

3. Producers

Primary emphasis with producers will be on education with emphasis on proper drug usage, e.g., which drugs are permitted and under what conditions. There will be no routine inspections for enforcement purposes. This will not preclude "for-cause" inspections or surveys to determine usage patterns for drugs, sources of the drugs, etc.

"For cause" inspection assignments will encompass either individual producers, or could be more broadly based. Such inspections might include, for example, a situation in which there is reason to believe that producers might be holding significant quantities of a drug of high enforcement priority (such as malachite green) and regulation at the manufacturer/distributor level is not feasible.

PART C

ENFORCEMENT PRIORITIES

I. LOW REGULATORY PRIORITY AQUACULTURE DRUGS

The following compounds have undergone review by the Food and Drug Administration and have been determined to be new animal drugs of low regulatory priority.

ACETIC ACID - 1000 to 2000 ppm dip for 1 to 10 minutes as a parasiticide for fish.

CALCIUM CHLORIDE - Used to increase water calcium concentration to ensure proper egg hardening. Dosages used would be those necessary to raise calcium concentration to 10-20 ppm CaCO₃.

- Used up to 150 ppm indefinitely to increase the hardness of water for holding and transporting fish in order to enable fish to maintain osmotic balance.

CALCIUM OXIDE - Used as an external protozoacide for fingerlings to adult fish at a concentration of 2000 mg/L for 5 seconds.

CARBON DIOXIDE GAS - For anesthetic purposes in cold, cool, and warm water fish.

FULLER'S EARTH - Used to reduce the adhesiveness of fish eggs to improve hatchability.

GARLIC (Whole Form) - Used for control of helminth and sea lice infestations of marine

salmonids at all life stages.

ICE - Used to reduce metabolic rate of fish during transport.

MAGNESIUM SULFATE - Used to treat external monogenic trematode infestations and external crustacean infestations in fish at all life stages. Used in all freshwater species. Fish are immersed in a 30,000 mg MgSO₄/L and 7000 mg NaCl/L solutions for 5 to 10 minutes.

ONION (Whole Form) - Used to treat external crustacean parasites, and to deter sea lice from infesting external surface of salmonids at all life stages.

PAPAIN - Use of a 0.2% solution in removing the gelatinous matrix of fish egg masses in order to improve hatchability and decrease the incidence of disease.

POTASSIUM CHLORIDE - Used as an aid in osmoregulation; relieves stress and prevents shock. Dosages used would be those necessary to increase chloride ion concentration to 10-2000 mg/L.

POVIDONE IODINE - 100 ppm solution for 10 minutes as an egg surface disinfectant during and after water hardening.

SODIUM BICARBONATE - 142-642 ppm for 5 minutes as a means of introducing carbon dioxide into the water to anesthetize fish.

SODIUM CHLORIDE - 0.5% to 1.0% solution for an indefinite period as an osmoregulatory aid for the relief of stress and prevention of shock; and 3% solution for 10 to 30 minutes as a parasiticide.

SODIUM SULFITE - 15% solution for 5 to 8 minutes to treat eggs in order to improve their hatchability.

THIAMINE HYDROCHLORIDE - Used to prevent or treat thiamine deficiency in salmonids. Eggs are immersed in an aqueous solution of up to 100 ppm for up to four hours during water hardening. Sac fry are immersed in an aqueous solution of up to 1,000 ppm for up to one hour.

UREA and TANNIC ACID - Used to denature the adhesive component of fish eggs at concentrations of 15g urea and 20g NaCl/5 liters of water for approximately 6 minutes, followed by a separate solution of 0.75g tannic acid/5 liters of water for an additional 6 minutes. These amounts will treat approximately 400,000 eggs.

The Agency is unlikely to object to the use of these substances if the following conditions are met:

- (1) The substances are used for these indications;
- (2) The substances are used at the prescribed levels;
- (3) The substances are used according to good management practices;
- (4) The product is of an appropriate grade for use in food animals, and
- (5) There is not likely to be an adverse effect on the environment.

The Agency's enforcement position on the use of these substances should not be considered an approval nor an affirmation of their safety and effectiveness. Based on the information available at some time in the future, the Agency may take a different position on the use of any or all of these substances.

Classification of these substances as new animal drugs of low regulatory priority does not exempt facilities from complying with other Federal, State, and local environmental requirements. For example, facilities using these substances would still be required to comply with National Pollutant Discharge Elimination System (NPDES) requirements.

NOTE: The primary long range goals in enforcement prioritization will be to protect public health and encourage submission of INADs and NADAs with a view toward obtaining approvals to meet therapeutic and production needs in aquaculture.

(6) Labeling and GMPs for Low Priority Drugs.

- a. Labeling for low priority use will not be required for a chemical that is commonly used for nondrug purposes even if the manufacturer or distributor promotes the chemical for the permitted low priority use.
- b. However, a chemical that has significant animal or human drug uses in addition to the low priority aquaculture use will be required to be labeled for the low priority uses if the manufacturer or distributor establishes the intended low priority use for its product by promotion or other means.
- c. Where labeling is required, all other provisions of the Act pertaining to drugs except the approval requirement will apply. This includes registration, drug listing and Current Good Manufacturing Practices (CGMPs), etc.
- d.. Low regulatory priority compounds may be marketed for aquaculture use with drug claims (the claims permitted for such compounds) but must be of an appropriate quality for use in food animals.
- e. If drug claims appear on the product label, in product catalogs, or in promotional material, the following conditions must be met:

The product must have been manufactured according to CGMPs as defined in 21 CFR 210 & 211;

The product manufacturer must be registered with the FDA; and

The product must be drug-listed with FDA.

Material deviations in labeling or promotion from the permitted low priority claims might cause a particular product to be removed from the low priority category.

II. SPECIAL CATEGORY

Products found not to be low regulatory priority but regulatory action deferred pending further study:

Copper sulfate

Potassium permanganate

III. EXAMPLES OF DRUGS WITH HIGH ENFORCEMENT PRIORITY

Chloramphenicol Nitrofurans Fluoroquinolones and Quinolones Malachite Green Steroid Hormones