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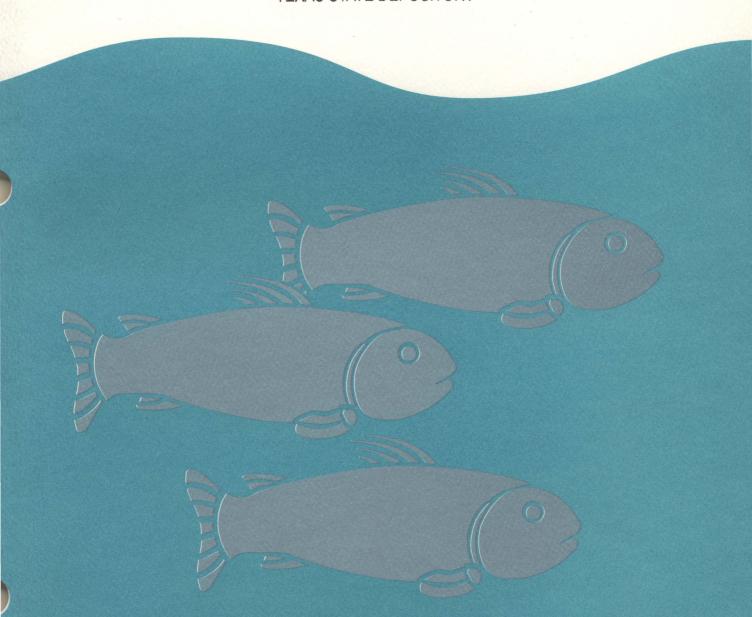
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Guide to Drug, Vaccine, and Pesticide Use in Aquaculture

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August 1994

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Guide to Drug, Vaccine, and Pesticide Use in Aquaculture

Prepared by the Federal Joint Subcommittee on Aquaculture, Working Group on Quality Assurance in Aquaculture Production, in cooperation with the Extension Service, U.S. Department of Agriculture

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Preface

The *Guide to Drug, Vaccine, and Pesticide Use in Aquaculture* has been prepared by the Working Group on Quality Assurance in Aquaculture Production, which was established by the Federal Joint Subcommittee on Aquaculture in November 1990. This publication provides current information on federally regulated drugs, vaccines, and pesticides in aquaculture production and in aquatic sites. Sources of additional information and assistance are also presented.

The Working Group on Quality Assurance in Aquaculture Production provides a national forum for addressing drug, biologic, and pesticide use in aquaculture through education and the coordination of related efforts in government, industry, and academia. The Working Group, chaired by Gary Stefan of the Center for Veterinary Medicine, Food and Drug Administration (FDA), is composed of representatives of the following agencies and organizations:

Federal and State Agencies

National Association of State Aquaculture Coordinators State Departments of Wildlife and Fisheries

U.S. Department of Agriculture

Animal and Plant Health Inspection Service

Cooperative State Research Service

Extension Service

Food Safety and Inspection Service

National Agricultural Library

U.S. Department of Health and Human Services

Food and Drug Administration

Center for Food Safety and Applied Nutrition

Center for Veterinary Medicine

U.S. Department of the Interior

Fish and Wildlife Service

National Biological Survey

U.S. Environmental Protection Agency

Trade, Industry, Professional, and Private Organizations

American Feed Industry Association

American Fisheries Society

Fish Culture Section

Fish Health Section

American Tilapia Association

American Veterinary Medical Association

Animal Health Institute

Atlantic Coast Shellfish Producers Association

Baitfish Industry

Catfish Farmers of America

Florida Tropical Fish Farms Association

Louisiana Crawfish Farmers Association

Maine Aquaculture Association

Marine Shrimp Industry

National Aquaculture Association

National Aquaculture Council

National Ornamental Goldfish Growers Association, Inc.

Pacific Coast Oyster Growers Association

Striped Bass Growers Association

U.S. Trout Farmers Association

Washington Fish Growers Association

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American Feed Industry Association

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American Tilapia Association
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Animal and Plant Health Inspection Service
Cooperative State Research Service
Extension Service
U.S. Department of Health and Human Services

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition
Center for Veterinary Medicine

U.S. Department of the Interior Fish and Wildlife Service

U.S. Trout Farmers Association

Special appreciation is expressed to Gary Jensen, USDA Extension Service, and Wendell Lorio, Louisiana Cooperative Extension Service, for compiling the *Guide*. The assistance of the following individuals in providing information and obtaining agency approvals and clearances is also acknowledged: Antonio Bravo, Environmental Protection Agency (EPA); Althaea Langston, USDA Animal and Plant Health Inspection Service; Gary Stefan, FDA Center for Veterinary Medicine; and Kim Young, FDA Center for Food Safety and Applied Nutrition. Rosalie Schnick, U.S. National Biological Survey, contributed valuable comments and suggestions. Marjorie Harter, editorial consultant; Frances Gould, Louisiana Cooperative Extension Service; and Tracy Martin, USDA Extension Service are acknowledged for their efforts in the development of the *Guide*.

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Introduction

The aquaculture industry in the United States has grown considerably in recent years and is now recognized as a significant supplier of food products for U.S. consumers. Aquaculture also provides aquatic stocks for recreational fishing, the restoration of threatened and endangered species, and wild stock enhancement, as well as for the bait, aquarium, and ornamental fish trades. In order to ensure the safety of aquatic food products, the integrity of the environment, the safety of target animals, and the safety of persons who administer various compounds, it is critical that all regulated aquaculture products be used correctly and responsibly.

Another important consideration is the implementation of aquacultural quality assurance programs. These industry-developed and driven programs are essential for U.S. producers and the entire U.S. aquaculture industry, regardless of type of system, location, size of operation, and species grown. Private and public aquacultural producers should use best management practices to provide consumers with safe, wholesome food products and to minimize the use of federally regulated products.

On some occasions, various drugs, disinfectants, pesticides, and veterinary biologics are needed to ensure the health, productivity, and well-being of cultured aquatic stocks and to maintain production efficiency. These regulated products must be used in such a manner as to avoid risks to public safety and animal health as well as potential loss of consumer trust.



It is the responsibility of everyone using, prescribing, and/or recommending the use of regulated products to know which products legally can be used under federal, state, and local regulations. Regulated-product uses may vary with different sites, life stages, and conditions.

This *Guide* presents information that can assist U.S. aquacultural producers in providing high-quality, wholesome products. Information is included on drugs, pesticides, vaccines, and other veterinary biologics that currently may be used in commercial or noncommercial aquacultural production.

The reader is encouraged to note the information presented in the Appendixes. Appendix A is concerned with FDA-regulated drugs for use in aquaculture. In Appendix B, EPA-registered pesticides for aquaculture and aquatic sites are listed. USDA-licensed biologics for fish are presented in Appendix C. Readers may find the glossary of common terms listed in Appendix D a handy reference. For sources of further information and assistance, see Appendix E. Appendix F lists sponsors, registrants, licensees, and permittees for the federally regulated products included in the *Guide*.

Although food additives and color additives are used in aquaculture, they are not the focus of this publication. More information on these products may be obtained by contacting governmental agencies or other sources of assistance listed in Appendix E.

Electronic Access

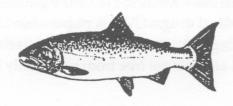
The guide can be accessed electronically via Internet using the Aquaculture Network Information Center (AquaNIC) of the Purdue Cooperative Extension Service and the Purdue University libraries. For details, contact AquaNIC at 317/494-6264 (telephone); 317/494-9347 (fax); or lswann@hub.ansc.purdue.edu (Internet e-mail).

Updating the Guide

New information on the regulatory status of products listed in the *Guide* will be provided biennially. To facilitate the updating process, it is suggested that this publication be bound in a three-ring binder.

As updated information becomes available, replacement pages will be distributed. Each new page should be inserted into the binder to replace the former one. The date of each original page appears just above the page number. Replacement pages will also be dated appropriately.

The electronic version of the *Guide* will be updated as changes occur. Individuals wishing updates on specific products may also contact the Food Animal Residue Avoidance Databank (FARAD) Regional Access Centers listed in Appendix E.



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Regulatory Agencies

Several federal and state agencies are involved in regulating the aquacultural use of drugs, vaccines, pesticides, and other products. Each federal agency has specific responsibilities, mandated by Congress, to regulate the products under its respective jurisdiction.

U.S. Food and Drug Administration

The Food and Drug Administration is responsible for ensuring the safety, wholesomeness, and proper labeling of food products; ensuring the safety and effectiveness of human and animal drugs; and protecting consumers from economic fraud. The Federal Food, Drug, and Cosmetic Act (FFDCA), the basic food and drug law of the United States, includes provisions for regulating the manufacture, distribution, and use of new animal drugs and animal feed. This law applies to public agencies and organizations as well as to private industry.

FDA's regulatory programs are intended to ensure compliance with existing laws. Enforcement activities include actions to correct and prevent violations, remove illegal products or goods from the market, and punish offenders. The testing of domestic and imported aquacultural products for drug and pesticide residues is part of these enforcement activities. The range of enforcement action includes warning letters, seizures, injunctions, and criminal prosecution. FDA's field offices are responsible for initiating and recommending regulatory action. These field offices use guidance provided by FDA headquarters, including the various FDA Centers, to determine whether violations have occurred and, if so, what enforcement action is warranted.

Center for Veterinary Medicine

FDA's 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 are safe and effective and that food products derived from treated animals are free from potentially harmful residues.

CVM approves new animal drugs based on data provided by a sponsor (usually a drug company). To be approved, an animal drug must be effective for the claim on the label and safe when used as directed for (1) treated animals; (2) persons administering treatment; (3) the environment, including nontarget organisms; and (4) consumers. CVM establishes tolerances and withdrawal periods as needed for all drugs approved for use in food-producing animals. CVM has the authority to grant investigational new animal drug (INAD) exemptions so that data can be generated to support the approval of a new animal drug.

Center for Food Safety and Applied Nutrition

FDA's Center for Food Safety and Applied Nutrition (CFSAN) conducts research on and develops standards for the composition, quality, nutrition, labeling, and safety of food, food additives, and color additives. The Center's responsibilities include domestic and imported seafood inspection and the development of seafood policies, standards, and programs, along with seafood research and educational activities. One ongoing program involves the annual pesticide and contaminant sampling of food items, including domestic and imported aquacultural products. CFSAN also reviews and approves industry petitions for the safe use of food and color additives. The Center's Office of Seafood has proposed mandatory seafood inspection regulations for the nation's seafood processors and seafood importers based on Hazard Analysis Critical Control Points (HACCP) principles. This is important for producers because the first critical control point is the quality of the raw product.

U.S. Environmental Protection Agency

The Environmental Protection Agency is responsible for registering or licensing all pesticides used in the United States under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). FIFRA requires that EPA register pesticides for specific uses, provided that the use does not pose an unreasonable risk to human health or the environment. Any pesticide sold or distributed in the United States must be registered by EPA. Places or establishments where pesticides are produced or formulated are also subject to registration.

In addition, EPA sets tolerances or maximum legal limits for pesticide residues in food commodities and animal feed under the Federal Food, Drug, and Cosmetic Act. The purpose of the tolerance program is to ensure that consumers are not exposed to harmful pesticide residues in food.

EPA is required by law to reregister those pesticides registered prior to 1984 in order to reflect changing registration standards that are critical to the protection of human health and the environment. Products regarded as pesticides include algicides, disinfectants, fish toxicants, and herbicides.

Animal and Plant Health Inspection Service

The Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture regulates all veterinary biologics produced in, shipped into, or exported from the United States. This includes vaccines, nondrug biological therapeutants, and test kits for the diagnosis of disease.

It is unlawful to prepare, sell, barter, or exchange worthless, contaminated, dangerous, or harmful veterinary biologics or to ship unlicensed veterinary biologics for experimental use in animals.

States may impose additional requirements on the use of veterinary biologics. For example, APHIS requires that conditional state approval for distribution of products be obtained before APHIS authorizes field trials with experimental products or before a conditionally licensed product is marketed in the state.



An extensive inspection program involves the monitoring of manufacturing site activities; the testing and release of product batches; and the monitoring of veterinary biologics after licensing to ensure that they are pure, safe, potent, and effective. Every batch of a product produced in the United States or offered for importation is tested by the manufacturer. In addition, samples are sent to APHIS, and each batch is subject to general and/or specific testing by APHIS to ensure that high quality is maintained.

Interagency Jurisdiction

FDA and EPA have some areas of mutual regulatory responsibility. A memorandum of understanding sets forth the responsibilities of each agency under FFDCA and FIFRA. The memorandum also provides guidance in the area of aquaculture, particularly as to which agency has jurisdiction over a particular substance for its intended use.

EPA has jurisdiction over disinfectants, sanitizers, and aquatic treatments used solely for the control of algae or bacterial slime and over any other aquatic treatments used solely for pest control that do not include claims for control of parasites or diseases of fish. EPA or a delegated state regulatory agency also regulates the National Pollutant Discharge Elimination System (NPDES) permit, which allows the discharge of drugs or pesticides into receiving waters.

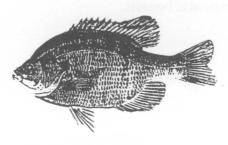
FDA has jurisdiction over new animal drugs, including products intended to treat or prevent parasites or diseases of fish, anesthetize aquatic species, and alter the sex or regulate the reproduction of aquatic species. FDA has taken the position that if a pesticide registered by EPA for aquaculture or aquatic site use is being used properly (i.e., the labeled conditions in fact exist in the facility or site at the time the pesticide is used, and the compound is not misused under FIFRA), FDA will not object to that proper use even though the pesticide may have a secondary therapeutic benefit.

State Regulatory Agencies

State Departments of Agriculture or other designated state agencies may also register federally approved pesticides to permit their legal distribution and sale within a state or territory. States may have additional regulatory requirements, including additional data and/or additional restrictions on use and licensing. These requirements can affect the distribution and use of pesticides that are purchased from a distributor in one state for intended use in another. States can also issue Experimental Use Permits for a pesticide with an EPA-approved state plan and can provide registration for additional uses of federally registered pesticides to meet special local needs.

Some states license or impose additional regulations on the use of certain veterinary biologics. Some states may not allow the use of specific products or may require that they be administered only by licensed veterinarians. States also participate in the approval of field trials of veterinary biologics in their respective jurisdictions and in the experimental use of certain veterinary biologics.

The use of a drug under an investigational new animal drug (INAD) exemption may require approval by a state agency to comply with any local, state, and/or regional EPA discharge regulations. Discharge approval is intended to ensure that the possible impacts of a discharge (effluent) containing a specific compound or its residues are addressed.



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Use of Federally Regulated Products

The proper use of regulated products in aquacultural production, handling, and processing promotes human, target organism, and environmental safety; ensures to the greatest extent possible the effectiveness of the products used; reduces overuse, expense, and possible undesirable side effects; and prevents illegal residues in edible products available for human consumption. Food safety and quality are critical factors that influence the long-term development and economic competitiveness of all food production.

Public perception of the safety of food is also very important. Through the proper use of regulated products, the U.S. aquaculture industry can benefit while ensuring public trust and consumer confidence in the safety of U.S. aquacultural products in domestic and international markets.

Safety Considerations

Producers need to establish systems and adopt controls in production and processing that ensure the proper use of regulated products. Producers should evaluate the need for the products carefully and should use them on a schedule to maximize product effectiveness and minimize the amount of the product used. They should also keep detailed chronological records of treatment and of the amounts of the product used.

Users should not mix different regulated products unless this is specifically recommended on the product label. Combining products can have many—mostly undesirable—effects. One or both products can be inactivated, and chemical reactions can produce harmful gases or other reaction products and by-products—some of them toxic.

Applicators and persons near treatment areas can be affected by various regulated products through contact, exposure to evaporated material in the air, or exposure to dusts or aerosols. Treated waters or airborne drift can carry

restricted products to distant locations, where the products may affect nontarget organisms and sites.

Accidental self-injection of some veterinary biologics and injectable drugs can cause local tissue reactions, allergic reactions, or infections. Use of common sense and strict compliance with product label directions can minimize undesirable effects in humans, nontarget plants and animals, and the environment. Seek professional advice when in doubt.

The Product Label

Always read and understand the product label before using any compound. Label directions and information are important for two reasons. First, they describe the conditions of use under which the product can be expected to be effective and safe. Second, labels for approved products describe uses allowed by law. Any departure from the directions and conditions on the product label or on special state labels could mean a violation of law.

The product label and package inserts provided with regulated products 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 labels list precautionary statements on environmental, physical, and chemical hazards. Pesticide toxicity is identified by signal words on the product label. The terms "danger" and "poison" are used with the most toxic products, whereas "warning" and "caution" are associated with those that are less toxic. The label also identifies restricted use pesticides (RUP).

Prescribed aquatic-use information is usually not found on the product labels of those substances determined by FDA to be unapproved new animal drugs of low regulatory priority (LRP). These compounds are listed in Appendix A (Table 2), as are the specific treatment rates and uses allowed by FDA. Generally, LRP substances are not marketed specifically for aquaculture use.

Economic Considerations

Drugs, pesticides, and vaccines are used to control or prevent specific diseases, water quality conditions, and pest (e.g., weed) or stress problems. These treatments should be used only when needed. Each treatment has an economic value in terms of treatment cost and expected economic benefit. The proper use of regulated products, some of which are quite costly, can be important in preventing significant economic losses. Such losses are more likely to occur if the actual problem is incorrectly diagnosed, if precautions for treatment are ignored, or if treatments are improperly applied.

The use of best management practices in aquatic animal husbandry and water quality maintenance can reduce the use of regulated products and thereby increase profitability. Higher production based on increased dependence on chemicals does not necessarily mean higher profits. Such short-term goals may lead to long-term problems.

Using regulated products at less than the concentrations or dosages specified on the label can cause the treatment to be ineffective or only partially effective. For example, water quality may not be sufficiently improved, pests may not be controlled, vaccines may not protect adequately, and resistant strains of disease organisms may develop.

Using these compounds at concentrations or in dosages greater than those specified on the label (overdosing or overtreating) wastes the product and can cause unwanted side effects, including stress and toxicity problems in aquatic stocks and nontarget organisms as well as environmental damage. Persons applying regulated products should recognize their legal responsibility for any harm to nontarget aquatic and nonaquatic species and for off-site damage.



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Options for Proper Drug Use

According to the Federal Food, Drug, and Cosmetic Act, a drug is defined as an article that is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; an article (other than food) intended to affect the structure or any function of the body of man or other animals; or an article that is recognized in official drug compendia. (See Appendix D.) A new animal drug is a drug intended for animals that is not generally recognized by qualified experts as safe and effective for the uses recommended on the label. New animal drugs are considered adulterated, and therefore in violation of the law, unless they have been approved by FDA or are the subject of an INAD exemption.

At present, no drugs used in aquaculture are considered by FDA to be generally recognized as safe (GRAS) or effective (GRAE) for their proposed uses. For a drug to be classified as GRAS or GRAE, general recognition by experts must be supported by published scientific studies that meet strict FDA standards.

There are several options for properly obtaining and using drugs and chemicals:

- **1. FDA-approved new animal drugs.** A limited number of new animal drugs are currently approved by FDA for use in food-producing aquatic species. Each drug is approved for specific species, for specific disease conditions, and at specific dosages. Refer to Appendix A (Table 1) for a listing of these approved drugs.
- **2. Investigational new animal drugs.** These drugs are used under an investigational new animal drug exemption. INAD exemptions are granted by FDA CVM to permit the purchase, shipment, and use of an unapproved new animal drug



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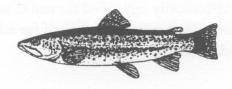
for investigational purposes. INAD exemptions are granted with the expectation that meaningful data will be generated to support a new animal drug approval.

Numerous requirements must be met for the establishment and maintenance of aquaculture INADs. There are two types of INADs: standard and compassionate. Aquaculture INADs, most of which are compassionate, consist of two types: routine and emergency (see Appendix D). A compassionate INAD exemption is used in cases in which the aquatic animal's health is of primary concern.

In certain situations, producers can use unapproved drugs as clinical investigators (under a compassionate INAD exemption), subject to FDA authorization. In these cases, producer facilities are used to conduct closely monitored clinical field trials. Producers are thus enabled not only to supply important information to contribute toward the approval of a new animal drug, but also to use unapproved drugs for emergency situations and for special needs in cases in which approved new animal drugs are not available.

FDA reviews protocols, authorizes specific conditions of use, and closely monitors any drug use under an INAD exemption. An application to renew this type of exemption is required each year. Data recording and reporting are required under the INAD exemption in order to support the approval of a new animal drug or an extension of approval for new uses of the drug.

3. Unapproved new animal drugs of low regulatory priority. Neither an approved new animal drug application (NADA) nor an INAD exemption is required for drugs in this category. Although FDA is not aware of safety prob-



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lems associated with the specific uses of these substances, their uses have not been shown to be safe and effective in well-controlled scientific studies. Regulatory action is unlikely if an appropriate grade is used, good management practices are followed, and local environmental requirements are met. (See Appendix A, Table 2.)

4. Extra-label use of an approved new animal drug. Extra-label drug use refers to the actual or intended use of an approved new animal drug in a manner that is not in accordance with the approved label directions. This includes, but is not limited to, use in species or for indications not listed on the label. **Under FDA** CVM's extra-label drug use policy, extra-label drugs can be prescribed only by a licensed veterinarian.

FDA CVM recognizes that there are some diseases for which no drugs are approved. A strict enforcement policy would not allow for the proper treatment of these conditions. CVM's extra-label drug use policy (*Compliance Policy Guide*, 7125.06) states that licensed veterinarians may consider extra-label drug use in treating food-producing animals if the health of animals is immediately threatened and if suffering or death would result from failure to treat the affected animals. The extra-label policy does not allow the use of drugs to prevent diseases (prophylactic use), improve growth rates, or enhance reproduction or fertility. Spawning hormones cannot be used under the extra-label policy. The veterinarian assumes responsibility for drug safety and efficacy and for potential drug residues in the animal. For further information regarding extra-label drug use, producers should contact their veterinarian.

Use of drugs in a manner other than the options discussed is subject to regulatory action by FDA.

Drugs in Aquaculture Feed

New animal drugs that are added to aquaculture feed are subject to FDA approval and must be specifically approved for use in aquaculture feed. Drugs approved for use in feed, like the drugs approved for administration in other forms, must be safe and effective.

Approved new animal drugs may be mixed in feed only for uses and at levels that are specified in FDA medicated-feed regulations. It is unlawful to add drugs to feed unless the drugs are approved for feed use. For example, producers may not top-dress feed with a water-soluble, over-the-counter antibiotic product.

Some medicated feeds, such as Romet 30, may be manufactured only after FDA has approved a medicated-feed application (*Form FDA 1900*) submitted by the feed manufacturer. This requirement applies whether the producer or a commercial company makes the medicated feed. Neither an approved *Form 1900* nor FDA registration is required for the manufacture of certain other medicated feeds, such as those containing Terramycin. However, those who manufacture such feeds are subject to the regulations covering current good manufacturing practices and drug usage.

Water Treatments

Many of the chemicals used in aquaculture are applied directly to water. The federal agency (either FDA or EPA) with jurisdiction over chemicals applied to the water is determined by the intended use of the product.

Fish and other aquatic species are exposed to any compound present in the water. An off-flavor is an example of a condition that can develop when fish are exposed to certain compounds—even those found naturally in water.

Although some products may be beneficial when applied to aquaculture systems at low concentrations, they may also act as irritants or even become toxic at higher concentrations. The improper use or application of water treatments can cause severe stress, which can lead to an animal disease outbreak or even death. Some compounds can accumulate in the animal and may cause illegal chemical residues in tissues intended for human consumption. Illegal residues can also result from the improper use of products to control weeds or unwanted fish or to alter water quality. To prevent possible fish losses and illegal chemical residues from excessive treatment levels, always read and strictly follow product label directions.

Recordkeeping

Recordkeeping is essential for any aquaculture business and is a critical element of quality assurance programs. A good recordkeeping 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.

Good records provide a basis for sound, cost-effective management decisions. The treatment status of animals, ponds, and other areas is known at all times. Records are needed to determine dosage rates and certify withdrawal times. Processors may require records to demonstrate that all drugs and chemicals have been used properly. Federal seafood processing inspection regulations may also require such recordkeeping. Records provide valuable evidence and protection in liability cases.

Accurate recordkeeping is required for any producer using an INAD exemption in clinical field trials. In case of crop loss resulting from a natural disaster, proper records are necessary for eligibility and possible compensation under federal programs. Lenders may require that production input and output records be kept for at least 2 years.

New pesticide recordkeeping regulations for farmers went into effect in 1993. The regulations require that private as well as commercial users of restricted use pesticides keep records of the use of these compounds. No recordkeeping is required for general use pesticides, which do not have the restricted use pesticide designation. The records must indicate the date of use, the product name, the EPA product registration number, the size of the area treated, and the amount of the product used on the site as well as the name and license number of the applicator. Records must be kept for 2 years from the date of application.

Check with your county agricultural Extension office for recordkeeping help and recordkeeping requirements, such as those for restricted use pesticides. Assistance is also available for other farm recordkeeping systems.

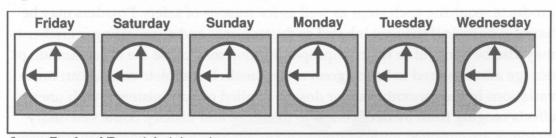
Calculating Withdrawal Times

Product withdrawal times must be observed to ensure that a product used in an aquatic site or on animals does not exceed legal tolerance levels in the animal tissue. Using proper withdrawal times helps to ensure that products reaching consumers are safe and wholesome.

All federally approved products list any specific required withdrawal times. Withdrawal information is found on the product label, package insert, or feed tag. An exception to withdrawal requirements is made for products used in an extra-label manner. Extra-label use may require the same or a different withdrawal time from that listed on the label, depending on the species, treatment, and other conditions. Withdrawal times for the extra-label use of an approved product are not listed on the label and must be determined by the prescribing licensed veterinarian.

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 drug, pesticide, or vaccine. For example, a treatment with a product that has a 5-day withdrawal time is completed at 9:00 a.m. on Friday (see Figure 1). At 9:00 a.m. on Saturday, the treated animals have completed their first withdrawal day. The fifth withdrawal day will end at 9:00 a.m. on Wednesday. Waiting restrictions may apply not only to the slaughter time for treated aquaculture stocks but also to treated water used for swimming, livestock watering, crop or turf irrigation, a potable drinking supply, or other purposes.

Figure 1. Product Withdrawal Times



Source: Food and Drug Administration.

Storage, Handling, Mixing, and Disposal

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.

Disinfectants, pesticides, and most drugs should be stored in a locked cabinet in a dry, well-ventilated utility area located away from children, animals, food, feed, and living areas. Some drugs and veterinary biologics require refrigerated storage; other products require storage in a freezer or at room temperature. All disinfectants, pesticides, drugs, and veterinary biologics should be stored away from bright light, because light can cause inactivation or deterioration of the product. Most of these compounds should be stored in a dark area, or at least in a closed carton.

Regulated products should be stored in their original containers, with the original label left attached to the container. Dampness in storage areas can cause paper packages to deteriorate, metal containers to rust, and metal and 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. High-temperature storage (above 80° or 90° F) can cause excessive pressure in and bursting of sealed containers. Exposure to high temperatures can also result in product deterioration, shortened shelf-life, premature inactivity, and inactivation.

Proper mixing, diluting, and reconstituting are essential for the effectiveness of products requiring such steps as well as for reasons of safety. Powders may be harmful or toxic if they are inhaled as dusts; fumes and evaporating ingredients may also be harmful or toxic. 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, with uneven effects ranging from ineffectiveness to overdose and toxicity. Some veterinary biologics are supplied with accompanying diluents that are necessary for reconstitution and the proper concentration of materials.

The use of any pesticide (and some other regulated products) requires adequate protection from exposure. Users should always read the product label for information on recommended personal protective equipment. Common-sense precautions should be followed, such as wearing gloves, long-sleeved shirts and long pants, socks, shoes or boots, a hat and goggles, protective glasses, and/or a face shield. Some pesticides may require use of a respirator. Persons mixing and/or applying pesticides, or working in an area where pesticides are being applied or have recently been applied, should shower and wash their clothes after actual or possible exposure.

As emphasized earlier, users should not mix different regulated products unless this is specifically recommended on the label. The combining of products can have many—mostly undesirable—effects. One or both products can be inactivated, and chemical reactions can produce harmful gases or other reaction products and by-products, some of them toxic. Following appropriate precautions can prevent accidental poisoning from pesticide contact with bare skin or from the inhalation of fumes or dust.

The pesticide label provides important product-specific information on mixing, diluting, storage, and disposal, as well as on first aid in the event of accidental poisoning. Material Safety Data Sheets, provided by product manufacturers upon request, are a source of additional information on safety precautions.



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It is important that unused portions of a regulated product and empty containers be disposed of properly. The best approach is to purchase only the amount of material that will be used within a reasonable time period and to use all of the product for its intended purpose. Empty containers must be disposed of, however, and often a quantity of the product is left over. Product labels provide instructions for safe disposal; these instructions should be followed. Improper disposal can result in product toxicity, environmental contamination, and liability problems.

Contact the county agricultural Extension office in your area for further information on product storage and handling and on local regulations for the disposal of pesticide containers.

Pesticide Applicator Certification

Restricted use pesticides can be purchased and applied only by a Certified Pesticide Applicator or under a Certified Applicator's direct supervision. Certification includes both "private" (mostly farmers) and "commercial" applicators. Pesticide certification programs are offered through state Departments of Agriculture and state Cooperative Extension Services and through EPA regional offices.

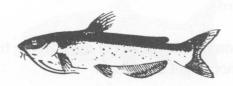
Fish toxicants listed in Appendix B (Table 2) provide examples of restricted use pesticides. For information on pesticide use, training programs, and certification requirements in any state, contact your county agricultural Extension office.

Importation of Regulated Products

To be imported, a new animal drug must either be approved by FDA or be intended for investigational use under an INAD exemption. Without approval or proper identification as an investigational new animal drug, a compound can be refused entry into the United States. If the drug is imported under false pretenses, the responsible person(s) involved are subject to enforcement action by FDA as well as the U.S. Customs Service.

Veterinary biologics may be imported only under a permit, and veterinary biologics for sale must meet U.S. requirements. To ensure compliance, manufacturing specifications are monitored, and manufacturing facilities are inspected. Manufacturers of veterinary biologics for experimental use or field testing must meet strict permit requirements and must have provided extensive information to APHIS prior to the issuance of a permit. Permits are not issued for preventive products if the organism in question does not exist in this country.

Regulations also require that before a person in a state or foreign country can sell or distribute any pesticide in the United States, he or she must obtain a registration from EPA. Pesticides produced by foreign manufacturers and imported into the United States must comply with all requirements applicable to domestic manufacturers. In addition, the regulations require an importer to submit to EPA a Notice of Arrival of Pesticides and Devices for review and for a determination as to whether the shipment should be sampled and/or permitted entry into the United States.



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Tips for Use of Regulated Products

- 1. Obtain a diagnosis of the problem(s) before applying any treatment.
- **2. Seek professional advice** if ever in doubt as to when or how to use regulated products.
- 3. Use regulated products only for those species and indications listed on the product label, unless extra-label use is specifically prescribed by a licensed veterinarian.
- 4. Read the product label carefully.
- **5.** Use the proper dosage, amount, or concentration for the species, area, and/or specific condition.
- 6. Use the correct method and route of application or administration, whether by spraying vegetation, water treatment (ponds, tanks, or immersion), injection, or oral administration (used with medicated feed and some biologics).
- 7. Calculate withdrawal times accurately.
- **8. Identify treated populations or stocks** with clear markings of production and holding units.
- 9. Do not use antibiotic drugs or medicated feed for disease prevention unless they are specifically approved for that use.
- **10. Do not substitute unlabeled or generic products** for trade-name products that are labeled and approved for aquaculture or aquatic site uses.
- 11. Keep accurate records.
- **12. Consider the environmental impact** of discharging treated water, including possible effects on nontarget organisms.

- 13. Adopt a producer quality assurance program or a Hazard Analysis Critical Control Points program that provides guidelines for preventing tissue residue violations and for producing high-quality, wholesome products for consumer use.
- **14. Be aware of personal safety measures** and proper procedures for farm workers and pesticide applicators who handle or apply regulated products.
- **15. Consider the economic consequences,** both short- and long-term, of treatment before using a regulated product.



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Appendixes

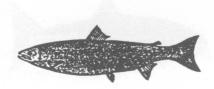
Federally Regulated Products and Diagnostic Test Kits

The legal status of regulated products approved, registered, or licensed for aquaculture or for aquatic site uses can change for a variety of reasons, such as new or terminated approvals, reregistrations, or new data. The product listings in this section are based on May 1994 data provided by the Food and Animal Residue Avoidance Databank. For updated information on the status of a regulated product, contact any FARAD Regional Access Center or other organizations and agencies listed in Appendix E.

It is especially important to avoid introducing potentially harmful chemicals into the food chain through improper product use. This can occur not only through direct exposure of food fish to such chemicals, but also through indirect means (for example, livestock contact with contaminated water).

Some products may be approved only for use with nonfood fish or for certain life stages of aquatic species. The use of products may also be restricted to specified aquatic sites (for example, drainage ditches) rather than sites containing aquatic food species.

It is the user's responsibility to know whether a particular product is approved for an intended use in aquaculture. Refer to the product label for information on dosages, conditions of use, withdrawal times, and other instructions for product use. Be sure to read the entire label.



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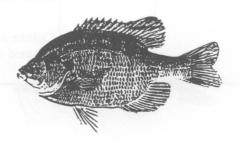
Appendix A

FDA-Regulated Drugs for Aquaculture

The drugs listed in this section include FDA-approved new animal drugs as well as unapproved new animal drugs of low regulatory priority for FDA. Federal approval of new animal drugs applies only to specific products that are the subject of approved new animal drug applications.

Active ingredients from sources other than the listed sponsors are not considered approved new animal drugs. Such products cannot legally be marketed or used.

States and other jurisdictions may impose additional regulatory requirements and restrictions on FDA-regulated drugs for aquaculture.



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Table 1. FDA-Approved New Animal Drugs

| Trade Name | NADA Number | Sponsor | Active Drug | Species | Uses |
|---------------------|---|---|--|--|--|
| Finquel (MS-222) | 42-427 | Argent Chemical Laboratories, Inc. | Tricaine methanesul- fonate | Ictaluridae, Salmonidae, Esocidae, and Percidae. (In other fish and cold-blooded animals, the drug should be limited to hatch- ery or laboratory use.) | Temporary immobilization (anesthetic) |
| Formalin-F 137-687 | 137-687 | Natchez Animal Supply | Formalin | Trout, salmon, catfish, large- mouth bass, and bluegill | Control of exter- nal protozoa and monogenetic trematodes |
| | | | Salmon, trout, and esocid eggs | Control of fungi of the family Saprolegniacae | |
| Paracide-F 140-831 | Argent Chemical Laboratories, Inc. | Formalin | Trout, salmon, catfish, large-mouth bass, and bluegill | Control of exter- nal protozoa and monogenetic trematodes | |
| | | | Salmon, trout, and esocid eggs | Control of fungi of the family Saprolegniacae | |
| Parasite-S 140-989 | 140-989 | Western Chemical Inc. | Formalin | Trout, salmon, catfish, large- mouth bass, and bluegill | Control of exter- nal protozoa and monogenetic trematodes |
| | | | | Salmon, trout, and esocid eggs | Control of fungi of the family Saprolegniacae |
| | | | | Cultured penaeid shrimp | Control of exter- nal protozoan parasites |

(continued)

Table 1. FDA-Approved New Animal Drugs, continued

| Trade Name | NADA Number | Sponsor | Active Drug | Species | Uses |
|--|----------------|---------------------------------|---------------------------|---|---|
| Romet 30 | 125-933 | Hoffmann- LaRoche, Inc. | Sulfadimeth- oxine and | Catfish | Control of enteric septicemia |
| | | | ormetoprim | Salmonids | Control of furun- culosis |
| Sulfamera- zine in Fish Grade ¹ | 033-950 | American Cyanamid Company | Sulfamerazine | Rainbow trout, brook trout, and brown trout | Control of furun- culosis |
| Terramycin For Fish | 038-439 | Pfizer, Inc. | Oxytetra- cycline | Catfish | Control of bacterial hemorrhagic septicemia and pseudomonas disease |
| | | les est as lea | | Lobster | Control of gaffke- mia |
| | | | | Salmonids | Control of ulcer disease, furuncu- losis, bacterial hemorrhagic sep- ticemia, and pseudomonas disease |
| | | | | Pacific salmon | Marking of skele- tal tissue |

¹According to sponsor, this drug is not presently being distributed.



Table 2. Unapproved New Animal Drugs of Low Regulatory Priority for FDA¹

| Common Name | Permitted Use |
|------------------------------------|---|
| Acetic acid | Used as a dip at a concentration of 1,000-2,000 milligrams per liter (mg/L) for 1-10 minutes as a parasiticide for fish. |
| Calcium chloride | Used to increase water calcium concentration to ensure proper egg hardening. Dosages used would be those necessary to raise calcium concentration to 10-20 mg/L calcium carbonate. Also used to increase water hardness up to 150 mg/L to aid in maintenance of osmotic balance in fish by preventing electrolyte loss. |
| Calcium oxide | Used as an external protozoacide for fingerling to adult fish at a concentration of 2,000 mg/L for 5 seconds. |
| Carbon dioxide gas | Used for anesthetic purposes in cold, cool, and warmwater fish. |
| Fuller's earth | Used to reduce the adhesiveness of fish eggs in order to improve hatchability. |
| Garlic (whole) | Used for control of helminth and sea lice infestations in marine salmonids at all life stages. |
| Hydrogen peroxide | Used at 250-500 mg/L to control fungi on all species and at all life stages of fish, including eggs. |
| Ice | Used to reduce metabolic rate of fish during transport. |
| Magnesium sulfate (Epsom salts) | Used to treat external monogenetic trematode infestations and external crustacean infestations in fish at all life stages. Used in freshwater species. Fish are immersed in a solution of 30,000 mg/L magnesium sulfate and 7,000 mg/L sodium chloride for 5-10 minutes. |
| Onion (whole) | Used to treat external crustacean parasites and to deter sea lice from infesting external surface of fish at all life stages. |
| Papain | Used as a 0.2% solution in removing the gelatinous matrix of fish egg masses in order to improve hatchability and decrease the incidence of disease. |



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Table 2. Unapproved New Animal Drugs of Low Regulatory Priority for FDA,¹ continued

| Common Name | Permitted Use |
|----------------------------------|--|
| Potassium chloride | Used as an aid in osmoregulation to relieve stress and prevent shock. Dosages used would be those necessary to increase chloride ion concentration to 10-2,000 mg/L. |
| Povidone iodine compounds | Used as a fish egg disinfectant at rates of 50 mg/L for 30 minutes during water hardening and 100 mg/L solution for 10 minutes after water hardening. |
| Sodium bicarbonate (baking soda) | Used at 142-642 mg/L for 5 minutes as a means of introducing carbon dioxide into the water to anesthetize fish. |
| Sodium chloride (salt) | Used as a 0.5-1% solution for an indefinite period as an osmoregulatory aid for the relief of stress and prevention of shock. Used as a 3% solution for 10-30 minutes as a parasiticide. |
| Sodium sulfite | Used as a 15% solution for 5-8 minutes to treat eggs in order to improve hatchability. |
| Urea and tannic acid | Used to denature the adhesive component of fish eggs at concentrations of 15 g urea and 20 g NaCl/5 L of water for approximately 6 minutes, followed by a separate solution of 0.75 g tannic acid/5 L of water for an additional 6 minutes. These amounts will treat approximately 400,000 eggs. |

¹FDA is unlikely to object at present to the use of these low regulatory priority substances if the following conditions are met:

- 1. The drugs are used for the prescribed indications, including species and life stage where specified.
- 2. The drugs are used at the prescribed dosages.
- 3. The drugs are used according to good management practices.
- 4. The product is of an appropriate grade for use in food animals.
- 5. An adverse effect on the environment is unlikely.

FDA's enforcement position on the use of these substances should be considered neither an approval nor an affirmation of their safety and effectiveness. Based on information available in the future, FDA may take a different position on their use.

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

Appendix B

EPA-Registered Pesticides for Aquaculture/Aquatic Sites

The trade names and common names listed in this section are registered by EPA for application and use in aquatic sites. Before purchasing or using any commercial product, read the label carefully to make certain that the product is approved for its intended use. It is the responsibility of the applicator to use the proper compound(s) and to read and follow label directions.

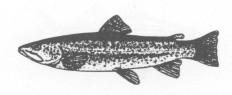
The following tables include general information rather than detailed instructions on the specific conditions of use for each product. A number of restrictions may apply to the use of some compounds. For example, a pesticide or fish toxicant may be approved only for use with nonfood fish species or for certain sites, such as drainage ditches. In some cases, a specified waiting time must elapse before treated water can be used for crop irrigation, livestock watering, or other purposes.

Restricted use products such as rotenone fish toxicants can be purchased only by a Certified Pesticide Applicator and can be applied only by a Certified Pesticide Applicator or under a certified applicator's direct supervision. To identify such products, look for the "restricted use pesticide" designation on the label.

The following explanations are necessary to understand the product listings in this section. The products are subject to manufacturers' name changes as well as inevitable lag time between EPA registration and updates of the EPA PEST-BANK database from which the listings are derived. Some products are not currently being distributed despite the fact that their EPA registrations are still active. EPA is currently reregistering all pesticides registered prior to 1984. In many cases, this process requires new data. Consequently, some product registrations are not being maintained.

Disinfectants are not included in this listing. Refer to FARAD for current information on EPA-registered disinfectants used to sanitize or disinfect facilities and equipment.

Always refer to the product label for details on recommended or approved treatment rates and usage as well as for any restrictions on use. Updated information on the status of regulated products may be obtained by contacting the Food Animal Residue Avoidance Databank or other sources of information and assistance listed in Appendix E.



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Table 1. EPA-Registered Algicides

| Trade Name | EPA Registration Number | Registrant | Indications for Use |
|-------------------------------------|-------------------------------|--|---|
| | Common N | ame: Chelated Co | pper |
| Algae-Rhap CU-7 Liquid | 55146-42 | Agtrol Chemical Products | Broad-range algicide for use in farm and fish ponds, lakes, and fish hatcheries. |
| Algimycin PLL | 7364-10 | Great Lakes Biochemical Co., Inc. | Algicide for small, ornamental ponds and pools. |
| Algimycin PLL-C | 7364-9 | Great Lakes Biochemical Co., Inc. | Algicide for pools, lakes, ponds, and similar waters. |
| Aquatrine Algaecide ¹ | 8959-33 | Applied Biochemists, Inc. | Algicide for fish and shrimp aquaculture facilities (e.g., ponds, tanks, and raceways). |
| Copper Control | 47677-1 | Argent Chemical Laboratories, Inc. | Algicide for fish ponds and hatcheries. |
| Copper Control Granular | 47677-8 | Argent Chemical Laboratories, Inc. | Algicide for fish ponds and hatcheries. |
| Cutrine Algaecide ¹ | 8959-1 | Applied Biochemists, Inc. | Algicide for fish ponds, lakes, and hatcheries. |

 $^{^{1}\}mbox{According to registrant, this product is not presently being distributed.}$



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Table 1. EPA-Registered Algicides, continued

| Trade Name | EPA Registration Number | Registrant | Indications for Use |
|--|-------------------------------|---|--|
| | Chelated | d Copper, continue | d |
| Cutrine Granular Algaecide ¹ | 8959-3 | Applied Biochemists, Inc. | Granular algicide for control of Chara and Nitella in fish ponds, lakes, and hatcheries. |
| Cutrine Plus Algaecide/Herbicide | 8959-10 | Applied Biochemists, Inc. | Algicide/herbicide for fish ponds, lakes, and hatcheries. |
| Cutrine Plus II Algaecide ¹ | 8959-20 | Applied Biochemists, Inc. | Algicide for fish ponds, lakes, and hatcheries. |
| Cutrine Plus Granular Algaecide | 8959-12 | Applied Biochemists, Inc. | Algicide (especially for Chara and Nitella) in fish ponds and hatcheries. |
| Komeen Aquatic Herbicide | 1812-312 | Griffin Corporation | Algicide for freshwater lakes and fish hatcheries. |
| K-Tea Algaecide | 1812-307 | Griffin Corporation | Algicide for freshwater lakes and fish hatcheries. |
| SCI-62 Algicide/ Bactericide | 61943-1 | Chem-A-Co, Inc. | Algicide/bactericide for lakes and ponds. |
| Slow Release Algimycin PLL Concentrate | 7364-26 | Great Lakes Biochemical Co., Inc. | Algicide for ponds, lakes; especially for Chara and Nitella. |
| Stocktrine II | 8959-34 | Applied Biochemists, Inc. | For algae control in stock- watering tanks, troughs, and ponds. |

 $^{^{1}\}mbox{According}$ to registrant, this product is not presently being distributed.

Table 1. EPA-Registered Algicides, continued

| Trade Name | EPA Registration Number | Registrant | Indications for Use |
|---|-------------------------------|-------------------------------|---|
| | Comm | on Name: Copper | |
| Alco Cutrine Algaecide RTU ¹ | 5481-140 | Amvac Chemical Corporation | Algicide for fish ponds, lakes, and hatcheries. |
| | Common Nar | ne: Copper as Eler | nental |
| Algon Algaecide | 11474-15 | Sungro Chemicals, Inc. | Algicide for use in lakes, fish ponds, and fish hatcheries. |
| A & V-70 Granular Algaecide ¹ | 12014-5 | A & V Inc. | Granular algicide for lakes and ponds. |
| AV-70 Plus Algicide | 12014-10 | A & V Inc. | Algicide for fish ponds, lakes, and hatcheries. |
| | Common Name: | Copper Sulfate Per | ntahydrate |
| Blue Viking Kocide Copper Sulfate Star Glow Powder | 1812-314 | Griffin Corporation | Algicide for freshwater lakes and ponds. |
| Blue Viking Kocide Copper Sulfate Star Shine Crystals | 1812-313 | Griffin Corporation | Algicide for lakes, ponds, and impounded water. |

 $^{^{1}\}mbox{According to registrant, this product is not presently being distributed.}$

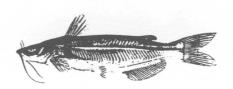


Table 1. EPA-Registered Algicides, continued

| Trade Name | EPA Registration Number | Registrant | Indications for Use |
|---|-------------------------------|---|--|
| | Copper Sulfate | Pentahydrate, co | ontinued |
| Calco Copper Sulfate ¹ | 39295-8 | Calabrian International Corporation | For algae control in impounded water, lakes, and ponds. |
| Copper Sulfate Crystals | 56576-1 | Chem One Corporation | For algae control in impounded lakes and ponds. |
| Copper Sulfate Large Crystals | 1109-1 | Boliden Intertrade, Inc. | For algae control in lakes and ponds. |
| Copper Sulfate Medium Crystals | 1109-19 | Boliden Intertrade, Inc. | For algae control in lakes and ponds. |
| Copper Sulfate Pentahydrate Algicide/Herbicide | 35896-19 | C.P. Chemicals | Algicide/herbicide for controlled-outflow lakes and ponds. |
| Copper Sulfate Pentahydrate Instant Powder ¹ | 1278-5 | Phelps Dodge Refining Corporation | Algicide for root and fungus control. |
| Copper Sulfate Powder | 1109-7 | Boliden Intertrade, Inc. | For algae control in lakes and ponds. |
| Copper Sulfate Superfine Crystals | 1109-32 | Boliden Intertrade, Inc. | For algae control in lakes and ponds. |
| Dionne Root Eliminator | 34797-39 | Qualis, Inc. | For algae control in lakes and ponds. |

 $^{^{1}\}mbox{According to registrant, this product is not presently being distributed.}$

Table 1. EPA-Registered Algicides, continued

| Trade Name | EPA Registration Number | Registrant | Indications for Use |
|--|-------------------------------|--|---|
| | Copper Sulfate | e Pentahydrate, co | ntinued |
| Granular Crystals Copper Sulfate | 1109-20 | Boliden Intertrade, Inc. | For algae control in lakes and ponds. |
| Kocide Copper Sulfate Pentahy- drate Crystals ¹ | 1812-304 | Griffin Corporation | Algicide for lakes and ponds. |
| Root Killer RK-11 ¹ | 8123-117 | Frank Miller & Sons, Inc. | For algae control in impounded water (e.g., lakes, ponds). |
| SA-50 Brand Copper Sulfate Granular Crystals | 829-210 | Southern Agricultural Insecticides, Inc. | For algae control in ponds. |
| Snow Crystals Copper Sulfate | 1109-21 | Boliden Intertrade, Inc. | For algae control in lakes and ponds. |
| Triangle Brand Copper Sulfate Crystals | 1278-8 | Phelps Dodge Refining Corporation | For algae control in impounded water, lakes, ponds, and reservoirs. |

¹According to registrant, this product is not presently being distributed.

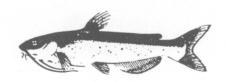
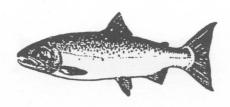


Table 2. EPA-Registered Fish Toxicants

| Trade Name | EPA Registration Number | Registrant | Indications for Use |
|---|-------------------------------|-------------------------------------|-------------------------|
| | Common | Name: Antimycin | |
| Fintrol Concentrate | 39096-2 | Aquabiotics Corporation | Fish toxicant/piscicide |
| | Common Name: | Cube Resins/Rotenor | ne |
| Chem Fish Regular | 1439-157 | Tifa Limited | Fish toxicant/piscicide |
| Chem Fish Synergized | 1439-159 | Tifa Limited | Fish toxicant/piscicide |
| Finely Ground Cube Powder | 6458-6 | Foreign Domestic Chemicals Corp. | Fish toxicant/piscicide |
| Fish-Tox-5 | 769-309 | Sureco, Inc. | Fish toxicant/piscicide |
| Martin's Rotenone Powder | 299-227 | C.J. Martin Company | Fish toxicant/piscicide |
| Noxfish Fish Toxicant Liquid Emulsifiable | 432-172 | Roussel Uclaf Corporation | Fish toxicant/piscicide |
| Nusyn-Noxfish Fish Toxicant | 432-550 | Roussel Uclaf Corporation | Fish toxicant/piscicide |
| Pearson's 5% Rotenone Wettable Powder | 19713-316 | Drexel Chemical Company | Fish toxicant/piscicide |
| Powdered Cube | 769-414 | Sureco, Inc. | Fish toxicant/piscicide |



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Table 2. EPA-Registered Fish Toxicants, continued

| Trade Name | EPA Registration Number | Registrant | Indications for Use |
|--|-------------------------------|---------------------------------------|-------------------------|
| | Cube Resins/ | Rotenone, continued | |
| Prentox Prenfish Toxicant | 655-422 | Prentiss Incorporated | Fish toxicant/piscicide |
| Prentox Rotenone Fish Toxicant Powder | 655-691 | Prentiss Incorporated | Fish toxicant/piscicide |
| Prentox Synpren Fish Toxicant | 655-421 | Prentiss Incorporated | Fish toxicant/piscicide |
| Rotenone 5% Fish Toxicant Powder | 47677-4 | Argent Chemical Laboratories, Inc. | Fish toxicant/piscicide |
| Rotenone 5% Liquid Emulsifiable | 47677-3 | Argent Chemical Laboratories, Inc. | Fish toxicant/piscicide |



Table 3. EPA-Registered Herbicides

| Trade Name | EPA Registration Number | Registrant | Indications for Use |
|------------------|-------------------------------|---------------------------------------|---|
| | Common Name | : Acid Blue and Ac | id Yellow |
| Aquashade | 33068-1 | Applied Biochemists, Inc. | Aquatic plant control through selective light filtering; usable in controlled-outflow natural and man-made lakes and ponds. |
| | Commo | n Name: Dichlober | nil |
| Acme Norosac 10G | 2217-679 | PBI/Gordon Corporation | Aquatic weed control for lakes and ponds. |
| Casoron 10-G | 400-178 | Uniroyal Chemical Company, Inc. | Aquatic herbicide for sub- merged weeds in nonflowing water. |
| | Common N | ame: Diquat Dibro | mide |
| Aqua Clear | 2155-63 | I. Schneid, Inc. | Contact, nonselective vegetation killer for aquatic weeds. |
| Aqua-Kil Plus | 37347-6 | Uni-Chem Corporation of Florida | Contact, nonselective vegetation killer to control aquatic weeds and grasses. |
| Aquaquat | 5080-4 | Aquacide Company | Liquid weed killer for lakes and ponds with controlled outflow. |

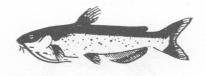


Table 3. EPA-Registered Herbicides, continued

| Trade Name | EPA Registration Number | Registrant | Indications for Use |
|-------------------------------------|-------------------------------|--|--|
| | Diquat D | ibromide, continu | ed |
| Aquatic Weed Killer ¹ | 10292-13 | Venus Laboratories, Inc. | For the elimination of aquatic weeds and algae. |
| Clean-Up | 2155-64 | I. Schneid, Inc. | Algicide and nonselective weed killer. |
| Conkill | 10088-13 | Athea Laboratories, Inc. | Contact, nonselective herbicide for aquatic weeds. |
| Contact Vegetation Controller | 8123-102 | Frank Miller & Sons, Inc. | For the control of aquatic vegetation. |
| Diquat-L Weed Killer 1/5 Lb. | 34704-589 | Platte Chemical Co., Inc. | Aquatic weed killer for controlled-outflow lakes and ponds. |
| Formula 268 Aqua- Quat | 1685-64 | State Chemical Manufacturing Company | Aquatic weed killer in lakes, ponds, and impounded water |
| Ind-Sol 435 | 10827-78 | Chemical Specialties, Inc. | Nonselective weed killer for controlled-outflow lakes and ponds. |
| Miller Liquid Vegetation Control | 8123-37 | Frank Miller & Sons, Inc. | For the control of aquatic vegetation. |
| No. 401 Water Plant Killer | 11515-29 | ABC Chemical Corporation | Contact, nonselective weed killer for aquatic weeds. |

¹According to registrant, this product is not presently being distributed.



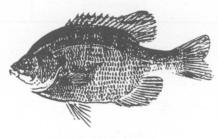
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Table 3. EPA-Registered Herbicides, continued

| Trade Name | EPA Registration Number | Registrant | Indications for Use | |
|--|-------------------------------|---------------------------------------|---|--|
| | Diquat D | Dibromide, continu | ed | |
| Norkem 500 | 5197-37 | Systems General, Inc. | Contact, nonselective weed killer for controlled-outflow lakes and ponds. | |
| P.D.Q. Non-Selective Weed Killer | 2155-43 | I. Schneid, Inc. | Algicide and non- selective weed killer. | |
| Reward | 10182-353 | Zeneca Professional Products | Aquatic and noncrop herbicide. | |
| Selig's Mister Trim No. 10 | 491-201 | Selig Chemical Industries | Contact, nonselective vegetation killer for aquatic weeds. | |
| Watrol | 1769-174 | NCH Corporation | Herbicide for aquatic weeds. | |
| Weedtrine D Aquatic Herbicide | 8959-9 | Applied Biochemists, Inc. | Aquatic herbicide for still lakes and fish ponds. | |
| Yardman 10663-11 | | Sentry Chemical Company | Nonselective weed, algae, and aquatic foliage killer. | |
| | Comm | on Name: Endotha | ıll | |
| Aquathol Granular Aquatic Herbicide | 4581-201 | Elf Atochem North America, Inc. | Aquatic herbicide for ponds and lakes. | |
| Aquathol K Aquatic Herbicide | 4581-204 | Elf Atochem North America, Inc. | Contact aquatic herbicide for lakes and ponds. | |

Table 3. EPA-Registered Herbicides, continued

| Trade Name | EPA Registration Number | Registrant | Indications for Use |
|--|-------------------------------|---|--|
| | End | othall, continued | |
| Hydrothol 191 Aquatic Algicide and Herbicide | 4581-174 | Elf Atochem North America, Inc. | Aquatic algicide/herbicide for lakes and ponds. |
| Hydrothol 191 Granular Aquatic Algicide and Herbicide | 4581-172 | Elf Atochem North America, Inc. | Aquatic algicide/herbicide for lakes and ponds. |
| | Comm | on Name: Fluridon | e |
| Sonar A.S. | 62719-124 | SePRO | Herbicide for the management of aquatic vegetation in fresh- water ponds, lakes, and drain- age canals. |
| Sonar SRP | SRP 62719-123 | | Herbicide for the management of aquatic vegetation in fresh- water ponds, lakes, and drain- age canals. |
| | Commo | n Name: Glyphosa | te |
| Rodeo 524-343 | | The Agricultural Group of Monsanto Company | Aquatic herbicide for freshwater and brackish water applications. |



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Table 3. EPA-Registered Herbicides, continued

| Trade Name | EPA Registration Number Registrant | | Indications for Use | | |
|---|------------------------------------|---|--|--|--|
| | Comi | mon Name: 2,4-D | 0-22 | | |
| Weed-Rhap A-4D | 5905-501 | Helena Chemical For control of aquatic well lakes and ponds. | | | |
| Weed-Rhap A-6D Herbicide | 5905-503 | Helena Chemical For control of aquatic weeds lakes and ponds. | | | |
| | Common N | ame: 2,4-D, Acetic | Acid | | |
| A C Aquacide Pellets | 5080-2 | Aquacide Company | Herbicide for submerged weeds in recreational lakes and ponds. Predominantly for broad-leafed plants. | | |
| nu et servi si seupe i | Common Name | e: 2,4-D, Butoxyeth | yl Ester | | |
| Aqua-Kleen | 264-109 | Rhone-Poulenc Agricultural Co. | For control of aquatic weeds in lakes and ponds. | | |
| Navigate | 264-109-8959 | Applied Bio- chemists, Inc. ¹ | For control of aquatic weeds in lakes and ponds. | | |
| Mary Street, and the street, work | Common Name | : 2,4-D, Dimethylar | nine Salt | | |
| Class 40A Phenoxy Herbicide | 1381-103 | Cenex/Land O'Lakes | For aquatic weeds in lakes and ponds. | | |
| Clean Crop Amine 2,4-D Granules ² | 34704-645 | Platte Chemical Co., Inc. | Aquatic herbicide for emersed/ submerged weeds. | | |
| Clean Crop Amine 6 2,4-D Herbicide | 34704-646 | Platte Chemical Herbicide for lakes and Co., Inc. | | | |
| Rhodia 2,4-D Gran 20 ² | 42750-16 | Albaugh Herbicide for aquatic w lakes and ponds. | | | |

 $^{^{1}\}mbox{Distributor}$ $^{2}\mbox{According to registrant, this product is not presently being distributed.}$

Table 3. EPA-Registered Herbicides, continued

| Trade Name | EPA Registration Number | Registrant | Indications for Use | | | | |
|---|-------------------------------|-----------------------------------|--|--|--|--|--|
| 2,4-D, Dimethylamine Salt, continued | | | | | | | |
| Riverdale 1D Amine | 228-238 | Riverdale Chemical Company | For control of broadleaf weeds in ponds. | | | | |
| Riverdale Solution Water Soluble | 228-260 | Riverdale Chemical Company | For control of aquatic weeds in lakes and ponds. | | | | |
| Riverdale 2,4-D 6 Amine | 228-242 | Riverdale Chemical Company | For control of aquatic weeds in lakes and ponds. | | | | |
| Riverdale Weedestroy AM-40 Amine Salt | 228-145 | Riverdale Chemical Company | For control of broadleaf weeds and aquatic weeds in lakes and ponds. | | | | |
| 2,4-D Amine 4 | 9779-263 | Terra International, Inc. | For control of water hyacinth in slow-moving waters, lakes, and ponds. | | | | |
| 2,4-D Amine 4 Herbicide | 42750-19 | Albaugh | Herbicide for aquatic weeds in lakes and ponds. | | | | |
| 2,4-D Amine 6 Herbicide | 42750-21 | Albaugh | Herbicide for aquatic weeds in lakes and ponds. | | | | |
| 2,4-D 380 Amine Weed Killer | 407-430 | Imperial, Inc. | Aquatic herbicide for lakes and ponds. | | | | |
| Weedar 64 264-2 | | Rhone-Poulenc Agricultural Co. | Broadleaf herbicide; toxic to aquatic invertebrates. | | | | |

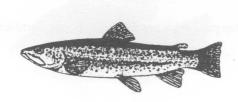


Table 3. EPA-Registered Herbicides, continued

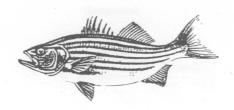
| Trade Name | EPA Registration Number | Registrant | Indications for Use | | | | |
|---|-------------------------------|----------------------------------|---|--|--|--|--|
| Common Name: 2,4-D, Isooctyl Ester | | | | | | | |
| Barrage (Weed-Rhap LV-5D Herbicide) | 5905-504 | Helena Chemical Company | For control of aquatic weeds in lakes and ponds. | | | | |
| Brush-Rhap Low Volatile 4-D Herbicide | 5905-498 | Helena Chemical Company | For control of aquatic weeds in lakes and ponds. | | | | |
| Riverdale 2,4-D Granules | 228-61 | Riverdale Chemical Company | For control of broadleaf and certain aquatic weeds. | | | | |
| Riverdale 2,4-D L. V. 4 Ester | 228-139 | Riverdale Chemical Company | For control of aquatic weeds in lakes and ponds. | | | | |
| Riverdale 2,4-D L. V. 6 Ester | 228-95 | Riverdale Chemical Company | For control of aquatic weeds in lakes and ponds. | | | | |
| SEE 2,4-D Low Volatile Ester Solventless Herbicide | 42750-22 | Albaugh | For aquatic weeds in lakes and ponds. | | | | |
| 2,4-D LV Ester 4 ¹ | 5905-90 | Helena Chemical Company | Selective aquatic herbicide. | | | | |
| 2,4-D LV Ester 6 ¹ | 5905-93 | Helena Chemical Company | Selective aquatic herbicide. | | | | |
| Visko-Rhap Low Volatile Ester 2D ¹ | 42750-17 | Albaugh | For aquatic weeds in lakes and ponds. | | | | |

 $^{^1\!\}text{According}$ to registrant, this product is not presently being distributed.

Table 3. EPA-Registered Herbicides, continued

| Trade Name | Registration | | Indications for Use | |
|---|--------------|--|--|--|
| | 2,4-D, Iso | octyl Ester, continu | ued | |
| Weed-Rhap Low Volatile Granular D Herbicide | 5905-507 | Helena Chemical Company | For control of aquatic weeds in lakes and ponds. | |
| Weed-Rhap LV-4D Herbicide | 5905-505 | 5905-505 Helena Chemical For co Company lakes a | | |
| Weed-Rhap 5905-508 LV-6D ¹ | | Helena Chemical Company | For control of aquatic weeds in lakes and ponds. | |

 $^{^1\!\!}$ According to registrant, this product is not presently being distributed.



Appendix C

USDA-Licensed Biologics for Fish

Veterinary biologics are used in the prevention, diagnosis, and treatment of animal diseases. Preventive and therapeutic veterinary biologics act on or in concert with the body's immune system to provide or enhance resistance to disease. Diagnostic veterinary biologics are used to detect the presence of a disease organism or diseased cells as well as to detect immunity in the fish against disease organisms.

Proper storage and administration of veterinary biologics is essential to ensure the maximum effectiveness of the product. Always read label directions and follow them carefully.



Table 1. Vaccines

| Trade Name | Product Name | USDA Product Code | Licensee/ Permittee | Species | Disease | |
|---|---|-------------------------|-------------------------|-----------|--|--|
| Autogenous Bacterin | | | BioMed, Inc. | Fish | Bacterial diseases | |
| Autogenous Bacterin | Autogenous Bacterin | 2051.00 | Jerry Zinn ¹ | Fish | Bacterial diseases | |
| Biojec 1500 | Aeromonas Salmonicida Bacterin | 2035.00 | BioMed, Inc. | Salmonids | Furunculosis | |
| Biojec 1900 | iojec 1900 Aeromonas Salmonicida-Vibrio Anguillarum- Salmonicida Bacterin | | BioMed, Inc. | Salmonids | Furunculosis, vibriosis | |
| Biovax 1100 | Yersinia Ruckeri Bacterin | | Biomed, Inc. | Salmonids | Yersiniosis (enteric red-mouth disease) | |
| Biovax 1150 Yersinia Ruckeri Bacterin | | 2638.01 | Biomed, Inc. | Salmonids | Yersiniosis (enteric red-mouth disease) | |
| Biovax 1200 | Vibrio Salmonicida Bacterin | 2870.00 | BioMed, Inc. | Salmonids | Vibriosis | |
| Biovax 1300 Vibrio Anguil- larum-Ordalii Bacterin | | 2858.02 | BioMed, Inc. | Salmonids | Vibriosis | |

 $^{^{1}}$ Permittee for Aqua Health, Ltd. (Canada).

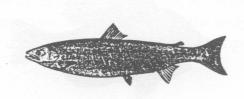


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Table 1. Vaccines, continued

| Trade Name | Product Name | USDA Product Code | Licensee/ Permittee | Species | Disease |
|---------------|--|-------------------------|-------------------------|-----------|--|
| Biovax 1600 | Vibrio Anguil- larum- Salmonicida Bacterin | 2868.00 | BioMed, Inc. | Salmonids | Vibriosis |
| Biovax 1700 | Vibrio Anguil- larum-Ordalii- Yersinia Ruckeri Bacterin | 2871.00 | BioMed, Inc. | Salmonids | Vibriosis, yersiniosis (enteric red-mouth disease) |
| Ermogen | Yersinia Ruckeri Bacterin | 2638.00 | Jerry Zinn ¹ | Salmonids | Yersiniosis (enteric red-mouth disease) |
| Escogen | Edwardsiella Ictaluri Bacterin | 2637.00 | Jerry Zinn ¹ | Catfish | Enteric septi- cemia |
| Furogen | Aeromonas Salmonicida Bacterin | 2035.01 | Jerry Zinn ¹ | Salmonids | Furunculosis |
| Vibrogen | Vibrio Anguil- larum-Ordalii Bacterin | 2858.02 | Jerry Zinn ¹ | Salmonids | Vibriosis |
| Vibrogen-2 | Vibrio Anguil- larum-Ordalii Bacterin | 2858.03 | Jerry Zinn ¹ | Salmonids | Vibriosis |

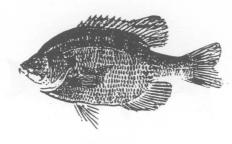
¹Permittee for Aqua Health, Ltd. (Canada).



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Table 2. Diagnostic Test Kits

| Trade Name | USDA Product Code | Licensee | Disease Detected | Species | Use |
|---------------|-------------------------|---------------------|--|-----------|------------|
| K-Dtect | 5800.00 | DiagXotics, Inc. | Renibacterium salmoninarum (bacterial kidney disease) | Salmonids | Laboratory |
| KwiK-Dtect | 5800.01 | DiagXotics, Inc. | Renibacterium salmoninarum (bacterial kidney disease) | Salmonids | Field |



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Appendix D

Glossary of Common Terms

Active ingredient

In a drug product, the ingredient responsible for the intended effect of the product. In any pesticide product, the component that kills or otherwise controls the target pests. (Pesticides are regulated primarily on the basis of their active ingredients.)

Autogenous bacterin

A bacterin (see below) made by a firm licensed to produce autogenous bacterins from organisms isolated from a particular farm, to be sold to and used on that farm only, and for a specified, limited time only.

Bacterin

A vaccine made from killed bacteria.

Best management practices

Husbandry practices that strive to ensure optimal health, production, and economic performance.

Clinical field trial

A research study of the effectiveness of a compound under actual commercial production conditions; involves strict adherence to FDA or USDA protocols and recordkeeping requirements.

Drug

An article that is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; an article (other than food) intended to affect the structure or any function of the body of man or other animals; or an article that is recognized in official drug compendia.

Drug sponsor

An individual or firm seeking FDA approval of a drug product.

Extra-label use

The actual or intended use of an approved new animal drug in a manner that is not in accordance with the approved label directions. Extra-label use is permitted only by or on the prescription of a licensed veterinarian when a valid veterinarian-client-patient relationship exists.

Hazard Analysis Critical Control Points (HACCP)

A systematic approach to hazard identification, assessment, and control that can be used by all concerned to ensure safe, sound, and properly labeled foods.

INAD exemption (standard)

Exemption authorized under the Federal Food, Drug, and Cosmetic Act to permit the shipment of new animal drugs in interstate commerce without an approved new animal drug application. Specifically limits the distribution of unapproved new animal drugs and their use to experts qualified by scientific training and experience to investigate the safety and effectiveness of animal drugs. In order for an individual or firm to obtain and use a new animal drug for clinical investigations, an investigational new animal drug (INAD) exemption for that drug must be granted by the FDA Center for Veterinary Medicine. Standard INAD exemptions typically are sought by pharmaceutical companies.

INAD exemption (emergency compassionate)

A type of compassionate investigational new animal drug exemption that is used for nonpredictable diseases or conditions and is authorized for one site, one disease, one drug, and one emergency INAD use for present disease outbreak only. Involves specific requirements, including data submission along with other information.



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INAD exemption (routine compassionate)

A type of investigational new animal drug exemption that allows producers to use an unapproved compound under certain conditions (e.g., an FDA decision that a particular producer qualifies as a clinical investigator) for purposes related to the health or well-being of an animal. Annual renewal applications are required, including data submission along with other information.

Inert ingredient

Ingredient in a drug or pesticide product that does not contribute to the intended activity of the product.

Low regulatory priority (LRP) substance

Unapproved new animal drug for which FDA has a policy of regulatory discretion that allows the use of such a substance without an approved new animal drug application or INAD exemption.

New animal drug

Any drug intended for 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 prescribed, recommended, or suggested in its labeling.

New animal drug application (NADA)

An application package submitted to FDA for review that requests the approval of a new animal drug. The application includes sufficient data to establish the safety and effectiveness of the drug product, along with other requirements.

Nontarget organisms

Organisms at which treatment is not aimed but which contact the product and may be affected by it.

Over-the-counter (OTC) drugs

Drugs that have adequate written directions for lay use and are permitted to be sold without a veterinary prescription.

Pest

An insect, rodent, nematode, or weed or any other form of terrestrial or aquatic plant or animal life or virus, fungus, bacteria, or other microorganism that is considered to be an annoyance and that may be injurious to health or to the environment.

Pesticide

Any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, and any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant.

Prescription (Rx) drug

An animal drug for which adequate directions for safe and effective use by a layperson cannot be written and which therefore must be prescribed by a licensed veterinarian. The label bears the statement, "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian."

Quality assurance program

A proactive, industry-driven code of production practices, carefully designed to ensure that producers supply a wholesome, safe product to consumers.

Registration

Under the Federal Insecticide, Fungicide, and Rodenticide Act, the formal listing with EPA of a new pesticidal active ingredient prior to its marketing or distribution in intra- or interstate commerce.

Restricted use pesticide (RUP)

A registered pesticide that has been classified for restricted use under the Federal Insecticide, Fungicide, and Rodenticide Act for some or all of its applications because it is toxic and requires special handling. Restricted use pesticides may be applied only 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.

Sponsor (drug)

An individual or company that applies for an INAD exemption to develop data with the intent of seeking a new animal drug approval for the compound used under the INAD exemption.

Target organism

The plant, animal, or microorganism that is treated or at which treatment is aimed.

Tissue residue

The drug, pesticide, or toxic breakdown product remaining in edible tissue after natural or technological processes of removal or degradation have occurred.

Tolerance

The maximum amount of pesticide or drug residue allowed by law to remain in or on a harvested crop or food animal product. EPA sets tolerances for pesticides and FDA sets tolerances for drugs so that treated crops or animals consumed do not pose an unreasonable risk to consumers. Tolerances are set for food-use crops on a per-crop basis. Tolerances are set for animal products on the basis of individual species and tissue (muscle, liver, etc.).

Vaccine

A preparation of killed microorganisms; living attenuated, fully virulent, or related nonvirulent microorganisms; or parts of micro- or macroorganisms that are administered to produce or increase immunity to a particular disease.

Veterinary biologics

All viruses, serums, 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.

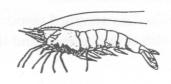
Veterinarian-client-patient relationship

Exists when (1) the veterinarian has assumed responsibility for making medical judgments regarding the health of the animals and the need for medical treat-

ment, and the client has agreed to follow the instructions of the veterinarian; (2) 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 (i.e., the veterinarian has recently seen and is personally acquainted with the keeping and care of the animals by virtue of an examination of the animals and/or by medically appropriate and timely visits to the premises where the animals are kept); and (3) the veterinarian is readily available for follow-up in case of adverse reactions or failure of treatment.

Withdrawal time

The minimum required period of time between the last drug treatment of an animal and the slaughter or release of that animal.



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Appendix E

Sources of Information and Assistance

A number of resources are available to persons seeking further information about drug, vaccine, and pesticide use in aquaculture. These resources include the following consumer hotlines, federal and state agency contacts, producer quality assurance programs, and organizations.

Consumer Hotlines

APHIS Consumer Hotline: 515/232-5789. The Animal and Plant Health Inspection Service Consumer Hotline can be used to report a problem with a veterinary biologic or diagnostic test kit or to obtain information about biologics.

EPA National Pesticide Telecommunications Network (NPTN) Hotline: 1-800/858-7378. Call this hotline for information on pesticide products; human and animal poisonings; protective equipment; safety; health and environmental effects; and clean-up and disposal procedures.

FDA Office of Seafood Hotline: 1-800/FDA-4010. The hotline can be used to obtain information on the safety of the seafood supply; various publications; and other assistance.

Federal Agency Contacts

U.S. Food and Drug Administration

Information on the drug approval process or on INADs:
Office of New Animal Drug Evaluation
Center for Veterinary Medicine
(HFV-100)
7500 Standish Place
Rockville, MD 20855
301/594-1620

Information on approved drugs, regulations, and policies:

Office of Surveillance and Compliance

Center for Veterinary Medicine

(HFV-200)

7500 Standish Place

Rockville, MD 20855

301/594-1761

Information on seafood standards, safety, and color additives:

Office of Seafood

Center for Food Safety and Applied Nutrition

(HFS-417)

200 C St., SW

Washington, DC 20204

202/254-3995

Information on food additives:

Division of Animal Feeds

Center for Veterinary Medicine

(HFV-220)

7500 Standish Place

Rockville, MD 20855

301/594-1731

USDA Animal and Plant Health Inspection Service

Licensing and program policy information:

Deputy Director

Veterinary Biologics

Animal and Plant Health Inspection Service

Rm. 838, Federal Building

6505 Belcrest Rd.

Hyattsville, MD 20782

301/436-8245

Inspection and enforcement information:

Deputy Director Veterinary Biologics, Field Operations Animal and Plant Health Inspection Service 223 S. Walnut Ave. Ames, IA 50010 515/232-5785

U.S. Environmental Protection Agency

Information on registration requirements, tolerances, and experimental use permits:

Office of Pesticide Programs
Environmental Protection Agency
Registration Division (7505W)
Registration Support Branch
401 M St., SW
Washington, DC 20460
703/308-8340

U.S. Department of the Interior

Information on chemicals and drugs used in aquaculture:

Technical Information Specialist National Biological Survey National Fisheries Research Center P.O. Box 818 LaCrosse, WI 54602-0818 608/781-6200

Information on investigational new animal drugs:

INAD Coordinator Fish and Wildlife Service Mailstop 820, Arlington Square 1849 C St., NW Washington, DC 20240 703/358-1715

Food Animal Residue Avoidance Databank

The Food Animal Residue Avoidance Databank (FARAD) provides information on drugs, pesticides, and other chemicals used in aquaculture. For customized assistance, contact one of the Regional Access Centers listed below.

California

Department of Environmental Toxicology
College of Agriculture and Environmental Sciences
University of California
Davis, CA 95616
916/752-7507
Internet e-mail: farad@ucdavis.edu

North Carolina

College of Veterinary Medicine North Carolina State University 4700 Hillsborough St. Raleigh, NC 27606 919/829-4431

Illinois

National Animal Poison Control Center College of Veterinary Medicine University of Illinois 1220 Veterinary Medicine Basic Sciences Building 2001 S. Lincoln Ave. Urbana, IL 61801 217/333-6731

State Agency Contacts

State-level sources of information on aquaculture topics include Cooperative Extension Services; Sea Grant Marine Advisory Services; Departments of Agriculture; and Departments of Natural Resources.

National NADA Coordinator

The National NADA Coordinator for Aquaculture acts as a liaison among various segments of the aquaculture industry and also as a liaison between the industry and FDA. The Coordinator's office serves as a repository for INAD information available to the public. The Coordinator also works with the aquaculture industry to identify data needed for complete data packages to support FDA approval of new animal drugs for aquaculture.

May 2-October 31 of each year: National NADA Coordinator 9740 SW Bay Shore Traverse City, MI 49684 616/947-9287

November 1-May 1 of each year: National NADA Coordinator 625 High Point Drive Mt. Dora, FL 32757 904/383-2589

Aquaculture Producer Quality Assurance Programs

The following national aquaculture associations either have completed or are in the process of developing industry-driven quality assurance programs. These programs are designed to improve production efficiency and to provide consumers with safe, wholesome, farm-raised aquatic foods.

For further information, contact any of the associations listed below.

American Tilapia Association, Kalona, IA: 319/683-2495 Catfish Farmers of America, Indianola, MS: 601/887-2699 National Aquaculture Association, Shepherdstown, WV: 1-800/626-3301 Striped Bass Growers Association, Columbia, SC: 803/734-2151 U.S. Trout Farmers Association, Shepherdstown, WV: 304/876-6666

Additional Information Sources and References

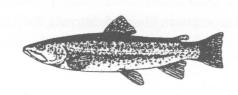
Office of Industry Programs
Center for Veterinary Medicine
U.S. Food and Drug Administration
7500 Standish Place
Rockville, MD 20855
301/443-1544

Office of Prevention, Pesticides and Toxic Substances U.S. Environmental Protection Agency 401 M St., SW Washington, DC 20460 202/260-2902

The following publications are available from the EPA Office of Prevention, Pesticides and Toxic Substances: *EPA's Pesticide Programs* (1991); *Citizen's Guide to Pesticides* (1991); *Pesticide Safety for Non-Certified Mixers, Loaders, and Applicators* (1986); and *Pesticide Safety for Farmworkers* (1985).

USDA National Agricultural Library Aquaculture Information Center 10301 Baltimore Blvd., Rm. 304 Beltsville, MD 20705 301/504-5558

Contact the USDA National Agricultural Library to obtain publications prepared by the Federal Joint Subcommittee on Aquaculture (JSA) and for additional copies of this publication. An especially helpful JSA publication is Federal Regulation of Drugs, Biologicals, and Chemicals Used in Aquaculture Production (1992).



Appendix F

Sponsors, Registrants, Licensees, and Permittees for Federally Regulated Products

The following section contains the names and addresses of current sponsors, registrants, licensees, and permittees for federally regulated products. These companies may be contacted for information on product availability as well as for other information related to product use.



A & V Inc. N62 W22632 Village Drive Sussex, WI 53089 414/246-6922

ABC Chemical Corporation 14288 Meyers Rd. Detroit, MI 48227 313/935-1550

The Agricultural Group of Monsanto Company 800 North Lindbergh Blvd. St. Louis, MO 63167 314/694-1000

Agtrol Chemical Products 7322 Southwest Freeway Suite 1400 Houston, TX 77074 713/995-0111

Albaugh 1517 N. Ankeny Blvd. Suite A Ankeny, IA 50021 515/964-9444

American Cyanamid Company Agricultural Research Division Quaker Bridge & Clarksville Road P.O. Box 400 Princeton, NJ 08543 609/799-0400 Amvac Chemical Corporation 4100 East Washington Blvd. Los Angeles, CA 90023 213/264-3910

Applied Biochemists, Inc. 6120 W. Douglas Avenue Milwaukee, WI 53218 414/464-8450

Aquabiotics Corporation P.O. Box 10576 Bainbridge Island, WA 98110 206/842-1708

Aquacide Company 1627 9th St. P.O. Box 10748 White Bear Lake, MN 55110 612/429-6742

Argent Chemical Laboratories, Inc. 8702 152nd Ave., NE Redmond, WA 98052 206/885-3777

Athea Laboratories, Inc. 7855 N. Faulkner Rd. P.O. Box 23926 Milwaukee, WI 53224 414/354-6417 Biomed, Inc. 1720 130th Avenue, NE Bellevue, WA 98005-2203 206/882-0448

Boliden Intertrade, Inc. 3379 Peachtree Rd., NE Suite 300 Atlanta, GA 30326 404/233-6811

Calabrian International Corporation 15,600 J.F. Kennedy Blvd. Suite 570 Houston, TX 77032 713/590-5007

Cenex/Land O'Lakes 5500 Cenex Drive P.O. Box 64089 St. Paul, MN 55164-0089 612/451-5151

Chem-A-Co, Inc. 721 North First St. Monticello, IN 47960 219/583-6842

Chem One Corporation P.O. Box 79133 Houston, TX 77279-9133 713/974-1104 Chemical Specialties, Inc. P.O. Box 312 San Marcos, TX 78666

C.J. Martin Company P.O. Box 630009 Nacogdoches, TX 75963 409/564-3711

C.P. Chemicals One Parker Place Fort Lee, NJ 07024 201/944-6020

DiagXotics, Inc. 27 Cannon Rd. Wilton, CT 06897 203/762-0279

Drexel Chemical Company P.O. Box 9306 Memphis, TN 38190 901/774-4370

Elf Atochem North America, Inc. 2000 Market St. Philadelphia, PA 19102 1-800/225-7788

Foreign Domestic Chemicals Corp. 95 Chestnut Ridge Rd. Montvale, NJ 07645 201/307-3333 Frank Miller & Sons, Inc. 13831 S. Emerald Ave. Riverdale, IL 60627 312/468-3500

Great Lakes Biochemical Co., Inc. 6120 West Douglas Ave. Milwaukee, WI 53218 414/464-1200

Griffin Corporation P.O. Box 1847 Valdosta, GA 31603 912/242-8635

Helena Chemical Company 6075 Poplar Avenue Suite 500 Memphis, TN 38119 901/761-0050

Hoffmann-LaRoche, Inc. 340 Kingsland St. Nutley, NJ 07110 201/235-5000

I. Schneid, Inc. 1429 Fairmont Ave., NW Atlanta, GA 30318 404/351-4705

Imperial, Inc. P.O. Box 98 Shenandoah, IA 51601 712/246-2150 NCH Corporation 2727 Chemsearch Blvd. Irving, TX 75062 Outside Texas: 1-800/527-9921 Within Texas: 1-800/442-7950

Natchez Animal Supply 201 John R. Junkin Dr. Natchez, MS 39120 601/445-0997

PBI/Gordon Corporation 1217 West 12th St. P.O. Box 014090 Kansas City, MO 64101-0090 816/421-4070

Pfizer, Inc.
North American Animal
Health Division
1107 South State, Rt. 291
Lee's Summit, MO 64081
816/524-5580

Phelps Dodge Refining Corporation Phelps Dodge Refinery P.O. Box 20001 El Paso, TX 79998 915/778-9881

Platte Chemical Co., Inc. 150 South Main St. Freemont, NE 68025 402/727-8222 Prentiss Incorporated

C.B. 2000

Floral Park, NY 11001

516/326-1919

Qualis, Inc.

4600 Park Avenue

Des Moines, IA 50321

515/243-3000

Rhone-Poulenc Agricultural Co.

P.O. Box 12014

Research Triangle Park, NC 27709

1-800/334-9745

Riverdale Chemical Company

425 West 194th St.

Glenwood, IL 60425

708/754-3330

Roussel Uclaf Corporation

95 Chestnut Ridge Road

Montvale, NJ 07645

201/307-9700

Selig Chemical Industries

P.O. Box 43106

Atlanta, GA 30378

404/691-9220

Sentry Chemical Company

1481 Rock Mountain Blvd.

Stone Mountain, GA 30086

404/934-4242

SePRO

11550 North Meridian St.

Suite 200

Carmel, IN 46032

317/580-8282

Southern Agricultural Insecticides, Inc.

P.O. Box 218

Palmetto, FL 34220

813/722-3285

State Chemical Manufacturing

Company

3100 Hamilton Avenue

Cleveland, OH 44114

216/861-7114

Sungro Chemicals, Inc.

P.O. Box 24632

Los Angeles, CA 90024

213/747-4125

Sureco, Inc.

P.O. Box 938

Fort Valley, GA 31030

912/825-3351

Systems General, Inc.

P.O. Box 152170

Irving, TX 75015-2170

Outside Texas: 1-800/527-9921

Within Texas: 1-800/442-7950

Terra International, Inc. 600 Fourth St. Sioux City, IA 51102-6000 712/277-1340

Tifa Limited 50 Division Avenue Millington, NJ 07946 908/647-4570

Uni-Chem Corporation of Florida P.O. Box 6336 Ft. Lauderdale, FL 33310 305/484-1401

Uniroyal Chemical Company, Inc. 74 Amity Rd. Bethany, CT 06524-3402 203/393-2163 Venus Laboratories, Inc. P.O. Box 607 855 Lively Blvd. Wood Dale, IL 60191 708/595-1900

Western Chemical Inc. 1269 Lattimore Rd. Ferndale, WA 98248 206/384-5898

Zeneca Professional Products P.O. Box 751 Wilmington, DE 19897 1-800-759-2500

Jerry Zinn Aqua Health, Ltd. Rt. 3, P.O. Box 299 Buhl, ID 83316 208/543-5369

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