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ENHANCED CONTENT - TABLE OF CONTENTS

Part 451	Concentrated Aquatic Animal Production Point Source Category	451.1 – 451.24
§ 451.1	General applicability.	
§ 451.2	General definitions.	
§ 451.3	General reporting requirements.	
Subpart A	Flow-Through and Recirculating Systems Subcategory	451.10 – 451.14
§ 451.10	Applicability.	
§ 451.11	Effluent limitations attainable by the application of the best practicable control technology currently available (BPT).	
§ 451.12	Effluent limitations attainable by the application of the best available technology economically achievable (BAT).	
§ 451.13	Effluent limitations attainable by the application of the best conventional technology (BCT).	
§ 451.14	New source performance standards (NSPS).	
Subpart B	Net Pen Subcategory	451.20 – 451.24
§ 451.20	Applicability.	
§ 451.21	Effluent limitations attainable by the application of the best practicable control technology currently available (BPT).	
§ 451.22	Effluent limitations attainable by the application of the best available technology economically achievable (BAT).	
§ 451.23	Effluent limitations attainable by the application of the best conventional technology (BCT).	
§ 451.24	New source performance standards (NSPS).	

Title 40

PART 451 - CONCENTRATED AQUATIC ANIMAL PRODUCTION POINT SOURCE CATEGORY

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.

Source: 69 FR 51927, Aug. 23, 2004, unless otherwise noted.

§ 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 recurrence.
- (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.