape prevention devices. We applied these costs to facilities that installed equipment conforming with State requirements for facilities producing non-native species (identified by the State). Management time includes quarterly production unit and discharge point inspections, eight hours a year to review applicable State and Federal regulations, and quarterly staff consultations.

F. Economic Impacts

There are a number of changes made to the costing and economic impact methods used for the final rule. EPA used data from the detailed survey to project economic impacts for the final rule, in contrast to the screener data and frequency factors used for the proposed rule. For existing commercial operations, EPA assessed the number of business closures among regulated enterprises, facilities, and companies by applying market forecasts and using a closure methodology that compares projected earnings with and without incremental compliance costs for the period 2005 to 2015. Other additional analyses include an analysis of moderate impacts by comparing annual compliance costs to sales, an evaluation of financial health using a modified U.S. Department of Agriculture's four-category (2×2) matrix approach, and an assessment of possible impacts on borrowing capacity. For new commercial operations, EPA evaluates whether the regulatory costs will result in a barrier to entry among new businesses. For noncommercial operations, EPA evaluated impacts using a budget test that compares incurred compliance costs to facility operating budgets. Additional analyses investigate whether a facility could recoup increased compliance costs through user fees and estimated the associated increase.

For today's final regulation, EPA modified its forecasting models to include certain data for recent years that became available after the Agency published its NODA (*see* 68 FR 75068–75105). This and other details about how EPA developed its economic

impact methodologies is presented in this preamble and in the Economic and Environmental Benefit Analysis of the Final Effluent Limitations Guidelines and Standards for the Concentrated Aquatic Animal Production Industry (''Economic and Environmental Benefit Analysis''), available in the rulemaking record.

G. Loadings

To estimate the baseline discharge loadings and load reductions for the proposed rule, EPA used the same model facility approach as used to estimate the compliance costs. Briefly, EPA first estimated pollutant loadings for untreated wastewater based on several factors for each model facility. As previously noted, feed used at CAAP facilities contributes to pollutant discharges in three ways: By-product feces, dissolved ammonia excretions, and uneaten feed (in dissolved and particulate forms). These byproducts of feed contribute to the pollutant load in the untreated culture water. EPA then used typical efficiency rates of removing specific pollutants from water to estimate load reductions for the treatment options and BMPs. EPA estimated frequency factors for treatment technologies and existing BMPs based on screener survey responses, site visits, and sampling visits. The occurrence frequency of practices or technologies was used to estimate the portion of the operations that would incur costs. Using the same frequency factors for technologies in place that were used to estimate costs, EPA estimated the baseline pollutant loads discharged, then calculated load reductions for the options.

As described in the NODA, EPA revised the loadings approach to incorporate facility-level information using data primarily from the detailed surveys. EPA also incorporated information included in comments concerning appropriate feed conversion ratios (FCRs).

EPA based its estimates of pollutant loads on the reported feed inputs included in the detailed surveys. EPA used the annual feed input and feed-to-pollutant conversion factors described in the TDD and DCN 63026 to calculate raw pollutant loads. EPA then analyzed each facility's detailed survey response to determine the treatment-in-place at the facility. Using published literature values to determine the pollutant removal efficiencies for the types of wastewater treatment systems used at CAAP facilities, EPA calculated a baseline pollutant load discharged from each surveyed facility. EPA used these pollutant removal efficiencies and raw pollutant loads to estimate the baseline loads. EPA validated the baseline load estimates with effluent monitoring data (DCN 63061).

For today's regulation, EPA evaluated secondary solids removal technologies and feed management. EPA assessed whether improved feed management in addition to primary solids settling might be as effective at reducing solids in the effluent as secondary settling. EPA found that feed management was the lower cost option compared to secondary solids removal technology. (As discussed in more detail below at VIII.B., EPA has now concluded that a rigorous feed management program alone will achieve significant reductions in solids at CAAP facilities.)

Pollutant removals associated with feed management result from more efficient feed use and less wasted feed. For its evaluation, EPA used feed conversion rates as a surrogate for estimating potential load reductions resulting from feed management activities. Note, EPA used FCR values as a means to estimate potential load reductions, not as a target to set absolute FCR limits for a facility or industry segment.

Based on the information in the detailed surveys, EPA calculated FCRs for 69 flow-through and recirculating system facilities. EPA validated the feeding, production and estimated FCRs by contacting each facility. For those facilities that were not able to supply accurate feed and/or production information, to enable EPA to estimate a FCR, EPA randomly assigned a FCR.

EPA attempted to capture and account for as much of the variation as possible when analyzing FCRs and in the random assignment process. For example, the production system, species, and system ownership (which are all known from the detailed surveys) were expected to influence feeding practices, so facilities were grouped according to these parameters. EPA included ownership as a grouping variable to account for some of the variation in production goals. Most commercial facilities that were evaluated are producing food-sized fish and generally are trying to maintain constant production levels at the facility; commercial facilities would tend to target maximum weight gain over a low FCR in determining their optimal feeding strategy. Non-commercial facilities are generally government facilities that are producing for stock enhancement purposes. Production goals are driven by the desire to produce a target size (length and weight) at a certain time of year for release. Non-commercial facility feeding goals may not place as great an emphasis on maximum growth. However, EPA expects that all facilities, regardless of production goals, can achieve substantial reductions in pollutant discharges over uncontrolled levels by designing and implementing an optimal feed input management strategy, including appropriate recordkeeping and documentation of FCRs.

The process for the random assignment of FCRs to facilities with incomplete information included:

- EPA grouped facilities by ownership, species, and production
- FCRs were estimated for each facility with sufficient data within a group
- The distributions of grouped data were examined for possible outliers, which were defined as FCRs less than 0.75 or greater than 3.0. When extreme values were found and validated, they were removed from the grouping. Although these extremes may be possible and a function of production goals, water temperature, etc., EPA was not able to validate and model all of the factors contributing to the extreme FCR rates. Facilities excluded because of extreme values were not assigned a random FCR, but were found to have a documented reason for the extreme value. For example, one facility produced broodstock for stock enhancement purposes. Some extreme values were updated based on validating information from the facility, and the updates were found to be within the range used for analysis.
- After removing outliers, the first and third quartiles were calculated for each grouping. The first quartile of a group of values is the value such that 25% of the values fall at or below this value. The third quartile of a group of values is the value such that 75% of the values fall at or below this value.
- For each grouping, the target FCR was assumed to be the first quartile value.
- For the facilities with no FCR information, a random FCR between the first and third quartiles was assigned.
- To account for variation in FCRs based on factors such as water temperature, EPA only costed additional feed management practices at a facility when the reported or randomly assigned FCR was within the upper 25% of the inter-quartile range. This was considered to be an indication of potential improvement in feed management.
- For some combinations of ownership, species, and production, there was not sufficient data to do the quartile analysis. In these cases, data

from a similar grouping of ownership, species, and production was used.

If a facility's FCR was in the upper 25% of the inter-quartile range or did not currently have secondary settling technologies in place, EPA assumed the facility would need to improve feed management practices. The improvement in feed management practices would result in increased costs due to increased observations and recordkeeping and in pollutant load reductions resulting from less wasted feed.

The approach for estimating the loadings for the final rule has not changed significantly from the approach taken in the NODA. In estimating the loadings and removals for the final rule, EPA considered incidental removals or removals gained from the control of solids through narrative limitations. As part of the loadings analysis, EPA considered incidental removals of metals, PCBs and one drug, oxytetracycline.

Metals may be present in CAAP effluents from a variety of sources. Some metals are present in feed (as federally approved feed additives), occur in sanitation products, or may result from deterioration of CAAP machinery and equipment. EPA has observed that many of the treatment measures used in the CAAP industry provide substantial reductions of most metals. The metals present are generally readily adsorbed to solids and can be adequately controlled by controlling solids.

Most of the metals appear to be originating from the feed ingredients. Trace amounts of metals at federally approved concentrations are added to feed in the form of mineral packs to ensure that the essential dietary nutrients are provided for the cultured aquatic animals. Examples of metals added as feed supplements include copper, zinc, manganese, and iron (Snowden, 2003).

EPA estimated metals load reductions from facilities that are subject to the final rule (*see* DCN 63011). The metals for which load reductions are analyzed are those which were present above the detection levels in the wastewater samples collected from CAAP facilities during EPA's sampling for this rulemaking. EPA used the net concentrations of the metal in the wastewater to estimate these loads. EPA estimated these load reductions as a function of TSS loads using data obtained from the four sampling episodes. For this analysis, EPA first assumed that non-detected samples had the concentration of half the detection limit. From the sampling data, EPA calculated net TSS and metals concentrations at different points in the facilities. EPA then calculated metal to TSS ratios (in mg of metal per kg of TSS) based on the calculated net concentrations. EPA removed negative and zero ratios from the samples. Finally, basic sample distribution statistics were calculated to derive the relationship between TSS and each metal.

EPA calculated estimated load reductions of PCBs from regulated facilities as a percentage of TSS load reductions. Since the main source of PCBs at CAAP facilities is through fish feed, a conversion factor was calculated to estimate the amount of PCBs discharged per pound of TSS. EPA assumed that 90% of the feed was eaten, and that 90% of the feed eaten would be assimilated by the fish. By combining the amount of food materials excreted by fish (10% of feed consumed) with the 10% of food uneaten, EPA was able to partition the PCBs among fish flesh and aqueous and solid fractions. Due to a lack of sampling data, EPA used a maximum level of 2μg/g, the FDA limit on PCB concentrations in fish feed, to estimate the maximum amount of PCBs that could possibly be in the TSS. This maximum possible discharge load in the TSS was estimated to be 21% of the PCBs in the feed. EPA considers this estimate to provide an upper bound on the amount of PCBs discharged from CAAP facilities, and the amount potentially removed by the rule. Even so, the estimates are quite low (0.52 pounds of PCBs discharged in the baseline). CAAP facilities are not a significant source of PCB discharges to waters of the U.S. (*see* DCN 63011).

EPA estimated the pollutant load of oxytetracycline discharged from in-scope CAAP facilities using data from EPA's detailed survey of the CAAP Industry. EPA first determined facility specific amounts of oxytetracycline used by each CAAP facility. For those facilities that reported using medicated feed containing oxytetracycline, EPA evaluated their responses to the detailed survey to determine the amount, by weight, of medicated feed containing oxytetracycline and the concentration of the drug in the feed. EPA then estimated the amount of oxytetracycline that was reduced at facilities in which feed management practices were applied in the cost and loadings analyses. The facility level estimates were then multiplied by the appropriate weighting factors and summed across all facilities to determine the national estimate of pounds of oxytetracycline reduced from discharges as a result of the regulation.

As part of a sampling episode, EPA also performed a preliminary study to develop a method to measure oxytetracycline in effluent from CAAP facilities. EPA took samples to analyze the effluent from a CAAP facility that produces trout during a time period in which oxytetracycline, in medicated feed, was being used to treat a bacterial infection in some of the animals at the facility. Results of the study indicate that oxytetracycline can be stabilized in samples when preserved with phosphoric acid and maintained below 4 °C prior to analysis. The method found levels of oxytetracycline to range from <0.2 μg/L (which was the method detection limit) in the supply and hatchery effluent to 110 μg/L in the influent to the offline settling basin. The level detected in the combined raceway effluent was 0.95 μg/L. See the analysis report (DCN 63011) for additional information.

H. Environmental Assessment and Benefits Analysis

EPA's environmental assessment and benefits analysis for the proposed rule consisted of two efforts. First, EPA reviewed and summarized literature it had obtained regarding environmental impacts of the aquaculture industry, focusing particularly on segments of the industry in the scope of the proposed rule. Second, EPA used estimates of pollutant loading reductions associated with the proposed requirements to assess improvements to water quality that might arise from the proposed requirements, and monetized benefits from these water quality improvements.

EPA's approach to the environmental assessment and benefits analysis for the final rule is similar to the approach for the proposed rule, except that EPA has incorporated new data, information, and methods that were not available at the time of proposal, particularly those sources described in Section V of this Preamble. For example, literature, discussions, and data submitted by stakeholders both through the public comment process on the proposed rule as well as at other forums were considered. EPA also used facility-specific data provided by or developed from the detailed survey responses. EPA has updated and revised its summary of material relating to environmental impacts of CAAP facilities in Chapter 7 of the Economic and Environmental Benefit Analysis for today's final rule (DCN 63010). EPA's revised benefits analysis are described in both Section X of this Preamble as well as in Chapter 8 of the Economic and Environmental Impact Analysis (DCN 63010).

VII. Who Is Subject to This Rule?

This section discusses the scope of the final rule and explains what wastewaters are subject to the final limitations and standards.

A. Who Is Subject to This Rule?

Today's rule applies to commercial (for-profit) and non-commercial (generally, publicly-owned) facilities that produce, hold or contain 100,000 pounds or more of aquatic animals per year. Any 12 month period would be considered a year for the purposes of establishing coverage under this rule.

While facilities producing fewer than 100,000 pounds of aquatic animals per year are not subject to this rule, in specific circumstances they may require NPDES permits that include limitations developed on a BPJ basis. An aquatic animal production facility producing fewer than 100,000 pounds of aquatic animals per year will be subject to the NPDES permit program if it is a CAAP as defined in 40 CFR 122.24. As explained in the proposed rule, EPA limited the scope of the regulation it was considering to facilities that are CAAPs above this production threshold.

The Agency concluded that facilities below the threshold would likely experience significant adverse economic impacts if required to comply with the proposed limitations. EPA concluded that these smaller CAAP facilities would have compliance costs in excess of 3 percent of revenues. Further, smaller CAAP facilities account for a smaller relative percentage of total CAAP TSS discharges and only limited removals would be obtained from the proposed BPT/BCT/BAT control. 67 FR 57872, 57884. Other types of facilities also not covered by today's action include closed pond systems (most of which do not meet the regulatory definition of a CAAP facility), molluscan shellfish operations, including nurseries, crawfish production, alligator production, and aquaria and net pens rearing native species released after a growing period of no longer than 4 months to supplement commercial and sport fisheries. This last exclusion applies primarily to Alaskan non-profit facilities which raise native salmon for release into the wild in flow-through systems and then hold them for a short time in net pens preceding their release. The flow-through portions of these facilities are within the scope of the rule, if they produce 100,000 pounds or more per year, but the net pen portions would be excluded from regulation. EPA determined for the types of excluded systems or production operations listed above either that they generate minimal pollutant discharges in the baseline or that available pollutant control technologies will reduce pollutant loadings from these operations by only minimal amounts. For further explanation, see the proposal at 67 FR 57572, 57885–86.

Facilities that indirectly discharge their process wastewater (*i.e.*, facilities that discharge to POTWs) are also not subject to today's rule. EPA did not propose and is not establishing pretreatment standards for existing or new indirect sources. As explained above, the bulk of pollutant discharges from CAAP facilities consists of TSS and BOD. POTWs are designed to treat these conventional pollutants. Moreover, CAAP facilities discharge nutrients in concentrations lower in full-flow discharges, and similar in off-line settling basin discharges, to nutrient concentrations found in human wastes discharged to POTWs. EPA has concluded that the POTW removals of TSS would achieve equivalent nutrient removals to those obtained by the options considered for this rulemaking for direct dischargers. EPA, therefore, concluded that there would be no pass through of TSS or nutrients needing regulation. Indirect discharging facilities are still subject to the General Pretreatment Standards (40 CFR 403) and any applicable local limitations. EPA has also determined that there are few indirect dischargers in this industry.

B. What If a Facility Uses More Than One Production System?

EPA has found that several detailed survey respondents are operating more than one type of production system. A facility is subject to the rule if the total production from any of the regulated production systems meets the production threshold. The facility would need to demonstrate compliance with the management practices required for each of the regulated production systems it is operating.

C. What Wastewater Discharges Are Covered?

This rule covers wastewaters generated by the following operations/processes: Effluent from flow-through, recirculating and net pen facilities. The flow-through and recirculating subcategory (Subpart A) applies to wastewaters discharged from these systems.

The type of production system determines the nature, quantity, and quality of effluents from CAAP facilities. Flow-through systems commonly use raceways or tanks and are characterized by continual flows of relatively large volumes of water into and out of the rearing units. Some flow-through systems discharge a single, combined effluent stream with large water volumes and dilute pollutant concentrations. Other flow-through systems have two or more discharge streams, with the process water in which the fish are raised as the primary discharge. This discharge, referred to as raceway effluent or bulk flow, is characterized by a large water volume and dilute pollutant concentrations. The secondary discharges from flow-through systems with multiple discharges result typically from some form of solids settling through an off-line settling basin (OLSB) or other solids removal devices. The discharges from off-line settling basins or solids removal devices have low water volumes and more concentrated pollutants. The supernatant from the OLSB may be discharged through a separate outfall or may be recombined prior to discharge with the raceway effluent.

Recirculating systems may also have two waste streams: Overtopping wastewater and filter backwash. Overtopping is a continuous blowdown from the production system to avoid the buildup of dissolved solids in the production system, and filter backwash is generated by cleaning the filter used to treat the water that is being recirculated back to the production system. Overtopping wastewater is usually small in volume (a fraction of the total system volume on a daily basis) and has higher TSS concentrations than a full flow discharge. Filter backwash wastewater is typically low in volume and is as concentrated as wastewater from similar devices at flow-through systems.

Net pen systems are located in open waters and thus are characterized by the flow and characteristics of the surrounding water body and by the addition of raw materials to the pens including feed, drugs and the excretions from the confined aquatic animals.

VIII. What Are the Requirements of the Final Regulation and the Basis for These Requirements?

This section describes, by subcategory, the options EPA considered and selected as a basis for today's rule. For each subcategory, EPA provides a discussion, as applicable, for the options considered for each of the regulatory levels identified in the CWA (*i.e.*, BPT, BCT, BAT, NSPS). For a detailed discussion of all technology options considered in the development of today's final rule, see the proposal (*see* 67 FR 57872), the NODA (*see* 68 FR 75068) or Chapter 9 of the Technical

Development (TDD) for today's final rule.

Based on the information in the record for the final CAAP rule, EPA has determined that the selected technology for the flow-through and recirculating systems subcategory and the net pens subcategory are technically available. EPA has also determined that the technology it selected as the basis for the final limitations or standards has effluent reductions commensurate with compliance costs and is economically achievable for the applicable subcategory. EPA also considered the age, size, processes, and other engineering factors pertinent to facilities in the scope of the final regulation for the purpose of evaluating the technology options. None of these factors provides a basis for selecting different technologies from those EPA has selected as its technology options for today's rule (*see* Chapter 5 of the TDD for the final rule for further discussion of EPA's analyses of these factors).

As previously explained, EPA adopted a production threshold cutoff as the principal means of reducing economic impacts on small businesses and administrative burden for control authorities associated with the treatment technologies it considered. EPA notes that certain direct dischargers that are not subject to today's effluent limitations or standards will still require a NPDES discharge permit developed on a case-by-case basis if they are CAAPs as defined in 40 CFR 122.24.

The new source performance standards (NSPS) EPA is today establishing represent the greatest degree of effluent reduction achievable through the best available demonstrated control technology. In selecting its technology basis for today's new source performance standards (NSPS), EPA considered all of the factors specified in CWA section 306, including the cost of achieving effluent reductions. EPA used the appropriate technology option for developing today's standards for new direct dischargers. The new source technology basis for both subcategories is equivalent to the technology bases upon which EPA is setting BPT/BCT/BAT (see Chapter 9 of the EEBA). EPA has thoroughly reviewed the costs of such technologies and has concluded that such costs do not present a barrier to entry. The Agency also considered energy requirements and other non-water quality environmental impacts for the new source technology basis and found no basis for any different standards from those selected for NSPS. Therefore, EPA concluded that the NSPS technology basis chosen for both subcategories constitute the best available demonstrated control technology. For a discussion on the compliance date for new sources, *see* section I.E. of today's final rule.

A. What Technology Options Did EPA Consider for the Final Rule?

Among the options EPA considered for the final rule for flow-through and recirculating systems in addition to the options presented in the proposed rule were (i) establishing no national effluent limitations (ii) establishing limitations and BMPs based on technology options A and B, and (iii) establishing narrative limitations based on BMPs only. Based on analysis presented in the NODA, EPA focused it analysis on these latter three options. For net pens, EPA considered three options: no national requirements, requirements equivalent to those proposed but for new sources only, and essentially the same requirements for existing and new sources as those in the proposed rule.

B. What Are the Requirements for the Flow-Through and Recirculating Systems Subcategory?

The following discussion explains the BPT/BCT/BAT limitations and NSPS EPA is promulgating for flow-through and recirculating system facilities.

1. BPT

After considering the technology options described in the previous section and the factors specified in section 304(b)(1)(B) of the CWA, EPA is establishing nationally applicable effluent limitations guidelines for flow-through and recirculating system CAAP facilities producing 100,000 pounds or more of aquatic animals per year for the reasons noted above at VIII.A.

EPA based the final requirements on production and operational controls that include a rigorously implemented feed management program. Programs of production and operational controls that include feed management systems, proper storage of material and adequate solids controls, and proper operation and maintenance are in wide use at existing flow-through and recirculating system facilities. Based on the detailed survey results, EPA estimates that such programs are currently used at 61 flow-through and recirculating facilities out of 242 total facilities. The costs of effluent removals associated with the evaluated practices are reasonable. The cost per pound of pollutant removed is $2.77 as measured using the higher of the removals for either BOD or TSS at each facility. (The removals for these parameters are not summed because of possible overlap and double counting.)

Based on its review of the data and information it obtained during this rulemaking, EPA has concluded that the key element in achieving effective pollution control at CAAP facilities is a well-operated program to manage feeding, in addition to good solids management. Feed is the primary source of TSS (and associated pollutants) in CAAP systems, and feed management plans are the principal tool for minimizing accumulation of uneaten feed in CAAP wastewater. Excess feed in the production system increases the oxygen demand of the culture water and increases solids loadings. In addition, solids from the excess feed usually settle and are naturally processed with the feces from the fish. Excess feed and feces accumulate in the bottom of flow-through and recirculating systems or below net pens. Ensuring that the aquatic animal species being raised receive the quantity of feed necessary for proper growth without overfeeding, and the resulting accumulation of uneaten feed, is a challenging task. Achieving the optimal feed input requires properly designing a site-specific feeding regimen that considers production goals, species, rearing unit water quality and other relevant factors. It also requires careful observation of actual feeding behavior, good record keeping, and on-going reassessment.

After full examination of the data supporting EPA's model technology, EPA has decided not to establish numerical TSS limitations. While the model technology will effectively remove solids to a very low level, EPA's data show wide variability, both temporally and across facilities, in the actual TSS levels achieved. EPA thus does not have a record basis for establishing numeric TSS limitations derived from its data set that are appropriate for all sites under all conditions. EPA believes that establishing a uniform numeric TSS limitation would result in requirements that are too stringent at some sites and not stringent enough at others. This is because feed management, while an effective pollution reduction technology for this industry, is not amenable to the same level of engineering process control as traditional treatment technologies used in other effluent guidelines. The basis for this conclusion is further explained below.

Clean Water Act sections 301(b)(1)(A) and 301(b)(2) require point sources to achieve effluent limitations that require the application of the BPT/BCT/BAT selected by the Administrator under section 304(b). Customarily, EPA implements this requirement through the establishment of numeric effluent

limitations calculated to reflect the levels of pollutant removals that facilities employing those technologies can consistently achieve. EPA traditionally uses a combination of sampling data and data reported in discharge monitoring reports from well-operated systems employing the model technology to calculate numeric effluent limitations.

In the proposed rule and the NODA, EPA used a similar approach to calculate numeric effluent limitations for TSS from a partial data set composed of well operated CAAP facilities employing a combination of wastewater treatment and management practices to reduce TSS concentrations in the discharged effluent. To reduce TSS discharge levels, the facilities examined by EPA used settling ponds and a number of different techniques, including feed management programs and periodic solids removal from both the culture water and settling ponds.

EPA's examination of well-operated facilities also identified several facilities using feed management and other operational and management controls alone that were achieving the same low levels of TSS discharge as facilities using settling ponds in combination with good feed management.

Based on EPA's examination of the data in its record, the Agency has concluded that a combination of settling technology and feed management control practices or rigorous feed management control and proper solids handling practices alone will achieve low levels of TSS. Operational measures like a feed management system, however, are not technologies that reflect the same degree of predictability as can be expected from wastewater treatment technology based on chemical or other physical treatment. While EPA is confident that its chosen technology can consistently achieve BPT treatment levels of solids removal, the Agency recognizes that feed management systems may not have the precision or consistently predictable performance from site to site that come with the traditional wastewater treatment technologies. The record confirms that there is variability in results associated with the use of feed management systems and other operational measures to control solids. Thus, EPA determined that it should not establish specific numeric TSS limitations based on the model technology. This conclusion is supported by a number of commenters who maintained that consistently achieving the proposed TSS levels would require installation of additional settling treatment structures, with little additional environmental benefit.

EPA's decision not to set uniform numeric TSS limitations based on rigorous feed management and good solids management is further supported by its analysis of measured or predicted TSS concentrations at facilities employing this technology. EPA's effluent monitoring data show differences in the measured TSS concentration in discharges at facilities employing feed management programs from the predicted TSS concentration levels derived using EPA's calculation from the data on feed used at BPT/BAT facilities. For this comparison, EPA calculated a TSS concentration that could be achieved through feed management plans using the data on feed and fish production at surveyed facilities. EPA then compared these concentrations, where available, with the actual TSS levels reported by those facilities in their discharge monitoring reports. The differences between the calculated TSS levels and reported levels may result from differences in application of feed management practices, variation in the flows or dilution of the effluent.

EPA recognizes that it would be feasible to calculate numeric effluent limitations for TSS based on treatment technologies alone, *i.e.*, eliminating best management practices from the technology basis for today's rule. EPA did not employ this approach for three reasons. First, EPA has determined that primary treatment in the form of quiescent zones in the culture water tanks and settling ponds by themselves are not the best technology available for treating TSS. Instead, rigorous feed management in conjunction with good solids handling practices constitutes a better technology for controlling this pollutant. Second, EPA is concerned that establishing numeric limitations for TSS based on primary and secondary settling may not be a practicable technology. Commenters pointed out that site and land availability constraints might limit their ability to install the additional treatment needed to achieve TSS limitations. Third, EPA believes based on its analysis of the data, that comparable discharge levels can be achieved using feed management and other management practices alone as can be achieved using these practices in combination with settling technologies. Thus, while settling technology may be amenable to more precise control, EPA believes that the overall environmental benefits of this technology relative to rigorous feed and solids handling management alone are negligible.

EPA is further concerned that establishing a numeric limit for TSS could provide an incentive for facilities to achieve the limit through dilution and would not reduce the pollutant loads discharged to receiving streams. While dilution is generally prohibited as a means of achieving effluent limitations, this prohibition is harder to enforce at CAAP facilities than in most other systems because the flow of culture water is dependent on a wide range of factors and is highly variable from one facility to another. Thus it would be impossible for regulatory authorities to determine if water use was being manipulated to dilute TSS concentration. Due to variations in water use from facility to facility, EPA also decided not to establish mass-based numeric TSS limitations on a national basis. Solids control operational measures such as feed management and the requirement to focus on the proper operation of existing solids control structures are expected to achieve reductions in the TSS concentrations and at the same time reduce the TSS loadings being discharged. This approach is supported by DMR data from facilities in Idaho which have had to comply with feed management BMP requirements in their general permit. This data demonstrates that improved performance can be achieved through BMPs (DCN 63012). A comparison of DMR data from Idaho prior to the issuance of a general permit in calendar year 1999 with data following compliance with the general permit indicates that 64 percent of the facilities have reduced the TSS loads discharged from the facility with an average TSS reduction of 75 percent.

For these reasons, EPA has expressed effluent limitations in this rule in the form of narrative standards, rather than as numeric values. EPA has a legal authority to do so. The CWA defines ''effluent limitation'' broadly, and EPA's regulations reflect this as well. Each provides that an effluent limitation is ''*any restriction*'' imposed by the permitting authority on quantities, discharge rates and concentrations of a pollutant discharged into a water of the United States. CWA section 502(11) (emphasis supplied); 40 CFR 122.2 (emphasis supplied). Neither definition requires an effluent limitation to be expressed as a numeric limit. The DC Circuit observed, ''Section 502(11) defines 'effluent limitation' as '*any* restriction' on the amounts of pollutants, not just a numerical restriction.'' *NRDC* v. *EPA,* 673 F.2d 400, 403 (DC Cir.) (emphasis in original), *cert. denied sub nom. Chemical Mfrs. Ass'n* v. *EPA,* 459 U.S. 879 (1982). In short, the definition of

''effluent limitation'' is not limited to a single type of restriction, but rather contemplates a range of restrictions that may be used as appropriate. EPA has concluded that it is appropriate to express today's BPT/BCT/BAT limitations in non-numeric form. These narrative limitations reflect a technology demonstrated to achieve effective solids removals while still giving facilities flexibility in determining how to meet them.

Today's BPT regulation requires CAAP facilities to comply with specified operational and management requirements—best management practices (BMPs)—that will minimize the generation and discharge of solids from the facility. These requirements are non-numeric effluent limitations based on the technologies EPA has determined are BPT.

The final regulation requires adoption of specified solids control practices. *See, e.g.*, § 451.11(a) and § 451.21(a). Thus, to control the discharge of solids from flow-through and recirculating system facilities, the final rule requires minimizing the discharge of uneaten feed through a feed management program. *See* § 451.11(a) of this rule. Complying with this limitation will require a CAAP facility to identify feeding practices which optimize the addition of feed to achieve production goals while minimizing the amount of uneaten feed leaving the rearing unit. Such a program should include practices such as periodic calibration of automatic feeders, visual observation of feeding activity and discontinuation of feeding when the animals stop eating. The rule also requires that CAAPs maintain records of feed inputs and estimates of the numbers and weight of aquatic animals in order to calculate representative feed conversion ratios. *See* § 451.11(a)(1) of this rule. Development of feed conversion ratios is a key component in a properly functioning feed management system because it allows the facility to calibrate more accurately the feeding needs of the species being raised. This, in turn, will result in further improvement in control of solids at the operation.

In addition to feed management, EPA also requires flow-through and recirculating system facilities to identify and implement procedures for routine cleaning. *See* § 451.11(a)(2). This will ensure that CAAP facilities develop practices to minimize the build-up and subsequent discharge of solids from the rearing units. The facility must also identify procedures with respect to harvesting, inventorying and grading of fish so as to minimize disturbance and discharge of solids from the facility during these activities.

The final rule also provides that facilities must remove dead fish and fish carcasses from the production system on a regular basis and dispose of them to avoid the discharge to waters of the U.S. § 451.11(a)(3). EPA is establishing an exception to this requirement when the permit writer authorizes a discharge to benefit the aquatic environment. The following example explains one circumstance in which a permit writer could authorize such a discharge. There are a number of federal, state, and tribal hatcheries that are raising fish for stocking or mitigation purposes. In some cases, these facilities have been approved to discharge fish carcasses along with the live fish that are being stocked. In these situations, the carcasses are serving as a source of nutrients and food to the fish being stocked in these waters. The exception would apply in these circumstances if the permitting authority determines that the addition of fish carcasses to surface water will improve water quality.

Facilities must also implement measures that address material storage and structural maintenance. In the case of material storage, EPA is requiring facilities to identify and develop practices to prevent inadvertent spillage of drugs, pesticides, and feed from the facility. § 451.11 (b). This would include proper storage of these materials. EPA is also requiring facilities to identify proper procedures for cleaning, containing and disposing of any spilled material. EPA's assessment, based on site visits and sampling visits, indicates that facilities may have varying degrees of spill prevention procedures and containment and structural maintenance practices to address these requirements.

The final rule also includes a requirement that facilities inspect and provide regular maintenance of the production system and the wastewater treatment system to ensure that they are properly functioning. § 451.11(c). One area of concern addressed by this requirement is the potential accumulation of solids (especially large solids such as carcasses and leaves) that could clog screens that separate the raceway from the quiescent zone. These solids could prevent the flow of water through the screen causing water to instead flow over the screen and impair the passage of solids into the quiescent zone. Proper maintenance should ensure that screens are regularly inspected and cleaned.

The final rule also requires that facilities conduct routine inspections to identify any damage to the production system or wastewater treatment system and that facilities repair this damage promptly. EPA has not specified any design requirement for structural components of the CAAP facility. Rather, it has adopted the requirement that facilities identify practices that will ensure existing structures are maintained in good working order. Flow-through and recirculating facilities are also required to keep records as described previously and to conduct routine training for facility staff on spill prevention and response.

As discussed further below, in the final rule, EPA is not establishing numeric limits for any drug or pesticide but is requiring CAAP facilities to ensure proper storage of drugs, pesticides and feed to prevent spills and any resulting discharge of spilled drugs and pesticides. EPA is also establishing a requirement to implement procedures for responding to spills of these materials to minimize their discharge from the facility. *See*§ 451.11(c)(2) of this rule. Facilities must also train their staff in spill prevention and proper operation and cleaning of production systems and equipment. *See* § 451.11(e) of this rule. The detailed survey did not provide information about spill prevention, but during site visits and sampling visits EPA identified containment systems and practices. EPA's site visit information indicated that CAAP facilities currently employ a number of different measures to prevent spills and some have established in-place systems to address spills in the event they occur. The effect of this narrative limitation will be to promote increased care in the handling of these materials. Its adoption as a regulatory requirement provides an additional incentive for facility operators currently employing effective spill control measures to continue such practices when handling drugs and pesticides. Moreover, because EPA has adopted the same requirements for existing and new sources (*see* discussion below), this will ensure that new sources employ the same highly protective measures as existing sources have employed successfully to protect against spills.

Today's regulation does not include any requirements specifically addressing the release of non-native species. The final regulation, however, includes a narrative effluent limitation that requires facilities to implement operational controls that will ensure the production facilities and wastewater treatment structures are being properly maintained. Facilities must conduct routine inspections and promptly repair damage to the production systems or wastewater treatment units. This requirement, described in more detail in

Section VI.D., will aid in preventing the release of various materials, including live fish.

2. BAT

EPA is establishing BAT at a level equal to BPT for the flow-through and recirculating system discharge subcategory. For this subcategory, EPA did not identify any available technologies that are economically achievable for the subcategory that would achieve more stringent effluent limitations than those considered for BPT. Because of the nature of the wastes generated from CAAP facilities, advanced treatment technologies or practices to remove additional toxic or nonconventional pollutants that would be economically achievable on a national basis do not exist beyond those already considered.

3. BCT

EPA evaluated conventional pollutant control technologies and did not identify a more stringent technology for the control of conventional pollutants for BCT limitations that would be affordable than the final requirements considered. Other technologies for the control of conventional pollutants include biological treatment, but this technology is not affordable for the subcategory as a whole. Consequently, EPA has not promulgated BCT limitations or standards based on a different technology from that used as the basis for BPT limitations and standards.

4. NSPS

After considering the technology options described in the proposal and NODA and evaluating the factors specified in section 306 of the CWA, EPA is promulgating standards of performance for new sources equal to BPT, BAT, and BCT. There are no more stringent technologies available for NSPS that would not represent a barrier to entry for new facilities, *see* Section IX for more discussion of the barrier to entry analysis. Because of the nature of the wastes generated in CAAP facilities, EPA has not identified advanced treatment technologies or practices to remove additional solids (*e.g.*, smaller particle sizes) in TSS or other pollutants that would be generally affordable beyond those already considered.

EPA determined that NSPS equal to BAT will not present a barrier to entry. The overall impacts from the effluent limitations guidelines on new sources would not be any more severe than those on existing sources. This is because the costs faced by new sources are generally the same as, or lower than, those faced by existing sources. It is generally less expensive to incorporate pollution control equipment into the design at a new facility than it would be to retrofit the same pollution control equipment in an existing plant. At a new facility, no demolition is required and space constraints (which can add to retrofitting costs if specifically designed equipment must be ordered) may be less of an issue.

C. What Are the Requirement for the Net Pen Subcategory?

The following discussion explains the BPT/BAT/BCT limitations and NSPS EPA is promulgating for Net Pen Systems.

1. BPT

After considering the technology options described in the proposal and the factors specified in Section 304(b)(1)(B) of the Clean Water Act, EPA is establishing nationally applicable effluent limitations for net pen facilities producing 100,000 pounds or more of aquatic animals per year. Today's BPT regulations requires CAAP net pen systems, like CAAP flow-through and recirculating systems, to comply with specified operational practices and management requirements. These requirements are non-numeric effluent limitations based on technologies EPA has evaluated and determined are cost-reasonable, available technologies.

Based on the detailed survey results, EPA estimates that such programs are currently in use at most or all the net pen systems. As a result, the cost to facilities of meeting the BPT requirements is very low. To EPA's knowledge, all existing net pen facilities that are currently covered by NPDES permits are subject to permit requirements comparable to today's limitations. Therefore, EPA concludes that the BPT limits are both technically available and cost reasonable for the net pen subcategory.

EPA rejected the establishment of numeric effluent limitations for net pens for obvious reasons. Because of the nature of the facilities, net pens cannot use physical wastewater control systems except at great cost. Located in open waters, nets are suspended from a floating structure to contain the crop of aquatic animals. Nets are periodically changed to increase the mesh size as the fish grow in order to provide more water circulating inside the pen. The pens are anchored to the water body floor and sited to benefit from tidal and current action to move wastes away from, and bring oxygenated water to, the pen. As a result, these CAAP facilities experience a constant in- and out-flow of water. Development of a system to capture the water and treat the water within the pen would be prohibitively expensive. EPA, therefore, rejected physical treatment systems as the basis for BPT limitations. Instead, EPA is promulgating narrative effluent limitations.

As was the case with flow-through and recirculating systems, feed management programs are a key element of the promulgated requirements for the reasons explained above and in the proposal at 67 FR 57872, 57887. Consequently, for the control of solids, the final regulation requires that net pen CAAP facilities minimize the accumulation of uneaten feed beneath the pen through the use of active feed monitoring and management practices. § 451.21(a). These strategies may include either real-time monitoring (*e.g.*, the use of video monitoring, digital scanning sonar, or upweller systems); monitoring of sediment quality beneath the pens; monitoring of the benthic community beneath the pens; capture of waste feed and feces; or the adoption of other good husbandry practices, subject to the permitting authority's approval.

As noted, feed management systems are effective in reducing the quantity of uneaten feed. Facilities should limit the feed added to the pens to the amount reasonably necessary to sustain an optimal rate of fish growth. In determining what quantity of feed will result in minimizing the discharge of uneaten feed while at the same time sustaining optimal growth, a facility should consider, among others, the following factors: The types of aquatic animals raised, the method used to feed the aquatic animals, the facility's production and aquatic animal size goals, the species, tides and currents, the sensitivity of the benthic community in the vicinity of the pens, and other relevant factors. In some areas, deep water and/or strong tides or currents may prevent significant accumulation of uneaten feed such that active feed monitoring is not needed. Several states with significant numbers of net pens (*e.g.*, Washington, Maine) already require feed management practices, which may include active feed monitoring, to minimize accumulation of feed beneath the pens. Facilities will need to ensure that whatever practices they adopt are consistent with the requirements of their state NPDES program.

In order to implement a feed management system, the facility must also track feed inputs by maintaining records documenting feed and estimates of the numbers and weight of aquatic animals in order to calculate

representative feed conversion ratios. § 451.21(g). As previously explained, development of feed conversion ratios are a necessary element in any effective feed management system.

Real-time monitoring represents a widely-used business practice that is employed by many salmonid net pen facilities to reduce feed costs. Net pen systems do not present the same opportunities for solids control as do flow-through or recirculating systems for the obvious reason that ocean water is continuously flowing in and out of the net pens. Therefore, in EPA's view, feed monitoring, including real time monitoring and other practices is an important and cost reasonable practice to control solids discharges.

The final rule includes a narrative limitation requiring CAAP net pen facilities to collect, return to shore, and properly dispose of all feed bags, packaging materials, waste rope and netting. § 451.21(b). This will require that net pen facilities have the equipment (*e.g.*, trash receptacles) to store empty feed bags, packaging materials, waste rope and netting until they can be transported for disposal. EPA is also requiring that net pens minimize any discharges associated with the transporting or harvesting of fish, including the discharge of blood, viscera, fish carcasses or transport water containing blood. § 451.21(c). During stocking or harvesting of fish, some may die. The final limitations require facilities to remove and dispose of dead fish properly on a regular basis to prevent discharge. Discharge of dead fish represents an environmental concern because they may spread disease and attract predators, which could imperil the structural integrity of the containment system. The wastes and wastewater associated with the transport or harvest of fish have high BOD and nutrient concentrations and should be disposed of at a location where they may be properly treated.

The final regulations also require net pen facilities to ensure the proper storage of drugs, pesticides, and feed to avoid spilling these materials and subsequent discharge. *See* § 451.21(e)(1) of this rule. Facilities must also implement procedures for properly containing, cleaning and disposing of any spilled material. *See* § 451.21(e)(2) of this rule. As previously discussed, excess feed may present a number of different environmental problems. Preventing spills of feed is consequently important. Additionally, net pens may use different pesticides and drugs in fish production. Preventing their release is similarly important. The final regulation also includes a narrative limitation, similar to that for CAAP flow-through and recirculating systems, requiring that net pen facilities adequately train facility personnel in how to respond to spills and proper clean-up and disposal of spilled material. *See* § 451.21(h) of this rule.

Next, the final regulation requires regular inspection and maintenance of the net pen § 451.21(f). This would include any system to prevent predators from entering the pen. Net pens are vulnerable to damage from predator attack or accidents that result in the release of the contents of the nets, including fish and fish carcasses. Given the economic incentive to prevent the loss of production, EPA assumes facilities will conduct routine inspections of the nets to ensure they are not damaged and make repairs as soon as any damage is identified. Most net pen facilities are already doing these inspections. However, in evaluating this technology option, EPA estimated costs for increased inspections at every net pen facility in order to ensure that costs are not underestimated.

Like the final BPT limitations for flow-through and recirculating systems, the BPT limitations for net pens do not include any requirements specifically addressing the release of non-native species. The final regulation, however, includes a narrative effluent limitation that requires facilities to implement operational controls that will ensure the production facilities and wastewater treatment structures are being properly maintained. Facilities must conduct routine inspections and promptly repair damage to the production systems or wastewater treatment units. EPA included this requirement to ensure achievement of the other BPT limitations for net pens such as the prohibition on the discharge of feed bags, packaging materials, waste rope and netting at net pens, and the requirement to minimize release of solids, fish carcasses and viscera. This requirement will also aid in preventing the release of other materials including live fish.

2. BAT

EPA is establishing BAT at a level equal to BPT for the net pen subcategory. For this subcategory, EPA did not identify any available technologies that are economically achievable that would achieve more stringent effluent limitations than those considered for BPT. Because of the nature of the wastes generated from CAAP net pen facilities, EPA did not identify any advanced treatment technologies or practices to remove additional toxic and nonconventional pollutants that would be economically achievable on a national basis beyond those already considered.

3. BCT

EPA evaluated conventional pollutant control technologies and did not identify a more stringent technology for the control of conventional pollutants for BCT limitations than the final requirements considered. Consequently, EPA has not promulgated BCT limitations or standards based on a different technology from that used as the basis for BPT limitations and standards.

4. NSPS

After considering the technology requirements described previously under BPT, and the factors specified in section 306 of the CWA, EPA is promulgating standards of performance for new sources equal to BPT, BAT, and BCT. There are no more stringent best demonstrated technologies available. Because of the nature of the wastes generated and the production system used, EPA has not identified advanced treatment technologies or practices that would be generally affordable beyond those already considered.

Although siting is not specifically addressed with today's standards, proper siting of new facilities is one component of feed management strategies designed to minimize the accumulation of uneaten feed beneath the pens and any associated adverse environmental effects. When establishing new net pen CAAP facilities, consideration of location is critical in predicting the potential impact the net pen will have on the environment. Net pens are usually situated in areas which have good water exchange through tidal fluctuations or currents. Good water exchange ensures good water quality for the animals in the nets. It also minimizes the concentration of pollutants below the nets. In implementing today's rule for new net pen operations, facilities and permit authorities should give careful consideration to siting prior to establishing a new net pen facility.

EPA has concluded that NSPS equal to BAT does not present a barrier to entry. The overall impacts from the effluent limitations guidelines on new source net pens are no more severe than those on existing net pens. The costs faced by new sources generally should be the same as, or lower than, those faced by existing sources. It is generally less expensive to incorporate pollution control equipment into the design at a new facility than it is to retrofit the

same pollution control equipment in an existing facility.

Although EPA is not establishing standards of performance for new sources for small cold water facilities (*i.e.*, those producing between 20,000 and 100,000 pounds of aquatic animals per year), such facilities would be subject to existing NPDES regulations and BPT/BAT/BCT permit limits developed using the permit writer's ''best professional judgment'' (BPJ). EPA, based on its analysis of existing data, determined that new facilities would most often produce 100,000 pounds of aquatic animals or more per year because of the expense of producing the aquatic animals. Generally, the species produced are considered of high value and are produced in such quantities to economically justify the production. For example, one net pen typically holds 100,000 pounds of aquatic animals or more. In reviewing USDA's Census of Aquaculture and EPA's detailed surveys, EPA has not identified any existing commercial net pen facilities producing fewer than 100,000 pounds of aquatic animals per year.

Offshore aquatic animal production is an area of potential future growth. As these types of facilities start to produce aquatic animals, those with 100,000 pounds or more per year will be subject to the new source requirements established for net pens as well as NPDES permitting.

D. What Monitoring Does the Final Rule Require?

The final rule does not require any effluent monitoring. In the case of net pen facilities, however, it does require CAAPs to adopt active feed monitoring and management practices that will most often include measures to observe the addition of feed to the pen. Net pen facilities subject to today's rule must develop and implement active feed monitoring and management strategies to minimize the discharge of solids and the accumulation of uneaten feed beneath the pen. Many existing net pen facilities use a real-time monitoring system such as video cameras, digital scanning sonar, or upweller systems to accomplish this. With a real-time monitoring system, when uneaten feed is observed falling beneath the pen feeding should stop. Depending on the location and other site-specific factors at the facility, a facility may adopt other measures in lieu of real time monitoring. These may include monitoring of sediment or the benthic community quality beneath the pens, capture of waste feed and feces or other good husbandry practices that are approved by the permitting authority.

E. What Are the Final Rule's Notification, Recordkeeping, and Reporting Requirements?

The final rule establishes requirements for reporting the use of spilled drugs, pesticides or feed that result in a discharge to waters of the U.S. by CAAP facilities. This provision ensures that, any release of spilled drugs, pesticides and feed to waters of the U.S. are reported to the permitting authorities to provide them with necessary information for any responsive action that may be warranted. This will allow regulatory authorities to reduce or avoid adverse impacts to receiving waters associated with these spills. EPA is requiring that any spill of material that results in a discharge to waters of the U.S. be reported orally to the permitting authority within 24 hours of its occurrence. A written report shall be submitted within 7 days. Facilities are required to report the identity of the material spilled and an estimated amount.

EPA is retaining for the final rule the proposed requirement that CAAP facilities report to the Permitting Authority whenever they apply certain types of drugs under the following conditions. First, the permittee must report drugs prescribed by a veterinarian to treat a species or a disease when prescribed for a use which is not an FDA-approved use (referred to as ''extralabel drug use'') as described further below. Second, the permittee must report drugs being used in an experimental mode under controlled conditions, known as Investigative New Animal Drugs (INADs). In EPA's view, notifying the Permitting Authority is necessary to ensure that any potential risk to the environment resulting from the use of these drugs can be addressed with site-specific remedies where appropriate. EPA strongly encourages reporting prior to use where feasible, as this provides the Permitting Authority with the opportunity to monitor or control the discharge of the drugs while the drugs are being applied. EPA has not made this an absolute requirement, however, in recognition of the fact that swift action on the part of veterinarians and operators is sometimes necessary to respond to and contain disease outbreaks.

The reporting requirement applies to the permittee and imposes no obligation on the prescribing veterinarian. The reporting requirement for extralabel drug use is not in any way intended to interfere with veterinarians' authority to prescribe extralabel drugs to treat aquatic animals or other animals in accordance with FFCDA and 40 CFR Part 530. This reporting requirement is promulgated to ensure that permitting authorities are aware of the use at CAAPs of extralabel drugs when such use may result in the release of the drug to waters of the U.S. Because the use is likely to involve adding the drug directly to the rearing unit, EPA believes there is a probability that these drugs may be released to waters of the U.S..

The regulation requires that a permittee must provide a written report to the permitting authority within seven days of agreeing to participate in an INAD study and an oral report preferably in advance of use, but in no event later than seven days after starting to use the INAD. The first written report must identify the drug, method of application, the dosage and what it is intended to treat. The oral report must also identify the drug, method of application, and the reason for its use. Within 30 days after the use of the drug at the facility, the permittee must provide another written report to the permitting authority describing the drug, reason for treatment, date and time of addition, method of addition and total amount added.

EPA has similar reporting requirements for extralabel drug use except that EPA is not requiring a written report in advance of use.

The reporting requirement applies only to those drugs that have not been previously approved for their intended use. Reporting would not be required for EPA registered pesticides and FDA approved drugs for aquatic animal uses when used according to label instructions. Reporting would only be required for INAD drugs and drugs prescribed by a veterinarian for extralabel uses. Because these classes of drugs have not been fully evaluated by FDA for the potential environmental consequences of the use being made of them EPA considers reporting ensures the permitting authority has enough information to make an informed response if environmental problems do occur. EPA has included an exception to the reporting requirement for cases where the INAD or extralabel drug has already been approved under similar conditions for use in another species or to treat another disease and is applied at a dosage that does not exceed the approved dosage. The requirement that the use be under similar conditions is intended to limit the exception to cases where the INAD or extralabel drug use would be expected to produce significantly different environmental impacts from the previously approved

use. For example, use of a drug that had been previously approved for a freshwater application, as an INAD in a marine setting would not be considered a similar condition of use, since marine ecosystems may have markedly different vulnerabilities than freshwater ecosystems. Similarly, the use of a drug approved to treat terrestrial animals used as an INAD or extralabel drug to treat aquatic animals would not be considered a similar condition of use. In contrast, the use of a drug to treat fish in a freshwater system that was previously approved for a different freshwater species would be considered use under similar conditions. EPA has concluded that when a drug is used under similar conditions it is unlikely that the environmental impacts would be different than those that were already considered in the prior approval of the drug.

The reporting requirements with respect to INADs are not burdensome. FDA regulations require that the sponsor of a clinical investigation of a new animal drug submit to the Food and Drug Administration certain information concerning the intended use prior to its use. Therefore, this information will be readily available to any CAAP facility that participates in an INAD investigation. Having advance information will enable the permitting authority to determine whether restrictions should be imposed on the release of such drugs.

EPA is also requiring all CAAP facilities subject to today's regulation to develop and maintain a Best Management Practices plan on site. This plan must describe how the permittee will achieve the required narrative limitations. The plan must be available to the permitting authority upon request. Upon completion of the plan, the permittee must certify to the permitting authority that a plan has been developed.

The proposal included a requirement to implement escape prevention practices at facilities where non-native species are being produced. EPA received comments supporting such controls to prevent the release of non-native species. EPA also received comments arguing against controls in this regulation because other authorities are already dealing with non-native species, and because of the complexities of determining what is a non-native species and when such species may become invasive. For example, species raised by Federal and State authorities for stocking may not be ''native,'' but would not generally impose a threat if escapes occurred.

Today's regulation does not include any requirements specifically addressing the release of non-native species. The regulation, however, includes a requirement for facilities to develop and implement BMPs to ensure the production and wastewater treatment systems are regularly inspected and maintained. Facilities are required to conduct routine inspections and perform repairs to ensure proper functioning of the structures. EPA included this requirement to promote achievement of BPT/BAT limitations on the discharge of feed bags, packaging materials, waste rope and netting at net pens, and on the discharge of solids, including fish carcasses and viscera at all facilities. This requirement, described in more detail in Section VI.D, will also aid in preventing the release of other materials, including live fish.

The final regulation also includes a requirement for facilities to report failures and damage to the structure of the aquatic animal containment system leading to a material discharge of pollutants. EPA realizes that most CAAP facilities take extensive measures to ensure structural integrity is maintained. Nonetheless, failures do occur with potentially serious consequences to the environment. The failure of the containment system can result in the release of sediment, fish and fish carcasses which, depending on the magnitude of the release, can have significant impacts on the environment. For net pen systems, failures include physical damage to the predator control nets or the nets containing the aquatic animals, which result in a discharge of the contents of the nets. Damage includes abrasion, cutting or tearing of the nets and breakdown of the netting due to rot or ultra-violet exposure. For flow-through and recirculating systems, a failure includes a collapse or damage of a rearing unit or wastewater treatment structure; damage to pipes, valves, and other plumbing fixtures; and damage or malfunction to screens or physical barriers in the system, which would prevent the unit from containing water, sediment, and the aquatic animals. In the event of a reportable failure as defined in the NPDES permit, EPA is requiring CAAP facilities to report to the permit authority orally within 24 hours of discovering a failure and to follow the oral report with a written report no later than seven days after the discovery of the failure. The oral report must include the cause of the failure and the materials that have likely been released. The written report must include a description of the cause of the failure, the time elapsed until the failure was repaired, an estimate of the types and amounts of materials released and the steps that will be taken to prevent a recurrence. Because the determination of what constitutes damage resulting in a ''material'' discharge varies from one facility to the next, EPA encourages permitting authorities to include more specific reporting requirements defining these terms in the permit. Such conditions might recognize variations in production system type and environmental vulnerability of the receiving waters.

Today's regulation requires record-keeping in conjunction with implementation of a feed management system. As previously explained, EPA is requiring flow-through, recirculating and net pen CAAP facilities subject to today's regulation to keep records on feed amounts and estimates of the numbers and weight of aquatic animals in order to calculate representative feed conversion ratios. The feed amounts should be measured at a frequency that enables the facility to estimate daily feed rates. The number and weight of animals contained in the rearing unit may be recorded less frequently as appropriate.

Flow-through and recirculating facilities subject to today's requirements must record the dates and brief descriptions of rearing unit cleaning, inspections, maintenance and repair. Net pen facilities must keep the same types of feeding records as described above and record the dates and brief descriptions of net changes, inspections, maintenance and repairs to the net pens.

IX. What Are the Costs and Economic Impacts Associated With This Rule?

This section discusses the costs and economic impact of the rule promulgated today.

A. Compliance Costs

The information below describes the rule's costs and how EPA determined these costs. A more detailed discussion of how EPA estimated compliance costs is included in the Technical Development Document (EPA–821–R–04–012) and the discussion of the economic impacts is included in the Economic and Environmental Benefits Analysis report (EPA–821–R–04–013). Both of these documents can be found on EPA's Web site, *www.epa.gov/ost/guide/aquaculture.*

1. How Did EPA Estimate the Costs of Compliance With the Final Rule?

EPA estimated costs associated with regulatory compliance for the options it considered to determine the economic

impact of the effluent limitations guidelines and standards on the aquaculture industry. The economic impact is a function of the estimated costs of compliance to achieve the requirements. These costs may include initial fixed and capital costs, as well as annual operating and maintenance (O&M) costs. Estimation of these costs began by identifying the practices and technologies that could be used as a basis to meet particular requirements. EPA estimated compliance costs for each facility, based on the specific configuration of the facility as provided in the detailed survey and the implementation of the practices or technologies to meet particular requirements.

EPA developed cost estimates for capital, land, annual O&M, and one-time fixed costs for the implementation of the different best management practices and treatment technologies targeted under the regulatory options. EPA developed the cost estimates from information collected from the detailed survey, site visits, sampling events, published information, vendor contacts, industry comments, and engineering judgment. EPA estimates compliance costs in 2001 dollars that it converted to 2003 dollars using the Engineering News Record construction cost index. All costs presented in this section are reported in pre-tax 2003 dollars, unless otherwise indicated.

The final regulation requires facilities to adopt various management practices to control pollutant discharges and incorporate these practices in a BMP plan. The detailed survey provided information on the use of BMPs at each surveyed facility. In its analyses, EPA estimated the costs associated with implementing various types of BMPs. As explained above, EPA has concluded that BMPs are an effective tool for controlling pollutant discharges. EPA assumed no additional costs for compliance for a facility for particular BMPs when the facility indicated that it had comparable BMPs in place, or EPA found strong evidence that such BMPs were already being implemented at the facility. For example, facilities reporting the use of drugs and pesticides that are located in Washington or Idaho were not costed for drug and pesticide BMPs because the general permits in these states require facilities to implement BMPs related to drugs and pesticides that are at least as stringent as these required by today's rule.

EPA is requiring each facility to develop a BMP plan that describes the practices and strategies it is using to comply with narrative limitations addressing solids control, including feed management, materials storage (*i.e.*, spill containment), structural maintenance, recordkeeping, and training. For net pen facilities, the BMP plan must also document provisions for complying with narrative limitations related to waste collection and disposal, minimization of discharges associated with transport or harvest, and carcass removal. EPA found that the net pen facilities responding to the detailed survey generally have operational measures in place that address these requirements.

The costs associated with BMP plan development include a one-time labor cost of 40 hours for management staff training and time to develop and write the plan. The plan that EPA costed included time for the manager to (1) identify all waste streams, wastewater structures, and wastewater and manure treatment structures at the site, (2) identify and document standard operating procedures for all BMPs used at the facility, and (3) define management and staff responsibilities for implementing the plan. EPA assumed that each employee at a facility would incur a one time cost of 4 hours for initial BMP plan review. EPA included an annual cost for four hours of management labor to maintain the plan and eight hours of management labor and 4 hours for each employee for training and an annual review of BMP performance. EPA included the cost of developing solids control, spill prevention, and structural maintenance components of the BMP plan in the estimates for all appropriate facilities. EPA also included recordkeeping and training costs as a part of annual operation and maintenance activities for the BMP components.

One part of the solids control component of the BMP plan is feed management. Based on feed and production data reported in the surveys, EPA evaluated the effectiveness of a facility's feed management programs. EPA calculated feed conversion ratios (FCRs) using pounds of feed per pound of live product. These calculated FCRs were compared for groups of facilities (*i.e.*, combinations of ownership, species and production system types such as commercial trout flow-through facilities or government salmon flow-through facilities). EPA found a wide range of FCRs (reported by facilities in their detailed surveys, which were validated by call backs to the facility) among apparently similar facilities within ownership-species-production system groupings.

For example, EPA had good data for 24 of 60 government trout producers using flow-through systems. They reported a range of FCRs of 0.79 to 1.80 with a median FCR of 1.30. If an individual facility's reported FCR was significantly greater than the median, EPA further evaluated the facility to ascertain the reason for the higher FCR. Facilities that produce larger fish, such as broodstock, might have higher FCRs because the larger fish produce less flesh per unit of food. Facilities with fluctuating water temperatures could also be less efficient than facilities with constant water temperatures. EPA assumed facilities lacking evidence of good feed management practices (based on the calculated FCR) would incur additional costs to improve or establish them. However, EPA did not apply costs for feed management BMPs for facilities with reasonable explanations for the higher FCRs because EPA assumed such facilities were already optimizing feed input or would be able to do so at reasonable cost.

EPA evaluated facilities that did not report FCRs or provide enough data for an estimate by assigning each facility a random FCR between the first and third quartiles of the FCR distribution of the group of facilities (*i.e.*, combinations of ownership, species, and production systems) where it was classified. For its analysis, EPA estimated target FCRs for each group as the 25th percentile value of the category. EPA used these target FCRs in its costing and loadings analyses, but does not intend to set any specific FCR targets at facilities (*see* DCN 62467). These facilities were assigned costs associated with feed management BMPs in the same manner as facilities with calculated FCRs.

Costs for the feed management BMP component include staff time for recordkeeping for feed delivery and daily feeding observations. Management activities associated with the feed management practices were weekly data reviews of feeding records, regular estimates of changes to feeding regimes for each group of aquatic animals, and staff consultations about feeding. For facilities that reported using drugs or pesticides, EPA evaluated costs for (1) storage containment, (2) spill prevention planning and training, and (3) reporting of INAD and extralabel drug uses. For storage containment, EPA evaluated the amount of product stored onsite and estimated containment structure costs specifically for the facility. This capital cost was for the purchase of commercially available drum storage units and pesticide cabinets that will contain spills in the event of leakage or accidental spills. EPA also estimated the costs for management to develop a spill prevention plan, which is included in the facility BMP plan, and annual staff

training at the facility (8 hours/year for managers and 4 hours/year for each employee). EPA assumed that reporting to the appropriate regulatory authority would occur 6 times per year for facilities reporting using INAD or extralabel drug uses. The reporting for each occurrence includes 20 minutes for an oral report and 1 hour for a written report. EPA considers these costing assumptions to be conservative and may overstate actual reporting frequency.

In addition, EPA estimated costs for inspections in order to maintain the structural integrity of the aquatic animal containment system. The costs include regular inspections of rearing units, solids storage units, and drug/pesticide storage units. EPA considers the aquatic animal containment system to include any physical barriers and practices used to prevent the release of materials from the containment system. For flow-through and recirculating facilities, the containment system includes wastewater treatment, for example, quiescent zones or settling basins, in addition to the rearing units and storage units. For net pens, the containment system includes the use of double nets or other techniques that may be used to deter predators. EPA also included costs for reporting of structural failure or damage to the containment system that results in a material discharge of pollutants to waters of the U.S.

For net pen systems, failures include physical damage to the predator control nets or the nets containing the aquatic animals, which result in a discharge of the contents of the nets. Damage includes abrasion, cutting or tearing of the nets and breakdown of the netting due to rot or ultra violet exposure. For flow-through and recirculating systems, a failure includes a collapse or damage of a rearing unit or wastewater treatment structure; damage to pipes, valves, and other plumbing fixtures; and damage or malfunction to screens or physical barriers in the system, which would prevent the unit from containing water, sediment, and the aquatic animals. The rule provides the permitting authorities may specify what constitutes damage and/or a material discharge on a site-specific basis for the purposes of triggering the reporting requirement. Based on available information related to containment system failures in the past, flow-through and recirculating facilities have had less incidences of failures than net pen facilities. Therefore, EPA estimated that 10 percent of the flow-through and recirculating facilities would incur a cost associated with the reporting of the failure whereas, for costing purposes, all net pen facilities were assumed to experience a failure. Again, EPA believes these assumptions are conservative and may overestimate the frequency of reportable failures.

EPA revised estimates for all labor costs using the employee and wage information supplied in the detailed surveys. For those facilities indicating they use unpaid labor for all or part of the facility operation, or that did not supply useable wage information, EPA used average State or regional wages for both staff and management labor. Separate estimates were used for commercial and non-commercial facilities.

2. What Are the Total National Costs?

Tables IX–1 and IX–2 summarize numbers of affected facilities and total annualized costs for today's final regulation. EPA estimates that a total of 242 facilities will be affected by today's final regulation. These counts include two non-profit flow-through facilities in Alaska producing 100,000 lb/year or more that did not receive a detailed questionnaire. More information is provided in the rulemaking record (DCN 63065). Table IX–1 summarizes the estimated number and type of facilities affected by the rule, based on the production threshold of 100,000 lb/year. These 242 facilities consists of 101 commercial facilities and 141 noncommercial facilities; noncommercial facilities include Federal, state, Alaskan non-profit, and Tribal hatcheries. Of the 101 commercial facilities, 32 are projected to be unprofitable prior to the final rule (*i.e.*, baseline closures) under cash flow analysis. EPA did not identify any academic/research facilities in the detailed questionnaire that produced 100,000 lbs/yr or more.

The estimated cost for this rule is $1.4 million per year (pre-tax, 2003 dollars). Noncommercial facilities account for about 81 percent of the total cost of the rule. These estimated total costs reflect aggregate compliance costs incurred by facilities that produce 100,000 lb/year or more and will be affected by today's final regulation. EPA's total cost estimates do not include costs that are incurred by the 32 commercial facilities that are considered baseline closures. To the extent that some projected baseline closures remain open and incur costs under this rule, despite analysis showing unprofitability in the baseline, national compliance costs, pollutant load reductions and potential benefits would be higher than projected.

TABLE IX–1.—ESTIMATED NUMBER OF AFFECTED FACILITIES WITH PRODUCTION 100,000 LBS/YR OR MORE

Organization	Estimated number of facilities (see note)		
	Baseline closures [1]	Not baseline closures [2]	Total
Commercial	32 (28)	69 [4] (69)	101 (97)
Noncommercial [3]	NA (NA)	141 (141)	141 (141)
Total	32 (28)	210 (210)	242 (238)

Note: Numbers in (parentheses) are facilities that are determined not to be in compliance with final rule requirements at the time this final rule is signed by the EPA Administrator.

NA: EPA does not determine closures for noncommercial facilities.

[1] Projected baseline closures are estimated using cash flow analysis. When net income analysis is assumed for earnings, the number of commercial baseline closures increases to 43. Baseline closures would not be projected to incur costs for a new rule in accordance with EPA's Guidelines for Preparing Economic Analyses (USEPA, EPA 240–R–00–003). Baseline closures (based on cash flow) are therefore not included in estimates of costs for this rule.

[2] Total costs and economic impacts for this rule are estimated using incremental compliance costs incurred by the facilities that are not baseline closures and not in compliance with the rule at time of final signature (*i.e.*, 210 facilities are expected to incur costs under this rule: 69 commercial and 141 noncommercial facilities).

[3] Noncommercial facilities include those operated by States, Tribes, the Federal Government, and Alaskan Non-Profits.

[4] Includes two facilities that are projected to be baseline closures using discounted cash flow analysis but are characterized by EPA as "Not Baseline Closures" due to unique facility-specific evidence associated with production, fish type, scale, and financial data (as outlined in DCN 20500 in the confidential record for this rule).

TABLE IX–2.—NATIONAL COSTS: TOTAL BY SUBCATEGORY

Production system	Owner	Pre-tax annualized costs ($000, 2003 dollars)
		Final option
Flow-through and Recirculating Systems	Commercial	$256
	Noncommercial [2]	$1,149
Net Pen	Commercial	$36
	Noncommercial [2]	$0
Total pre-tax [1]		$1,442

Note: Totals may not sum due to rounding.
[1] Total annual post-tax cost for the final option is $1,362.
[2] Noncommercial facilities include those operated by State, Federal, Alaska nonprofit, and Tribal facilities.

B. Economic Impacts

This section discusses the economic effects associated with the final rule.

1. How did EPA Estimate Economic Effects?

Existing Commercial Facilities. EPA uses several measures to evaluate possible impacts on existing commercial facilities. These measures examine the possibility of business closure and corresponding direct impacts on employment and communities and indirect and national impacts associated with closures. EPA also evaluates potential moderate impacts short of closure, as well as changes in financial health and borrowing capacity.

To evaluate impacts to commercial facilities, EPA conducts a closure analysis that compares projected earnings, with and without cost of compliance with the final regulation for the period 2005 to 2015. For this rule, EPA used discounted cash flow and net income to estimate earnings for closure analysis. The difference between cash flow and net income is depreciation (cash flow equals net income plus depreciation). Analysis using net income is more likely to identify baseline closures and could demonstrate additional regulatory closures associated with the rule. Table IX–3.5 presents closure results obtained using both discounted cash flow and net income. All other analytical results (for example, other measures of economic impacts, costs and benefits) presented in this final action reflect discounted cash flow as the basis for earnings. EPA also examines the effects of attributing a wage rate to unpaid labor and found that imputing costs for unpaid labor and management would not change the projected economic impacts of the rule.

Closure analysis assumes that (1) producers are unable to pass on the costs of incremental pollution control to consumer through higher prices and (2) costs and earnings are discounted assuming a 7 percent real discount rate to account for the time value of money and place earnings and costs on a comparable basis. EPA considers that the rule will result in a facility closure if a facility shows (1) positive discounted cash flow (or net income) without the rule and (2) negative discounted cash flow (or net income) with the rule for two out of three forecasting scenarios. The forecasting methods give a range of trends: (1) Optimistic or upward (USDA CPI Food at Home, Fish and Seafood Sector), (2) pessimistic or downward (weighted average, based on facility production, of USDA trout price data or U.S. Department of Labor, Bureau of Labor Statistics, Fish PPI, Producer Price Index—Unprocessed and packaged fish, not seasonally adjusted), and (3) neutral or no change (average of 1999–2001 earnings collected in the detailed questionnaire). In an effort to evaluate the effects of relying on two out of three forecasts to define closures, EPA also analyzed closures using a more conservative assumption whereby closures are defined as occurring when negative earnings are projected under only one of three forecast scenarios.

EPA does not assess potential for closure under the rule if a facility is projected to have negative earnings under baseline conditions (*i.e.*, baseline closure). Baseline closures are defined as facilities that are projected to have negative earnings under 2 or 3 of the forecasting methods before they incur pollution control costs (*i.e.*, baseline closures). EPA's standard methodology when using forecasts in closure models is to use a ''weight of evidence'' approach across a set of reasonable assumptions regarding future industry behavior. This allows EPA to recognize uncertainty in the forecasts without placing undue emphasis on any one set of ''timing and initial conditions''. Using this methodology, EPA determined that 32 out of 101 commercial facilities are baseline closures, assuming discounted cash flow for earnings. When EPA adopts net income as the basis for earnings, baseline closures are projected to be 43. When EPA projects closures based on negative earnings in one out of three forecasts, baseline closures are projected to be 34. EPA notes that this type of analysis identifies candidates for closure; information on facility-level costs and earnings may be too uncertain to allow precise prediction of which operations will actually close, in the absence of the rule.

In addition to its closure analysis, EPA also prepared additional analyses to assess potential effects, short of closure, on existing businesses, including an analysis of additional moderate impacts using a sales test, an evaluation of financial health using an approach similar to that used by USDA, and an assessment of possible impacts on borrowing capacity. Use of these measures has the advantage that they mirror analyses that investment and lending institutions perform to evaluate industries and businesses.

First, to assess whether there are additional moderate impacts to facilities, EPA uses a sales test to compare the pre-tax annualized cost of the final rule to the revenues reported for facilities that passed the baseline closure analysis. EPA considers that facilities show additional moderate impacts if they are not projected to close but incur compliance costs in excess of 5 percent of facility revenue; this threshold is consistent with threshold values established by EPA in previous regulations and is determined to be appropriate for this rulemaking.

Second, EPA calculates impacts on financial health at the company level using USDA's 2×2 matrix (*i.e.*, four-level) categorization of financial health based on a combination of net cash income and debt/asset ratios. The categories are favorable, marginal

solvency, marginal income, and vulnerable. EPA considers any change in financial health category as an impact of the rule.

Finally, EPA performs a credit test by calculating the ratio of the pre-tax annualized cost of an option and the after-tax Maximum Feasible Loan Payment (MFLP) (*i.e.*, 80 percent of after-tax cash flow). EPA identified companies with a ratio exceeding 80 percent of MFLP as being impacted by this rule (*i.e.*, the test threshold is therefore actually 64 percent of the after-tax cash flow).

For the purposes of EPA's analysis, the Agency assumes (1) no growth in production to offset incremental costs and (2) that the costs of the rule are not passed on to consumers. The facility must absorb all increased costs. If it cannot do so and remain in operation, all production is assumed lost. EPA's assumption of no cost pass through is a conservative approach to evaluating economic achievability among regulated entities. To evaluate market and trade level impacts, EPA assumes all costs are shifted onto the broader market level as a way of assessing the upper bound of potential impacts.

The Economic and Environmental Benefit Analysis, available in the rulemaking record, provides more detail on EPA's analysis (DCN 63010).

Noncommercial Facilities. For today's final rule, EPA collected information on how U.S. Fish and Wildlife Service and State agencies make decisions about operating or closing public hatcheries. EPA confirmed that public hatcheries close; the U.S. Fish and Wildlife Service hatchery system once had as many as 250 hatcheries and it now operates fewer than 90 facilities. Closures may result from funding cuts (*e.g.*, Mitchell Act Funds and the Willard National Fish Hatchery or General Funds for State Hatcheries) or revision of a program's mission and goals (*e.g.*, increase focus on endangered species versus provision of recreational services). Closures may also result from water quality impacts associated with aquaculture activities. The costs of upgrading pollution control at public hatcheries are not generally the primary reason for closure, but costs may tip the balance of a particular hatchery toward a closure decision. See the Economic and Environmental Benefits Analysis (DCN 63010) for more details.

In the absence of well defined tests for projecting public facility closures, EPA compares pre-tax annualized compliance costs to 2001 operating budgets for public facilities (''Budget Test''). For the purposes of this analysis, costs exceeding 5 percent and 10 percent are assumed to signal potential ''moderate'' and ''adverse'' impacts, respectively. EPA examines the ability of State-owned hatcheries to recoup compliance costs through increases in funding derived solely from user fees. All States and the District of Columbia have fishing license fees for residents. The license fees are not raised every year even though costs increase through inflation. Instead, when fees are raised or a fish stamp instituted, the incremental or new fee is usually a round number such as $3, $5, or $10. A $3 to $5 hike in State fishing license fees translates into an increase in fees of about 20 percent to 35 percent. Although all States report having fishing license fees, if a state hatchery reports no funding from user fee sources, EPA considers that facility to be unable to recoup increased costs through increased funding from user fees.

More detailed information is provided in the Economic and Environmental Benefit Analysis and the rulemaking record.

New Commercial Facilities. To assess effects on new businesses, EPA's analysis considers the barrier that compliance costs due to the effluent guidelines regulation may pose to entry into the industry. In general, it is less costly to incorporate waste water treatment technologies as a facility is built than it is to retrofit existing facilities. Therefore, where a rule is economically achievable for existing facilities, it will also be economically achievable for new facilities that can meet the same guidelines at lower cost. Similarly, even where the cost of compliance with a given technology is not economically achievable for an existing source, such technology may be less costly for new sources and thus have economically sustainable costs. It is possible, on the other hand, that to the extent the up-front costs of building a new facility are significantly increased as a result of the rule, prospective builders may face difficulties in raising additional capital. This could present a barrier to entry. Therefore, as part of its analysis of new source standards, EPA evaluates barriers to entry. If the requirements promulgated in the final regulation do not give existing operators a cost advantage over new source operators, then EPA assumes new source performance standards do not present a barrier to entry for new facilities.

EPA's analysis includes all commercial facilities within scope of the rule, including those that are baseline closures. EPA examines the (1) proportion of commercial facilities that incur no costs, (2) proportion of commercial facilities that incur no land or capital costs, and (3) ratio of incremental land and capital costs to total company assets. The cost to asset ratio is calculated using company data because asset data were collected only at the company level; company impacts cannot be extrapolated to the national-level because sampling weights are based on facilities, not companies. EPA calculates the ratio for each company and uses the average of the ratios. More information is provided in the Economic and Environmental Impact Analysis available in the rulemaking record.

2. What Are the Results of the Economic Analysis?

Existing Commercial Facilities. Table IX–3 shows the impacts on commercial operations from today's regulation. As shown, EPA projects no facility closures as a result of the final rule under the cash flow analysis. No closures are projected for enterprises or companies. Correspondingly, there are no employment and other direct and indirect impacts estimated for this rule as a consequence of closures using cash flow analysis and negative earnings in two of three forecast scenarios. When the closure analysis is conducted using net income as a basis for earnings, EPA projects two closures out of 58 commercial facilities (*see* Table IX–3.5). When the closure analysis is conducted using only one of three forecast scenarios, EPA also identifies two closures out of 67 commercial facilities (*see* Section IX.B.1 for discussion of forecast methods). Based on these results, EPA concludes that the final rule option is economically achievable. EPA notes that all other analytical results (for example other measures of economic impacts, costs) presented in this final action reflect discounted cash flow as the basis for earnings; EPA's analyses indicate that use of net income will not materially change results.

EPA expects some operations will incur moderate impacts, short of closure, based on an analysis that shows that some operations will incur compliance costs in excess of 5 percent of annual revenue. For the final regulation, 4 of 69 commercial facilities incur costs greater than 5 percent of sales, affecting about 5 percent of regulated facilities in the flow-through and recirculating subcategory; no additional facilities have costs exceeding 3 percent of revenues. No commercial facilities have costs that exceed 10 percent of annual revenue. EPA's analysis shows no expected change in financial health. One company fails the USDA credit test as

a result of the final regulation. These results are based on data from companies represented in the Agency's detailed questionnaire. These results further support EPA's conclusion that the final options are economically achievable for commercial facilities (and companies). More information is provided in the Economic and Environmental Benefit Analysis available in the rulemaking record (DCN 63010)

Noncommercial Facilities. Table IX–3 also shows the impacts on noncommercial operations from today's regulation. Four facilities incur costs exceeding 10 percent of budget. EPA assumes that those facilities that face costs exceeding 10 percent of their budget would be adversely affected by the final regulation. None of these facilities report the use of user fee funds. These results indicate that 3 percent of all non-commercial operations may be adversely affected by the final option. Under EPA's assumed criteria for determining economic achievability, these operations may be vulnerable to closure.

Twelve facilities incur costs exceeding 5 percent of annual budgets under the final rule. These results indicate that an additional 6 percent of all non-commercial operations (not counting those adversely affected) would experience some moderate impact, short of closure, associated under this final rule. Some of these facilities report the use of user fees revenues, implying potential flexibility in meeting the incremental costs.

No in-scope Alaskan nonprofit facilities responded to EPA's detailed questionnaire, but EPA did identify two in-scope facilities based on screener data. These facilities were costed using screener data and economic impacts were projected based on publicly available revenue data for 2001. Neither facility is projected to incur costs greater than 3 percent of revenues.

Given that the results of EPA's analysis project that a small share of regulated noncommercial facilities may incur costs exceeding 10 percent of budget, estimated at 3 percent of facilities, the Agency has determined that these final technology options to be economically achievable for noncommercial facilities. For more information, see the Economic and Environmental Benefit Analysis available in the rulemaking record.

New Commercial Facilities. EPA estimated that about 4 percent of regulated facilities do not incur any costs under the final regulation, and about 76 percent of facilities incur no land or capital costs. The incremental land and capital costs, where they were incurred, represented less than 0.2 percent of total assets. This final regulation should therefore not present barriers to entry for new businesses.

TABLE IX–3.—ECONOMIC IMPACTS: EXISTING COMMERCIAL & NONCOMMERCIAL OPERATIONS

Threshold test	Number of in-scope facilities in the Analysis [1]	Impacts projected under final option
Commercial Operations		
Closure Analysis (discounted cash flow) [2]	69	0
Sales test >3% (facility level)	69	4
Sales test >5% (facility level)	69	4
Sales test >10% (facility level)	69	0
Change in Financial Health (Company level) [3]	34	0
Credit test >80% (Company level) [3]	34	1
Noncommercial Facilities [6]		
Budget test >3% (all facilities)	141	19
State owned only (# with user fees) [5]	106	12 (8)
Federal owned only	33	7
Alaskan Non-Profit [4]	2	0
Budget test >5% (all facilities)	141	12
State owned only (# with user fees) [5]	106	8 (8)
Federal owned only	33	4
Alaskan Non-Profit [4]	2	0
Budget test >10% (all facilities)	141	4
State owned only (# with user fees) [5]	106	0 (0)
Federal owned only	33	4
Alaskan Non-Profit [4]	2	0

Source: Estimated by USEPA using results from facility-specific detailed questionnaire responses, see Chapter 3.

[1] There are 101 in-scope commercial facilities, represented by 34 unweighted companies. Of the 101 facilities, 32 are baseline closures, assuming cash flow analysis, leaving 69 commercial facilities that can be analyzed. Closure analysis and sales test are performed at facility level; financial health and credit tests performed at company level; and all noncommercial tests performed at facility level.

[2] Closure analysis results obtained using discounted cash flow and closure defined as negative earnings in two of three forecast scenarios. *See* Table IX–3.5 for results under different assumptions.

[3] Analysis performed at the company level. The statistical weights, however, are developed on the basis of facility characteristics and therefore cannot be used for estimating the number of companies.

[4] Two Alaska non-profit organizations are within the scope of this rule, but did not receive a detailed survey. They were costed using screener survey data. Economic impacts were calculated using publically available information.

[5] Some State-owned facilities reported that they relied, in part, on funds from State user fee operations. These numbers are reported in parenthesis and are included in the overall numbers as well.

[6] There is a potential for a small number of Tribal facilities to be present within the population of non-commercial facilities, despite the absence of a line item for Tribal facilities above. In its screener survey which was a census of the industry, EPA identified a number of Tribal facilities that might be subject to the proposed rule for the CAAP category (DCN 51401). However, all of the tribal facilities represented by the detailed survey were determined to not be in scope.

Because the detailed survey is a sample, there is uncertainty associated with the conclusion that there are no tribal facilities in scope for the final rule. For this reason, EPA believes there may be a few in-scope tribal facilities that have not been analyzed. As part of the analyses conducted prior to the NODA, based on the screener data, EPA estimated impacts for tribal facilities producing between 20,000 and 100,000 pounds per year for Option B (more costly than the final option). These results are for facilities that are not within the scope of the final rule, but they provide evidence that the final rule is expected to be economically achievable for tribal facilities.

TABLE IX–3.5.—CLOSURE ANALYSIS FOR COMMERCIAL FACILITIES UNDER DIFFERENT ASSUMPTIONS

	Number of in-scope facilities in the analysis [1]	Closures projected under final option
Closure Analysis (discounted cash flow) [2]	69	0
Closure Analysis (Net Income) [2]	58	2
Closure Analysis (one out of three forecasts) [3]	67	2

[1] There are 32, 43, and 34 baseline closures projected under discounted cash flow, net income and one out of three forecasts respectively. Baseline closures are not analyzed for regulatory closure and therefore subtracted from the 101 in-scope facilities.

[2] Discounted cash flow and net income are two different assumptions used to estimate earnings under closure analysis (*see* Section IX.B.1 for details). Closures defined as occurring when negative earnings are projected under at least two of three forecast methods.

[3] Analysis assumes earnings estimated using cash flow and closure defined, more conservatively, as occurring when negative earnings are projected under only one of three forecast methods.

3. What Are the Projected Market Level Impacts?

EPA was not able to prepare a market model analysis for this rule because of the complex interaction between commercial and non-commercial operations (*e.g.,* trout are raised commercially, but also for restoration and recreation), wild catch accounts for a large share of the market for some species, and USDA Census data indicate that there is a high degree of concentration of specific species, such as trout and some other food fish. Literature on estimated measures of elasticity of supply and demand is limited and exist for only a few species, such as catfish which are not covered by this regulation. The Agency does therefore not report quantitative estimates of changes in overall supply and demand for aquaculture products and changes in market prices. For more information, *see* Chapter 3.6 of the Economic and Environmental Benefit Analysis for the proposed rulemaking available in the docket (DCN 63010). However, EPA does not expect significant market impacts as a result of today's final rule because economic impacts are expected to be low (*see* discussion above) and the overall cost of the rule is low, as compared to the total value of the U.S. aquaculture industry. Long-term shifts in supply associated with this rule are unlikely given expected continued competition from domestic wild harvesters and low-cost foreign suppliers. For additional information, see the Economic and Environmental Impact Analysis available in the rulemaking record.

4. What Are the Potential Impacts on Foreign Trade?

Foreign trade impacts are difficult to predict, since agricultural exports are determined by economic conditions in foreign markets and changes in the international exchange rate for the U.S. dollar. In addition, for today's final rule, EPA was not able to perform a market model analysis for this rule and did not obtain quantitative estimates of changes in overall supply and demand for aquaculture products and changes in market prices, as well as changes in traded volumes including imports and exports.

Nevertheless, EPA believes that the impact of this final rule on U.S. aquaculture trade will not be significant. Because of the relatively small market share of U.S. aquaculture producers in world markets, EPA believes that long-term shifts in supply associated with this rule are unlikely given expected continued competition from domestic wild harvesters and already lower-cost foreign suppliers in China and other Asian nations. Under a scenario that assumes the total costs of the rule are absorbed by the domestic market, EPA estimates that U.S. aquaculture prices would rise by slightly more than 1 cent per pound. Under the alternative assumption that all costs are born by facility operators, impacts are projected to be small and would not significantly affect production (*see* Section IX.B.2).

5. What Are the Potential Impacts on Communities?

The communities where aquaculture facilities are located may be affected by the final regulation if facilities cut back operations. However, EPA projects no commercial facility closures as a result of this rule, assuming discounted cash flow (two closures are projected using net income as shown in Table IX–3.5), indicating minimal likelihood of measurable impacts on (1) direct losses in commercial production, revenue, or employment; and (2) local economies and employment rates. Should some facilities cut back operations as a result of this final regulation, EPA cannot project how great these impacts would be as it cannot identify the communities where impacts might occur. Under a scenario that assumes the total costs of the rule are absorbed by the domestic market, EPA estimates that U.S. aquaculture prices would rise by slightly more than 1 cent per pound. (See EPA's Economic and Environmental Benefit Analysis.)

Closures of non-commercial facilities could also result in employment impacts on communities. EPA projects four noncommercial facilities, with a total employment of 16 employees could experience impacts such that they would be vulnerable to closure (*i.e.,* costs exceed 10 percent of annual budget). The communities in which these facilities are located could experience moderate impacts, but, as noted in Section IX.B.2, environmental compliance costs are generally a contributing rather than the deciding factor in closure decisions. EPA therefore does not expect significant impacts on communities as a result of today's final rule.

C. What Do the Cost-Reasonableness Analyses Show?

EPA performed an assessment of the total cost of the final rule relative to the expected effluent reductions. EPA based its ''cost reasonableness'' (CR) analysis on estimated costs, loadings, and

removals. See EPA's Development Document in the rulemaking record for additional details.

Table IX.4 shows the cost-reasonableness values for conventional pollutants. EPA estimates BOD and TSS removals for each facility for each option. Because BOD can be correlated with TSS, EPA selected the higher of the two values (not the sum) to avoid possible double-counting of removals. For the Flow-through and Recirculating Systems Subcategory, cost-reasonableness is $2.77/lb. Cost-reasonableness is undefined for the Net Pen Subcategory systems because these facilities have adequate treatment to achieve requirements for pollutants (*i.e.,* no incremental removals are estimated for these facilities).

TABLE IX–4.—COST-REASONABLENESS: BOD OR TSS

Subcategory	Pre-tax annualized costs ($2003)	BOD or TSS removals (lb) [1]	Cost-reasonableness ($2003/pound)
Flow-through and Recirculating Systems	$1,405,866	506,839	$2.77
Net pen	$35,640	0	Undefined

[1] EPA determines the higher of BOD or TSS mass removal for each facility and then aggregates pounds across facilities.
Undefined: Facilities in this group are not projected to achieve incremental removals of the pollutants in this table (*i.e.,* no incremental removals are estimated).

X. What Are the Environmental Benefits for This Rule?

A. Summary of Environmental Benefits

Today's final action does not establish numeric limits for total suspended solids (TSS) or other pollutants from flow-through and recirculating systems. It establishes BMPs for solids control, materials storage, structural maintenance, recordkeeping, and training. The final rule also requires the permittee to develop a BMP plan on-site describing how the permittee will achieve the BMP requirements and make the plan available to the permitting authority upon request. The facilities are also to maintain the structural integrity of the aquatic animal containment system. The final rule also establishes BMP requirements for net pen systems that address feed management, waste collection and disposal, discharges associated with transport and harvest, carcass removal, materials storage, structural maintenance, recordkeeping, and training. Net pen facilities are to develop and maintain a BMP plan on-site describing how the permittee is to achieve the BMP requirements. The permittee must make the plan available to the permitting authority upon request. Both the flow-through and recirculating and net pen subcategories have reporting requirements for (1) the use of INADs and extralabel drugs use, (2) failure or damage to the structural integrity of the aquatic animal containment system, and (3) spills of drugs, pesticides and feed which result in discharge of pollutants to waters of the U.S. The requirements, according to EPA loadings estimates, will reduce facility discharges of TSS, total nitrogen (TN), total phosphorus (TP), and biochemical oxygen demand (BOD). EPA has also estimated reductions for metals and some feed contaminants as a result of these final requirements. EPA could not quantify baseline or regulated loads for drugs and pesticides.

These requirements and loading reductions (TSS, TN, TP, BOD, metals, and feed contaminants) could affect water quality, the uses supported by varying levels of water quality, and other aquatic environmental variables (*e.g.,* primary production and populations or assemblages of native organisms in the receiving waters of regulated facilities). These impacts may result in environmental benefits, some of which have quantifiable, monetizable value to society. For today's final action, EPA has only monetized benefits from water quality improvements resulting from reductions in TSS, TN, TP, and BOD.

TABLE 1.—SUMMARY OF ENVIRONMENTAL BENEFITS OF FINAL RULE

Type of benefit	Monetized value ($2003)
Improved water quality from reduced TSS, TN, TP, and BOD loadings due to improved solids control, including feed management	$66,000–$99,000
Reduced inputs to receiving water of metals and feed contaminants	not monetized
Reduced inputs of drugs and pesticides	not monetized
Reduced inputs of materials as a result of structural maintenance and material storage requirements	not monetized

B. Non-Monetized Benefits

1. Metals and Other Additives and Contaminants

CAAP facilities may release metals and other feed additives and contaminants to the environment in limited quantities; proper management of solids and other management practices may reduce environmental risk from these releases. Trace amounts of metals are added to feed in the form of mineral packs to ensure that the essential dietary nutrients are provided. In general, FDA establishes safety limits for feed additives and must address environmental safety concerns associated with such additives under the requirements of the Federal Food, Drug, and Cosmetic Act (FFD&CA) and National Environmental Policy Act (NEPA). Trace amounts of metals may also be present as feed contaminants. Metals may also be introduced into the environment from CAAP machinery, equipment, and structures (*e.g.,* net pens treated with antifouling copper compounds). Other feed additives may include FDA-approved compounds used to improve the coloring of fish flesh. Organochlorine contaminants such as polychlorinated biphenyls (PCBs) also may be present as trace residues regulated by FDA in some fish feeds.

EPA estimates that today's final rule will reduce total suspended solids (TSS) released by CAAP facilities by about half a million pounds per year. Metals and other feed contaminants that may be released to the environment from CAAP facilities are in large part associated with waste solids. EPA estimates that reductions in TSS will be accompanied by incidental removals of metals and PCBs. EPA estimated metal reductions of approximately 2,700 pounds per year nationally and a maximum of PCB reductions of 0.04 lbs

per year. For further discussion of metals and other feed additives and contaminants, see the Economic and Environmental Impact Analysis and Technical Development Document for this final rule (DCNs 63010 and 63009).

2. Drugs and Pesticides

CAAP facilities employ drugs and pesticides for a variety of therapeutic and water treatment purposes. Facilities release treated waters that may contain residual amounts of drugs, pesticides, and their byproducts directly to the environment. Drugs used for therapeutic purposes are regulated by FDA. Prior to approving drugs for use, FDA must evaluate the environmental safety of animal drugs as required by FFDCA and NEPA. While FDA is required to consider environmental impacts of approved and investigational drugs under these authorities, the environmental safety of drugs used under FDA's ''investigational new animal drug'' (INAD) program may not be fully characterized. The INAD program is an important mechanism that enables the collection of data that can be used to characterize and establish the environmental safety of new drugs. For compilations of technical literature supporting FDA's environmental assessments of therapeutants used at CAAP facilities, see the FDA's Center for Veterinary Medicine (CVM) Web site (*www.fda.gov/cvm*). It should be noted that FDA environmental assessments are not site-specific and may not cover all discharge scenarios (*e.g.*, multiple dischargers to a single receiving water) or applications (*e.g.*, extralabel applications of drugs). For additional discussion of this topic, see Chapter 7 of EPA's Environmental Impact Analysis for this final rule.

Today's final rule requires the proper storage of drugs, pesticides, and feed to prevent spills that may result in a discharge from CAAP facilities. For reasons explained in Section VI.G (Loadings) of this Preamble, EPA has not quantified expected reductions in the release of drugs and pesticides to the environment nor environmental benefits that might result. Today's final rule also requires CAAP facilities to report to permitting authorities whenever an investigative drug or an extralabel drug is used in amounts exceeding a previously approved dosage, as described above in Section VIII.E. This requirement is expected to better enable permitting authorities to monitor the potential for environmental risks that could result from such uses. EPA has not quantified benefits that might arise as a result of this requirement.

C. Monetized Benefits

1. Case Study Framework

As was done for EPA's proposed rule, EPA estimated monetized benefits of the regulation based on predicted improvements in water quality in the receiving waters of facilities that were expected to have load reductions as a result of the rule. EPA's water quality modeling for today's final action differs from the proposal modeling, however, in that for the final rule, more detailed, facility-specific operational and environmental data were obtained, both from information provided by facilities on the detailed surveys as well as other sources. This more detailed data provided EPA with a better basis for developing representative case studies on which to perform water quality modeling and valuation and for extrapolating from case studies to a national benefit estimate.

To select a set of representative case studies from among the facilities for which EPA had detailed data, EPA assumed that three factors primarily drive water quality improvements at any given facility: (1) The magnitude of pollutant load reductions under the final rule, (2) effluent pollutant concentrations at baseline (prior to regulatory reductions), and (3) the ratio of facility effluent flow to receiving water streamflow (''dilution ratio''). EPA then created categories based on combinations of values (low and high) for each of these factors. For example, the ''LLL'' category means facilities with ''low'' pollutant reductions under the final rule, ''low'' baseline effluent concentrations, and ''low'' dilution ratios; this category is expected to experience the smallest benefits of the final regulation. In this manner, eight categories were created (LLL, LLH, LHL, LHH, HLL, HLH, HHL, HHH; *see* Table 2). EPA then assigned all detailed survey facilities with non-zero load reductions in the scope of the final rule to an appropriate category based on the three factors described above. For more details on the categorization procedure, *see* Chapter 8 of the Economic and Environmental Impact Analysis for today's final action [DCN 63010].

EPA then developed a ''case study'' for one facility in each of the five categories expected to experience the greatest water quality improvement (EPA did not develop case studies for all categories partly because of resource constraints). EPA multiplied the estimated benefits for each case study by the total number of facilities assigned to that category to estimate a total national benefit for that category. No benefits were estimated for the three categories for which case studies were not developed. Benefits for these categories are expected to be small relative to those included in the analysis. The total national benefit estimate was estimated as the sum of benefits for all categories.

2. Economic Valuation Method

Economic research indicates that the public is willing to pay for improvements in water quality and several methods have been developed to translate changes in water quality to monetized values, as noted in EPA's ''Guidelines for Preparing Economic Analyses (EPA–240–R–00–003, 2003;). At proposal, EPA based the water quality benefits monetization on results from a stated-preference survey conducted by Carson and Mitchell (1993) (DCN 20157). We divided household willingness-to-pay (WTP) values for changes in recreational water ''use classes'' by the number of ''water quality index'' points (an index based on water quality variables; see below) in each use class. We assigned a portion of the value for each unit change to achieving the whole step. Recently, EPA developed an alternative approach, also based on Mitchell and Carson's work. Mitchell and Carson also expressed their results as an equation relating a household's WTP for improved water quality to the change in the water quality index and household income. An important feature of this approach is that it is less sensitive to the baseline use of the water body. This approach is also consistent with economic theory in that it exhibits a declining marginal WTP for water quality (see more information on this approach in DCNS 40138 and 40595). While caution must be used in manipulating valuations derived from stated preference surveys, this valuation function approach helps address some concerns about earlier applications of the water quality benefits monetization method. (*See* DCN 40595 for a more detailed discussion).

3. Water Quality Modeling

As was done for the proposed rule, EPA applied the Enhanced Stream Water Quality Model (QUAL2E, *http://www.epa.gov/waterscience/wqm/*) to simulate changes in receiving water quality resulting from reductions in TSS, BOD, total nitrogen, and total phosphorus estimated by EPA to result from the regulatory requirements of this final rule. QUAL2E is a one-dimensional water quality model that assumes steady state flow but allows simulation of diurnal variations in temperature, algal photosynthesis, and respiration. The model projects water

quality by solving an advective-dispersive mass transport equation. Water quality constituents simulated include conservative substances, temperature, bacteria, BOD_5, DO, ammonia, nitrate and organic nitrogen, phosphate and organic phosphorus, and algae.

Resource and data limitations constrained the number of QUAL2E applications that could be performed. EPA developed a QUAL2E case study for the following categories: LHL, LHH, HLH, HHL, and HHH. EPA did not prepare case studies for the LLL, LLH, and HLL categories because (a) no facilities were in the HLL category and (b) EPA focused modeling resources on categories expected to represent a larger proportion of benefits. Water quality improvements for facilities in the LLL and LLH categories were expected to be smaller than the improvements for the facilities in the other categories.

4. Calculation of ''Water Quality Index''

Simulated water quality changes for each case study must be translated into a composite ''index'' value for the monetization method described in Section X.B.2 above. EPA more recently developed a six-parameter WQI (''WQI–6'') based on TSS, BOD, DO, FC, plus nitrate (NO_3) and phosphate (PO_4). The new index more completely reflects the type of water quality changes that will result from loading reductions for TSS, total nitrogen (TN), total phosphorus (TP), and BOD. Final rule benefits presented here were estimated on the basis of WQI–6.

5. Estimated National Water Quality Benefits

EPA monetized water quality benefits for each of the 5 QUAL2E case studies performed (Table 2). Using the methods described above, the Agency estimates that the total national benefit from water quality improvements arising from TSS, BOD, TN, and TP reductions from this rule are $66,000—$99,000. This range reflects varying assumptions that the Agency implemented to reflect some sources of uncertainty. Furthermore, this range of water quality-based benefits of this regulation may be uncertain for several reasons including:

- EPA did not estimate benefits for the facilities in the LLL and LLH extrapolation categories. However, it is not expected that inclusion of these facilities would greatly increase monetized water quality benefits.
- EPA's monetization method mainly captures benefits for recreational uses of the streams. Economic research indicates that there are significant ''non-use'' values associated with some dimensions of water quality. Analysis using monetization methods that fully captures non-use values could increase the estimated benefits for this rule if it significantly affects these dimensions. EPA does not have enough information to determine if this is the case.
- Other receiving water impacts are not captured in the QUAL2E modeling, such as build-up of organic sediments in stream channels. Research included in the administrative record for today's final action documents that such accumulations can impair aquatic ecosystems. Benefits from reducing these effects are not captured in EPA's analysis of water quality-based benefits of today's final action.

TABLE 2.—EXTRAPOLATED TOTAL NATIONAL WATER QUALITY BENEFIT ESTIMATE, FINAL OPTION

A Extrapolation category	B Total national benefit for extrapolation category ($2003)
LLL–LLH	not estimated
LHL–LHH	$2,126–$5,330
HLL–HLH	$6,591–$12,031
HHL–HHH	$57,497–$81,255
Total	$66,214–$98,616

In general, however, the relatively small recreational benefits projected for the rule suggest that non-monetized benefits categories are likely to be small as well.

XI. What Are the Non-Water Quality Environmental Impacts of This Rule?

Under Sections 304(b) and 306 of the Clean Water Act, EPA may consider non-water quality environmental impacts (including energy requirements) when developing effluent limitations guidelines and standards. Accordingly, EPA has considered the potential impact of today's final regulation on air emissions, energy consumption, and solid waste generation.

A. Air Emissions

With the implementation of feed management, the final rule decreases the amount of solid waste generated and land applied from CAAP facilities. Land application is a common waste disposal method in the CAAP industry; therefore, the amount of ammonia released as air emissions would be expected to decrease as the quantity of waste applied to cropland decreases. EPA estimates the decrease in ammonia emissions to be 8,182 pounds of ammonia per year. This is a decrease of about 8 % over the ammonia emissions presently estimated for the industry. For additional details about air emissions from CAAP facilities, see Chapter 11 of the TDD.

B. Energy Consumption

EPA estimates that implementation of today's rule would result in a net decrease in energy consumption for aquaculture facilities. The decrease would be based on electricity used today to pump solids from raceways to solids settling ponds, which will no longer be generated, from wastewater treatment equipment. EPA determined that the decrease in energy consumption for flow-through and recirculating systems is estimated at 4,900 kilowatt-hour (kW-h). This represents about 1.3×10^{-7} percent of the national generated energy.

C. Solid Waste Generation

EPA estimates that implementation of today's rule would result in an estimated reduction of 2.3 million pounds of sludge, on a wet basis (assuming 12 percent solids) for flow-through and recirculating facilities. This reduction is due to feed management that results in less solid waste generated.

XII. How Will This Rule Be Implemented?

This section helps permit writers and CAAP facilities implement this regulation. This section also discusses the relationship of upset and bypass provisions, variances, and modifications to the final limitations and standards. For additional implementation information, see Chapter 2 of the Technical Development Document for today's rule.

A. Implementation of Limitations and Standards for Direct Dischargers

Effluent limitations guidelines and new source performance standards act as important mechanisms to control the discharges of pollutants to waters of the United States. These limitations and standards are applied to individual facilities through NPDES permits issued by the EPA or authorized States under Section 402 of the Act.

In specific cases, the NPDES permitting authority may elect to establish technology-based permit limits for pollutants not covered by this regulation. In addition, where State water quality standards or other provisions of State or Federal law require limits on pollutants not covered by this regulation (or require more stringent limits or standards on covered pollutants in order to attain and maintain water quality standards), the

permitting authority must apply those limitations or standards. See CWA Section 301(b)(1)(C).

The final regulation establishing narrative limitations for the flow-through and recirculating system and net pen subcategories requires that a point source must meet the prescribed limitations expressed as operational practices or ''any modification to these requirements as determined by the permitting authority based on its exercise of its best professional judgment.'' Sections 451.11 and 451.21. This provision authorizes the permitting authority to tailor the specific NPDES permit limits that implement the guideline limitations to individual sites. As previously explained, the final narrative requirements, in many cases, require achievement of environmental end points. There may be circumstances which require some modification to these requirements to best accomplish these environmental end points, or to accommodate specific circumstances at a particular site. The provision allows the permitting authority to address such situations by incorporating in the NPDES permit specific tailored conditions that accomplish the intent of the narrative limitations. The CWA recognizes that it should provide mechanisms for addressing certain unique, site-specific situations in the guidelines regulation. Here, EPA has provided upfront in this rule such a mechanism.

1. What Are the Compliance Dates for Existing and New Sources?

New and reissued NPDES permits to direct dischargers must include these effluent limitations unless water quality considerations require more stringent limits, and the permits must require immediate compliance with such limitations. If the permitting authority wishes to provide a compliance schedule, it must do so through an enforcement mechanism.

New sources must comply with the new source standards (NSPS) of this rule when they commence discharging CAAP wastewater. Because the final rule was not promulgated within 120 days of the proposed rule, the Agency considers a discharger to be a new source if its construction commences after September 22, 2004.

2. Who Does Part 451 Apply To?

In Section VI.A. of this preamble and Chapter 2 of the TDD, EPA provides detailed information on the applicability of this rule. 40 CFR part 451 will apply to existing and new concentrated aquatic animal production facilities that produce 100,000 pounds or more of aquatic animals per year in flow-through, recirculating, and net pen systems. There is an exception for net pen systems rearing native species released after a growing period of no longer than 4 months to supplement commercial and sport fisheries.

B. Upset and Bypass Provisions

A ''bypass'' is an intentional diversion of the streams from any portion of a treatment facility. An ''upset'' is an exceptional incident in which there is unintentional and temporary noncompliance with technology-based permit effluent limitations because of factors beyond the reasonable control of the permittee. EPA's regulations concerning bypasses and upsets for direct dischargers are set forth at 40 CFR 122.41(m) and (n) and for indirect dischargers at 40 CFR 403.16 and 403.17.

C. Variances and Modifications

While the CWA requires application of effluent limitations established pursuant to section 301 to all direct dischargers, the statute also provides for the modification of these national requirements in a limited number of circumstances. Moreover, the Agency established administrative mechanisms to provide an opportunity for relief from the application of the national effluent limitations guidelines for categories of existing sources for toxic, conventional, and nonconventional pollutants.

1. Fundamentally Different Factors Variances

EPA will develop effluent limitations or standards different from the otherwise applicable requirements if an individual discharging facility is fundamentally different with respect to factors considered in establishing the limitation of standards applicable to the individual facility. Such a modification is known as a ''fundamentally different factors'' (FDF) variance.

Early on, EPA, by regulation provided for the FDF modifications from the BPT effluent limitations, BAT limitations for toxic and nonconventional pollutants and BCT limitations for conventional pollutants for direct dischargers. FDF variances for toxic pollutants were challenged judicially and ultimately sustained by the Supreme Court. (*Chemical Manufacturers Assn* v. *NRDC*, 479 U.S. 116 (1985)).

Subsequently, in the Water Quality Act of 1987, Congress added new Section 301(n) of the Act explicitly to authorize modifications of the otherwise applicable BAT effluent limitations or categorical pretreatment standards for existing sources if a facility is fundamentally different with respect to the factors specified in Section 304 (other than costs) from those considered by EPA in establishing the effluent limitations or pretreatment standard. Section 301(n) also defined the conditions under which EPA may establish alternative requirements. Under Section 301(n), an application for approval of a FDF variance must be based solely on (1) information submitted during rulemaking raising the factors that are fundamentally different or (2) information the applicant did not have an opportunity to submit. The alternate limitation or standard must be no less stringent than justified by the difference and must not result in markedly more adverse non-water quality environmental impacts than the national limitation or standard.

EPA regulations at 40 CFR Part 125, Subpart D, authorizing the Regional Administrators to establish alternative limitations and standards, further detail the substantive criteria used to evaluate FDF variance requests for direct dischargers. Thus, 40 CFR 125.31(d) identifies six factors (*e.g.*, volume of process wastewater, age and size of a discharger's facility) that may be considered in determining if a facility is fundamentally different. The Agency must determine whether, on the basis of one or more of these factors, the facility in question is fundamentally different from the facilities and factors considered by EPA in developing the nationally applicable effluent guidelines. The regulation also lists four other factors (*e.g.*, infeasibility of installation within the time allowed or a discharger's ability to pay) that may not provide a basis for an FDF variance. In addition, under 40 CFR 125.31(b) (3), a request for limitations less stringent than the national limitation may be approved only if compliance with the national limitations would result in either (a) a removal cost wholly out of proportion to the removal cost considered during development of the national limitations, or (b) a non-water quality environmental impact (including energy requirements) fundamentally more adverse than the impact considered during development of the national limits.

The legislative history of Section 301(n) underscores the necessity for the FDF variance applicant to establish eligibility for the variance. EPA's regulations at 40 CFR 125.32(b)(1) are explicit in imposing this burden upon the applicant. The applicant must show that the factors relating to the discharge controlled by the applicant's permit which are claimed to be fundamentally different are, in fact, fundamentally

different from those factors considered by EPA in establishing the applicable guidelines. In practice, very few FDF variances have been granted for past ELGs. An FDF variance is not available to a new source subject to NSPS or PSNS.

Facilities must submit all FDF variance applications to the appropriate Director (defined at 40 CFR 122.2) no later than 180 days from the date the limitations or standards are established or revised (see CWA section 301(n)(2) and 40 CFR 122.21(m)(1)(i)(B)(2)). EPA regulations clarify that effluent limitations guidelines are ''established'' or ''revised'' on the date those effluent limitations guidelines are published in the **Federal Register** (see 40 CFR 122.21 (m)(1)(i)(B)(2)). Therefore, all facilities requesting FDF variances from the effluent limitations guidelines in today's final rule must submit FDF variance applications to their Director (as defined at 40 CFR 122.2) no later than February 21, 2005.

2. Economic Variances

Section 301(c) of the CWA authorizes a variance from the otherwise applicable BAT effluent guidelines for nonconventional pollutants due to economic factors. The request for a variance from effluent limitations developed from BAT guidelines must normally be filed by the discharger during the public notice period for the draft permit. Other filing time periods may apply, as specified in 40 CFR 122.21(1)(2). Specific guidance for this type of variance is available from EPA's Office of Wastewater Management.

D. Best Management Practices

Sections 304(e), 308(a), 402(a), and 501(a) of the CWA authorize the Administrator to prescribe BMPs as part of effluent limitations guidelines and standards or as part of a permit. EPA's BMP regulations are found at 40 CFR 122.44(k). Section 304(e) of the CWA authorizes EPA to include BMPs in effluent limitations guidelines for certain toxic or hazardous pollutants for the purpose of controlling ''plant site runoff, spillage or leaks, sludge or waste disposal, and drainage from raw material storage.'' Section 402(a)(1) and NPDES regulations [40 CFR 122.44(k)] also provide for best management practices to control or abate the discharge of pollutants when numeric limitations and standards are infeasible. In addition, Section 402(a)(2), read in concert with Section 501(a), authorizes EPA to prescribe as wide a range of permit conditions as the Administrator deems appropriate in order to ensure compliance with applicable effluent limitations and standards and such other requirements as the Administrator deems appropriate.

E. Potential Tools To Assist With the Remediation of Aquaculture Effluents

A potential option to assist land owners with aquaculture effluent quality is the Environmental Quality Incentives Program (EQIP). This is a voluntary USDA conservation program. EQIP was reauthorized in the Farm Security and Rural Investment Act of 2002 (Farm Bill 2002). The Natural Resources Conservation Service (NRCS) administers EQIP funds.

EQIP applications are accepted throughout the year. NRCS evaluates each application using a state and locally developed evaluation process. Incentive payments may be made to encourage a producer to adopt land management, manure management, integrated pest management, irrigation water management and wildlife habitat management practices or to develop a Comprehensive Nutrient Management Plan (CNMP). These practices would provide beneficial effects on reducing sediment and nutrient loads to those aquaculture operations dependent on surface water flows. In addition, opportunities exist to provide EQIP funds to foster the adoption of innovative cost effective approaches to address a broad base of conservation needs, including aquaculture effluent remediation. NRCS does not at present have standards that apply specifically to waste handling at aquaculture facilities, thus EQIP funds for aquaculture projects would only apply to practices related to other agricultural aspects of a facility such as CNMPs for the land application of solids.

XIII. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order 12866, [58 FR 51,735 (October 4, 1993)] the Agency must determine whether the regulatory action is ''significant'' and therefore subject to OMB review and the requirements of the Executive Order. The Order defines ''significant regulatory action'' as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

Pursuant to the terms of Executive Order 12866, it has been determined that this rule is a ''significant regulatory action.'' As such, this action was submitted to OMB for review. Changes made in response to OMB suggestions or recommendations will be documented in the public record.

B. Paperwork Reduction Act

The information collection requirements in this rule have been submitted for approval to the Office of Management and Budget (OMB) under the *Paperwork Reduction Act,* 44 U.S.C. 3501 *et seq.* The information collection requirements are not enforceable until OMB approves them.

EPA has several special reporting and monitoring provisions in this regulation as previously explained. The provisions include reporting requirements (1) for the use of INAD or extralabel drug uses; (2) for failure or damage to the containment system (including the production system(s) and all the associated storage and water treatment systems) that results in a material discharge of pollutants to waters of the U.S; and (3) for spills of drugs, pesticides or feed. Section 308(a) of the CWA authorizes the Administrator to require the owner or operator of any point source to file reports as required to carry out the objectives of the Act. This ELG requires reporting in the event that drugs are used which are either under a conditional approval as an Investigative New Animal Drugs (INADs) or are prescribed by a licensed veterinarian for treatment of a disease or a species that is outside the approved use of the specific drug, referred to as extralabel drug use, unless the INAD or extralabel drug use is under similar conditions and dosages as a previously approved use. EPA believes this reporting requirement is appropriate for these classes of drugs, because they have not undergone the same degree of review with respect to their environmental effects as approved drugs. The final regulation also requires reporting when the facility has a failure in the structural integrity of the aquatic animal containment systems that results in a material discharge of pollutants. EPA believes this reporting is necessary

to alert the permitting authority to the release of large quantities of material from these facilities. The rule also allows the permitting authority to specify in the permit what constitutes damage and/or material discharge of pollutants for particular facilities based on consideration of relevant site-specific factors.

Burden means the total time, effort, or financial resources expended by persons to generate, maintain retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information. EPA estimates that the reporting and recordkeeping requirements included in today's regulation will result in a total annual burden of 45,000 hours and cost $808,000.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9. When this ICR is approved by OMB, the Agency will publish a technical amendment to 40 CFR part 9 in the **Federal Register** to display the OMB control number for the approved information collection requirements contained in this final rule.

C. Regulatory Flexibility Act

The RFA generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

For purposes of assessing the impacts of today's rule on small entities, small entity is defined as: (1) A small business that is primarily engaged in concentrated aquatic animal production, as defined by North American Industry Classification (NAIC) codes 112511 and 112519, with no more than $0.75 million in annual revenues; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of today's final rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. The small entities directly regulated by the final rule are primarily commercial businesses that fall within the NAIC codes for finfish farming, fish hatcheries, and other aquaculture. The Small Business Administration size standard for these codes is $0.75 million in annual revenues. Among the costed facilities, EPA identified 38 facilities belonging to small businesses or organizations. Of the 38, 37 facilities are owned by small businesses and 1 is an Alaskan facility operated by a small non-profit organization that is not dominant in its field. For the purposes of the RFA, Federal, and State governments are not considered small governmental jurisdictions, as documented in the rulemaking record (DCN 20121). Thus, facilities owned by these governments are not considered small entities, regardless of their production levels. EPA identified no public facilities owned by small local governments. No small organization is projected to incur impacts. Of the 101 commercial facilities, 37 (37 percent) are owned by small businesses. Under EPA's closure analyses no small business is projected to close as a result of the final rule, assuming discounted cash flow (two small business closures are projected using net income). In addition to considering the potential for adverse economic impacts, EPA also evaluated the possibility of other, more moderate financial impacts. Expressed as a comparison of compliance costs to sales, only 4 facilities belonging to small businesses (11 percent of small businesses, and 4 percent of commercial facilities) are likely to incur costs that exceed 3 percent of sales. One small business fails the USDA credit test.

Although this final rule will not have a significant economic impact on a substantial number of small entities, EPA nonetheless designed the rule to reduce the impact on small entities. The scope of the final rule is restricted to CAAP facilities that produce 100,000 lbs/year or more. This means that of the approximately 4,000 aquaculture facilities nationwide, as identified by USDA's Census of Aquaculture, EPA's final regulation applies to an estimated 101 commercial facilities or approximately 2.6 percent of all operations. Among commercial facilities, EPA identifies 38 facilities (37 percent of in-scope facilities) as small businesses using SBA's definition. Finally, EPA based the final rule on a technology option that has lower costs and fewer impacts (including impacts on small businesses) than several other technology options that were considered as possible bases for the final rule.

EPA conducted outreach to small entities and convened a Small Business Advocacy Review Panel prior to proposal to obtain the advice and recommendations of representatives of the small entities that potentially would be subject to the rule's requirements. The Agency convened the Small Business Advocacy Review Panel on January 22, 2002. Members of the Panel represented the Office of Management and Budget, the Small Business Administration, and EPA. The Panel met with small entity representatives (SERs) to discuss the potential effluent guidelines and, in addition to the oral comments from SERs, the Panel solicited written input. In the months preceding the Panel, EPA conducted outreach with small entities that would potentially be affected by this regulation. On January 25, 2002, the SBAR Panel sent some initial information for the SERs to review and provide comment on. On February 6, 2002, the Panel distributed additional information to the SERs for their review. On February 12 and 13, the Panel met with SERs to hear their comments on the information distributed in these mailings. The Panel also received written comments from the SERs in response to the discussions at this meeting and the outreach materials. The Panel asked SERs to evaluate how they would be affected and to provide advice and recommendations regarding early ideas to provide flexibility. See Section 8 of the Panel's Report (DCN 31019) for a complete discussion of SER comments. The Panel evaluated the assembled materials and small-entity comments on issues related to the elements of an Initial Regulatory Flexibility Analysis. A copy of the Panel's report is included in the rulemaking docket. EPA provided responses to the Panel's most significant findings in the Notice of Proposal Rulemaking (67 FR 57918–57920). In general, the requirements of this final rule address the concerns raised by SERs and are consistent with the Panel's recommendations.

D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of

their regulatory actions on State, local, and tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures to State, local, and tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

EPA has determined that this rule does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and tribal governments, in the aggregate, or the private sector in any one year. The total annual cost of this rule is estimated to be $1.4 million. Thus, today's rule is not subject to the requirements of Sections 202 and 205 of UMRA.

E. Executive Order 13132: Federalism

Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.''

This rule does not have Federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. EPA estimates that, when promulgated, these revised effluent guidelines and standards will be incorporated into NPDES permits without significant additional costs to authorized States.

Further, the revised regulations would not alter the basic State-Federal scheme established in the Clean Water Act under which EPA authorizes States to carry out the NPDES permitting program. EPA expects the revised regulations to have little effect, if any, on the relationship between, or the distribution of power and responsibilities among, the Federal, State and local governments. Thus, Executive Order 13132 does not apply to this rule.

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 the Federal government and the Indian tribes, or on this distribution of power and responsibilities between the Federal government and Indian tribes.''

The final rule does not have tribal implications. It will not have substantial direct effects on tribal governments, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175. The Executive Order provides that EPA must ensure meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications. EPA's rulemaking process has provided that opportunity for meaningful and timely input. EPA first published a notice of proposed rulemaking for CAAPs in September 2002, requesting comment on the proposal. In December 2003, EPA issued a Notice of Data Availability describing options for changes to the proposed rule. As noted, EPA identified a number of tribal facilities in its screener survey, however further evaluation did not identify any in-scope tribal facilities based on subsequent evaluation of the detailed survey information from a sample of these facilities. Thus EPA has not had a basis to have any formal consultation with Tribal officials. EPA has however concluded that the final rule will not have a substantial direct effect on one or more Indian Tribes, will not impose substantial direct compliance costs on Indian tribal governments, nor pre-empt tribal law.

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

Executive Order 13045 (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 and 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 rule is not subject to Executive Order 13045 because it is not an economically significant rule under E.O. 12866.

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

This rule is not a ''significant energy action'' as defined in Executive Order 13211, ''actions concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355 (May 22, 2001)) because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. As part of the Agency's consideration of non-water quality impacts, EPA has estimated the energy consumption associated with today's requirements. The rule will result in a net decrease in energy consumption for flow-through and recirculating systems. The decrease would be based on electricity used today to pump solids from raceways to solids settling ponds, which will no longer be generated, from wastewater treatment equipment. EPA estimated the decrease in energy consumption for

flow-through and recirculating systems at 4,900 kilowatt-hour (kW-h). Comparing the annual decrease in electric use resulting from the final requirements to national annual energy use, EPA estimates the decrease to be 1.3×10^{-7} percent of national energy use. Therefore, we conclude that this rule is not likely to have any adverse energy effects.

I. National Technology Transfer and Advancement Act

As noted in the proposed rule, Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (''NTTAA''), Public Law 104–113, 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, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

Today's rule does not establish any technical standards, thus NTTAA does not apply to this rule.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

The requirements of the Environmental Justice Executive Order are that EPA will review the environmental effects of major Federal actions significantly affecting the quality of the human environment. For such actions, EPA reviewers will focus on the spatial distribution of human health, social and economic effects to ensure that agency decision makers are aware of the extent to which those impacts fall disproportionately on covered communities. This is not a major action. Further, EPA does not believe this rulemaking will have a disproportionate effect on minority or low income communities because the technology-based effluent limitations guidelines are uniformly applied nationally irrespective of geographic location. The final regulation will reduce the negative effects of concentrated aquatic animal production industry waste in our nation's waters to benefit all of society, including minority and low-income communities. The cost impacts of the rule should likewise not disproportionately affect low-income communities given the relatively low economic impacts of today's final rule.

K. 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 publication of the rule in the **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 September 22, 2004.

List of Subjects in 40 CFR Part 451

Environmental protection, Concentrated aquatic animal production, Waste treatment and disposal, Water pollution control.

Dated: June 30, 2004.

Stephen L. Johnson,

Acting Deputy Administrator.

■ For the reasons set forth in the preamble, chapter I of title 40 of the Code of Federal Regulations is amended by adding part 451 to read as follows:

PART 451—CONCENTRATED AQUATIC ANIMAL PRODUCTION POINT SOURCE CATEGORY

Sec.

Authority: 7 U.S.C. 135 *et seq.*, 136–136y; 15 U.S.C. 2001, 2003, 2005, 2006, 2601–2671, 21 U.S.C. 331j, 346a, 348; 31 U.S.C. 9701; 33 U.S.C. 1251 *et seq.*, 1311, 1313d, 1314, 1318, 1321, 1326, 1330, 1342, 1344, 1345(d) and (e), 1361; 42 U.S.C. 241, 242b, 243, 246, 300f, 300g, 300g–1, 300g–2, 300g–3, 300g–4, 300g–5, 300g–6, 300j–2, 300j–3, 300j–4, 300j–9, 1857 *et seq.*, 6901–6992k, 7401–7671q, 7542, 9601–9657, 11023, 11048; E.O. 11735, 38 FR 21243, 3 CFR, 1971–1975 Comp., 973.

§ 451.1 General applicability.

As defined more specifically in each subpart, this Part applies to discharges from concentrated aquatic animal production facilities as defined at 40 CFR 122.24 and Appendix C of 40 CFR Part 122. This Part applies to the discharges of pollutants from facilities that produce 100,000 pounds or more of aquatic animals per year in a flow-through, recirculating, net pen or submerged cage system.

§ 451.2 General definitions.

As used in this part:

(a) The general definitions and abbreviations in 40 CFR part 401 apply.

(b) *Approved dosage* means the dose of a drug that has been found to be safe and effective under the conditions of a new animal drug application.

(c) *Aquatic animal containment system* means a culture or rearing unit such as a raceway, pond, tank, net or other structure used to contain, hold or produce aquatic animals. The containment system includes structures designed to hold sediments and other materials that are part of a wastewater treatment system.

(d) *Concentrated aquatic animal production facility* is defined at 40 CFR 122.24 and Appendix C of 40 CFR Part 122.

(e) *Drug* means any substance defined as a drug in section 201(g)(1) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321).

(f) *Extralabel drug use* means a drug approved under the Federal Food, Drug and Cosmetic Act that is not used in accordance with the approved label directions, see 21 CFR part 530.

(g) *Flow-through system* means a system designed to provide a continuous water flow to waters of the United States through chambers used to produce aquatic animals. Flow-through systems typically use rearing units that are either raceways or tank systems.

Rearing units referred to as raceways are typically long, rectangular chambers at or below grade, constructed of earth, concrete, plastic, or metal to which water is supplied by nearby rivers or springs. Rearing units comprised of tank systems use circular or rectangular tanks and are similarly supplied with water to raise aquatic animals. The term does not include net pens.

(h) *Investigational new animal drug (INAD)* means a drug for which there is a valid exemption in effect under section 512(j) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 360b(j), to conduct experiments.

(i) *New animal drug application* is defined in 512(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C 360b(b)(1)).

(j) *Net pen system* means a stationary, suspended or floating system of nets, screens, or cages in open waters of the United States. Net pen systems typically are located along a shore or pier or may be anchored and floating offshore. Net pens and submerged cages rely on tides and currents to provide a continual supply of high-quality water to the animals in production.

(k) *Permitting authority* means EPA or the State agency authorized to administer the National Pollutant Discharge Elimination System permitting program for the receiving waters into which a facility subject to this Part discharges.

(l) *Pesticide* means any substance defined as a ''pesticide'' in section 2(u) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136(u)).

(m) *Real-time feed monitoring* means a system designed to track the rate of feed consumption and to detect uneaten feed passing through the nets at a net pen facility. These systems may rely on a combination of visual observation and hardware, including, but not limited to, devices such as video cameras, digital scanning sonar, or upweller systems that allow facilities to determine when to cease feeding the aquatic animals. Visual observation alone from above the pens does not constitute real-time monitoring.

(n) *Recirculating system* means a system that filters and reuses water in which the aquatic animals are produced prior to discharge. Recirculating systems typically use tanks, biological or mechanical filtration, and mechanical support equipment to maintain high quality water to produce aquatic animals.

§ 451.3 General reporting requirements.

(a) *Drugs.* Except as noted below, a permittee subject to this Part must notify the permitting authority of the use in a concentrated aquatic animal production facility subject to this Part of any investigational new animal drug (INAD) or any extralabel drug use where such a use may lead to a discharge of the drug to waters of the U.S. Reporting is not required for an INAD or extralabel drug use that has been previously approved by FDA for a different species or disease if the INAD or extralabel use is at or below the approved dosage and involves similar conditions of use.

(1) The permittee must provide a written report to the permitting authority of an INAD's impending use within 7 days of agreeing or signing up to participate in an INAD study. The written report must identify the INAD to be used, method of use, the dosage, and the disease or condition the INAD is intended to treat.

(2) For INADs and extralabel drug uses, the permittee must provide an oral report to the permitting authority as soon as possible, preferably in advance of use, but no later than 7 days after initiating use of that drug. The oral report must identify the drugs used, method of application, and the reason for using that drug.

(3) For INADs and extralabel drug uses, the permittee must provide a written report to the permitting authority within 30 days after initiating use of that drug. The written report must identify the drug used and include: the reason for treatment, date(s) and time(s) of the addition (including duration), method of application; and the amount added.

(b) Failure in, or damage to, the structure of an aquatic animal containment system resulting in an unanticipated material discharge of pollutants to waters of the U.S. In accordance with the following procedures, any permittee subject to this Part must notify the permitting authority when there is a reportable failure.

(1) The permitting authority may specify in the permit what constitutes reportable damage and/or a material discharge of pollutants, based on a consideration of production system type, sensitivity of the receiving waters and other relevant factors.

(2) The permittee must provide an oral report within 24 hours of discovery of any reportable failure or damage that results in a material discharge of pollutants, describing the cause of the failure or damage in the containment system and identifying materials that have been released to the environment as a result of this failure.

(3) The permittee must provide a written report within 7 days of discovery of the failure or damage documenting the cause, the estimated time elapsed until the failure or damage was repaired, an estimate of the material released as a result of the failure or damage, and steps being taken to prevent a reccurrence.

(c) In the event a spill of drugs, pesticides or feed occurs that results in a discharge to waters of the U.S., the permittee must provide an oral report of the spill to the permitting authority within 24 hours of its occurrence and a written report within 7 days. The report shall include the identity and quantity of the material spilled.

(d) *Best management practices (BMP) plan.* The permittee subject to this Part must:

(1) Develop and maintain a plan on site describing how the permittee will achieve the requirements of § 451.11(a) through (e) or § 451.21(a) through (h), as applicable.

(2) Make the plan available to the permitting authority upon request.

(3) The permittee subject to this Part must certify in writing to the permitting authority that a BMP plan has been developed.

Subpart A—Flow-Through and Recirculating Systems Subcategory

§ 451.10 Applicability.

This subpart applies to the discharge of pollutants from a concentrated aquatic animal production facility that produces 100,000 pounds or more per year of aquatic animals in a flow-through or recirculating system.

§ 451.11 Effluent limitations attainable by the application of the best practicable control technology currently available (BPT).

Except as provided in 40 CFR 125.30 through 125.32, any existing point source subject to this subpart must meet the following requirements, expressed as practices (or any modification to these requirements as determined by the permitting authority based on its exercise of its best professional judgment) representing the application of BPT:

(a) *Solids control.* The permittee must:

(1) Employ efficient feed management and feeding strategies that limit feed input to the minimum amount reasonably necessary to achieve production goals and sustain targeted rates of aquatic animal growth in order to minimize potential discharges of uneaten feed and waste products to waters of the U.S.

(2) In order to minimize the discharge of accumulated solids from settling ponds and basins and production systems, identify and implement procedures for routine cleaning of

rearing units and off-line settling basins, and procedures to minimize any discharge of accumulated solids during the inventorying, grading and harvesting aquatic animals in the production system.

(3) Remove and dispose of aquatic animal mortalities properly on a regular basis to prevent discharge to waters of the U.S., except in cases where the permitting authority authorizes such discharge in order to benefit the aquatic environment.

(b) *Materials storage.* The permittee must:

(1) Ensure proper storage of drugs, pesticides, and feed in a manner designed to prevent spills that may result in the discharge of drugs, pesticides or feed to waters of the U.S.

(2) Implement procedures for properly containing, cleaning, and disposing of any spilled material.

(c) *Structural maintenance.* The permittee must:

(1) Inspect the production system and the wastewater treatment system on a routine basis in order to identify and promptly repair any damage.

(2) Conduct regular maintenance of the production system and the wastewater treatment system in order to ensure that they are properly functioning.

(d) *Recordkeeping.* The permittee must:

(1) In order to calculate representative feed conversion ratios, maintain records for aquatic animal rearing units documenting the feed amounts and estimates of the numbers and weight of aquatic animals.

(2) Keep records documenting the frequency of cleaning, inspections, maintenance and repairs.

(e) *Training.* The permittee must:

(1) In order to ensure the proper clean-up and disposal of spilled material adequately train all relevant facility personnel in spill prevention and how to respond in the event of a spill.

(2) Train staff on the proper operation and cleaning of production and wastewater treatment systems including training in feeding procedures and proper use of equipment.

§ 451.12 Effluent limitations attainable by the application of the best available technology economically achievable (BAT).

Except as provided in 40 CFR 125.30 through 125.32, any existing point source subject to this subpart must meet the following requirements representing the application of BAT: The limitations are the same as the corresponding limitations specified in § 451.11.

§ 451.13 Effluent limitations attainable by the application of the best conventional technology (BCT).

Except as provided in 40 CFR 125.30 through 125.32, any existing point source subject to this subpart must meet the following requirements representing the application of BCT: The limitations are the same as the corresponding limitations specified in § 451.11.

§ 451.14 New source performance standards (NSPS).

Any point source subject to this subpart that is a new source must meet the following requirements: The standards are the same as the corresponding limitations specified in § 451.11.

Subpart B—Net Pen Subcategory

§ 451.20 Applicability.

This subpart applies to the discharge of pollutants from a concentrated aquatic animal production facility that produces 100,000 pounds or more per year of aquatic animals in net pen or submerged cage systems, except for net pen facilities rearing native species released after a growing period of no longer than 4 months to supplement commercial and sport fisheries.

§ 451.21 Effluent limitations attainable by the application of the best practicable control technology currently available (BPT).

Except as provided in 40 CFR 125.30 through 125.32, any existing point source subject to this subpart must meet the following requirements, expressed as practices (or any modification to these requirements as determined by the permitting authority based on its exercise of its best professional judgment) representing the application of BPT:

(a) *Feed management.* Employ efficient feed management and feeding strategies that limit feed input to the minimum amount reasonably necessary to achieve production goals and sustain targeted rates of aquatic animal growth. These strategies must minimize the accumulation of uneaten food beneath the pens through the use of active feed monitoring and management practices. These practices may include one or more of the following: Use of real-time feed monitoring, including devices such as video cameras, digital scanning sonar, and upweller systems; monitoring of sediment quality beneath the pens; monitoring of benthic community quality beneath the pens; capture of waste feed and feces; or other good husbandry practices approved by the permitting authority.

(b) *Waste collection and disposal.* Collect, return to shore, and properly dispose of all feed bags, packaging materials, waste rope and netting.

(c) *Transport or harvest discharge.* Minimize any discharge associated with the transport or harvesting of aquatic animals including blood, viscera, aquatic animal carcasses, or transport water containing blood.

(d) *Carcass removal.* Remove and dispose of aquatic animal mortalities properly on a regular basis to prevent discharge to waters of the U.S.

(e) *Materials storage.*

(1) Ensure proper storage of drugs, pesticides and feed in a manner designed to prevent spills that may result in the discharge of drugs, pesticides or feed to waters of the U.S.

(2) Implement procedures for properly containing, cleaning, and disposing of any spilled material.

(f) *Maintenance.*

(1) Inspect the production system on a routine basis in order to identify and promptly repair any damage.

(2) Conduct regular maintenance of the production system in order to ensure that it is properly functioning.

(g) *Recordkeeping.*

(1) In order to calculate representative feed conversion ratios, maintain records for aquatic animal net pens documenting the feed amounts and estimates of the numbers and weight of aquatic animals.

(2) Keep records of the net changes, inspections and repairs.

(h) *Training.* The permittee must:

(1) In order to ensure the proper clean-up and disposal of spilled material adequately train all relevant facility personnel in spill prevention and how to respond in the event of a spill.

(2) Train staff on the proper operation and cleaning of production systems including training in feeding procedures and proper use of equipment.

§ 451.22 Effluent limitations attainable by the application of the best available technology economically achievable (BAT).

Except as provided in 40 CFR 125.30 through 125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the application of BAT: The limitations are the same as the limitations specified in § 451.21.

§ 451.23 Effluent limitations attainable by the application of the best conventional technology (BCT).

Except as provided in 40 CFR 125.30 through 125.32, any existing point source subject to this subpart must achieve the following effluent

limitations representing the application of BCT: The limitations are the same as the limitations specified in § 451.21.

§ 451.24 New source performance standards (NSPS).

Any point source subject to this subpart that is a new source must meet the following requirements: The standard is the same as the limitations specified in § 451.21.

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