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American Fisheries Society
Fish Culture Section

Guide to Using Drugs, Biologics, and Other Chemicals in Aquaculture

FCS Working Group on Aquaculture Drugs, Chemicals, and Biologics

CONTENTS

PREFACE ii
Acknowledgments ii
Access iii
INTRODUCTION 1
REGULATORY AUTHORITIES AND THEIR PURVIEWS 2
DRUGS 3
Approved and conditionally approved drugs 3
Low regulatory priority drugs 3
Deferred regulatory status drugs 4
Investigational new animal drugs (INADs) 4
BIOLOGICS 5
About biologics 5
Approved biologics 6
DISINFECTANTS 8
About disinfectants 8
About biosecurity 9
PESTICIDES 9
About pesticides 9
Pesticide applicator certification 10
Pesticides commonlyused in aquatic weed managment 11
APPLICATION TECHNIQUES 12
Immersion treatment 13
Oral treatment 14
Injection treatment 14
CALCULATIONS 15
Unit conversion 15
Withdrawal times 15
BEST MANAGEMENT PRACTICES AND OTHER CONSIDERATIONS 15
Best management practices 15
Safety considerations 17
Handling, storage, and disposal of regulated products 17
Record-keeping 18
Establishing a valid veterinarian-client-patient relationship and working with fish health professionals 18
TABLE 1. Approved and conditionally approved aquaculture drugs and indications. 20
TABLE 2. Low regulatory priority aquaculture drugs, indications, and doses. 21
TABLE 3. Investigational new animal drug exemptions for aquaculture drugs held by the U.S. Fish and Wildlife Service as part of the National INAD Program. 22
TABLE 4. Product and water volumes for preparing baths of AQUAVAC-ESC or AQUAVAC-COL for vaccinating catfish. 23
TABLE 5. Disinfectants and their use for field gear and hard surfaces. 24
TABLE 6. Treatment responses of various types of aquatic vegetation to herbicides most commonly used for aquatic weed management in aquaculture. 26
GLOSSARY 58
Acronyms 58
Terms 58
CHEMICAL FACILITY ANTI-TERRORISM STANDARDS 59

PREFACE

The Guide to Using Drugs, Biologics, and Other Chemicals in Aquaculture (Guide) describes regulated products that are approved for use in U.S. aquaculture. The Guide also describes drugs that are not yet approved for use in the U. S. but that can be used under an Investigational New Animal Drug (INAD) exemption and drugs that are considered to be of low regulatory priority (LRP) enforcement. The Guide was developed by the Working Group on Aquaculture Drugs, Chemicals, and Biologics established by the Fish Culture Section of the American Fisheries Society. The Working Group was created to facilitate communication and cooperation between public and private aquaculture interests, academic and agency researchers, and regulators to address needs and issues associated with the approval and use of aquatic animal drugs, biologics, and other regulated products in aquaculture. In this role, the Working Group created the Guide as an update and extension of the Guide to Drug, Vaccine, and Pesticide use in Aquaculture, originally developed by the Federal Joint Subcommittee on Aquaculture Working Group on Quality Assurance in Aquaculture Production in cooperation with various other agency and industry partners. The current Guide continues in the spirit of the previous document, serving as a comprehensive introduction to the use of regulated products in aquaculture and a resource for fish culturists.

THIS GUIDE IS INTENDED FOR INFORMATIONAL AND EDUCATIONAL PURPOSES ONLY. It is not meant as a prescriptive tool nor does it replace the advice of professional fish health biologists or licensed veterinarians. While every effort was made to ensure the accuracy of the information and calculations included in the Guide, the user is ultimately responsible for ensuring the accuracy of the calculations, administrations and legal use of applied products. Before using any drug or chemical that may be discharged into U.S. waters, contact your local National Pollutant Discharge Elimination System (NPDES) authority. Before using a drug authorized for use only under INAD exemption, make sure that you are a participant in the INAD program that is authorized to allow use of that drug. We provide no warranty nor guarantee for any calculations provided in the companion Treatment Calculator and all calculations should be verified by the user before use. Mention or display of a trademark, propriety product, or firm in this Guide does not constitute endorsement by the American Fisheries Society, the Fish Culture Section, or the Working Group.

All information contained in the Guide is accurate as of the revision date indicated on the upper left of the cover page. However, allowed uses of regulated products in aquaculture are dynamic and subject to change between revisions. IT IS THE RESPONSIBILITY OF INDIVIDUALS ADMINISTERING REGULATED PRODUCTS TO READ AND FOLLOW LABEL INSTRUCTIONS, AND BE AWARE OF ANY CHANGES IN RELEVANT REGULATION PRIOR TO USING THESE PRODUCTS.

ACKNOWLEDGMENTS

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GUIDE REVISIONS and COMMENTS/SUGGESTIONS

The Guide will be revised periodically to ensure that information herein is accurate and current. Revisions will include new drug approvals and licensed vaccines, new claims for existing drug approvals, and information on new Investigational New Animal Drugs. In addition, revisions may include comments or suggestions provided by users of the Guide (if applicable). Please send comments or suggestions to Jesse Trushenski (saluski@siu.edu) or Jim Bowker (jim_bowker@fws.gov).

ACCESS

The Guide and companion Treatment Calculator are available on the following websites:

American Fisheries Society Fish Culture Section
http://www.fishculturesection.org/

U. S. Fish and Wildlife Service's Aquatic Animal Drug Approval Partnership Program
http://www.fws.gov/fisheries/aadap/home.htm

INTRODUCTION

Aquaculture is an established and growing industry in the U.S., and an increasingly important supplier of foods for U.S. consumers. The industry also produces baitfish for sport-fishing and ornamental fish for the pet trade. In addition, federal and state fish hatcheries raise millions of fish for stocking in U.S. waters to support commercial and recreational fisheries and species restoration efforts. Aquaculture is an important contributor to U.S. agriculture and a cornerstone of aquatic natural resources management.

All aquaculture operations will have a demand for drugs, biologics, and other chemicals, collectively referred to as "regulated products". This may include: 1) disinfectants as part of biosecurity protocols, 2) herbicides and pesticides used in pond maintenance, 3) spawning aids, 4) vaccines used in disease prevention, or 5) marking agents used in resource management. Despite the best efforts of fish culturists to avoid pathogen introductions, therapeutic drugs are also occasionally needed to control mortality, infestations, or infections. It is critical that culturists have access to regulated products that are safe and effective and apply them in a manner that is consistent with their intended use, best management practices, and relevant rules and regulations.

The Federal Food, Drug, and Cosmetic Act (FFDCA) defines the term "drug" broadly to include articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease, articles (other than food) intended to affect the structure or function of the body, and articles recognized in official drug compendia. In aquaculture, this includes compounds that one would typically think of as drugs—antibiotics and other therapeutic compounds, fish sedatives and anesthetics, gender manipulators and spawning aids, etc. However, it's important to remember that innocuous, common household compounds—hydrogen peroxide, salt, and ice—are also considered drugs. A general misconception is that products that are considered by the U.S. Food and Drug Administration (FDA) to be generally recognized as safe (GRAS) or effective (GRAE) can be legally used on fish; however, such products cannot be used on fish unless they have been approved by FDA for the intended purpose. There are various approval categories and ways in which approved drugs can be used legally, as well as ways in which drugs that are not yet approved can be used. Regardless of which category the drug falls under, drugs should be used judiciously in aquaculture. The drugs section covers the various types of approved drugs and uses, and also describes some common application methods.

Disinfectants are compounds which have antimicrobial properties that are generally applied to equipment and structures and are not intended to have a therapeutic effect on cultured animals. Greater emphasis on biosecurity in aquaculture has led to increased demand for disinfectants and greater need for aquaculturists to understand how to apply these compounds safely and effectively. Although a number of compounds classified as drugs in aquaculture may also be considered disinfectants in other industries, they are described in the section on drugs. The disinfectants section describes the most common uses for disinfectants in aquaculture, as well as appropriate compounds and application rates for aquaculture facilities.

Pesticides are not widely used in aquaculture; however, herbicides can be an important part of aquatic weed management in pond production. Certain algicides, and fish and invertebrate toxicants may also be used in some situations. The pesticides section of the Guide will focus on the most common pesticides applications in aquaculture.

Biologics include a range of products of biologic origin used in the diagnosis, prevention, and treatment of diseases. In aquaculture, the most commonly used biologics are vaccines used to immunize animals and prevent infections from occurring. The biologics section of the Guide will go over the vaccines that are currently available for use in aquaculture, as well as provide recommendations for their usage.

This Guide is intended to serve as a resource to assist aquaculturists to use regulated products legally and judiciously. The principles outlined in this Guide are intended to provide directions for the use of drugs, biologics, and other chemicals in ways that ensure the safety of treated animals, end-users, consumers of farm-raised seafood, and the environment. The Guide is not meant to be a comprehensive resource, but rather a primer and resource for finding further information. The Guide presents the following information related to the use of drugs, pesticides, vaccines and other biologics, and disinfectants in aquaculture:

- Regulatory authorities and their purviews
- Guidance to approved compounds and their uses
- Application methods and example calculations
- Where to find more information

IT IS THE RESPONSIBILITY OF THOSE USING, PRESCRIBING, AND/OR RECOMMENDING THE USE OF REGULATED PRODUCTS TO KNOW WHICH PRODUCTS CAN BE LEGALLY USED AND WITH WHAT RESTRICTIONS UNDER FEDERAL, STATE, AND ANY OTHER LOCAL REGULATIONS. REMEMBER, REGULATED PRODUCT USES MAY VARY BY LOCATION, SPECIES, LIFE STAGE, AND CULTURE CONDITIONS OR METHODS.

REGULATORY AUTHORITIES AND THEIR PURVIEWS

Several federal and state agencies are involved in regulating drugs, biologics, and other chemicals used in aquaculture. Each federal agency has specific, congressionally mandated responsibilities to regulate the products under their jurisdictions. In the case of aquaculture, there is some overlap between these federal agencies, as well as with state and local regulatory bodies.

The U.S. Food and Drug Administration (FDA) has many responsibilities under the FFDCA, including regulating the manufacture, distribution, and use of new animal drugs and animal feed and ensuring their safety and efficacy. The FDA Center for Veterinary Medicine (CVM) regulates the manufacture, distribution, and use of animal drugs. CVM is responsible for ensuring that drugs used in food-producing animals, including fish, are safe and effective and that foods derived from treated animals are free from potentially harmful drug residues. FDA has jurisdiction over new animal drugs, including products intended to treat aquatic animal parasites or diseases, manipulate gender or reproduction of aquatic species, or anesthetize or sedate aquatic animals.

The U.S. Environmental Protection Agency (EPA) is tasked with various responsibilities under a range of laws, including registration and licensing of pesticides. EPA is responsible for ensuring that registered pesticides meet scientific and regulatory standards for the protection of human health and the environment, as well as tolerances to ensure a reasonable certainty of no harm from pesticide residues in food. With respect to aquaculture, EPA has jurisdiction over disinfectants, sanitizers, and aquatic treatments used solely for the control of algae, bacterial slime, or pest control (excluding pathogens in or on fish). As authorized by the Clean Water Act, EPA also administers the National Pollutant Discharge Elimination System (NPDES) which prohibits the discharge of pollutants, including regulated products, into waters of the United States.

The Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture (USDA) regulates all veterinary biologics, including vaccines, bacterins, antisera, diagnostic kits, and other products of biological origin. These duties are performed by the APHIS Center for Veterinary Biologics (CVB), which is charged with assuring that pure,

safe, potent and effective veterinary biologics, are available for the diagnosis, prevention, and treatment of animal diseases. CVB is responsible for testing, licensing, and quality control monitoring of vaccines and other biologics used in U.S. aquaculture.

State agencies may also regulate the use of drugs, biologics, and other chemicals in aquaculture. While many state agencies simply defer to the federal regulations and regulatory authorities, others impose additional requirements and restrictions beyond those in the federal regulations. For further information on the regulatory authorities that have jurisdiction over aquaculture in your area, you may consult "State/Territory Permits and Regulations Impacting the Aquaculture Industry", the "Guide to Federal Aquaculture Programs and Services", or the National Association of State Aquaculture Coordinators (directory of State Aquaculture Coordinators available here).

DRUGS

APPROVED AND CONDITIONALLY APPROVED DRUGS

All drugs used to control mortality associated with bacterial diseases or infestation density of parasites, sedate or anesthetize fish, induce spawning, change gender, or in any other way change the structure or function of aquatic species must be approved by the CVM. Approved drugs are compounds for which FDA CVM has evaluated data and concluded that the drug is effective in achieving the stated claim; is safe to the target fish, humans who might consume treated fish, and the environment when applied at labeled doses; and can be manufactured according to CVM criteria. If a drug has been proven safe and is manufactured according to CVM criteria, it may be marketed as a conditionally approved drug while additional data is collected to show that the drug is effective. It is illegal to use (1) unapproved drugs for any purpose or (2) approved drugs in a manner other than that specified on the product label unless the drugs are being used under the strict conditions of an investigational new animal drug (INAD) exemption or an extra-label prescription issued by a licensed veterinarian.

Table 1 lists drugs currently approved or conditionally approved by CVM for use in aquatic species. For more information about specific approved and conditionally approved drugs, click the individual drug links in Table 1. For further information about approved and conditionally approved drugs, users can refer to the FDA CVM list of approved aquaculture drugs, or the USFWS AADAP website.

REMEMBER, ANY USE OF AN APPROVED DRUG IN A MANNER NOT SPECIFICALLY NOTED ON THE DRUG'S LABEL IS ILLEGAL, UNLESS USED WHERE PERMITTED UNDER AN INAD OR UNDER AN EXTRA-LABEL PRESCRIPTION BY A LICENSED VETERINARIAN.

LOW REGULATORY PRIORITY DRUGS

Although technically unapproved for use in fishes, low regulatory priority (LRP) drugs are compounds that CVM considers to be of comparatively little risk to aquatic organisms, human consumers, or the environment. CVM has stated that it is unlikely to regulate the use of LRP drugs if the following five conditions are met: 1) the substances are used for the listed 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 compounds described in Table 2 are considered to be of low regulatory priority when used for the indications listed. A fact sheet for Ovadine® (iodine) is the only one included in this Guide. For further information, please refer to the "Enforcement Priorities for Drug Use in Aquaculture".

DEFERRED REGULATORY STATUS DRUGS

Two compounds, copper sulfate and potassium permanganate, have been given "deferred regulatory status", pending further evaluation by CVM. Both copper sulfate and potassium permanganate are or have been EPA registered pesticides with approved uses in aquaculture settings (see Pesticides). At this time, either compound can be used to treat external protozoan or metazoan infestations as well as external bacterial or fungal infections on fish. For further information about these compounds, please click the fact sheet links above, or refer to the sections in the Guide on Pesticides or INAD drugs. For further information about deferred regulatory action, please refer to the FDA CVM "Enforcement Priorities for Drug Use in Aquaculture".

INVESTIGATIONAL NEW ANIMAL DRUGS (INADs)

Investigational New Animal Drug (INAD) exemptions are granted by CVM to permit the purchase, interstate shipment, and use of unapproved animal drugs for investigational purposes. There are two types of INADs: standard and compassionate. A standard INAD authorizes the use of an unapproved drug to develop data through use in animals that may not be released into the environment or slaughtered for human consumption. Compassionate INAD exemptions authorize the use of an unapproved drug in fish on a production scale and, because a slaughter authorization is granted as part of the compassionate INAD authorization, allows the release of treated fish for slaughter or release into the environment; a compassionate INAD authorization allows treated fish to enter the human food chain. Although compassionate INAD exemptions are used primarily in cases where the aquatic animals' health is of primary concern, investigators are still required to collect information and administer the drug according to the methods authorized in the compassionate INAD protocol. Under a compassionate INAD, CVM must be provided with information regarding use patterns, including the amount of the drug that was used, how many fish were treated, the outcome of the treatment, etc. In short, INAD exemptions allow aquaculturists access to unapproved drugs which have a reasonable expectation of effectiveness for the proposed indication to better manage the health of cultured fish while providing critical information regarding the safety and effectiveness of the drug under a diverse set of rearing conditions which would otherwise not be evaluated in the drug approval process.

Several individuals and organizations hold INAD exemptions for certain drugs, but the largest INAD exemption holder is the U.S. Fish and Wildlife Service (USFWS) which operates the National INAD Program (NIP) out of the Aquatic Animal Drug Approval Partnership Program (AADAP; Bozeman, MT). Prior to 1998, all INAD exemptions held by the USFWS were restricted to use by Service facilities only. With the establishment of the NIP in 1998, non-USFWS entities were allowed to participate in the USFWS compassionate INAD exemption program. Through the NIP, a wealth of data have been generated that may be useful in supporting broad new animal drug approvals for a variety of drugs. The NIP is operated on a cost-reimbursable basis, and participating agencies/organizations must sign a Cooperative Agreement with the USFWS. This agreement establishes the obligations and procedures to be followed by the USFWS and all cooperators to allow the use of specific drugs and chemicals under USFWS-held INAD exemptions as set forth by CVM.

This Guide focuses on the INAD exemptions available as part of the NIP, and additional information is provided for each of the NIP drugs below. For more detailed information about these compounds and what they can be used for, please click the fact sheet links below in Table 3. For information about the NIP or individual NIP drugs, please refer to the

USFWS AADAP program website. For further information about INAD exemptions and current exemption holders, refer to the FDA CVM website which includes information for contacting CVM with further questions.

BIOLOGICS

ABOUT BIOLOGICS

Veterinary biologics are products designed to diagnose, prevent, or treat diseases in animals. Although the term "biologic" can potentially refer to a wide range of products, those used in fish are generally classified as vaccines or bacterins: vaccines contain live organisms (bacteria or viruses) or killed viruses, whereas bacterins contain inactivated cultures of bacteria. Both are used to increase the natural ability of the animal to resist the disease caused by the organism from which the biologic product is derived. Biologics differ from drugs functionally (biologics affect the fish's immune system while drugs affect the disease-causing agent) and in terms of how they are applied (preventative, before infection application vs. therapeutic, post-infection application). Also, most biologics leave no chemical residues in animals.

There are a number of licensed, commercial veterinary biologics that are currently approved for use in fish; these products are described below. Autogenous vaccines are a specific subset of biologics that are derived from specific pathogens associated with a specific facility. Some fish culture facilities use autogenous vaccines and find them to be highly beneficial tools for fish health management; however, given the specificity of these biologics and their use patterns, they are not the focus of the Guide. As with drugs or any other compound used in aquaculture, it is recommended to seek professional advice about the specific biologic product you are interested in using before using it for the first time. However, there are some general recommendations that apply to the use of any biologic:

- Follow all recommendations provided on the product label or other product literature, including proper storage temperature.
- Shake biologic product well before using, and use all the opened product at once, i.e., don't store opened biologics for use at a later date.
- Biologics should only be applied to healthy fish.
- If human exposure (e.g. accidental injection) of the biologic product occurs, immediately seek medical advice.

REMEMBER THAT VACCINATION IS JUST ONE COMPONENT OF A COMPLETE FISH HEALTH PROGRAM, AND CANNOT PREVENT ALL FISH HEALTH PROBLEMS. SEEK PROFESSIONAL ADVICE REGARDING APPROPRIATE VACCINE USE BEFORE APPLICATION

For more information on using biologics in aquaculture production, users are encouraged to consult USDA APHIS Program Aid No. 1713 "Veterinary Biologics: Use and Regulation" and "Use of Vaccines in Finfish Aquaculture". For additional information about veterinary biologics, you can also consult the USDA APHIS CVB website, which includes contact information for further questions. Additionally, a reference poster with information about currently approved biologics can be ordered, viewed, and/or downloaded free of charge from the USFWS AADAP website. For information about preparing immersion baths or delivering injections, please refer to the Application Techniques section.

APPROVED BIOLOGICS

True Name: Aeromonas Salmonicida Bacterin (Trade Name: Furogen Dip)

Use: Aids in prevention of furunculosis in salmonids, ≥2 g, caused by *Aeromonas salmonicida*

Dose and Administration: Each liter of bacterin is sufficient to vaccinate 100 kg (220 lbs.) of fish. Add 1 L of bacterin to 9 L of clean hatchery water to make a 10-L vaccine bath. Aerate the bath. Net, drain, and immerse 5-kg (11 lb.) batches of fish in the bath for 60 seconds. The bath may be reused up to 20 times before discarding.

Permittee: Novartis Animal Health US, Inc., Larchwood Iowa 51241; U.S. Vet. Permit No. 303A

Precautions: Withhold food from fish for 24 hours prior to vaccination; do not vaccinate within 21 days of slaughter or release of catchable-sized fish

True Name: Aeromonas Salmonicida-Vibrio Anguillarum-Ordalii-Salmonicida Bacterin (Trade Name: Lipogen Forte)

Use: Aids in prevention of furunculosis, vibriosis, and cold water vibriosis in salmonids ≥10 g.

Dose and Administration: Anesthetize fish to immobilize and administer a 0.1 mL injection intraperitoneally, one fin length ahead of the pelvic fins, along the ventral midline of each fish. Warming vaccine to room temperature before use may facilitate injection.

Permittee: Novartis Animal Health US, Inc., Larchwood Iowa 51241; U.S. Vet. Permit No. 303A

Precautions: Withhold food from fish for 48 hours prior to vaccination; do not vaccinate within 60 days of slaughter or release of catchable-sized fish.

True Name: Arthrobacter Vaccine, Live Culture (Trade Name: Renogen)

Use: Aids in prevention of bacterial kidney disease (BKD) caused by *Renibacterium salmoninarum* in healthy salmonids, ≥10 g.

Dose and Administration: Anesthetize fish until immobilized and then administer 0.1 mL of the resuspended vaccine intraperitoneally, along the midline, one fin length ahead of the pelvic fins. The recommended minimum post-vaccination period is 400 degree-days (°C) before pathogen exposure.

Permittee: Novartis Animal Health US, Inc., Larchwood Iowa 51241; U.S. Vet. Permit No. 303A

Precautions: Do no vaccinate fish within 60 days of slaughter or release of catchable-sized fish; do not administer antimicrobial drugs 14 days before or after vaccination; oxytetracycline administration is contraindicated within the 6 weeks before or after vaccination; diagnostic kits which employ the use of polyclonal antiserum against *Renibacterium salmoninarum* should not be used to screen fish vaccinated with this product for at least 4 weeks after vaccination since kidney samples from vaccinated fish will yield positive test results, regardless of natural infection; for maximum efficacy, vaccination should precede exposure to *Renibacterium salmoninarum* by at least 400 degree days (°C) .

True Name: Infectious Salmon Anemia Virus Vaccine, Aeromonas Salmonicida-Vibrio Anguillarum-Ordalii-Salmonicida Bacterin, Killed Virus (Trade Name: Forte V1)

Use: Aids in prevention of infectious salmon anemia (ISA), furunculosis, vibriosis, and cold water vibriosis in salmonids ≥30 g.

Dose and Administration: Anesthetize fish to immobilize and administer a 0.15 mL injection intraperitoneally, one fin length ahead of the pelvic fins, along the ventral midline of each fish. Warming the vaccine to room temperature may facilitate injection.

Permittee: Novartis Animal Health US, Inc., Larchwood Iowa 51241; U.S. Vet. Permit No. 303A

Precautions: Withhold food from fish 48 hours prior to vaccination, do not vaccinate within 60 days of slaughter; do not vaccinate fish during the period of smoltification; oil adjuvanted vaccines administered by intraperitoneal injection in fish may cause visceral adhesions; this vaccine is intended to be used in young fish stock, the effects of vaccination of

broodstock has not been determined; during vaccination, the water temperature of the holding tanks should be 2-12 °C (36-54 °F); for maximum efficacy, it is recommended that vaccination precede exposure to specified pathogens by at least 800 degree days (°C).

True Name: Yersinia Ruckeri Bacterin (Trade Name: Ermogen)

Use: Aids in prevention of enteric redmouth disease, caused by *Yersinia ruckeri* serotype 1 in healthy salmonids, ≥2 g.

Dose and Administration: Each liter of bacterin is sufficient to vaccinate 100 kg (220 lbs.) of fish. Add 1 L of bacterin to 9 L of clean hatchery water to make a 10-L vaccine bath. Aerate the bath during vaccination. Net, drain, and immerse 5-kg (11 lb.) batches of fish in the bath for 30 seconds. The bath may be reused up to 20 times before discarding.

Permittee: Novartis Animal Health, US, Inc., Larchwood, Iowa 51241, U.S. Vet Permit No. 303A

Precautions: Vaccination should precede exposure to specified pathogens by at least 250 degree days (°C); withhold food from fish 24 hours prior to vaccination; do not vaccinate within 21 days of slaughter or release of catchable-sized fish.

True Name: Flavobacterium Columnare Bacterin (Trade Name: FryVacc1)

Use: Aids in prevention of columnaris disease caused by *Flavobacterium columnare* in healthy salmonids ≥3 g.

Dose and Administration: Each liter of bacterin is sufficient to vaccinate 100 kg (220 lbs.) of fish. Add 1 L of bacterin to 9 L of clean hatchery water to make a 10-L vaccine bath. Aerate the bath during vaccination. Net, drain, and immerse 5-kg (11 lb.) batches of fish in the bath for 30 seconds. The bath may be reused up to 20 times before discarding.

Permittee: Novartis Animal Health, US, Inc., Larchwood, Iowa 51241, U.S. Vet Permit No. 303A

Precautions: Do not vaccinate within 21 days of slaughter or release of catchable-sized fish.

True Name: Vibrio Anguillarum-Ordalii Bacterin (Trade Name: Vibrogen 2)

Use: Aids in prevention of vibriosis caused by *Vibrio anguillarum* serotypes I and II and *Vibrio ordalii* in healthy salmonids ≥2 g.

Dose and Administration: For immersion vaccination, each liter of bacterin is sufficient to vaccinate 100 kg of fish. Add 1 L of bacterin to 9 L of clean hatchery water to make a 10-L vaccine bath. Aerate the bath during vaccination. Net, drain, and immerse 5-kg (11 lb.) batches of fish in the bath for 30 seconds. The bath may be reused up to 20 times before discarding. For injection vaccination, anesthetize fish ≥10 g in size to immobilize and administer a 0.1 mL injection of undiluted bacterin intraperitoneally, one fin length ahead of the pelvic fins, along the ventral midline of each fish.

Permittee: Novartis Animal Health, US, Inc., Larchwood, Iowa 51241, U.S. Vet Permit No. 303A

Precautions: Do not vaccinate within 21 days of slaughter or release of catchable-sized fish; withhold food from fish 48 hours prior to vaccination

True Name: Flavobacterium Columnare Vaccine, Avirulent Live Culture (Trade Name: AQUAVAC-COL)

Use: Aids in prevention of columnaris disease due to *Flavobacterium columnare* infection in healthy catfish ≥7 days of age.

Dose and Administration: One vial is sufficient to vaccinate 7.5 lbs. of catfish in 5 gal. of water. When applied to fry at 7 days post hatch (average size of 13,000 catfish/lb. or 29 catfish/g or 812 catfish/oz.), each vial of vaccine is sufficient to vaccinate 100,000 fry in 5 gal. of water. When vaccinating catfish older than 7 days post hatch, each 10-pack of vaccine is sufficient to vaccinate 75 lbs. of catfish in 50 gal. of water. See Table 4 and package insert for additional information.

Licensee: Merck Animal Health (formerly Intervet, Inc., Omaha, Nebraska 68103, U.S. Est. No. 165A)

Precautions: Do not vaccinate within 21 days of slaughter or release of catchable-sized fish; withhold food from fish 48 hours prior to vaccination; vaccination not recommended when water temperatures are below 21 °C (70 °F) or above 29 °C (85 °F)

True Name: Edwardsiella Ictaluri Vaccine, Avirulent Live Culture (Trade Name: AQUAVAC-ESC)

Use: Prevention of enteric septicemia of catfish (ESC) disease due to *Edwardsiella ictaluri* infection

Dose and Administration: Each vial is sufficient to vaccinate 7.5 pounds of catfish in 5 gal of water. When applied to fry at 7 days post hatch (average size of 13,000 catfish/lb. or 29 catfish/gram or 812 catfish/oz.), each vial of vaccine is sufficient to vaccinate 100,000 fry in 5 gal. of water. When vaccinating catfish older than 7 days post hatch, each ten-pack of vaccine is sufficient to vaccinate 75 pounds of catfish in 50 gal of water. See Table 4 and package insert for additional information.

Licensee: Merck Animal Health (formerly Intervet, Inc., Omaha, Nebraska 68103, U.S. Est. No. 165A)

Precautions: Do not vaccinate within 21 days of slaughter or release of catchable-sized fish, withhold food from fish 48 hours prior to vaccination, vaccination not recommended when water temperatures are below 21 °C (70 °F) or above 29 °C (85°)F

DISINFECTANTS

ABOUT DISINFECTANTS

Disinfectants are physical or chemical agents that are used to destroy microorganisms, usually on inanimate objects including hard surfaces and equipment. In aquaculture, disinfectants can also include compounds used to destroy microorganisms living on the surface of fish eggs. These agents are used in aquatic animal rearing facilities as part of biosecurity protocols (see below) to control the spread of aquatic animal pathogens or nuisance/invasive species. In the case of compounds applied to eggs, disinfectants can be used as part of a comprehensive fish health management plan. Disinfectants are related to, but different from sanitizers, antiseptics, biocides, and sterilizers: biocides and sterilizers are agents that kill all forms of life, not just microbes; antiseptics refer to antimicrobial agents that are used to destroy microbes on living tissues; and sanitizers are compounds that clean and disinfect at the same time.

It is important to recognize that not all disinfectants are effective or appropriate in all circumstances. For example, iodine is appropriate for disinfecting eggs, but it is quickly neutralized by biological material and exposure to light and can stain clothing and equipment. As a result, iodine is not a good disinfectant for foot baths or net dips. Conversely, chlorine is particularly good for sanitizing nets, siphons, and other equipment, but is highly toxic to aquatic organisms unless neutralized. Disinfection can be optimized by selecting the appropriate agent for each scenario, and by following these general recommendations:

- Remove dirt, vegetation, or other debris before disinfecting.
- Use the recommended disinfectant concentrations/intensities.
- Allow sufficient contact time for disinfection to occur.

A large number of chemical and physical agents can be used to disinfect field gear and other hard surfaces. Recommended uses for these different disinfectants are summarized in Table 5. Relatively few agents are appropriate for use as egg disinfectants. For more information about disinfectants in aquaculture, users are encouraged to refer to World Organization for Animal Health (OIE) Manual of Diagnostic Tests for Aquatic Animals which includes a chapter on methods for disinfection of aquaculture establishments.

ABOUT BIOSECURITY

"Biosecurity" refers to practices used to prevent the introduction and spread of disease-causing organisms and nuisance/invasive species. Although many common fish pathogens and parasites are present in virtually all environments and are difficult or impossible to eradicate (e.g., *Flavobacterium columnare*, the causative agent of columnaris disease), others have a regional distribution (e.g., Viral Hemorrhagic Septicemia in the Western and Northeast U.S., the Great Lakes region, and Eastern Canada) or easier to avoid or contain (e.g., yellow grub). Biosecurity procedures can be particularly useful in minimizing risk of regionally distributed pathogens as well as those considered to have a ubiquitous distribution. Additionally, certain fish diseases are considered more serious than others (e.g., OIE-reportable fish pathogens including Viral Hemorrhagic Septicemia and Whirling Disease) and in regions where these diseases are known to exist, strict biosecurity protocols may be required or at least strongly encouraged.

Biosecurity is commonly associated with disinfection, but comprehensive biosecurity plans can go well beyond simple disinfection procedures to include everything from facility layout and design, to livestock sourcing and quarantine, to record-keeping. Biosecurity practices vary from one situation to the next, based on the potential risks associated with the type of facility, culture species, and pathogens or invasive/nuisance species that are involved. However, proper use of disinfectants as described in this Guide to minimize the risk of introducing fish pathogens from one location to another is a common feature of most aquaculture biosecurity plans.

For more information about biosecurity, users can refer to an aquaculture biosecurity manual and accompanying annotated presentation that were developed for Illinois aquaculture facilities, "Biosecurity Protection for Fish Operations" which focuses on Arkansas aquaculture operations, or the North Central Regional Aquaculture Center "Biosecurity for Aquaculture Facilities in the North Central Region" fact sheet. Although originally developed with regional facilities and biosecurity concerns in mind, the strategies described in these resources are largely applicable to aquaculture facilities throughout the U.S. Users may also wish to review "Sanitation Practices for Aquaculture Facilities" for further information.

PESTICIDES

ABOUT PESTICIDES

The list of pesticides registered for aquatic pest management in the U.S. continues to expand every year, however, only a handful of products are labeled for use in aquaculture production. There are three ways that pesticides can be legal for use in aquaculture production: 1) a full national EPA registration, 2) 24c Special Local Needs Registration (24c SLN), or 3) Section 18 Emergency Exemption. Full national EPA registration means that the product label will include specific instructions for use in aquaculture. Certain aquatic herbicides (described further below) and the insecticide Dimilin® 25W hold full national EPA registrations for certain applications in aquaculture. 24c SLN registrations are allowed under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) for pesticides that are needed for problems that are localized to certain regions and for which the pesticide manufacturer is unlikely to pursue separate national registrations. If there is a "Special Local Need" for a pesticide, a farmer or group or farmers can work together with the manufacturer that holds the national registration for a pesticide to get a special supplemental label approved to meet a local need. It is also possible to obtain a "3rd party 24c" where a trade association develops a supplemental label for a national product and has it approved through state regulators and the EPA. A 3rd party 24c does not require the support or consent of the manufacturer, but the trade association holding the supplemental label may be responsible for annual registration fees. This is a very common practice in terrestrial agriculture where a crop may only be grown in a small region or when a particular pest may only be present in a limited area. The main benefit to a 24c SLN registration is that

the supplemental label can often be approved without the need for additional scientific studies. For all 24c registrations, the need must be limited and local, there must not already be a compound labeled for the same purpose, the pesticide must already have a full national registration for some other use, and use must be limited to the region and purpose included on the supplemental label. A Section 18 Emergency Exemption is similar to a 24C SLN registration, but is intended to address emergency situations like the sudden emergence of a new pest. Requirements are similar to a 24c SLN registration, but are designed so that conditional approval can be obtained in just a few days. Section 18 Emergency Exemptions are temporary 'stop-gap' measures, and are intended to be replaced by 24c SLN registrations or full national registrations if the problem persists. Several pesticides are regionally available to aquaculturists through the 24c SLN and Section 18 Emergency Exemption mechanisms. The best source for information about pesticides which may be available via these alternative pathways is your Cooperative Extension Service office or your local aquaculture trade association.

For specific information about pesticides currently registered for use in the U.S., you can also consult the EPA's National Pesticide Information Retrieval System (NPIRS). NPIRS is a searchable online database of currently registered pesticides, which also links to EPA's Pesticide Product Label System (PPLS) where users can access electronic copies of pesticide product labels and directions for use. Please visit the NPIRS system and access the Pesticides Search system. From here, you can search by active ingredient ("copper sulfate") or product trade name ("Triangle Brand"[1]). From the search results, you can access product reports for compounds matching your search criteria. From the Product Report page, you can link directly to the PPLS system to access the current label images, which includes application methods, cautionary and safety information, details on compound storage and disposal, etc. Please note that the NPIRS and PPLS databases were not designed to be searchable by specific use patterns, i.e., aquatic weed management in aquaculture. However, they are a good resource for finding out more about what products are currently available based on active ingredients, and of those products available, which ones are labeled for aquatic applications.

CERTAIN ACTIVE INGREDIENTS MAY BE FOUND IN PRODUCTS LABELED FOR AQUATIC AND NON-AQUATIC USES. ALTHOUGH THE ACTIVE INGREDIENT MAY BE THE SAME, IT IS NOT LEGAL TO USE A PESTICIDE PRODUCT IN AQUACULTURE UNLESS IT IS LABELED FOR SUCH USE.

PESTICIDE APPLICATOR CERTIFICATION

Some pesticides are classified as "restricted use" and are not available to the general public because of the hazards associated with these compounds or their use patterns. Restricted-use pesticides can be purchased and applied only by a Certified Pesticide Applicator or under the supervision of a Certified Applicator. Pesticide Certification Programs are offered through state agencies responsible for pesticide regulation. For information on pesticide use, training programs, and certification requirements in any state, contact your local Cooperative Extension Service office.

IT IS THE RESPONSIBILITY OF THE USER TO UNDERSTAND THE RISKS ASSOCIATED WITH USING AQUATIC PESTICIDES AND HERBICIDES AND TO KNOW AND COMPLY WITH ALL RELEVANT REGULATIONS GOVERNING THEIR USE IN AQUACULTURE. USE ONLY PESTICIDE AND HERBICIDE PRODUCTS THAT ARE LABELED FOR USE IN AQUACULTURE AND FOLLOW ALL LABEL INSTRUCTIONS AND SAFETY PRECAUTIONS.

[1] Triangle Brand® is as an example trade name for copper sulfate; use as an example here does not represent endorsement of this product.

PESTICIDES COMMONLY USED IN AQUATIC WEED MANAGEMENT

Aquatic vegetation management is necessary to maintain optimal culture conditions in pond culture as well as the structural integrity of the ponds themselves. If left unchecked, submerged and emergent plants and algae can alter water quality and make feeding and harvesting difficult; over time submerged and emergent plants can even weaken levees. Herbicides are just one part of a comprehensive aquatic weed management plan that should include physical removal methods (seining and raking), biological control methods (stocking grass carp *Ctenopharyngodon idella*) and strategies to prevent vegetation from taking hold (e.g. fertilizing ponds to maintain plankton blooms to shade out aquatic vegetation). Although these methods may be cost-effective 'first lines of defense' against aquatic weeds, herbicides may be necessary to manage aquatic weeds in pond culture. For more information on using herbicides in aquaculture production including application methods and calculations, users should consult the Aquatic Weed Management publication series from the Southern Regional Aquaculture Center: "Control Methods", "Herbicides", and "Herbicide Safety, Technology and Application Techniques". Additional information about the efficacy of aquatic herbicides against various plants and algae is provided in Table 6. For more information about aquatic herbicides used in pond management, visit the AQUAPLANT website, which provides detailed information about numerous herbicides, application methods, and a photo index for identification of aquatic weeds.

Copper sulfate* ('blue stone') or *chelated coppers are commonly used contact algicides. However, copper can also be toxic to fishes, particularly in waters with low alkalinity. In waters with alkalinity ≤50 mg/L, copper application rates needed to control algae can cause fish kills. Using copper in waters with alkalinity ≤20 mg/L is extremely risky and should be avoided, along with copper applications in warm weather.

2,4-D is a translocated (moves within the plant) herbicide used to control emergent and submerged weeds. 2,4-D is available in both liquid and granulated forms, either as an ester or an amine compound. Although either form is relatively safe, the amine forms are slightly less toxic to fish and may be better for aquatic applications.

Diquat is a liquid contact herbicide used to control floating, emergent, or submerged weeds and filamentous algae. Diquat must be used with a non-ionic surfactant when applied to emergent foliage. Also, because Diquat binds clay particles, it is not effective in muddy, turbid waters.

Endothall is a contact herbicide available in liquid or granular forms as a dipotassium salt or mono-(N,N-dimethylalkylamine) salt. Because the amine salt is more toxic to invertebrates and fish, the dipotassium salt is more commonly used in aquaculture applications. However, the two compounds have different efficacies in controlling aquatic weeds: the amine salt of endothall is effective against many submerged plants and some algae (e.g., Hydrothol® formulations); the dipotassium salt of endothall is only effective in controlling submerged weeds (e.g., Aquathol® formulations).

Glyphosate is a translocated herbicide commonly used to control shoreline vegetation and some emergent aquatic weeds. It is most effective when applied during the weed's flowering or fruiting stage. A non-ionic surfactant may be necessary for some products or applications.

Fluridone is a translocated herbicide used to control most submerged and emergent weeds. It is available in liquid and pelleted forms. Unlike other commonly used herbicides, fluridone is not effective for spot treatment (i.e., the whole pond must be treated), and it kills weeds slowly which can allow for easier management of dissolved oxygen consumption as the plants die and decompose.

APPLICATION TECHNIQUES

In the midst of a disease outbreak or other fish health problem, it can be tempting to react immediately in the hopes of resolving the problem quickly. Although it is important to be aware of early warning signs and to respond promptly to fish health concerns should they arise, it is equally important to fully evaluate the situation and your options before deciding on any course of action. In short, fish culturists should *respond* to fish health issues, not *react*. Fish Hatchery Management (2nd Edition) outlines a series of questions culturists should ask themselves before applying a treatment to a group of fish:

1. Does the loss rate, severity, or nature of the disease warrant treatment?
2. Is the disease treatable, and what is the prognosis for successful treatment?
3. Is it feasible to treat the fish where they are, considering the cost, handling, and prognosis?
4. Is it worthwhile to treat the fish or will the cost of treatment exceed their value?
5. Are the fish in good enough condition to withstand the treatment?
6. Will the treated fish be released or harvested soon and is adequate withdrawal or recovery time available?

The answers to these questions will vary from one situation to the next and, in some cases, may require consultation with a veterinarian or a fish health professional (see section below). Although most aquaculture operations are concerned with managing the health of *populations*, not individual fish, animal welfare should also be considered when evaluating fish health issues. Taking the time to consider these questions can mean the difference between making rash, ineffective decisions and resolving problems using sound fish health management.

Assuming the decision to treat has been made, it is important to consider several additional factors that will determine treatment and application options as well as their likelihood of success:

1. The water supply
2. The fish
3. The treatment
4. The disease

Some of these factors are obvious, and are likely to have been given some independent consideration already (e.g., the fish and the disease involved). However, these factors should be considered together, in the 'big picture' context. Some species or life stages of fish are more or less sensitive to certain regulated products, some treatments require discharge of the treated water that may not be possible in certain culture systems, some diseases don't respond to certain treatments, etc. When applying a treatment, users must take all of the relevant factors into consideration to ensure the greatest likelihood of success. The following checklist (adapted from Fish Hatchery Management, 2nd Edition) may be helpful in planning, applying, and evaluating a treatment:

Before treating

1. Accurately determine the water volume, flow rate, and temperature.
2. Accurately determine the number and total weight of fish in the rearing unit.
3. Confirm the identity, expiration date, and active ingredient concentration of the regulated product to be applied.
4. Double-check treatment calculations. Beware of confusion from mixing metric and standard units.
5. Have aeration devices ready for use if needed.

6. If treated water is to be discharged, make sure all appropriate permits are in place and regulatory authorities have been notified.
7. If possible, conduct a bioassay on a small group of fish before treating the entire population in the rearing unit.

When treating

1. Dilute the regulated product with rearing water before applying it (or follow product directions)
2. Ensure the regulated product is well-mixed and evenly applied in the rearing units.
3. Observe fish closely and frequently during treatment for signs of distress.
4. Monitor temperature and dissolved oxygen levels in the rearing unit during treatment.
5. Except for oral treatments, discontinue feeding during treatment. Fish are unlikely to feed during treatment, and uneaten feed will foul the system and may reduce the efficacy of some treatments.
6. Discontinue treatment and restore normal culture conditions if fish become distressed.

After treating

1. Observe fish frequently for at least 24 hours following treatment.
2. Do not stress treated fish for at least 48 hours.
3. Recheck fish to determine efficacy of treatment

Depending on the regulated product, life stage of fish, and rearing system, appropriate application techniques will vary considerably. However, regulated products will typically be applied via culture water, food, or direct injection. The following sections are adapted from text describing treatment methods in Fish Disease—Diagnosis and Treatment and Fish Hatchery Management, 2nd Edition.

IMMERSION TREATMENT

In many cases, treatments will be applied by adding the regulated product to the culture water and applied as a dip, flush, prolonged bath, indefinite bath, or constant flow treatment.

For dip treatments, small numbers of fish are exposed to a strong concentration of the regulated product for a short period of time, usually no more than a minute. Given the handling involved and the potential for overdose because of the high product concentrations used, dip treatments are usually only used with relatively innocuous compounds (e.g., salt) and when the fish are going to be handled anyway (e.g., when fish are to be moved from one rearing unit to another).

Flush treatments consist of adding a solution of the treatment product at the inflow to a rearing unit and allowing it to flush through the system. Flush treatments are typically only feasible in raceways or other similarly configured systems. This type of treatment is not appropriate for regulated products with a narrow margin of safety, as it can be difficult to ensure uniform distribution and mixing of the product throughout the water column.

For prolonged bath treatments, water flow is temporarily stopped and the appropriate amount of the regulated product is added to the rearing unit. After a specified amount of time, the water flow is restored and the treatment is flushed from the rearing unit. As with other treatments, it is critical that the compound be adequately mixed and distributed to ensure uniform concentrations. Since water flow is off during the treatment, it is important to ensure that adequate aeration is provided, and depending on the length of the treatment and stocking density, that water quality is

monitored. Indefinite baths are similar to prolonged baths, except that the rearing system has a very large volume or little-to-no water exchange (e.g., ponds or water reuse systems). In the case of indefinite baths, lower product concentrations are used and are allowed to dissipate slowly through natural processes (absorption, chelation, photodegradation, etc.) or limited water exchange.

Constant flow treatments are applied to raceways and other flow-through systems when it is impossible or impractical or turn off water flow for a prolonged bath. For these treatments, inflow rates are calculated and an appropriate amount of regulated product is metered in at the inflow for the duration of the treatment. This type of treatment can be quite efficient, but given the amount of regulated product needed, these treatments can be costly and raise discharge issues.

Charged, constant flow treatments are a combination of prolonged bath and constant flow treatments, and can be used in laminar flow raceways. The treatment begins in the same manner as a prolonged bath treatment, where the water flow is temporarily stopped and the appropriate amount of regulated product is added to treat the entire volume of static water. Immediately after the treatment is applied, water flow is restored as part of a constant flow treatment, where the regulated product is metered into the rearing unit to maintain the treatment concentration for the rest of the treatment period. This type of treatment is often the most effective, but like traditional constant flow treatments, cost and discharge issues may prevent its use in all situations.

When applying water-borne treatments, it is important to consider that temperature and water chemistry can affect the toxicity of regulated products (e.g., copper sulfate in low alkalinity water), and the rate of product degradation or inactivation. Regulated products can have unintended effects on other biota, such as nitrifying bacteria, vegetation, and zoo- or phyto-plankton, and can create significant increases in biological oxygen demand. Finally, remember that water borne treatments may not be effective for some systemic infections.

ORAL TREATMENT

For the treatment of some diseases, particularly systemic infections, the regulated product must be introduced into the body of the fish. This is most commonly done through the use of medicated feed. Some regulated products may be applied as a 'top dressing' to normal feeds by end users (e.g., Romet® TC), usually by mixing pellets with medicated oil or gelatin solution and allowing the pellets to dry before feeding. Other regulated products, such as AQUAFLOR® (a veterinary feed directive [VFD] drug) must be incorporated into medicated feeds by licensed commercial feed mills (for more information about VFD drugs, see "Guidance for industry—Veterinary Feed Directive Regulation Questions and Answers"). In general, there is less flexibility with respect to medicated feeds: veterinarians cannot issue prescriptions for off-label use of drugs in oral treatments, including off-label use of VFD-medicated feeds. Given that most diseases cause fish to feed more slowly or stop feeding altogether, it is important to implement oral treatments early to ensure the maximum likelihood of success. As with all feeds, it is important to store medicated feeds in a cool, dry place, and to use them before the expiration date.

INJECTION TREATMENT

Direct injections of regulated products may be feasible for large or valuable fish (e.g., broodstock), particularly if there are small numbers of individuals to be treated. Injections are most commonly given intraperitoneally (IP, in the body cavity) or intramuscularly (IM, in the muscle). In either case, proper positioning of the needle is crucial to avoid damage to the internal organs. IP injections are typically given near the base of the pelvic fins at a ~45° angle to the ventral surface, aligning the needle along the axis of the body to avoid the internal organs. IM injections are typically given in

the dorsal musculature at a depth of approximately 0.5-1.0 cm with the needle at a ~45° angle to the side of the body. For more information about applying injection treatments, see "Hormone Preparation, Dosage Calculation, and injection Techniques for Induced Spawning of Fish". Although this publication is focused on the use of spawning agents, the injection techniques described are applicable to any injectable regulated product used in aquaculture.

CALCULATIONS

It is critical that regulated product dosage and application rates are correctly calculated. The Guide includes a companion Treatment Calculator for all approved drugs—please refer to the Treatment Calculator for more information on the use of approved drugs in static or flow-through tanks or in feeds. To calculate treatment application rates for ponds as well as tanks, users may consult the Southern Regional Aquaculture Center publications "Calculating Area and Volume of Ponds and Tanks" and "Calculating Treatments for Ponds and Tanks".

UNIT CONVERSION

Depending on the regulated product, how it is applied, and the units of measure routinely used at a facility, it may be necessary to convert temperature, volume, weight, or length units. Online calculators are particularly useful tools (e.g., online converter located here or the iGoogle Unit Converter gadget), but the following conversions may also be used for manual calculations:

Volume	Weight	Length	Temperature
1 gal. = 3.78 L	1 lb. = 453 g or 0.453 kg	1 inch = 2.54 cm	˚C = (˚F – 32) × (5/9)
1 L = 0.26 gal	1 kg = 2.2 lbs.	1 cm = 0.39 in	˚F = [˚C × (9/5)] + 32
1 tsp. = 5 mL		3.28 feet = 1 m	

WITHDRAWAL TIMES

Product withdrawal times must be observed to ensure that a product used in a target animal does not exceed legal tolerance levels in the animal tissue at the time the edible portion is made available for human consumption. Following proper withdrawal times helps to ensure that products reaching consumers are safe and wholesome. Withdrawal information is found on the product label, package insert, or feed tag of any approved product. Withdrawal requirements for drugs used in an extra-label manner must be determined by the prescribing licensed veterinarian. Prescribing veterinarians may wish to refer to the "Phish Pharm" database, which provides information on drug metabolism in fish and may be helpful in determining proper withdrawal times for extra-label drug use.

Withdrawal times are usually reported as a specific number of days. Each withdrawal day is a full 24 hours, starting from the last time an animal receives or is exposed to a regulated compound. Withdrawal time restrictions may also apply to the use of treated water for swimming, livestock watering, crop or turf irrigation, potable drinking supply, or other purposes.

BEST MANAGEMENT PRACTICES AND OTHER CONSIDERATIONS

BEST MANAGEMENT PRACTICES

The proper use of regulated products in aquaculture promotes human, aquatic animal, and environmental health and safety. Judicious use of regulated products ensures, to the greatest extent possible, the effectiveness of the products used and reduces overuse and unnecessary expense. By using regulated products properly, aquaculturists comply with the state and federal laws and maintain public trust and consumer confidence in cultured aquatic animals and seafood products.

Drugs, biologics, pesticides, and disinfectants can be costly, but when properly applied, they can be important tools in preventing significant economic losses and promoting animal welfare. However, these tools will not be optimally effective if the underlying problem is misdiagnosed or left uncorrected, or if the regulated products are not used as intended. Productivity is not the same as production efficiency, and greater yields based upon increased dependence on drugs or other regulated compounds do not necessarily translate to greater profits. Aquaculture facilities that can only raise fish through continuous reliance on regulated products to control disease or pests often find themselves out of business. Common sense and good culture practices can reduce the need for regulated products and increase the efficiency and/or cost-effectiveness of aquaculture operations.

There are numerous best management practices that users can employ to use regulated products safely and effectively in aquaculture, including:

- Diagnose the problem(s) before applying any regulated product.
- Seek professional advice on when and how to use regulated products.
- Use regulated products only for those species and indications listed on the label (exception - some drugs may allow extra-label use if specifically prescribed by a licensed veterinarian.
- Read and follow the product label directions for use.
- Use the proper dosage, amount, or concentration for the species, area, and/or specific condition; apply the full exposure regimen regardless of whether the signs which led to treatment are diminished. This is especially important when administering antibiotic and other compounds to which resistance could develop.
- Minimize handling and consider withholding feed on days when fish are to be treated.
- Use the correct method and route of application or administration (e.g. spraying aquatic vegetation, static [pond, tank or raceway] or continuous flow [tank or raceway] immersion water treatment, injection, or oral administration [medicated feeds]).
- Calculate withdrawal times accurately.
- Identify treated populations or stocks of production and holding units with clear markings.
- Do not use antibiotic drugs or medicated feed for disease prevention.
- Do not substitute unlabeled or industrial grade products for trade-name products that are labeled and approved for aquaculture or aquatic site uses.
- Keep accurate records.
- Consider the environmental impact of discharging treated water, including possible effects on non-target organisms.
- Adopt a producer quality assurance program (e.g., Hazard Analysis and Critical Control Points - HACCP) that provides guidelines for preventing tissue residue violations and for producing high-quality, wholesome products for consumer use.
- Be aware of requirements concerning personal safety measures and proper procedures for farm workers and pesticide applicators that handle or apply regulated products.
- Consider the economic consequences, both short- and long-term, of treatment before using a regulated product.

SAFETY CONSIDERATIONS

Literature provided with regulated products is an important source of information about how to use products safely and effectively, as well as in compliance with the law. Product labels and package inserts provided with drugs and biologics present information on proper storage, mixing, dosage, and administration; date of expiration; diluting or reconstituting the product; safe disposal of the unused product and product containers; and withdrawal times. Pesticide and disinfectant product labels describe how, when, and where the product may be applied, targets they are intended to control, and any precautionary statements on their environmental, physical, and chemical hazards. Any departure from the directions and conditions on the product label could mean a violation of law, and might pose a safety risk. Material Safety Data Sheets (MSDS's) provided by the product manufacturer (also available online through online databases such as this; links to MSDS's are also provided in each of the fact sheets below) are a source of additional information on safety precautions.

ALWAYS READ AND UNDERSTAND THE PRODUCT LITERATURE BEFORE USING ANY REGULATED PRODUCT, AND WHEN IN DOUBT, SEEK PROFESSIONAL ADVICE.

Users and others nearby can be affected by direct contact (including accidental injection) with regulated products or by inhalation exposure to vapors or airborne particulates. Treated waters or airborne drift can carry regulated products to an area or location where the products may have unintended effects on non-target species, including the general public. Users should always read the product label for information on required or recommended personal protective equipment. Common-sense precautions should be followed, such as wearing gloves, long-sleeved shirts, long pants, socks, shoes or boots, a hat and goggles, protective glasses, and/or a face shield. Some regulated products may require use of a respirator. In particular, individuals mixing and/or applying pesticides, or working in an area where pesticides are being applied or have recently been applied, should consider showering and washing their clothes afterwards. Work clothing potentially contaminated with pesticides should be washed separately from household laundry. Following product label directions and using common sense can minimize undesirable effects in humans, non-target plants and animals, and the environment.

HANDLING, STORAGE, AND DISPOSAL OF REGULATED PRODUCTS

Do not mix different regulated products unless it is specifically recommended on the product label. Combining products can have undesirable, effects (e.g., one or both products can be inactivated, or chemical reactions can produce harmful gases or create other safety hazards). Always follow label directions for storing, handling, mixing, diluting, reconstituting, and disposing of regulated products and their containers. This preserves the activity and quality of the product and helps prevent misuse, damaging effects on plants and animals, human injury, and environmental contamination. Proper mixing, diluting, and reconstituting are essential to ensure the effectiveness of products and the safety of their use. Improper dilution may cause the concentration or dosage administered to be too great or too small. Incomplete mixing can cause variations in the concentration or dosage applied or administered, and uneven effects (e.g. 'hot spots' which can cause fish mortality).

Regulated products should be stored in secure locations according to the product label; generally dry, well-ventilated areas located away from people, animals, human or animal foods and living areas are best. Some regulated products (e.g. drugs, biologics) are required to be refrigerated or frozen storage whereas others should be stored at ambient (room) temperatures; regardless of the specific temperature storage recommendations, it is prudent to avoid exposing regulated products to sun or other bright light and large changes in temperature or humidity. High-temperature storage (>80-90˚F) can cause excessive pressure to build in sealed containers, causing them to burst and leak. Exposure to high

temperatures can also result in product deterioration or inactivation and shortened shelf-life. Substantial changes in regulated product concentration may occur if stored incorrectly (e.g., drug concentration in one medicated feed was virtually unchanged when stored frozen but decreased 7–10% after 1 month and up to 30% after 3 months when stored at room temperature). All pesticides, drugs, and veterinary biologics should be stored in their original containers with the original label attached. If aliquots of regulated products are temporarily stored in smaller containers, all containers should be properly labeled. Don't store regulated products in other containers for long periods unless specifically authorized by the product label; the material in some containers may actually enhance degradation of the regulated product or directly react with the product creating a potentially hazardous situation. Dampness in storage areas can cause paper packages to deteriorate, metal containers to rust, and metal or glass containers to lose their labels. Disinfectants, pesticides, and drugs should not be stored where flooding is possible, or in sites where they might spill or leak into the environment. Secondary containment systems are recommended to contain spills.

Unused portions of a regulated product and empty containers should be disposed of properly. The best approach is to purchase only the amount of material that is immediately needed and use the entire product within a reasonable time period. Empty containers must be disposed of, however, and often a quantity of the product is left over. Product labels provide instructions for safe disposal. Improper disposal can result in product toxicity or environmental contamination, exposing the facility to liability from misuse. Many states run programs to collect and properly dispose of unwanted pesticides at no or low cost to participants. Nearly all states have plastic pesticide container collection and recycling programs coordinated by the Ag Container Recycling Council (ACRC). Further information on state pesticide disposal programs is available on the EPA website.

RECORD-KEEPING

Record-keeping is essential for any aquaculture business, and the use of some regulated products may require it. Good records provide a basis for sound, cost-effective management decisions. A good record-keeping system helps producers keep track of specific treatments and their results with identifiable, known populations or stocks of aquatic animals, as well as the specific water and land areas involved. By implementing good record-keeping practices, the status of all animals and culture systems can be determined at any time by all personnel.

Processors may require records demonstrating that all regulated products have been used properly and in accordance with necessary withdrawal times. Accurate record keeping is required for any producer using an INAD exemption in INAD field trials. Pesticide regulations require that users maintain records of restricted-use pesticides. While record-keeping may not be mandatory for general-use pesticides and other regulated product uses, there is certainly merit in documenting results for the purposes of adaptive management and decision-making in the future.

ESTABLISHING A VALID VETERINARIAN-CLIENT-PATIENT RELATIONSHIP AND WORKING WITH FISH HEALTH PROFESSIONALS

A valid veterinarian-client-patient relationship is required for extra-label use of drugs in aquaculture, as well as for use of veterinary feed directive drugs. Having a good working relationship with a veterinarian is also a good management practice for any aquaculture operation. The regulatory definition of a valid veterinarian-client-patient relationship is as follows:

1. A veterinarian has assumed the responsibility for making medical judgments regarding the health of (an) animal(s) and the need for medical treatment, and the client (the owner of the animal or animals or other caretaker) has agreed to follow the instructions of the veterinarian;

2. There is sufficient knowledge of the animal(s) by the veterinarian to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s); and
3. The practicing veterinarian is readily available for follow-up in case of adverse reactions or failure of the regimen of therapy. Such a relationship can exist only when the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal(s) by virtue of examination of the animal(s) and/or by medically appropriate and timely visits to the premises where the animal(s) are kept. (21 CFR Part 530).

A directory of aquatic veterinarians and disease diagnostic laboratories is available online. In addition to establishing a working relationship with a licensed veterinarian, users are also strongly encouraged to work with American Fisheries Society Fish Health Section-certified Fish Pathologists or Aquatic Animal Health Inspectors (directories available here). Fish Pathologists and Aquatic Animal Health Inspectors have been professionally certified to possess the competence, training, and ethics required to effectively serve the aquatic animal health needs of fisheries programs and aquaculture. Aquaculturists are encouraged to work with both fish health professionals and licensed veterinarians to create and maintain complete, effective fish health programs at their facilities.

Table 1. Approved and conditionally approved aquaculture drugs and indications. Click here to return to text.	
Compound	**Indication(s)**
AQUAFLOR® Active ingredient: 50% florfenicol	To control mortality due to enteric septicemia associated with *Edwardsiella ictaluri* in catfish To control mortality due to furunculosis in freshwater-reared salmonids To control mortality due to coldwater disease in freshwater-reared salmonids
AQUAFLOR®-CA1 Active ingredient: 50% florfenicol (conditionally approved)	To control mortality due to columnaris disease in catfish
35% PEROX-AID® Active ingredient: 35% hydrogen peroxide	To control mortality due to saprolegniasis in all freshwater-reared finfish eggs To control mortality due to bacterial gill disease in freshwater-reared salmonids To control mortality due to external columnaris disease in coolwater finfish and channel catfish
Chorulon® Active ingredient: chorionic gonadotropin	To improve spawning function in male and female brood finfish
Parasite-S Formalin-F Formacide-B Paracide-F Active ingredient: formalin Note: Approved labels for the formalin products listed above may differ from one another. Read the product label before use	To control external protozoa in all finfish To control monogenetic trematodes in all finfish To control fungi of the family Saprolegniaceae in all finfish eggs To control protozoan parasites in penaeid shrimp To control external protozoa in salmon, trout, catfish, largemouth bass, and bluegill To control monogenetic trematodes in salmon, trout, catfish, largemouth bass, and bluegill To control fungi of the family Saprolegniaceae in salmon, trout, and esocid eggs
Romet® 30 and Romet® TC Active ingredients: sulfadimethoxine and ormetoprim	To control furunculosis in salmonids To control enteric septicemia in catfish
Pennox® 343 Active ingredient: oxytetracycline hydrochloride	To mark skeletal tissues in finfish fry and fingerlings
Terramycin® 200 for Fish Active ingredient: oxytetracycline dihydrate	To control ulcer disease, furunculosis, bacterial hemorrhagic septicemia, and pseudomonas disease in salmonids To control mortality due to coldwater disease in freshwater-reared salmonids To control mortality due to columnaris disease in all freshwater-reared *Oncorhynchus mykiss* To control bacterial hemorrhagic septicemia and pseudomonas disease in catfish To control gaffkemia in lobster
Finquel® Tricaine-S® Active ingredient: tricaine methanesulfonate	To temporarily immobilize fish of the families Ictaluridae, Salmonidae, Esocidae, and Percidae. In other fish and cold-blooded animals, the drug should be limited to hatchery or laboratory use

Table 2. Low regulatory priority aquaculture drugs, indications, and doses. Click here to return to text.		
Compound	**Indication(s)**	**Dose**
Acetic Acid	Parasiticide for fish	1000-2000 ppm dip for 1-10 minutes
Calcium chloride	Used to aid in egg hardening Used to aid in maintaining osmotic balance during fish holding and transport	10-20 ppm CaCO3 (eggs) ≤150 ppm CaCO3, indefinitely (fish)
Calcium oxide	External protozoacide for fish	2000 ppm dip for 5 sec
Carbon dioxide gas	Anesthetic for fish	
Fuller's Earth	Used to reduce the adhesiveness of fish eggs	
Garlic (whole form)	To control helminth and sea lice infestations of marine salmonids at all life stages	
Ice	Used to reduce the metabolic rate of fish during transport	
Magnesium sulfate	Used to treat external monogenic trematode infestations in fish Used to treat external crustacean infestations in fish	30,000 ppm MgSO4 + 7000 ppm NaCl dip for 5-10 min
Onion (whole form)	Used to treat external crustacean parasites infestations of salmonids Used to deter sea lice from infesting external surface of salmonids	
Papain	Used to remove the gelatinous matrix from fish egg masses	0.2% solution
Potassium chloride	Used to aid in osmoregulation, relieve stress, and prevent shock in fish	10-2000 ppm Cl1-
Povidone iodine	Egg surface disinfectant	100 ppm for 10 min during or after water hardening
Sodium bicarbonate	Used to introduce carbon dioxide into the water for anesthetizing fish	142-642 ppm for 5 min
Sodium chloride (salt)	Used as an osmoregulatory aid to relieve stress and prevent shock in fish Parasiticide for fish	0.5-1.0% indefinitely 3% dip for 10-30 min
Sodium sulfite	Used to improve hatchability (decrease adhesiveness) of fish eggs	1.5% solution for 5-8 min
Thiamine hydrochloride	Used to prevent or treat thiamine deficiency in salmonids	≤100 ppm for ≤4 h during water hardening (eggs) ≤1000 ppm for ≤1 h (sac-fry)
Urea and tannic acid	Used to reduce the adhesiveness of fish eggs	Immersion in 3 ppt urea + 4 ppt NaCl for ~6 min followed by separate immersion in 150 ppm tannic acid for ~6 min (treats approximately 400,000 eggs)

Table 3. Investigational new animal drug exemptions for aquaculture drugs held by the U.S. Fish and Wildlife Service as part of the National INAD Program. Click here to return to text.

Compound	Indication(s)
Common carp pituitary	To induce ovulation and spermiation in fish
Catfish pituitary	To induce ovulation and spermiation in fish
Halamid® Actamide Active ingredient: chloramine-T	To prevent mortality associated with bacterial gill disease or external flavobacteriosis in certain salmonids, sturgeon, perch, sunfish, bass and other coolwater and warmwater fish species To control mortality associated with bacterial gill disease or external flavobacteriosis in a variety of salmonid fish species To control mortality associated with bacterial gill disease or external flavobacteriosis in certain species of sturgeon, perch, sunfish, bass, and other coolwater and warmwater fish
Reward® Active ingredient: diquat	To control mortality caused by bacterial gill disease or external columnaris in a variety of freshwater fish species
Aquaflor® Active ingredient: 50% florfenicol	To control mortality associated with enteric septicemia, coldwater disease, furunculosis, and other various fish pathogens in all fish (except those uses/fish species listed on the label of the approved product)
35% PEROX-AID® Active ingredient: 35% hydrogen peroxide	To control mortality caused by ectoparasites of the genera *Ambiphrya, Chilodonella,Dactylogyrus, Epistylis, Gyrodactylus, Ichthyobodo, Ichthyophthirius, Trichodina,Trichophrya, Argulus*, *Salmincola*, *Lernaea,* and *Ergasilus* in freshwater fish species To control mortality caused by ectoparasites of the genera *Neobenedenia*, *Amyloodinium*, *Cryptocaryon*, and *Uronema* in marine fish species
Luteinizing hormone releasing hormone analog (LHRHa)	To induce ovulation and spermiation in fish
Pennox® 343 Active ingredient: oxytetracycline hydrochloride	To control of mortality associated with furunculosis, bacterial hemorrhagic septicemia, enteric redmouth, flexibacteriosis, and vibriosis in salmonids To control mortality associated with enteric septicemia in catfish To control mortality associated with bacterial hemorrhagic septicemia, pseudomonas disease, and flexibacteriosis in catfish, sturgeon, temperate basses, and other cool and warmwater fish
Terramycin® 200 for Fish Active ingredient: oxytetracycline dihydrate	To control mortality caused by coldwater disease, columnaris, flexibacteriosis, enteric redmouth, bacterial hemorrhagic septicemia caused by Aeromonads and Pseudomonads, and other gram negative systemic bacteria in salmonids To control mortality caused by deep-seated bacterial infections in freshwater and marine fish To control mortality caused by a variety of bacterial pathogens sensitive to oxytetracycline in non-salmonid freshwater and marine fish species To control mortality caused by withering syndrome in abalone to mark skeletal tissue in freshwater and marine fish
SE-MARK® Active ingredient: calcein	For skeletal marking of freshwater and marine finfish
Ovaplant® Active ingredient: salmon gonadotropin releasing hormone analogue (sGnRHa)	To induce ovulation and spermiation in fish
Benzoak® Active ingredient: benzocaine	To temporarily sedate/anesthetize fishes
AQUI-S®20E Active ingredient: eugenol	To temporarily sedate/anesthetize fishes
SLICE® Active ingredient: emamectin benzoate	To control mortality caused by external parasites in a variety of freshwater fish species
17α-methyl testosterone	To produce populations comprising over 90% phenotypically male fish
Copper sulfate	To control external protozoan and metazoan parasites, and bacterial and fungal infections in a variety of warmwater fish species
Potassium permanganate	To control external protozoan and metazoan parasites, and bacterial and fungal infections in a variety of warmwater fish species

Table 4. Product and water volumes for preparing baths of AQUAVAC-ESC or AQUAVAC-COL for vaccinating catfish. Click here to return to text.

	Number of 7 day post hatch catfish fry to be vaccinated as a single group				
	200,000	400,000	600,000	800,000	1,000,000
Vials of vaccine	2	4	6	8	10
Gallons of water	10	20	30	40	50
	Pounds of catfish ≥7 days to be vaccinated as a single group				
	15	30	45	60	75
Vials of vaccine	2	4	6	8	10
Gallons of water	10	20	30	40	50

Table 5. Disinfectants and their use for field gear and hard surfaces. See bottom of table for definitions of abbreviations. Click here to return to text.

Disinfectant Concentration Contact Time	Surfaces	Deactivated by organic matter	Corrosive	NZMS	ZQM	MC Spores	MC Tams	IHNV	VHS	SVCV	KHV	ISA	IPN	LMBV	WSIV	RANA	BKD	FUR, ERM	CWD, COL	Chytrid	Disposal	Pros and Cons
Low Level Disinfectants: Kill most vegetative bacteria, some fungus, some enveloped viruses, do not kill mycobacteria or bacterial spores.																						
Benzalkonium chloride (QAC) 500ppm Contact 10 min (except as noted)	Plastics, floors, counter tops	Y	N	Y	Y	Y 10 min	Y 10 min	Y	Y 5 min	Y	Y		N	Y	Y		1000 ppm	Y		Y 5 min	unknown	**Pros**: easily accessible, non-corrosive **Cons**: highly toxic to fish, disposal issues, not labeled for aquatic use, bath type use
Didecyl dimethyl ammonium chloride (QAC) 400ppm Contact 5 min (except as noted)	Plastics, floors, counter tops	Y	N	Y	Y	Y 5 min	Y 1 min	Y 5 min	Y 5 min	Y 5 min	Y 5 min		N	Y 5 min	Y 5 min	Y 10 min	1000 ppm	Y 5 min		Y 1 min	unknown	**Pros**: non-corrosive, no rinse spray on **Cons**: disposal issues, hard to find, not labeled for aquatic use
Phenols (Lysol, Pinesol) Contact 15 min	Hard surfaces	N	N	Y	Y				Y												unknown	**Pros**: common household products **Cons**: not labeled for use of field gear, irritating to skin, must rinse
Intermediate Level Disinfectants: Kill vegetative bacteria, most viruses and most fungi, but not resistant bacterial spores																						
Chlorine 200-500ppm 10-60 min	All surfaces except plastics	Y	Y	N	Y 60 min	Y 15 min	Y 10 min	Y 5 min	Y 5 min	Y 10 min		Y 15 min	Y 30 min	Y 10 min		Y 15 min	Y 5 min	Y 10 min		Y 10 min	neutralize with sodium thiosulfate	**Pros**: works well, inexpensive, readily available **Cons**: highly corrosive, odors, human toxicity?
Virkon Aquatic 0.5%-1% 5-30 min (except as noted)	Waders, boots boats nets, all field gear	Y	N	Y 60 min	Y*		Y 5 min	Y 5 min	Y 10 min	Y 10 min		Y 10 min	Y 10 min	Y 20 min		Y 1 min	Y 10 min	Y 5 min		Y 1 min	dilute, pour on ground away from surface waters	**Pros**: non-corrosive, considered environmentally safe, biodegradable, can use as a no-rinse spray on **Cons**: cost, efficacy not determined for some pathogens
Ethyl Alcohol 70-80%	Hands, tools, counter tops	N	N	N	Y				Y				Y	N						Y	unknown	**Pros**: readily available **Cons**: evaporates quickly and may not get proper contact time, expensive, not good for field equipment, fixes organics to hard surfaces, inactivated by sunlight, flammable
Isopropyl Alcohol 60-80% 10-30 min (except as noted)					30				2				10							1	unknown	
Iodine 100-250ppm 20-30 min (except as noted)	Better as antiseptic on tissues	Y	Y	N	N	N	N	Y 10 min	Y 10 min	Y 20 min		Y 5 min		Y 10 min				500 30 min		Y 1 min	neutralize with sodium thiosulfate	**Pros**: antiseptic, inexpensive, **Cons**: corrosive to metals, stains, long contact time, cannot over concentrate, highly toxic to aquatic animals

Table 5. Disinfectants and their use for field gear and hard surfaces (continued). Click here to return to text.

Disinfectant Concentration Contact Time	Surfaces	Deactivated by organic matter	Corrosive	NZMS	ZQM	MC Spores	MC Tams	IHNV	VHS	SVCV	KHV	ISA	IPN	LMBV	WSIV	RANA	BKD	FUR, ERM	CWD, COL	Chytrid	Disposal	Pros and Cons
High Level Disinfectants: Destroy vegetative bacteria, mycobacteria(TB), fungi, enveloped (lipid or hydrophilic) and non enveloped virus (non lipid), but not necessarily bacterial spores. Must be capable of sterilization when contact time is extended.																						
Hydrogen Peroxide **3-5%** **5 min** **(except as noted)**		N	Y	15 min			N	Y	Y	Y	Y	Y	Y	Y	Y		Y	Y			unknown	**Pros**: can add to QACs & iodine to make them more effective **Cons**: destroys soft tissues when over exposed
Peroxigard **1:16**			N					Y	Y	Y				Y							unknown	**Pros**: no-rinse spray on
Formaldehyde **1%-3%**	better when mixed w alcohol	N	N	N				?	16 h	5 h		16 h	5 min							5 min	titrations	**Pros**: easily accessible **Cons**: highly toxic, odors, personal protective gear required to protect applicator
Other Disinfection Options																						
Heat				5 m	15 m		5 m 75˚C (167˚F)	2 m 50˚C (122˚F)	5 m 55˚C(131 ˚F)	30 m 60˚C (140˚F)		2 m 50˚C (122˚F)	30 m 60˚C (140˚F)			15 m 60˚C (140˚F)	10 m 80˚C (176˚F)			5 m 60˚C (140˚F)	NA	
Ozone **8 ppm** **3 min**									Y				Y					Y	Y			
pH **>12 or <4** **> 4 hr**									Y	Y	Y pH <4											
Complete Drying **>20˚C**					7 d	60 d	1 h		14 d	5 d				5 d		4 d				6 h	NA	

Recommended active ingredient concentrations appear in red under the chemical along with the general minimum contact time. In columns where a Y appears, the contact time is listed below in minutes (min), hours(h), or days (d). If there is a blank, it is unknown at this time. If a contact time for a chemical was longer than feasible recommended time (generally longer than 1 hour) or the compound is known to not be effective, an N appears in the column. For example, a 10% formalin solution will only kill 20% of NZMS in a 1 hour exposure, therefore, it is listed as a N. Please remember that it is in violation of federal law to use a disinfectant other than how it is labeled.

Pathogen and/or invasive/nuisance species abbreviations are as follows: NZMS= New Zealand mud snail, ZQM = zebra/quagga mussels, MC Spores = Myxobolus cerebralis (whirling disease) myxospores, MC Tams = Myxobolus cerebralis (whirling disease) triactinomycon spores, IHNV =infectious hematopoietic necrosis virus , VHS = viral hemorrhagic septicemia virus, SVCV = spring viremia of carp virus , KHV = koi herpes virus, ISA = infectious salmon anemia virus, IPN = infectious pancreatic necrosis virus, LMBV = largemouth bass virus, WSIV = white sturgeon iridovirus, RANA = ranavirus, BKD = bacterial kidney disease, FUR = furunculosis, ERM =enteric redmouth, CWD = coldwater disease, COL = columnaris disease, Chytrid = chytrid fungus

Table 6. Treatment responses[1] of various types of aquatic vegetation to herbicides most commonly used for aquatic weed management in aquaculture. Table adapted from "Herbicides". Click here to return to text.

	Aquatic Herbicide Active Ingredient					
Vegetation Type	Copper & Copper Complexes	2,4-D	Diquat	Endothall	Glyphosate	Fluridone
Algae						
Planktonic	E	P	P	G[2]	P	P
Filamentous	E	P	G	G[2]-P[3]	P	P
Chara/Nitella	E	P	P	G[2]-P[3]	P	P
Floating Plants						
Duckweeds	P	F[4]	G	P	P	E
Salvinia	P	G	G	UNK	G	E
Water Hyacinth	P	E	E	UNK	G	P
Watermeal	P	F	F	UNK	UNK	G
Submerged Plants						
Coontail	P	G	E	E	P	E
Elodea	P		E	F	P	E
Fanwort	P	F	G	E	P	E
Naiads	P	F	E	E	P	E
Parrotfeather	P	E	E	E	F	E
Pondweeds	P	P	G	E	P	E
Emergent Plants						
Alders	P	E	F	P	E	P
Arrowhead	P	E	D	G	E	E
Buttonbush	P	F	F	P	G	P
Cattails	P	F	D	P	E	F
Common Reed	P	F	F	UNK	E	F
Water Lilies	P	E[5]	P	UNK	G	E
Frog's Bit	P	E	E	UNK	UNK	UNK
Pickerelweed	P	G	G	UNK	F	P
Sedges and Rushes	P	F	F	UNK	G	P
Spike Rush	P	UNK	G	UNK	P	G
Smartweed	P	E	F	UNK	E	F
Southern Watergrass	P	P	UNK	UNK	E	G
Water Pennywort	P	G	G	UNK	G	P
Water Primrose	P	E	F	P	E	F
Willows	P	E	F	P	E	P

[1] E = excellent control, G = good control, F = fair control, P = poor control, UNK = unknown or no response
[2] Hydrothol® formulations
[3] Aquathol® formulations
[4] Liquid 2,4-D formulations
[5] Granular 2,4-D formulations

FLORFENICOL

TRADE NAME: AQUAFLOR® and AQUAFLOR®-CA1, available from Merck Animal Health[2]

AQUAFLOR® and AQUAFLOR®-CA1 are Type A medicated articles (premix) which may be incorporated into feed to prepare a Type C medicated feed.

APPROVED INDICATIONS:
All below indications are 10 mg of florfenicol per kg of body weight per day for 10 consecutive days:

- For the control of mortality in catfish due to enteric septicemia of catfish associated with *Edwardsiella ictaluri*.
- For the control of mortality in freshwater-reared salmonids due to coldwater disease associated with *Flavobacter psychrophilum*.
- For the control of mortality in freshwater-reared salmonids due to furunculosis associated with *Aeromonas salmonicida.*
- For the control of mortality in catfish due to columnaris disease due to *Flavobacterium columnare.*

PRECAUTIONS:
Avoid inhalation, oral exposure, and direct contact with skin or eyes. Operators mixing and handling AQUAFLOR® and AQUAFLOR®-CA1 should use protective clothing, gloves, goggles and NIOSH-approved dust mask. Wash thoroughly with soap and water after handling. If accidental eye contact occurs, immediately rinse thoroughly with water. If irritation persists, seek medical attention. Not for human consumption. Keep out of reach of children.

Fish treated with florfenicol may become sensitive to sunlight.

WITHDRAWAL PERIOD:
12 days

REFERENCES:
AQUAFLOR®/Florfenicol literature related to fish
Material Safety Data Sheet for AQUAFLOR®

CLICK HERE TO RETURN TO TABLE

[2] Formerly Intervet/Schering Plough Animal Health

FORMALIN

TRADE NAME: Formalin-F, Formacide-B, Paracide-F, Parasite-S (available from Natchez Animal Supply Company, B.L. Mitchell Inc., Argent, and Western Chemical Inc.)

APPROVED INDICATIONS:
Formalin is approved for : (a) for the control of external protozoa (*Chilodonella* spp., Costia spp., *Epistylis* spp., *Ichthyophthirius* spp., *Scyphidia* spp. and *Trichodina* spp.), and the monogenetic trematode parasites (*Cleidodiscus* spp., *Dactylogyrus* spp., and *Gyrodactylus* spp.) on all finfish, (b) for the control of fungi of the family Saprolegniaceae on all finfish eggs and (c) for the control of external protozoan parasites (*Bodo* spp., *Epistylis* spp., and *Zoothamnium* spp.) on penaeid shrimp.

DOSAGE:
FOR THE CONTROL OF EXTERNAL PARASITES ON FINFISH

Aquatic Species	Administer in tanks or raceways for up to 1 hour (µL/L)	Administer in earthen ponds indefinitely (µL/L)
Salmon and trout -above 50˚F -below 50˚F	 - up to 170 - up to 250	 15-25**,*** 15-25**,***
All other finfish	up to 250	15-25**,***

**=Use lower concentration when ponds, tanks, or raceways are heavily loaded with phytoplankton, or finfish, to avoid oxygen depletion due to the biologic oxygen demand created by decay of dead phytoplankton. Alternatively, a higher concentration might be used if dissolved oxygen is strictly monitored.
***=Although the indicated concentrations are considered safe for cold and warm water finfish, a small number of each lot or pond to be treated should always be used to check for any unusual sensitivity to formalin before proceeding.

FOR THE CONTROL OF FUNGI OF THE FAMILY SAPROLEGNIACEAE ON FINFISH EGGS

Aquatic Species	Administer in Hatchery Systems (µL/L)
Eggs of all finfish except Acipenseriformes	1000 to 2000 for 15 minutes**
Eggs of Acipenseriformes	up to 1500 for 15 minutes**

**=Apply in constant flow water supply of incubating facilities. A preliminary bioassay should be conducted on a small sub-sample of finfish eggs to determine sensitivity before treating an entire group. This is necessary for all species because egg sensitivity can vary with species or strain and the unique conditions at each facility.

PRECAUTIONS:
Can cause central nervous system (CNS) depression. Slightly irritating to the respiratory system. May cause sensitization by inhalation. Reports have associated repeated and prolonged occupational overexposure to solvents with permanent brain and nervous system damage. Toxic if inhaled. Harmful if swallowed. Can cause central nervous system (CNS) depression. Corrosive to the digestive tract. Causes burns. May be fatal or cause blindness if swallowed. Harmful in contact with skin, may cause sensitization by skin contact. Corrosive to eyes.

WITHDRAWAL PERIOD: None.

REFERENCES:
Material Safety Data Sheet for Formalin-F®, Formacide-B®, Paracide-F®, and Parasite-S®
Formalin literature related to fish
Chemical Facility Anti-Terrorism Standards Fact Sheet

CLICK HERE TO RETURN TO TABLE

HUMAN CHORIONIC GONADOTROPIN

TRADE NAME: Chorulon® (available by prescription from Merck Animal Health[3])

Chorulon® is a freeze-dried preparation of chorionic gonadotropin (human Chorionic Gonadotropin [hCG]) for intramuscular administration after reconstitution with the accompanying sterile diluents. Each 10 mL vial contains 10,000 I.U. chorionic gonadotropin (equivalent to 10,000 USP Units chorionic gonadotropin) and 10 mg mannitol with mono- and disodium phosphate to buffer the pH of the solution.

APPROVED INDICATIONS:

- Chorulon® is indicated for use as an aid in improving spawning function in male and female brood finfish.
    - Treatments should be administered via intramuscular injection just ventral to the dorsal fin for one to three injections. Any single injection should be administered, depending on the fish species, at a dose of 50 to 510 I.U./lb. body weight (BW) for males and 67 to 1816 I.U./lb. BW for females (see Table 1 below). Depending on body weight and dose administered, it may be necessary to divide the dose among two or more injection sites to avoid injecting a large volume (>1 mL) at a single site.

- No withdrawal period is required for brood finfish treated according to label directions. The total dose administered (all injections combined) should not exceed 25,000 I.U. (25 mL) per fish in fish intended for human consumption.

*The safety and effectiveness of Chorulon® has not been tested on all fish species under all possible fish culture conditions. If you are unsure whether your fish will react adversely to treatment with Chorulon®, conduct an initial bioassay on a small number of fish before treating an entire group.

USE LIMITATIONS/RESTRICTIONS/REQUIREMENTS:

Labeling restricts Chorulon® to use by or on order of a licensed veterinarian. Chorionic gonadotropin is a protein. In the unlikely event of an anaphylactic reaction, epinephrine should be administered. The administration of an antihistamine may also be indicated.

Keep out of reach of children. Once reconstituted, Chorulon® should be used immediately. Unused solution should be disposed of properly and not stored for future use.

PRECAUTIONS:

Exposure to Chorulon® powder or reconstituted product may cause irritation or allergic reaction at site of contact. Accidental injection may cause result in menorrhagia (abnormally long menstrual cycle). Personal protective equipment should always be used when handling this chemical. Before use, read the Material Safety Data Sheet.

[3] Formerly Intervet/Schering Plough Animal Health

DOSAGE AND ADMINISTRATION:

To reconstitute, transfer the contents of one vial of sterile diluent into one vial of freeze-dried powder. The resulting 10 mL of Chorulon® contains 10,000 I.U. chorionic gonadotropin. Summaries of doses tested in representative fish species are contained within the following tables. The dose of Chorulon® to be used in other species of finfish may differ from those species listed in the tables, but should fall within the suggested range of 50 to 510 I.U./lb. BW for males and 67 to 1816 I.U./lb. BW for females.

Tested fish species/dose combinations of hCG found to be effective.

Common Name, *Scientific Name,* Family	*Tested Dose(s) (I.U./lb. BW/injection)* Male	Female	Number of Injections	Injection Interval (h)
Yellow perch, *Perca flavescens,* Percidae	not tested	67-300	1	-
Striped bass, *Morone saxatilis*, Percichthyidae	50-500	75-252	1	-
White bass, *Morone chrysops*, Percichthyidae	65-510	91-750	1	-
Razorback sucker, *Xyrauchen texanus*, Catostomidae	not tested	100	3	24
Walleye, *Sander vitreum*, Percidae	75-400	145-830	1-3	72
Red snapper, *Lutjanus campechanus*, Lutjanidae	250	500	1	-
Sauger, *Stizostedion canadense*, Percidae	500	500-1000	1	-
Chinese catfish, *Clarius fuscus*, Clariidae	not tested	1816	1	-

Tested fish species/dose combinations of hCG found to be safe.

Common Name, *Scientific Name,* Family	*Tested Dose(s) (I.U./lb. BW/injection)* Male	Female	Number of Injections	Injection Interval (h)
White bass, *Morone chrysops*, Percichthyidae	750	1500	1	-
Walleye, *Stizostedion vitreum*, Percidae	750	1500	1	-
Grass carp, *Ctenopharyngodon idella*, Cyprinidae	2500	5000	1	-
Channel catfish, *Ictalurus punctatus*, Ictaluridae	2500	5000	1	-

WITHDRAWAL PERIOD: None for brood finfish treated according to label directions.

REFERENCES:

Material Safety Data Sheet for Chorulon®

Human Chorionic Gonadotropin literature related to fish

CLICK HERE TO RETURN TO TABLE

HYDROGEN PEROXIDE

TRADE NAME:

35% PEROX-AID® (available from Western Chemical Inc, or Eka Chemicals Inc.)

APPROVED INDICATIONS:

- For the control of mortality in freshwater-reared finfish eggs due to saprolegniasis.
  - 500 to 1,000 mg/L for 15 minutes in a continuous flow system once per day on consecutive or alternate days until hatch for all coldwater and coolwater species of freshwater-reared finfish eggs.
  - 750 to 1,000 mg/L for 15 minutes in a continuous flow system once per day on consecutive or alternate days until hatch for all warmwater species of freshwater-reared finfish eggs.

- For the control of mortality in freshwater-reared salmonids due to bacterial gill disease associated with *Flavobacterium branchiophilum.*
  - 100 mg/L for 30 minutes or 50 to 100 mg/L for 60 minutes once per day on alternate days for three treatments in a continuous flow water supply or as a static bath.

- For the control of mortality in freshwater-reared coolwater finfish and channel catfish due to external columnaris disease associated with *Flavobacterium.*
  - 50 to 75 mg/L for 60 minutes once per day on alternate days for three treatments in a continuous flow water supply or as a static bath (coolwater species of freshwater-reared finfish (except northern pike & paddlefish) and channel catfish).
  - 50 mg/L for 60 minutes once per day on alternate days for three treatments in continuous flow water supply or as a static bath (coolwater species of freshwater-reared finfish fry (except northern pike, pallid sturgeon, and paddlefish) and channel catfish fry).

*Initial bioassay on a small number is recommended before treating the entire group. Use with caution on walleye; other species may also be sensitive to hydrogen peroxide.

PRECAUTIONS:

Hydrogen peroxide is a strong oxidizer and personal protective equipment should always be used when handling this chemical (Note: Prolonged exposure may cause skin irritation or burns). Before use, read the Material Safety Data Sheet and Product Fact Sheet for 35% PEROX-AID®.

WITHDRAWAL PERIOD: None.

DISCHARGE LIMITS:

Consult with NPDES authority before first use of hydrogen peroxide. The FDA considers the use of hydrogen peroxide as a waterborne therapeutant in intensive and extensive freshwater aquaculture operations constitutes no significant threat to the environment, the populations of organisms residing there, or public health and safety if receiving water concentrations do not exceed 0.7 mg/L on a short-term basis. This acute water quality benchmark should be included on the product label to alert effluent regulatory authorities of the potential need to establish discharge limits at individual facilities using hydrogen peroxide based on site-specific conditions. Monitoring of effluent concentrations should only be required for those facilities that discharge to receiving water with either minimal flow relative to the hatchery discharge or that have minimal oxidizable material in the receiving water. Because hydrogen peroxide undergoes rapid degradation in eutrophic waters, most freshwater facilities with large holding

ponds will probably discharge hydrogen peroxide at concentrations far below the proposed 0.7 mg/L acute benchmark. FDA's Environmental Assessment

REFERENCES:

Hydrogen peroxide literature related to fish eggs.
Hydrogen peroxide literature related to fish.
Material Safety Data Sheet for 35% PEROX-AID®
Chemical Facility Anti-Terrorism Standards Fact Sheet

CLICK HERE TO RETURN TO TABLE

OXYTETRACYLINE DIHYDRATE

TRADE NAME: Terramycin® 200 For Fish (available from Phibro Animal Health)

APPROVED INDICATIONS:

- For the control of mortality in freshwater-reared salmonids due to coldwater disease associated with *Flavobacterium psychrophilum.*
- For the control of mortality in freshwater-reared *Oncorhynchus mykiss* due to columnaris disease associate with *Flavobacterium columnare.*
- To add to the label the previously approved indication for marking of skeletal tissue in Pacific salmon.

DOSAGE:

- Salmonids and catfish: 2.5 to 3.75 g oxytetracycline/100 lb. fish per day for 10 consecutive days.
- Pacific salmon: 250 mg/kg of fish per day administered as the sole ration for 4 consecutive days.
- Freshwater-reared salmonids: 3.75 g /100 lb. fish per day for 10 consecutive days.

PRECAUTIONS:
Certain components of animal feeds, including medicated premixes, possess properties that may be a potential health hazard or a source of personal discomfort to certain individuals who are exposed to them. Human exposure should, therefore, be minimized by observing the general industry standards for occupational health and safety.

Precautions such as the following should be considered: dust masks or respirators and protective clothing should be worn; dust-arresting equipment and adequate ventilation should be utilized; personal hygiene should be observed; wash before eating or leaving a work site; be alert for signs of allergic reactions—seek prompt medical treatment if such reactions are suspected.

Not for human use.

CALCULATIONS: See companion Treatment Calculator and information below.

To achieve a dosage of 2.5 or 3.75 g oxytetracycline dihydrate/100 pounds of fish:

Feeding Rate (%)	Oxytetracycline dihydrate in Type C Medicated Feed (g/ton)	Pounds of Type B Medicated Feed per ton of feed	Pounds of total biomass that one ton of Type C Medicated Feed will treat
1	5,000 or 7,500	250.0 or 375.0	200,000
2	2,500 or 3,750	125.0 or 187.5	100,000
3	1,667 or 2,500	83.3 or 125.0	66,667
4	1,250 or 1,875	62.5 or 93.8	50,000
5	1,000 or 1,500	50.0 or 75.0	40,000
6	833 or 1,250	41.7 or 62.5	33,333
7	714 or 1,071	35.7 or 53.6	28,571
8	625 or 938	31.3 or 46.9	25,000
9	556 or 833	27.8 or 41.7	22,222
10	500 or 750	25.0 or 37.5	20,000
15	333 or 500	16.7 or 25.0	13,333

WITHDRAWAL PERIOD:
Pacific salmon, skeletal marking: 7 days
Salmonids, therapeutic use: 21 days
Catfish, therapeutic use: 21 days

REFERENCES:
Appendix A: Oxytetracycline dihydrate literature related to fish
Material Safety Data Sheet for Terramycin®200 for Fish

CLICK HERE TO RETURN TO TABLE

OXYTETRACYLINE HYDROCHLORIDE

TRADE NAME: Pennox® 343 (source of drug: PennField Animal Health)

APPROVED INDICATIONS:

Pennox® 343 should be applied as a static immersion bath at the following dose/duration range for skeletal marking of finfish fry and fingerlings.

*The safety and effectiveness of Pennox® 343 has not been tested on all fish species under all possible fish culture conditions. If you are unsure whether your fish will react adversely to treatment with Pennox® 343, conduct an initial bioassay on a small number of fish before treating an entire group.

USE LIMITATIONS/RESTRICTIONS/REQUIREMENTS:
New manufacturer/product; information pending.

DOSAGE:

- Treat with 200 – 700 mg OTC/L for 2 – 6 hrs.
- Upon completion of treatment, fish should immediately be moved to fresh water.
- Marking of fish larvae less than 10 days old is more effective than marking older juveniles.

PRECAUTIONS:
Infants and mothers exposed during pregnancy may develop discoloration of the teeth. May cause eye and/or skin irritation. Personal protective equipment should always be used when handling this chemical. Before use, read the Material Safety Data Sheet for oxytetracycline hydrochloride.

High concentrations of oxytetracycline hydrochloride may acidify immersion baths, and buffers may be necessary to maintain pH within ranges appropriate for fish.

WITHDRAWAL PERIOD:
None.

REFERENCES:
Pennox® 343/oxytetracycline hydrochloride literature related to fish
Material Safety Data Sheet for Pennox® 343

CLICK HERE TO RETURN TO TABLE

ROMET® 30 and ROMET® TC

TRADE NAME:

Romet® 30 (available from FDA-licensed feed mills)
Romet® TC (available from Aquatic Health Resources)

Romet® 30 is an antimicrobial powder containing ormetoprim sulfadimethoxine for treatment of furunculosis in salmonids and enteric septicemia in catfish.

Romet® TC is a new formulation including hydrolyzed fish protein concentrate that significantly improves the palatability of Romet feeds. Growers can count on effective disease control because better palatability means improved medicated feed consumption and more antibiotic up-take.

APPROVED INDICATIONS:

- To control furunculosis in salmonids (trout and salmon) caused by *Aeromonas salmonicida.*
  - Administer medicated feed to achieve a dose rate of 50 mg/kg body weight (BW)/d for 5 consecutive days.
  - This use has a 42-day withdrawal time.

- To control of enteric septicemia of catfish caused by *Edwardsiella ictaluri.*
  - 50 mg per kilogram of body weight for five consecutive days.
  - This use has a 3-day withdrawal time.

*The safety and effectiveness of Romet® or Romet® TC has not been tested on all fish species under all possible fish culture conditions. If you are unsure whether your fish will react adversely to treatment with Romet® or Romet® TC, conduct an initial bioassay on a small number of fish before treating an entire group.

USE LIMITATIONS/RESTRICTIONS/REQUIREMENTS:

If fish show no improvement within 2 to 3 days, or if signs of disease reappear after termination of treatment, reevaluate management practices, diagnosis of outbreak, and establish susceptibility of the bacterial isolate(s) to the drug.

Labels for feeds containing Romet® must contain appropriate indications, limitations and warnings as well as required feed ingredient information.

Romet® 30 is a Type A medicated article (medicated premix) and is only available from an FDA-licensed feed mill.

Romet® TC is a Type B medicated article and is available from Aquatic Health Resources and approved for on-farm use (i.e., top coating).

PRECAUTIONS:

Romet® is considered irritating to the skin and eyes. Contact may cause allergic reaction in sensitive individuals. Personal protective equipment should always be used when handling this chemical. Before use, read the Material Safety Data Sheets.

PREPARATION OF MEDICATED FEEDS (Romet® 30 is only available from FDA-licensed feed mills):

Establish the weight of fish to be treated and calculate the amount of feed needed per day according to fish size and water temperature. Calculate the amount of Romet® 30 required for medicating the feed at the rate of 16.7 g of Romet® 30 per 100 kg (7.6 g of Romet® 30/100 lb.) of fish body weight per day.

Medication of Feed Before Pelletizing or Extruding

Thoroughly mix the calculated amount of Romet® 30 into the mash feed prior to pelletizing or extruding. Refer to the dosage table below for recommended levels of use.

Romet® 30 Recommended Levels

Feeding Rate (%)	Lbs of Romet® 30 per ton of feed
1	33.30
2	16.70
3	11.10
4	8.33
5	6.66

Romet® TC Recommended Levels

Feeding Rate (%)	Lbs. of Romet® TC to add to 1/2 gal of water for each 100 lbs. of feed
1	2.50
2	1.25
2.5	1.00
5	0.50

Medication of Feed After Pelletizing

Prepare a liquid slurry by suspending Romet® 30 in edible vegetable oil or 5% gelatin solution. Coat the pelleted fish feed with the slurry, which should be constantly agitated to ensure uniform suspension of the Romet® 30 during addition. As a general rule, one gallon of vegetable oil or gelatin solution is required to coat 200 lbs. of pellets. For example, to medicate 6666 lb. of fish for one day, with a 3% body weight feed intake, mix 1.1 lbs. of Romet® 30 with one gallon of vegetable oil to prepare a slurry to be used for coating 200 lbs. of pellets. Pellets may be placed in a cement mixer (if fifty lbs. or more are to be coated) or spread on plastic or a smooth concrete surface for the coating process. The pellets should be mixed constantly but gently while the slurry is being slowly added to insure even distribution without undue pellet breakage. The coated pellets are then spread out and allowed to air dry for several hours. Rebag and store under proper feed storage conditions.

WITHDRAWAL PERIOD:

Salmonids: 42 days

Catfish: 3 days

DISCHARGE LIMITS: The Unites States Environmental Protection Agency (USEPA) has not established a Reportable Quantity (RQ) for releases of this material. State and local regulations vary and may impose additional reporting requirements.

REFERENCES:

Material Safety Data Sheets for Romet® 30 and Romet® TC

Romet® 30/Romet® TC literature related to fish

CLICK HERE TO RETURN TO TABLE

TRICAINE METHANESULFONATE

TRADE NAME: Finquel, TRICAINE-S (available from Western Chemical, Inc.)

APPROVED INDICATIONS:
Tricaine methanesulfonate is approved for the temporary immobilization of fish, amphibians, and other aquatic, cold-blooded animals. It has been recognized as a valuable tool for the proper handling of these animals during manual spawning (fish stripping), weighing, measuring, marking, surgical operations, transport, photography, and research.

DOSAGE: 10-1,000 mg/L.

PRECAUTIONS:
May cause skin irritation. May be harmful if absorbed through the skin. May cause eye irritation.
Dust may be irritating to the mucous membranes and upper respiratory tract. May be harmful if inhaled.
May be harmful if swallowed.

CALCULATIONS:
See companion treatment calculator.

PRACTICAL ADMINISTRATION:
Do not use within 21 days of harvesting fish for food.

When used in food fish, use should be restricted to *Ictaluridae*, *Salmonidae*, *Esocidae*, and *Percidae* and water temperature should not exceed 10°C (50°F).

WITHDRAWAL PERIOD:
21 days

REFERENCES:
Material Safety Data Sheets for Finquel and TRICAINE-S
Tricaine methanesulfonate literature related to fish

CLICK HERE TO RETURN TO TABLE

17α-METHYLTESTOSTERONE

TRADE NAME:

17α-Methyltestosterone (administered in feed available from Rangen Inc.)

- Use as an in-feed medication to produce populations comprising over 90% phenotypically male fish

ALLOWABLE USES UNDER INAD #11-236 (USFWS/AADAP):

- Administer 17MT-medicated feed to achieve a dose rate of 9 mg/kg body weight (BW)/d for 28 consecutive days.
- Initiate treatment when fry are ≤10-d old.

  Note: 17MT will typically be top-coated into standard tilapia starter diet at a rate of 60 mg MT/kg.
- Withdrawal period: 120 days for 'Batch Culture' (from last day of treatment).

  ***Note*:** Batch culture is defined as when all fish in a group/lot enter and leave the lot at the same time.
- There is a withdrawal weight of 350 g/individual fish for 'Partial Harvest/Restock Culture'.

  ***Note*:** Partial harvest/restock culture is defined as the mixing of different lots of fish during the grow-out period and selective harvest from the production unit at various times.

REFERENCES:

USFWS INAD Fact Sheet

Material Safety Data Sheet for 17α-Methyltestosterone

FDA Authorization and/or Categorical Exclusion Letters for USFWS INAD

17α-Methyltestosterone literature related to fish

CLICK HERE TO RETURN TO TABLE

BENZOCAINE

TRADE NAME: Benzoak® (available from Frontier Scientific, Inc.)

- Administer as a static bath to sedate fish

ALLOWABLE USE UNDER INAD 11-740 (USFWS INAD):

- BENZOAK® should be added directly to the full-volume of water in the treatment tank. Immediately after the addition of BENZOAK® to the treatment tank, mix thoroughly to ensure uniform distribution of anesthetic. Note: Do not make a concentrated stock of solution of BENZOAK® before actual use.
- Dose to be administered: Benzoak® should be applied at benzocaine concentrations ranging from 10 - 100 mg/L (**note: Benzoak® is 20% benzocaine**). Dosage may vary with respect to species, water temperature, and level of anesthesia desired.
- Dosing interval and repetition: Benzoak® will be applied as a single treatment event, and will not require repeated treatments.
- Duration of treatment: Fish should be immersed in a solution of Benzoak® until the desired endpoint (sedation/anesthesia) is achieved. After completion of treatment and handling, fish should immediately be placed fresh water.
- Withdrawal period: none for fish that will not be catchable for 72 or more hours after release or are illegal for harvest during that 72 hour period. There is no withdrawal period associated with use of BENZOAK® on fish that die that will be buried or rendered into non-edible products.

REFERENCES:

USFWS INAD Fact Sheet
Material Safety Data Sheet for Benzoak®
FDA Authorization and/or Categorical Exclusion Letters for USFWS INAD
Benzocaine literature related to fish

CLICK HERE TO RETURN TO TABLE

CALCEIN

TRADE NAME: SE-MARK® (available from Western Chemical, Inc.)

- Administer as a static immersion bath to mark skeletal tissue of fish

ALLOWABLE USES UNDER INAD 10-987 (USFWS INAD):

- Use one of the following two treatment regimens:
    - Treat with 125 - 250 mg/L (finfish or mussels) for 1-6 hr.
    - Treat with 2.5 – 5.0 g/L (finfish only) for 1 – 7 min note: it is anticipated that most fish treated at this concentration range will need to be pre-treated with a 1-5% solution of non-iodized salt for ~3.5 min to facilitate calcein uptake via osmotic induction.
- Upon completion of treatment, fish or mussels should immediately be moved to fresh water.
- SE-MARK® may be applied as a single treatment event, or as repeated treatments. Repeated treatments may be conducted to establish multiple marks. If a multiple treatment regimen is used, an interval of at least 2 days should be observed between treatment events.
- When exposed to ultraviolet light, calcein exhibits a bright green fluorescence. Optimal fluorescence occurs when calcein is exposed to blue light of ~500 nm wavelength.
- Withdrawal period: none .
- Treatment is restricted to fish weighing $\leq$2 g and juvenile mussels.

REFERENCES:

USFWS INAD Fact Sheet
Material Safety Data Sheet for SE-MARK®
FDA Authorization and/or Categorical Exclusion Letters for USFWS INAD
Calcein literature related to fish

CLICK HERE TO RETURN TO TABLE

CATFISH PITUITARY

TRADE NAME: Channel Catfish Pituitary (available from Hybrid Catfish Company)

- Administer by injection to enhance gamete maturation in a variety of catfish species

ALLOWABLE USES UNDER INAD 11-468 (USFWS INAD):

- CP is obtained as a fresh material by dissection from adult channel catfish (*Ictalurus punctatus*). Whole pituitaries are desiccated using an alcohol/acetone rinse, ground into a powder, and stored in sterile vials containing 1 g of a dessicated brownish/white powder.
- The standard dose rate is 10 mg CP/kg body weight. Although certain situations may require a higher dosage rate, the total dose will never exceed 25 mg CP/kg body weight.
- CP should be dissolved in sterile physiological saline or sterile water and administered as either an intraperitoneal (IP) or intramuscular (IM) injection.
- Dependent upon the species/strain involved, CP may be administered as a single treatment, or as a multiple treatment. It is anticipated that a multiple treatment regimen consisting of a single "priming" dose (2 mg/kg) followed by a single "resolving" dose (8 mg/kg; administered approximately 12-14 hrs later) will be most often used.
- CP treatment has been shown to be most effective when administered during the final stages of gamete maturation. In most cases, CP will be used within 4 weeks of the time fish are normally expected to spawn.
- Withdrawal period: 3-d. Treated fish that are not susceptible to legal harvest for 3 days post-treatment may be released immediately. There is no withdrawal period required for fish from brood stock treated with CP.

REFERENCES:

USFWS INAD Fact Sheet
Material Safety Data Sheet for Catfish Pituitary
FDA Authorization and/or Categorical Exclusion Letters for USFWS INAD
Catfish pituitary literature related to fish

CLICK HERE TO RETURN TO TABLE

CHLORAMINE-T

TRADE NAME:
Halamid® (available from Western Chemical, Inc.)
Actamide (available from B.L. Mitchell, Inc.)

- Administer as a static bath to control mortality caused by bacterial gill disease (BGD) and external flavobacteriosis in a variety of freshwater fish species.

ALLOWABLE USES UNDER INAD 9321 (USFWS INAD):

- To prevent mortality associated with BGD or external flavobacteriosis.
  - Administer 15 mg/L for 60 min one day per week.
- To control mortality associated with BGD or external flavobacteriosis in a variety of salmonid fish species and in certain species of sturgeon, perch, sunfish, bass, and other coolwater and warmwater fish.
  - Administer 10, 15, or 20 mg/L for 60 min in a continuous flow or static bath system on three consecutive or alternate days.
- Withdrawal period: none.

Each facility using chloramine-T under the USFWS INAD must report investigational use to their National Pollution Discharge Elimination System (NPDES) authority and inform them of the effluent discharge limit of 0.1 ppm for this drug. Discharge of concentrations ≥ 0.1 ppm must be in compliance with discharge limits set by the local NPDES permitting agencies.

REFERENCES:
USFWS INAD Fact Sheet
Material Safety Data Sheet for Halamid®
FDA Authorization and/or Categorical Exclusion Letters for USFWS INAD
Chloramine-T literature related to fish

CLICK HERE TO RETURN TO TABLE

COMMON CARP PITUITARY

TRADE NAME: Common Carp Pituitary (available from Stoller Fisheries or Argent Laboratories)

- Administer by injection to enhance gamete maturation in a variety of catfish species

ALLOWABLE USES UNDER INAD 8391 (USFWS INAD):

- CCP is obtained by dissection as a fresh material from adult common carp (*Cyprinus carpio*). Whole pituitaries are desiccated using an alcohol/acetone rinse, ground into a powder, and stored in vials containing 1- 25 g of a desiccated powder.
- Standard dosage rates are 4-10 mg CCP/kg body weight. Although certain situations may require a higher dosage rate, the total dose is not to exceed 25 mg CCP/kg body weight.
- CCP should be dissolved in sterile physiological saline or sterile water and administered as either an intraperitoneal (IP) or intramuscular (IM) injection.
- Depending on the species/strain involved, CCP may be administered as a single or multiple dose treatment. The multiple dose treatment administers a single "priming" dose followed by a single "resolving" dose.
- CCP treatment has been shown to be most effective when administered during the final stages of gamete maturation. In most cases, CCP will be used within 4 weeks of the time fish are normally expected to spawn.
- Withdrawal period: none

REFERENCES:

USFWS INAD Fact Sheet
Material Safety Data Sheet for common carp pituitary
FDA Authorization and/or Categorical Exclusion Letters for USFWS INAD
Common carp pituitary literature related to fish

CLICK HERE TO RETURN TO TABLE

DIQUAT

TRADE NAME: Reward® (available from Syngenta Crop Protection, Inc.)

- Administer as a static bath to control mortality caused by bacterial gill disease (BGD) and external flavobacteriosis in a variety of freshwater fish species.

ALLOWABLE USES UNDER INAD 10-969 (USFWS INAD):

- To control mortality caused by BGD or external columnaris in a variety of freshwater fish species.
  - Administer 2 – 18 mg/L daily on 1, 2, 3, or 4 consecutive or alternate days for 1-4 hr.
  - Administer 19 – 28 mg/L on 1, 2, or 3 consecutive days for 30-60 min.
  - Flush the treatment solution from the rearing unit after treatment.
- Prophylactic (or preventative) treatment **is not authorized**.
- The following withdrawal periods have been established for this product:
  - 5 days – channel catfish, muskellunge, tiger muskellunge, and northern pike.
  - 30 days – all other fish species.
  - Fish that will not be available for harvest (e.g. by recreational angling) until 30 d after treatment may be released immediately after treatment.
- Withdrawal period for channel catfish, muskellunge, tiger muskellunge, and northern pike: 5 days
- Withdrawal period for all other fish species: 30 days.
- Note that REWARD® is 37.3% diquat dibromide.

REFERENCES:

USFWS INAD Fact Sheet
Material Safety Data Sheet for Reward®
FDA Authorization and/or Categorical Exclusion Letters for USFWS INAD
Diquat dibromide literature related to fish

CLICK HERE TO RETURN TO TABLE

EMAMECTIN BENZOATE

TRADE NAME: SLICE® (available from Merck Animal Health[4])

- Use as an in-feed medication to control mortality caused by external parasites (copepods) in a variety of freshwater fish species.

ALLOWABLE USES UNDER INAD 11-370 (USFWS INAD):

- Treatment concentration: 50 µg emamectin benzoate per kg of fish biomass per day in medicated feed.
- Treatment regimen: 7 days (consecutive).
- SLICE® should be administered as a single treatment event, with no repetition of treatment.
- Withdrawal period: 60 days.

REFERENCES:

USFWS INAD Fact Sheet

Material Safety Data Sheet for SLICE®

FDA Authorization and/or Categorical Exclusion Letters for USFWS INAD

SLICE®/emamectin benzoate literature related to fish

CLICK HERE TO RETURN TO TABLE

[4] Formerly Intervet/Schering Plough Animal Health

EUGENOL

TRADE NAME: AQUI-S®20E (available from Western Chemical, Inc.)

- Administer as a static bath to sedate fish

ALLOWABLE USE UNDER INAD 11-741 (USFWS INAD):

- AQUI-S®20E should be added directly to the full-volume of water in the treatment tank. Immediately after the addition of AQUI-S®20E to the treatment tank, mix thoroughly to ensure uniform distribution of anesthetic. Note: Do not make a concentrated stock of solution of AQUI-S®20E before actual use.
- Dose to be administered: AQUI-S®20E should be applied at eugenol concentrations ranging from 10 - 100 mg/L (**note: AQUI-S®20E is 10% eugenol**). Dosage may vary with respect to species, water temperature, and level of anesthesia desired.
- Dosing interval and repetition: AQUI-S®20E will be applied as a single treatment event, and will not require repeated treatments.
- Duration of treatment: Fish should be immersed in a solution of AQUI-S®20E until the desired endpoint (sedation/anesthesia) is achieved. After completion of treatment and handling, fish should immediately be placed fresh water.
- Withdrawal period: none for fish that will not be catchable for 72 or more hours after release or are illegal for harvest during that 72 hour period. There is no withdrawal period associated with use of AQUI-S®20E on fish that die that will be buried or rendered into non-edible products.

REFERENCES:

USFWS INAD Fact Sheet

Material Safety Data Sheet for AQUI-S®20E

FDA Authorization and/or Categorical Exclusion Letters for USFWS INAD

AQUI-S®20E/Eugenol literature related to fish

CLICK HERE TO RETURN TO TABLE

FLORFENICOL

TRADE NAME: Aquaflor® (source of drug: Merck Animal Health)

- Use as an in-feed medication to control mortality caused by caused by bacterial diseases in a variety of freshwater and marine fish.
- Aquaflor® may not be used under an INAD for use patterns for which it has already received FDA-approval (e.g., treatment of ESC in catfish and treatment of coldwater disease or furunculosis in freshwater-reared salmonids (NADA 141-246), and treatment of columnaris in catfish (NADA 141-259).

ALLOWABLE USES UNDER INAD 10-697 (USFWS INAD):

- All fish species – administer a dose rate of 10 or 15 mg florfenicol per kg fish body weight per day for 10 days.
- Use to control mortality associated with:
  - ESC, coldwater disease, and furunculosis (in fish species not listed on the label of the approved product).
  - Other bacterial pathogens (including enteric redmouth, bacterial hemorrhagic septicemia caused by Aeromonads and Pseudomonads, and other gram negative systemic bacteria).
  - When cultured under a variety of rearing or environmental conditions.
- Withdrawal period for salmonids: 21 days.
- Withdrawal period for non-salmonids: 28 days.
- There is no withdrawal period associated with use of Aquaflor® on fish not susceptible to legal harvest.

REFERENCES:

USFWS INAD Fact Sheet

Material Safety Data Sheet for Aquaflor®

FDA Authorization and/or Categorical Exclusion Letters for USFWS INAD

Aquaflor®/florfenicol literature related to fish

CLICK HERE TO RETURN TO TABLE

HYDROGEN PEROXIDE

TRADE NAME: 35% PEROX-AID® (available from Western Chemical, Inc.)

- Administer as a static bath to control mortality caused by ectoparasites in a variety of freshwater and marine fish species.

ALLOWABLE USES UNDER INAD 11-669 (USFWS INAD):

- To control mortality caused by ectoparasites of the genera *Ambiphrya, Chilodonella, Dactylogyrus, Epistylis, Gyrodactylus, Ichthyobodo, Ichthyophthirius, Trichodina,Trichophrya, Argulus*, *Salmincola*, *Lernaea,* and *Ergasilus* in freshwater fish species when treated under a variety of rearing or environmental conditions.
- To control mortality caused by ectoparasites of the genera *Neobenedenia*, *Amyloodinium*, *Cryptocaryon*, and *Uronema* in marine fish species when treated under a variety of rearing or environmental conditions.
- The following treatment regimens may be used when treating freshwater or marine fish species:
    - Administer 100, 150, or 200 mg/L for 30 min once daily on 3 consecutive or alternate days; treatment with 200 mg/L is restricted to situations where the user has demonstrated to the Study Monitor that lower concentrations were ineffective, or where the user intends to test multiple treatment concentrations simultaneously.
    - Administer 50, 75, or 100 mg/L for 60 min once daily on 3 consecutive or alternate days.
- Withdrawal period: none.
- 35% PEROX-AID® contains 35% hydrogen peroxide, w/w.

Each facility using hydrogen peroxide under the USFWS INAD must report investigational use to their National Pollution Discharge Elimination System (NPDES) authority and should inform them of the acute water quality benchmark of 0.7 mg/L hat has been derived by FDA for hydrogen peroxide.

REFERENCES:

USFWS INAD Fact Sheet
Material Safety Data Sheet for 35% PEROX-AID®
FDA Authorization and/or Categorical Exclusion Letters for USFWS INAD
Hydrogen peroxide literature related to fish
Chemical Facility Anti-Terrorism Standards Fact Sheet

CLICK HERE TO RETURN TO TABLE

LHRHa

TRADE NAME: Luteinizing Hormone–Releasing Hormone analogue (available from Western Chemical, Inc.)

- Administer by injection to enhance gamete maturation in a variety of variety of fish species.

ALLOWABLE USES UNDER INAD 8061 (USFWS INAD):

- LHRHa is available in vials containing 1, 5, or 25 mg LHRHa/vial. LHRHa should be diluted with sterile physiological saline immediately prior to intended use.
- Standard hormone dose rates are 5 to 20 µg LHRHa/kg BW. Although higher dose rates may be used, the total dose may not exceed 100 µg/kg BW.
- LHRHa should be dissolved in sterile physiological saline and administered as either an intraperitoneal (IP) or intramuscular (IM) injection. Intraperitoneal injections are typically administered in females whereas IM injections are typically administered in males.
- The LHRHa dose may be administered as a single injection or multiple injections depending on the species or strain treated. Multiple treatment regimens will generally consist of a single "priming" dose followed by a single "resolving" dose.
- LHRHa treatment has been shown to be most effective when administered during the final stages of gamete maturation. In most cases, LHRHa will be used within 4 weeks of the time fish are normally expected to spawn.
- Withdrawal period: 14 days.
- No withdrawal period for fish not susceptible to legal harvest.

REFERENCES:

USFWS INAD Fact Sheet
Material Safety Data Sheet for LHRHa
FDA Authorization and/or Categorical Exclusion Letters for USFWS INAD
LHRHa literature related to fish

CLICK HERE TO RETURN TO TABLE

OXYTETRACYCLINE DIHYDRATE
Medicated feed therapy

TRADE NAME: Terramycin® 200 for Fish (source of drug: Phibro Animal Health)

- Use as an in-feed medication to control mortality caused by caused by bacterial diseases in a variety of freshwater and marine fish and abalone.
- Terramycin® 200 for Fish may not be used under an INAD for use patterns for which it has already received FDA-CVM approval. For more information, see NADA 038-439.

ALLOWABLE USES UNDER INAD 9332 (USFWS INAD):

- Salmonids – administer in medicated feed at a dose rate of 55 to 88 mg/kg BW/d for 10 consecutive days to control mortality associated with Gram negative pathogens.
  - There is a 21 d withdrawal period associated with use of this product at this dosage.
- Freshwater and marine fish species – administer in medicated feed at a dose rate of 220 mg/kg BW/d for 14 consecutive days to control susceptible Gram negative pathogens in fish reared in water temperatures exceeding 4°C.
  - Treatment may not be administered to fish in net pens.
  - Withdrawal period: 70 days.
- Non-salmonid freshwater and marine fish species – use at the standard dosage for the control of mortality caused by a variety of bacterial pathogens sensitive to oxytetracycline.
  - Treatment may not be administered to fish in net pens.
  - Withdrawal period: 40 days.
- Abalone – use at a dosage up to 6.0 g active drug per 100 lbs body weight per day for 14 days to control mortality caused by withering syndrome.
  - Withdrawal period: 35 days.
- Freshwater and marine fish species – use at a dosage of either 2.5 – 3.75 or 10.0 grams of active drug per 100 pounds of fish per day for 14 days to mark skeletal tissue in a variety of freshwater and marine fish species.
  - Withdrawal period: 21 days for salmonids.
  - Withdrawal period: 40 days for non-salmonids.
  - Withdrawal period (at the high dose): 70 days.
- No withdrawal period is required for fish or abalone that will not be catchable/harvested during the established withdrawal after release or are illegal for harvest.
- Note that Terramycin® 200 for Fish contains 200 g oxytetracycline (from oxytetracycline dihydrate) per pound of Type A Medicated Article.

REFERENCES:

USFWS INAD Fact Sheet
Material Safety Data Sheet for Terramycin® 200 for Fish
FDA Authorization and/or Categorical Exclusion Letters for USFWS INAD
Terramycin® 200 for Fish/oxytetracycline literature related to fish

CLICK HERE TO RETURN TO TABLE

OXYTETRACYCLINE HYDROCHLORIDE
for immersion therapy

TRADE NAME: Pennox® 343 (source of drug: PennField Animal Health)

- Administer as a static bath to control mortality caused by bacterial diseases in a variety of freshwater and marine fish species.

ALLOWABLE USES UNDER INAD 9033 (USFWS INAD):

- Salmonids – administer at a dosage of 20 mg/L for 1 h as a single administration to control mortality associated with furunculosis, bacterial hemorrhagic septicemia, enteric redmouth, flexibacteriosis, and vibriosis.
    - Withdrawal period: 21 days.
- Salmonids – administer at a dosage of 20 mg/L for 1 h once daily for 1 to 4 consecutive days to control mortality associated with furunculosis, bacterial hemorrhagic septicemia, enteric redmouth, flexibacteriosis, and vibriosis.
    - Withdrawal period: 60 days.
- Catfish - administer at a dosage of 20 mg/L for 1 h as a single administration to control mortality associated with enteric septicemia.
    - Withdrawal period: 21 days.
- Catfish, sturgeon, temperate bass, and other cool and warmwater fish species listed in USFWS INAD 9033 – administer at a dosage of 20 mg/L for 1 h as a single administration to control mortality associated with bacterial hemorrhagic septicemia, pseudomonas disease, and flexibacteriosis.
    - Withdrawal period: 21 days.
- Catfish, sturgeon, temperate bass, and other cool and warmwater fish species listed in USFWS INAD 9033 – administer at a dosage of 20 mg/L for 1 h once daily for 1 to 4 consecutive days to control mortality associated with enteric septicemia in catfish, and bacterial hemorrhagic septicemia, pseudomonas disease, and flexibacteriosis.
    - Withdrawal period: 60 days.

REFERENCES:

USFWS INAD Fact Sheet
Material Safety Data Sheet for Pennox® 343
FDA Authorization and/or Categorical Exclusion Letters for USFWS INAD
Pennox® 343/oxytetracycline hydrochloride literature related to fish

CLICK HERE TO RETURN TO TABLE

SALMON GONADOTROPIN RELEASING HORMONE ANALOGUE

TRADE NAME:
Ovaplant® Salmon Gonadotropin – Releasing Hormone analogue (available from Western Chemical, Inc.; Manufacturer - Syndel International Inc.)

- Administer as a pellet implant in a variety of fish species.

ALLOWABLE USES UNDER INAD 11-375 (USFWS INAD):

- sGnRHa (Ovaplant®) is available in pellets containing 75, 150, or 250 µg sGnRH per pellet. Forty to 60% of the sGnRH is putatively released within 24 hours with the remainder released over the next 7 to 21 days.
- Standard hormone dosage rates will be 10-75 µg /kg body weight. Although certain situations involving very small broodfish (e.g. fish less than 1 kg BW) may require a higher dosage rate, dosage will never exceed 150 µg /kg body weight. Investigators should use the following guidelines as proposed by Syndel International Inc.:
    - Ovaplant® 75 µg - For fish 1 kg to 8 kg.
    - Ovaplant® 150 µg - For fish 8 kg to 15 kg.
    - Ovaplant® 250 µg - For fish 15 kg to 20 kg.
- sGnRHa should be injected into the dorsal musculature using a Ralgun® or other similar injection device. Injections should be administered into the musculature immediately anterior and lateral (on either side) to the dorsal fin.
- sGnRHa will be administered as single treatment event only.
- sGnRHa treatment has been shown to be most effective when administered during the final stages of gamete maturation. In most cases, sGnRHa will be used within 4 weeks of the time fish are normally expected to spawn.
- Withdrawal period: Treated fish may not be released (all treated fish must be maintained indefinitely or destroyed).

REFERENCES:
USFWS INAD Fact Sheet
Material Safety Data Sheet for Ovaplant®
FDA Authorization and/or Categorical Exclusion Letters for USFWS INAD
sGnRHa literature related to fish

CLICK HERE TO RETURN TO TABLE

COPPER SULFATE

TRADE NAME: Triangle Brand® Copper Sulfate (available from Freeport-McMoran Copper & Gold, Inc.)

- Administer as a static bath to control Ichthyophthiriasis (Ich) on catfish and mortality associated with Saprolegniasis on catfish eggs.

ALLOWABLE USES UNDER INAD# 9101 (USFWS)**, 10046 (Freeport-McMoran) and/or 11401 (USDA-ARS):**

- Administer by immersion in standing bath or flow-through treatment to control external parasites, bacteria, and fungi
- Variable treatment concentrations (dependent on total alkalinity) can be used to control external protozocan and metazoan parasites, and bacterial and fungal infections in a variety of warmwater fish species.
- Although a single treatment event is general efficacious, repeated treatments may be used.
- Withdrawal period: 7 days, though no withdrawal period is required for fish that are not susceptible to legal harvest for a period of 7 days post-treatment.
- For the treatment of ichthyophthiriasis (*Ichthyophthirius multifiliis*) on Ictalurid catfish cultured in earthen ponds.
    - Administer 0.4 to 1 mg/L per 100 mg/L total alkalinity (as $CaCO_3$) as an indefinite exposure once daily for 5 to 11 consecutive days.
- To control mortality associated with Saprolegniasis on channel catfish eggs.
    - Administer 10 mg/L to the water of a flow-through hatching trough once daily until the embryos (eggs) develop eyes; flow rate should allow for 1 exchange every 30 minutes.

If total alkalinity is less than 50 mg/L, Copper Sulfate treatments are not recommended. If total alkalinity is over 300 mg/L, no more than 3 mg/L Copper Sulfate should be used. Copper Sulfate may be very toxic to fish in soft or acid waters so preliminary testing is necessary. Copper Sulfate should be tested on a small batch of fish in a sample of the pond water before treating the entire population of fish. This product should only be used in earthen catfish ponds. Application of Copper Sulfate to catfish ponds may cause short-term reductions in the populations of aquatic invertebrates, plants and algae residing within these ponds. Dissolved oxygen may be depleted due to decaying material so careful monitoring of dissolved oxygen is recommended and supplemental aeration may be required to maintain satisfactory oxygen levels. If there is a heavy algal bloom or no aeration, Copper Sulfate treatments are not recommended since treatment could cause oxygen concentrations to drop and result in fish kills.

The concentration of free copper ions may be affected by water quality parameters such as alkalinity, dissolved solids, temperature, pH, and hardness. For instance, water with low dissolved solids may have a higher concentration of free copper than water with high dissolved solids; a higher concentration of free copper can increase toxicity. Do not discharge pond water for at least 72 hours after the final Copper Sulfate application in order to avoid causing toxicity to aquatic life in receiving waters. When completely draining a pond, the last 20-25% of pond volume should be released slowly to prevent possible resuspension of sediment with elevated copper concentrations. Drains on empty ponds that have previously been treated with Copper Sulfate should be closed to prevent erosion and sediment discharge. Sediments removed from ponds during cleaning should be used to repair earthwork and embankments, or should be disposed of in a manner that will prevent copper contamination of surface or ground water.

REFERENCES:

USFWS INAD Fact Sheet
Material Safety Data Sheet for Triangle Brand® copper sulfate pentahydrate
Copper Sulfate literature related to fish

CLICK HERE TO RETURN TO TEXT

CLICK HERE TO RETURN TO TABLE

POTASSIUM PERMANGANATE

TRADE NAME: CAIROX® Potassium Permanganate (available from Carus Corporation)

- Administer as a static bath to control external protozoan and metazoan parasites, and bacterial and fungal infections in a variety of warmwater fish species.

ALLOWABLE USES UNDER INAD 9246 (USFWS)**, 10223 (Carus Corporation) and 10298 (USDA-ARS):**

- Use at a dosage of 1 - 10 mg/L for 1 hour. Although a single treatment event is generally efficacious, repeated treatments may be used.
- Withdrawal period: none for fish that are not susceptible to legal harvest for a period of 7 days post treatment associated with use of Cairox® Potassium Permanganate.

CALCULATIONS:

1. Calculate the 15-min potassium permanganate ($KMnO_4$) demand (PPD) of the rearing unit (see "The Use of Potassium Permanganate in Fish Ponds").

2. Multiply the PPD by 2.5 to obtain the treatment rate (mg/L). Treatment rates determined in this way very closely estimate the concentration of active $KMnO_4$ needed for effective disease treatment; however, the chemical should be applied in increments of 2 - 4 mg/L to avoid too-high short-term concentrations. The maximum treatment rate is not to exceed 10 mg/L.

3. Administer treatment for 1-h in a static-bath or flow-through system.

REFERENCES:

USFWS INAD Fact Sheet
Material Safety Data Sheet for Cairox®
Potassium permanganate literature related to fish
Chemical Facility Anti-Terrorism Standards Fact Sheet

CLICK HERE TO RETURN TO TEXT

CLICK HERE TO RETURN TO TABLE

IODINE

TRADE NAME: Ovadine® (available from Western Chemical, Inc.)

INDICATIONS:
Iodine is not an FDA approved drug. Iodine is on the Low Regulatory Priority Aquaculture Drugs list. The guideline for iodine use is to surface disinfect salmonid eggs is a 100 ppm iodophor solution for 10 minutes as an egg surface disinfectant during and after water hardening.

PRECAUTIONS:
Eye irritant

CALCULATIONS:

	Desired Available Iodine Concentration *100 ppm (1:100 dilution)*
Per Liter of Water	10 mL Iodine
Per Gallon Water	37.8 mL Iodine
	1.28 oz Iodine

PRACTICAL ADMINISTRATION:

Immerse eggs in a solution of 100 PPM available Iodine for 10 minutes.

Rinse eggs with clean water after treatment.

Iodine is non-toxic to green, fertilized and eyed eggs at the recommended application concentration.

REFERENCES:
Material Safety Data Sheet for Ovadine®
Iodine literature related to fish

CLICK HERE TO RETURN TO TABLE

GLOSSARY

ACRONYMS

AADAP:	Aquatic Animal Drug Approval Partnership
AFS:	American Fisheries Society
APHIS:	Animal and Plant Health Inspection Service
BMP:	Best Management Practice
BW:	Body Weight
CVB:	Center for Veterinary Biologics, FDA
CVM:	Center for Veterinary Medicine, FDA
EPA:	Environmental Protection Agency
FCS:	Fish Culture Section
FDA:	Food and Drug Administration
FFDCA:	Federal Food, Drug, and Cosmetic Act
FIFRA:	Federal Insecticide, Fungicide, and Rodenticide Act
GRAE:	General Recognized As Effective
GRAS:	Generally Recognized As Safe
INAD:	Investigational New Animal Drug
MSDS:	Material Safety Data Sheet
NADA:	New Animal Drug Application
NPIRS:	National Pesticide Information Retrieval System
PPLS:	Pesticide Product Label System
USDA:	U.S. Department of Agriculture
USFWS:	U.S. Fish and Wildlife Service
VFD:	Veterinary Feed Directive
WGADCB:	Working Group on Aquaculture Drugs, Chemicals, and Biologics

TERMS

Active ingredient:	In a drug product, the ingredient responsible for the intended effect of the product (e.g., florfenicol is the active ingredient in Aquaflor®). In a disinfectant or pesticide product, the component that kills or otherwise controls the target pest.
Algicide:	Pesticide that selectively kills or targets algae.
Autogenous vaccine/bacterin:	Biologics prepared from microorganisms which have been freshly isolated from a fish. Autogenous vaccines or bacterins are administered to a population of fish at the same facility to increase resistance to the specific pathogen strain found at that location. Note such biologics can only be sold and used only on the facility from where the source pathogen was isolated, for a limited, specified period of time, and under the supervision of a licensed veterinarian.
Bacterin:	Biologics used to increase the natural ability of fish to resist disease caused by a specific pathogen. Bacterins contain inactivated cultures of bacteria or other nonviral organisms.
Best Management Practices:	Fish culture and husbandry practices that strive to ensure optimal animal health, growth and production, and economic performance.

Certified pesticide applicator:	A person who has successfully completed a state Pesticide Certification Program and is therefore authorized to purchase, apply, and supervise others using restricted use pesticides.
Contact herbicide:	Herbicide that kills only those portions of a plant to which it is directly applied.
Deferred Regulatory Status drug:	Unapproved new animal drug for which FDA has a policy of regulatory discretion that allows certain uses of such a drug without an approval by FDA or INAD exemption.
Drug:	An article that is intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animal; an article (other than food) intended to affect the structure or function of the body of man or other animal; or an article that is recognized in official drug compendia.
Drug sponsor:	An individual or company seeking FDA approval of a drug product. Sponsor must be a U.S. individual or company (or a U.S. subsidiary of a foreign company), and must submit the New Animal Drug Application to the FDA.
Extra-label use:	The use of an approved new animal drug in a manner that is not in accordance with the approved label directions. Such use is permitted only via a prescription by a licensed veterinarian in the context of a valid veterinarian-patient-client relationship.
Herbicide:	Pesticide that selectively kills or targets plants.
INAD exemption (compassionate):	An INAD exemption that allows producers to use an unapproved drug under certain conditions for purposes related to the health and well-being of an animal. Use of an INAD under a compassionate exemption must be done under a “Use Protocol” accepted by the FDA Center for Veterinary Medicine. Annual reporting to FDA is required to continue to use an INAD under a compassionate exemption.
INAD exemption (standard):	Exemption authorized under the Federal Food, Drug, and Cosmetic Act to permit the interstate shipment of new animal drugs that have not yet been approved by FDA and limits the distribution of such drugs for the purpose of conducting an INAD field trial to evaluate the safety and effectiveness of the drug. Standard INAD exemptions are typically sought by pharmaceutical or chemical companies and are granted by the FDA Center for Veterinary Medicine.
INAD field trial:	Trials conducted under a compassionate INAD exemption following procedures described in a “Use Protocol” developed for that drug. INAD investigators are required to collect data to demonstrate the safety and effectiveness of an INAD in support of a new animal drug approval.
Low Regulatory Priority drug:	Unapproved new animal drug for which FDA has a policy of regulatory discretion that allows the use of such a drug without an approval by FDA or INAD exemption.

New Animal Drug:	Any drug intended for the use in animals other than people, the composition of which is not generally recognized among experts qualified by scientific training and experience as safe and effective for use under the conditions described on the label.
New Animal Drug Application:	An application package submitted to FDA that requests the approval of a new animal drug. The application includes data to substantially demonstrate that the drug is safe to humans, the environment, the target animal (fish), is as effective as claimed, and can be manufactured and packaged according to FDA guidelines.
Non-target organisms:	Organisms exposed to and potentially affected by regulated products other than the organisms for which treatment was intended.
Over-the-counter drug:	Drugs that are permitted to be sold without a veterinary prescription.
Pest:	An organism (commonly insects, rodents, and weeds) that is considered to be an annoyance and may be injurious to health or to the environment.
Pesticide:	Any substance intending for preventing, destroying, repelling, or mitigating any pest, including plants.
Prescription drug:	An animal drug that must be prescribed by a licensed veterinarian. Labels of such drugs bear the statement "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian."
Registration:	Under the Federal Insecticide, Fungicide, and Rodenticide Act, the formal listing with EPA of a new pesticide active ingredient prior to its marketing or distribution.
Regulated product:	Products such as drugs, biologics, pesticides, and disinfectants that may be used in aquaculture, but only according to allowed uses stipulated by federal, state, and other applicable rules and regulations.
Restricted use pesticide:	A registered pesticide that has been classified for restricted use under the Federal Insecticide, Fungicide, and Rodenticide Act for some or all of it applications due to its toxicity and special handling requirements. Restricted use pesticides may only be applied by trained, certified applicators or by individuals under their direct supervision and may be utilized only for those uses covered by the certified applicator's certification.
Target organism:	The organism for which regulated product treatment is intended.
Tissue Residue:	The amount of a compound or its metabolites remaining in edible tissue after exposure to a regulated product.
Translocated herbicide:	Also referred to as systemic herbicides, these herbicides are absorbed and transported through plant tissues and can therefore kill the target following application to any part of the plant.
Vaccine:	Biologics containing living organisms used to increase the natural ability of fish to resist disease caused by a specific pathogen.

Veterinary biologics:	All viruses, toxins, and analogous products of natural or synthetic origin, such as diagnostics, antitoxins, vaccines, and live microorganisms intended for use in the diagnosis, treatment, or prevention of diseases of animals.
Veterinary-client-patient relationship:	Exists when (a) the veterinarian has assumed responsibility for making medical judgments regarding the health of the animals and the need for medical treatment, and client has agreed to follow the instructions of the veterinarian, (b) there is sufficient knowledge of the animals by the veterinarian to initiate at least a general or preliminary diagnosis of the medical condition of the animals, and (c) the veterinarian is readily available for follow-up in case of adverse reactions or failure of treatment.
Veterinary feed directive:	A written statement that authorizes the owner or caretaker of animals to obtain and use animal feed containing VFD drugs to treat their animals in accordance with the FDA-approved directions for use. A VFD drug is a new animal drug approved under the Federal Food, Drug, and Cosmetic Act. VFD drugs are limited to use under the professional supervision of a licensed veterinarian. No extra-label uses of VFD drugs are permitted.
Withdrawal time:	The minimum required period of time between the last treatment of an animal and the slaughter or release of that animal.

Do you raise fish?

Do you use formalin, hydrogen peroxide, potassium permanganate, or other chemicals?

You may be subject to Department of Homeland Security Chemical Facility Anti-Terrorism Standards

What is CFATS? Responsibility for chemical security is shared among federal, state, and local governments, as well as the private sector. Chemical Facility Anti-Terrorism Standards (CFATS) were developed by the Department of Homeland Security (DHS) to allow for cooperative monitoring and control of various chemicals that present one or more security issues if released, stolen or diverted, or could be used for purposes of sabotage or intentional contamination.

Who is subject to CFATS? The Department of Homeland Security has issued CFATS for any facility that manufactures, uses, stores, or distributes certain chemicals at or above a specified quantity. **This includes aquaculture facilities that use or store these chemicals of interest.**

What are the chemicals of interest? DHS has identified more than 200 chemicals of interest (http://www.dhs.gov/xlibrary/assets/chemsec_appendixa-chemicalofinterestlist.pdf). Chemical use patterns will vary, and each facility is responsible for evaluating their own chemical use patterns and determining which are subject to CFATS. However, the chemicals of interest most likely to be found at aquaculture facilities are:

Formalin/Formaldehyde Solution--subject to CFATS if ≥1% solution and ≥15,000 lbs. stored
Hydrogen Peroxide—subject to CFATS if ≥35% solution and ≥400 lbs. stored
Potassium Permanganate—subject to CFATS if commercial grade and ≥400 lbs. stored

What should I do if I think my facility is subject to CFATS? If you use or store any of the chemicals of interest in volumes above the CFATS thresholds, you must register to access the Chemical Security Assessment Tool (http://www.dhs.gov/files/programs/gc_1169501486197.shtm). Once you are registered, complete a Top-Screen preliminary assessment to determine risks at your facility. Depending on the level of risk associated with your facility's chemical use patterns, you may be required to complete a Security Vulnerability Assessment and you may need to develop a Site Security Plan. These added steps are only necessary for those facilities determined to be high-risk by DHS.

You may already be doing everything necessary to prevent misuse of chemicals at your facility, but it is your responsibility to be sure and report what you are doing.

Don't let your chemicals be their next weapon!

For More Information:
Contact the CFATS help desk at CSAT@DHS.GOV
Call 1-866-323-2957
Visit www.dhs.gov/chemicalsecurity