

Environmental Protection Agency

§ 451.2

§ 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.