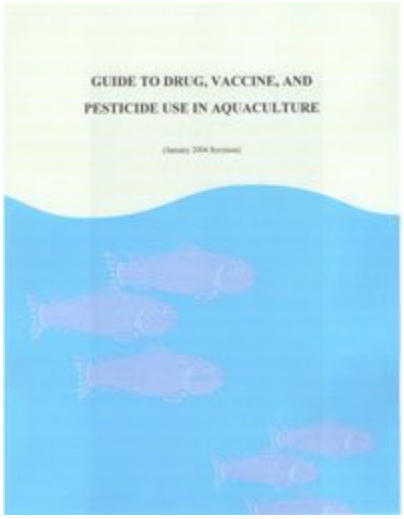

GUIDE TO DRUG, VACCINE, AND PESTICIDE USE IN AQUACULTURE

(April, 2007 Revision)

.pdf version

Prepared by
The Federal Joint Subcommittee on Aquaculture
Working Group on Quality Assurance in Aquaculture Production

in cooperation with the
Animal and Plant Health Inspection Service (APHIS)
and the
Cooperative State Research, Education, and Extension Service (CSREES)
United States Department of Agriculture

Center for Veterinary Medicine
and
Center for Food Safety and Applied Nutrition
Food and Drug Administration
United States Department of Health and Human Services

and the
Office of Pesticide Programs
United States Environmental Protection Agency

This revision of the original GUIDE TO DRUG, VACCINE, AND PESTICIDE USE IN AQUACULTURE (Texas Agricultural Extension Service Publication No.: B-5085, 1994), has been prepared by the Working Group on Quality Assurance in Aquaculture Production, which was established by the Federal Joint Subcommittee on Aquaculture (JSA) in November, 1990. This publication provides current information on federally regulated drugs, vaccines, and pesticides that may be used in aquaculture production and in aquatic sites according to product label directions. Sources of additional information and assistance are also presented.

PREFACE

The Working Group on Quality Assurance in Aquaculture Production provides a national forum for addressing drug, biologics, and pesticide use in aquaculture through education and the coordination of related efforts in government, industry, and academia. The Working Group, co-chaired by Kevin Greenlees of the Center for Veterinary Medicine (CVM), Food and Drug Administration (FDA) and Gary Jensen of the Cooperative State Research, Education, and Extension Service (CSREES), United States Department of Agriculture (USDA), is composed of representatives of the following agencies and organizations:

Federal and State Agencies

State Departments of Wildlife and Fisheries	U.S. Department of Health and Human Services	Fish and Wildlife Service (FWS)
U.S. Department of Agriculture	Food and Drug Administration (FDA)	U.S. Geological Service (USGS)
Agricultural Research Service (ARS)	Center for Food Safety and Applied Nutrition (CFSAN)	U.S. Environmental Protection Agency
Animal and Plant Health Inspection Service (APHIS)	Center for Veterinary Medicine (CVM)	
Cooperative State Research, Education, and Extension Service (CSREES)	U.S. Department of the Interior	

Trade, Industry, Professional, and Private Organizations

American Feed Industry Association	Baitfish Industry	National Association of State Aquaculture Coordinators
American Fisheries Society	Catfish Farmers of America	National Ornamental Goldfish Growers Association, Inc.
AFS Fish Culture Section	Florida Tropical Fish Farms Association	Striped Bass Growers Association
AFS Fish Health Section	Louisiana Crawfish Farmers Association	U.S. Trout Farmers Association
American Tilapia Association	Marine Shrimp Industry	Washington Fish Growers Association
American Veterinary Medical Association *Guide for the Use of Antimicrobial Drugs in Aquaculture* *Aquatic Animal Veterinarians and Diagnostic Laboratories Database*	National Aquaculture Association	
Animal Health Institute	National Aquaculture Council	

United Nations Food and Agriculture Organization (FAO)

The responsible use of antibiotics in aquaculture

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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, 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 cultured animals, and the safety of persons who administer various compounds, it is critical that all regulated aquaculture products be used correctly and responsibly.

An important initiative is the development and implementation of aquaculture-producer, quality-assurance programs. These industry-driven and industry-developed 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, to insure the safety and quality of the nation's food supply. These programs identify potential safety hazards associated with drugs and chemicals and directly support mandatory U.S. Hazard Analysis Critical Control Point (HACCP)-based regulations for processors and importers. Additionally, private and public aquaculture producers should use Best Management Practices (BMP) to provide consumers with safe, wholesome food products and attempt to minimize the use of federally regulated products whenever possible. This *Guide* serves as an important resource to assist aquaculture producers and others to use federally approved products legally, correctly, and responsibly.

On some occasions, various drugs, 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, the environment, 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 CAN BE LEGALLY USED, AND WITH WHAT RESTRICTIONS, UNDER FEDERAL, STATE, AND LOCAL REGULATIONS. REGULATED PRODUCT USES MAY VARY WITH DIFFERENT SITES, LIFE STAGES, AND CULTURE CONDITIONS.

This *Guide* presents information that can assist U.S. aquaculture 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 non-commercial aquaculture production.

The reader is encouraged to note the information presented in the Appendices. Appendix A addresses 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 to be 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, color additives, and disinfectants are used in aquaculture, they are not within the scope of this publication. More information on these products may be obtained by contacting the U.S. Food and Drug Administration's Center for Food Safety and Nutrition (CFSAN), or Center for Veterinary Medicine (CVM), or U.S. Environmental Protection Agency's Office of Pesticide Programs (OPP), or other sources of assistance in Appendix E.

UPDATING THE *GUIDE*

This electronic version of the *Guide* will be updated periodically. Individuals wishing current updates on specific products may contact the individual federal regulatory agencies responsible for these products. Contact information for federal agencies responsible for these products can be found in Appendix E.

REGULATORY AGENCIES

Several federal and state agencies are involved in regulating drugs, vaccines, pesticides, and other products used in aquaculture. Each federal agency has specific responsibilities, mandated by Congress, to regulate the products under their respective jurisdictions.

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 usually 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: treated animals; persons administering treatment; the environment, including non-target organisms; and 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.

CVM guide to judicious use of antimicrobials for aquatic veterinarians

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 implemented mandatory seafood inspection regulations for the nation's seafood processors and seafood importers based on HACCP principles (effective date, November 25, 1997). 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 (EPA) 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, when used according to label restrictions. Any pesticide sold or distributed in the United States must be registered by EPA. It is illegal to use a pesticide in a manner inconsistent with its product label, which must be approved by the Agency during the registration process. 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 FFDCA. The purpose of the tolerance program is to ensure a reasonable certainty of no harm to consumers from pesticide residues in food.

EPA is required by law to re-register those pesticides registered prior to 1984 in order to ensure that such pesticides meet current scientific and regulatory standards for the protection of human health and the environment. Furthermore, EPA must re-assess tolerances to ensure a reasonable certainty of no harm from pesticide residues in food. Products regarded as pesticides include (but are not limited to) algicides, fish toxicants, aquatic herbicides, and toxicants for controlling invertebrates.

Animal and Plant Health Inspection Service
Safeguarding American Agriculture

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 distributed in the United States. This includes vaccines, bacterins, allergens, antibodies, antitoxins, toxoids, certain immunostimulants and cytokines, natural or synthetic immunizing substances such as carbohydrates, proteins, genes or genetic sequences, 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 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 offered for distribution and sale in the United States 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 share 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.

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 step in to regulate such 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 provide registration for additional uses of federally registered pesticides to meet special local needs under section 24(c) of FIFRA. Products registered for special local needs under section 24(c) are listed separately in each table of EPA-registered products in Appendix B.

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.

USE OF FEDERALLY REGULATED PRODUCTS

The proper use of regulated products in aquacultural production, handling, and processing promotes human, cultured 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 harmful and 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 in a way that maximize product effectiveness and minimize the amount of the product used. **They should also keep detailed chronological records of treatment and 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 non-target 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, non-target plants and animals, and the environment. Seek professional advice when in doubt.

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 product labels describe how, when, and where the product may be applied, as well as the target pests they are intended to control. Pesticide labels also 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 acutely toxic products, whereas "WARNING" and "CAUTION" are associated with those that are less acutely 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 upon 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. Some pesticide product labels may give maximum allowable application rates. Depending on the target pest and environmental conditions, something less than the maximum rate may be sufficient. Users are encouraged to practice Integrated Pest Management techniques in an effort to minimize the frequency and rate of pesticide applications and considering the best means for control of multiple pests.

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

OPTIONS FOR PROPER DRUG USE

According to the FFDCA, 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 Generally Recognized as 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 or Conditionally-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. Conditional approvals have recently been authorized under the Minor Use and Minor Species Animal Health Act. Conditional approvals will be recognized by clear statements on the label identifying them as such. Conditional approvals are granted to products that have demonstrated all safety components of the New Animal Drug Application, but have yet to complete the effectiveness component. At the time of conditional approval, the drug must only have been shown to have a

"reasonable expectation of effectiveness." The full effectiveness component must be completed within 5 years of the conditional approval. At that point the product will have the full FDA approval.

Indexed drugs have also been authorized for early life stages and non-food minor species new animal drugs, but this avenue of legal use will not be available until after implementing regulations have been put in place. Please check the FDA CVM website at http://www.fda.gov/cvm/minortoc.htm or contact FDA CVM for further information.

2. **Investigational New Animal Drugs**. These drugs are used under an investigational new animal drug exemption. INAD exemptions are granted by FDA CVM to allow for the purchase, shipment, and use of unapproved new animal drugs for collection of efficacy and safety data that will support a decision on drug approval. Numerous requirements must be met for the establishment and maintenance of aquaculture INADs. An INAD exemption is provided with the expectation that useful data will be generated and submitted to FDA CVM. FDA authorizes specific conditions of use and monitors all drugs under each INAD exemption. Adequate drug accountability, data recording, and reporting are foremost among requirements for INAD exemptions. Additional information concerning INAD exemptions may be found on the CVM website at: http://www.fda.gov/cvm/nadaappr.htm or by contacting CVM's Division of Therapeutic Drugs for Food Animals at: 301-827-7580.
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 problems 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**. The Animal Medicinal Drug Use Clarification Act (AMDUCA) was passed by Congress in 1994. The Final Rule which implements AMDUCA was published on November 7, 1996. Licensed Veterinarians, within a valid veterinarian-client-patient relationship, can prescribe FDA-approved new animal drugs or new human drugs for an extra-label use. Extra-label use of a drug refers to the actual or intended use of an approved new animal drug in a manner not described on the label. This includes but is not limited to species, frequency, route of administration, dose, withdrawal time and conditions of use. This extra-label use is limited to treat modalities when the health of an animal is threatened, or when suffering or death of the animal may result if not treated.

THE IMPLEMENTING REGULATIONS IN TITLE 21, CODE OF FEDERAL REGULATIONS (CFR) PART 530 DESCRIBES IN DETAIL THE PROVISIONS OF THIS ACT. EXTRA-LABEL USE OF AN FDA-APPROVED VETERINARY OR HUMAN NEW DRUG NOT PRESCRIBED BY A LICENSED VETERINARIAN UNDER THE PROVISION IN TITLE 21, PART 530 OF THE CFR IS A VIOLATION OF THE FOOD, DRUG AND COSMETIC ACT.

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 regulations (21 CFR 530) 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 regulations do 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

In the November 19, 1999, Federal Register FDA published a final rule amending the new animal drug regulations to implement the medicated-feed mill licensing requirements of the Animal Drug Availability Act of 1996 (ADAA). The ADAA replaced the requirement for feed mills to have an approved medicated feed application (MFA) for the manufacture of each medicated feed with the need for medicated feed mills to be licensed by FDA. Licensed facilities are allowed to manufacture animal feeds containing Category II, Type A medicated articles. In addition, the ADAA amended the Federal, Food, Drug, and Cosmetic Act to provide the Agency with the authority, to the extent consistent with the public health, to exempt facilities that manufacture certain types of medicated feed from the requirement of obtaining a medicated feed mill license. This rule removed the medicated feed procedural regulations from Title 21, Part 514 of the CFR and adds a new section, Title 21, Part 515 of the Code of Federal Regulations (CFR). The final rule became effective on December 20, 1999. There are more details on these regulations on the CVM website at: http://www.fda.gov/cvm/feedmilltoc.htm.

The FDA published a Compliance Policy Guide (CPG), effective April 23, 2001, to allow regulatory discretion for the extra-label use of medicated feeds in minor species (any species other than cattle, horses, pigs, dogs, cats, chickens, or turkeys). All aquatic species are minor species. A CPG is FDA's direction to its field inspectors. It describes the actions that they should take when they encounter a given situation. This CPG lets inspectors know that FDA will not ordinarily take regulatory action against producers, veterinarians, or feed mills who use or produce medicated feeds for extra-label use in minor species. This does not make the use legal, it simply means that, at this time, the FDA has chosen not to take action when medicated feeds are used under the conditions described in the CPG.

The policy applies only to minor species. The medicated feed must already be approved for use in a major species. The feed must be formulated and labeled at the feed mill according to its approved labeling for the major species. If the medicated feed is to be used for a food-producing minor species, the medicated feed must be one approved for use in another food-producing species. If the medicated feed is to be used in an aquaculture species, the medicated feed must be one approved for use in another aquaculture species. The policy applies to farmed wildlife species, but not to unconfined wildlife. The medicated feed may be used in an extra-label manner only under the written recommendation and oversight of a licensed veterinarian. Only therapeutic extra-label uses of medicated feed are included. This excludes production claims such as increased weight gain or feed efficiency. The specific responsibilities of the animal producer, veterinarian, and the feed mill are all outlined in the text of the

CPG. If the conditions of the CPG are not met or if tissue-residue violations occur, then regulatory action may be taken against the producer or the veterinarian, or in some cases against the feed mill.

The full text of the CPG is the version that you should consult. A copy of the full text of the CPG is available on the FDA Home Page at: http://www.fda.gov/ora/compliance_ref/cpg/cpgvet/cpg615-115.html

If you prefer a paper copy, you may submit a written request for a copy of CPG number 615.115 to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855. Please send one self-addressed adhesive label or envelope with your request.

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.

RECORD KEEPING

Record keeping is essential for any aquaculture business and is a critical element of quality assurance programs. Record keeping may also be required of producers by processors purchasing fish from them to comply with HACCP requirements. A good record keeping system helps producers keep track of specific treatments and their results with identifiable, known populations or stocks of aquatic animals, as well as the specific water and land areas involved.

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 record keeping. Records provide valuable evidence and protection in liability cases.

Accurate record keeping 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.

Pesticide record keeping regulations for pesticides designated as "restricted use" require that private, as well as commercial users, keep records of the use of these compounds. There are no mandatory record keeping requirements for pesticides, that do not have the restricted-use pesticide designation, but there might be merit in keeping some records for documenting beneficial effects, as well as non-efficacious treatments. The records for restricted-use pesticides 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 record keeping help and record keeping requirements, such as those for restricted-use pesticides. States may also mandate additional record keeping requirements. Assistance is also available for other farm record- keeping 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 drug and vaccine 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. 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.

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.

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 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 degrees Fahrenheit) 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 required or 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. Contaminated work clothing should be washed separately from household laundry.

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.

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.

Many States run programs to collect and properly dispose of unwanted pesticides at no or low cost to participants. Nearly all States have plastic pesticide container collection and recycling programs coordinated with the Ag Container Recycling Council (ACRC). For further information on:

- Pesticide disposal programs, contact your State agency that regulates pesticides. Information on state pesticide disposal programs is available at: http://www.epa.gov/pesticides/regulating/disposal_contacts.htm
- Pesticide container recycling programs, contact the ACRC (http://www.acrecycle.org/ , 877-952-2272).
- Product storage and handling, contact the county agricultural Extension office in your area. Information on pesticide storage and handling is available at: http://www.epa.gov/pesticides/regulating/storage_resources.htm

PESTICIDE APPLICATOR CERTIFICATION

Restricted-use pesticides can be purchased and applied only by a Certified Pesticide Applicator or under under the supervision of a Certified Applicator. Certification includes, but is not limited to, "private" (mostly farmers) and "commercial" applicators. Pesticide Certification Programs are offered through state agencies responsible for pesticide regulation.

Some of the 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 local Cooperative Extension Service 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.

Pesticides produced by foreign manufacturers and imported into the United States must comply with all requirements applicable to domestic manufacturers including registration and labeling requirements. 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.

TIPS FOR USE OF REGULATED PRODUCTS

There are numerous actions and practices that producers can take to use regulated products safely and also achieve desired results in both managing targeted pests or diseases economically and minimizing any potential impact on the environment. The following list provides recommendations and guidance to users of federally regulated products in aquaculture.

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 label, unless extra-label use is specifically prescribed by a licensed veterinarian.
4. Read and follow directions for use on 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 aquatic 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 or 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 non-target organisms.
13. Adopt a producer quality assurance program or a HACCP program that provides guidelines for preventing tissue residue violations and for producing high-quality, wholesome products for consumer use.
14. Be aware of requirements concerning 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.

CITATION

Texas Agricultural Extension Service. Publication No.: B-5085. 1994. *Guide to Drug, Vaccine, and Pesticide Use in Aquaculture*. The Texas A&M University System.

To cite the web-based revised *Guide*, Please cite the URL: http://aquanic.org/jsa/wgqaap/drugguide/drugguide.htm and the time and date the *Guide* was accessed. For example:

Guide to Drug, Vaccine, and Pesticide Use in Aquaculture. 2004 revision, http://aquanic.org/jsa/wgqaap/drugguide/drugguide.htm . Accessed (month, day, year).

APPENDICES: 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, re-registrations, or new data. The drug and vaccine product listings in this section are based on data provided by the Food and Animal Residue Avoidance Databank (FARAD). For updated information on the status of a regulated drug and vaccine product, contact any FARAD Regional Access Center or other organizations and agencies listed in Appendix E. The listings of registered pesticides were compiled by the U.S. Environmental Protection Agency's Office of Pesticide Programs.

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 non-food 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 and adhere strictly to its requirements and restrictions for use.

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. FDA approved products are listed in the publication FDA Approved Animal Drug Products (Green Book) available online at http://www.fda.gov/cvm/Green_Book/greenbook.html. Specific new animal drugs can be looked up using the Database of Approved Animal Drug Products available online at http://dil.vetmed.vt.edu/NADA/

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

Table 1. FDA-Approved New Animal Drugs (.pdf version)
Table 2. Unapproved New Animal Drugs of Low Regulatory Priority for FDA (* See NOTE at bottom of table.) (.pdf version)

APPENDIX B: EPA-REGISTERED PESTICIDES FOR AQUACULTURE/AQUATIC SITES

The pesticide products listed in this section are registered by EPA for application and use in aquatic sites, as of January, 2004. 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.

This listing of pesticide products in this appendix is intended as a guide to help potential pesticide users identify products which may be legally used in aquacultural applications. However, it is not an entirely complete listing of all products for all possible uses in aquaculture.

In addition, it is possible that some products may be listed here that may not be legally used in aquaculture in the manner desired or intended by a potential user. If the label of any pesticide product listed herein does not indicate that the product is legal for use on the site or in the manner the user intends to use it, the listing of that product in this *Guide* **DOES NOT** make it legal for that or any other non-labeled use.

The reason that this appendix may unintentionally exclude or include some EPA-registered pesticide products legal for use in aquaculture, stems from the way pesticide products are registered. Any pesticide active ingredient may be the active ingredient in many different pesticide products. Each product has its own separate directions for use, which include what use site(s) it may be used on and what target pest(s) it may be used to control. The label is consistent with the use site(s) and pest(s) for which the product is registered. A pesticide use site is the term used to describe what the product is intended to protect (from the pest), or, in some cases, where the product is to be used (description of type of physical setting, not geographical location). Although for most agricultural uses, the use site is of the former type, meaning a crop, (e.g., corn) for most aquatic uses, the use site is the latter type, (e.g., lakes, ponds, or fish hatcheries). In many cases the site is defined even more narrowly, (e.g., "ponds (farm) (water treatment)," or, "oyster ponds (water treatment))." However, under EPA's current use-site nomenclature, in no case is the use site termed "aquaculture." Suitability for use in aquaculture must be determined by carefully reading the product label. Therefore, it is difficult to find a precise list of all possible products, from among the over 19,000 pesticide products registered (as of January, 2004), which may be used in some manner in aquaculture.

For this reason, a small group of individuals knowledgeable in aquaculture was selected by Gary Jensen, co-chair of the Working Group on Quality Assurance in Aquaculture Production, to assist EPA in selecting which products to include in this *Guide*. To include all products registered for any aquatic site would have included many products which are clearly not for aquacultural uses. EPA supplied the group of aquaculture experts with its complete list of site codes and pest codes used for registration of pesticides. The group selected the sites and the pests which they felt are of significant interest to the aquaculture industry in the U.S. and supplied that listing to EPA. EPA then searched its database of registered products to determine a listing of all products which are registered for use on at least one of the sites AND for control of at least one of the pests which were on the site and pest listings supplied by the group. Finally, EPA refined the list of products resulting from the search through a review of those product labels. Again, however, EPA cannot guarantee that this process and review resulted in a 100% accurate listing of pesticide products legal for use in aquaculture.

All of the pests selected by the group discussed above to be included in this *Guide* fell into the categories of pests controlled by algicides, fish toxicants, aquatic herbicides, and invertebrate toxicants. In order to limit the scope of the pesticide product listings to those of primary interest to the aquaculture industry, we excluded disinfectants, terrestrial herbicides, and lampreycides unless such products also fit into one of the other above categories. For example, if an aquatic herbicide also is registered for use as a terrestrial herbicide, it is included under aquatic herbicide listings, but terrestrial weed pests are not listed under it's target pests. EPA decided not to include a large number of products which are registered

under a "generic" calcium hypochlorite, or sodium hypochlorite, label, which allows many uses including aquaculture uses. Although many of these excluded products are legal for use in aquaculture, they do not have specific directions for use in aquaculture and may not be marketed for such use. However, there are a number of other calcium hypochlorite or sodium hypochlorite products which do have specific directions for use in aquaculture, and these are included in the tables in this appendix.

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 NON-FOOD 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 someone under a Certified Applicator's direct supervision. To identify such products, look for the "restricted-use" designation for the product in this appendix and on the label. In addition, most products designated in this appendix as "restricted-use" have the additional restriction that each application must be approved by appropriate State and Federal Fish and Wildlife Agencies, as is noted for each such product.

The product listing is subject to various changes as the registrants of the products amend or modify their registrations and EPA continues to evaluate the registrations under a variety of regulatory programs. Some products are not currently being distributed despite the fact that their EPA registrations are still active. EPA is currently re-registering all pesticides registered prior to 1984. In many cases, this process requires new data from the registrant. Consequently, some product registrations are not being maintained. Anyone interested may search EPA’s Pesticide Product Information System on the California Department of Pesticide Regulation website at http://www.cdpr.ca.gov/docs/epa/epamenu.htm to get updated product information, which may be more current than the information in this Guide. PPIS contains information concerning all pesticide products registered in the United States. It includes registrant name and address, chemical ingredients, toxicity category, product names, distributor brand names, site/pest uses, pesticidal type, formulation code, and registration status.

How pesticide product tables in Appendix B are organized and should be used

There is a separate table for each pesticide type, i.e., algicides, fish toxicants, aquatic herbicides, and invertebrate toxicants. Each table is divided into products registered under FIFRA, section 3, and (if applicable) Special Local Needs products registered under FIFRA, section 24(c). Section 3 registrations are generally legal for use nationally on the registered use sites, with some exceptions listed on labels. Products registered under section 24(c) are each for use in a single state, which is why they are listed separately. Within the parts of each table for sections 3 and 24(c), the products are grouped and listed alphabetically by the active ingredient they contain. All products containing the same active ingredient in each part of each table are listed alphabetically by product name (trade name). If a user knows the

pesticide type, active ingredient, and product name of a particular pesticide, they can easily find that product listing to obtain further information about the product (EPA registration number, registrant name, whether the product is designated as restricted use, the applicable registered use sites, and the applicable registered target pests). The user may simply find the appropriate table (e.g., aquatic herbicides), then find the active ingredient alphabetically, then find the product alphabetically within the listings for that active ingredient. If a user does not know the active ingredient or product name, but wants to find aquatic herbicides for certain weeds, for example, they may scan the use sites and target pests listed under each product listing in the aquatic herbicide table, to find available products.

After a user has identified a product which they are interested in using, they should obtain and review a copy of the product label to be certain the product is registered for the specific use they intend to use it for, prior to buying the product.

ALWAYS REFER TO THE PRODUCT LABEL FOR DETAILS ON RECOMMENDED OR APPROVED TREATMENT RATES AND USAGE AS WELL AS FOR ANY RESTRICTIONS ON USE.

The best way to identify a particular product is with the EPA registration number. For most pesticide products, the user should be able to access a copy of the label through the Pesticide Product Label System (PPLS) on EPA's website at http://www.epa.gov/pesticides/pestlabels. PPLS is a collection of images of pesticide labels which have been approved by EPA. If for any reason a user is not able to access the label for a particular product through PPLS, they should find another source. Users may wish to contact the registrant for the product to obtain a copy of the label. The registrant for each product is also listed in the tables. A list of all registrants, with addresses and telephone numbers, is included in Appendix F. Pesticide distributors may provide copies of some product labels. A copy of a pesticide product label may also be obtained through a request under the Freedom of Information Act (FOIA). Interested parties should first pursue the sources of labels discussed above, but as a last resort (because it may take longer) a FOIA request may be made. Instructions for making a FOIA request by mail or e-mail can be found in Appendix E, under U.S. Environmental Protection Agency.

Some listed products are of more than one pesticide type, meaning that they control pests in more than one group. For example, many products included in the following tables are both algicides and fish toxicants. Some are for various other combinations of pesticide types addressed in this *Guide*. In order to include a complete listing of identified products for each pesticide type, products which are of multiple-pesticide types are listed repeatedly, once in each applicable table. Each time a product is listed, all applicable pesticide types are indicated under "type." Only the four pesticide types included in this appendix (algicides, fish toxicants, aquatic herbicides, and invertebrate toxicants) are indicated for each product. Some products included here may also be of other types, but those types were determined to be not of significant interest to the aquaculture industry, or not within the scope of this *Guide*. Likewise, each time a product is repeated in another table (pesticide type), all of the use sites and target pests applicable to aquaculture are listed, regardless of pesticide type.

Appendix B -Table 1. EPA-Registered Algicides (.pdf version)

Appendix B - Table 2. EPA-Registered Fish Toxicants (.pdf version)

Appendix B - Table 3. EPA-Registered Aquatic Herbicides (.pdf version)

Appendix B - Table 4. EPA-Registered Invertebrate Toxicants (.pdf version)

Appendix F EPA-Registrant Contact List (.pdf version)

Definition of terms used in pesticide product tables in Appendix B

Product name: The trade name under which a pesticide product is sold.

EPA registration #: A hyphenated, two-part unique number assigned by EPA to identify each product registration. The first part of the number is the assigned company number (called the establishment number), which is specific to a given chemical company, or registrant; the second part is the specific product number. The registration number must appear on the product's label.

Type: This refers to pesticide type, and describes the type (or group) of organism which the product is targeted for control, e.g., algicide, aquatic herbicide. A product is of a type if it is registered for control of one or more target pests within that pest group.

Common name A.I.: The common name (as opposed to the chemical name) of the active ingredient. The active ingredient is the chemical or substance in a pesticide product that prevents, destroys, repels, or mitigates a pest, or is a plant regulator, defoliant, desiccant, or nitrogen stabilizer.

Registrant: The term given to a person or company that has registered a pesticide product under FIFRA.

Restricted use: A pesticide that is available for purchase and use only by certified pesticide applicators or persons under their direct supervision. This designation is assigned to a pesticide product because of its relatively high degree of potential human and/or environmental hazard.

Use site: The term used to describe where, or on what, a pesticide product is registered for use, and may therefore be legally used. A use site is what the product is intended to protect (from the pest), or, in some cases, where the product is to be used (description of type of physical setting, not geographical location).

Target pest: A pest for which a pesticide product is registered to control; the pest which is intended to be controlled by a pesticide. A pest is defined in FIFRA as any insect, rodent, nematode, fungus, weed or any other form of terrestrial or aquatic plant or animal life, or any virus, bacteria, or other micro-organism which the Administrator of EPA declares to be a pest.

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 (link to APHIS website)

Table 2. Diagnostic Test Kits (.pdf version)

APPENDIX D: GLOSSARY OF COMMON TERMS (.pdf version)

APPENDIX E: SOURCES OF INFORMATION AND ASSISTANCE (.pdf version)

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.

For comments, contact webmaster at:
mailto:mmayeaux@csrees.usda.gov