§ 450.23 Effluent limitations reflecting the best conventional pollutant control technology (BCT).

Except as provided in 40 CFR 125.30 through 125.32, any point source subject to this subpart must achieve, at a minimum, the following effluent limitations representing the degree of effluent reduction attainable by application of the best conventional pollutant control technology (BCT). The effluent limitations are described at § 450.21.

§ 450.24 New source performance standards reflecting the best available demonstrated control technology (NSPS).

Any new source subject to this subpart must achieve, at a minimum, the following new source performance standards representing the degree of effluent reduction attainable by application of the best available demonstrated control technology (NSPS): The standards are described at § 450.22.

PART 451—CONCENTRATED AQUATIC ANIMAL PRODUCTION POINT SOURCE CATEGORY

Sec.

Subpart A—Flow-Through and Recirculating Systems Subcategory

Subpart B—Net Pen Subcategory

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)