JIFSAN Good Aquacultural Practices Program

Antibiotics: Use of Chemotherapeutics

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Antibiotics and chemotherapeutics are an important component of good aquaculture practices. However, they must be used with extreme care to guard against improper use and to assure that all regulations and requirements are followed.

Concerns

Development of antibiotic resistance in both target pathogens and normal bacterial flora is a concern in aquaculture production. Concerns focus on human and environmental safety issues, and on the potential for the establishment of antibiotic resistant zoonotic pathogens in wild stocks (FDA 2006).

An integral part of good veterinary practices is a regime in which every effort is made to maximize therapeutic efficiency and minimize selection of resistant bacteria. Judicious use principles are a guide for proper use of antibiotics under the direction of a veterinarian (FDA 2006).

Veterinarian Responsibilities

Veterinarians are responsible for diagnosis of disease conditions, and work directly with fish health professional on the production operation. They should be available for questions/concerns following treatment, and are responsible for on site health care of the aquatic species.

Treatments must only be used when needed. Use of drugs in a manner other than the options discussed here are subject to regulatory action by the FDA. There are 4 options for proper drug use in the USA: (1) FDA-approved or conditionally approved new animal drugs; (2) investigational new animal drugs (INAD); (3) unapproved new animal drugs of low regulatory priority; and (4) extra-label use of approved new animal drugs (JSA 2004).

Options for Proper Drug Use-USA

FDA Approved or Conditionally Approved New Animal Drugs

Approved or conditionally approved drugs in the USA must be used for specific species and life stages. They must also be used for specific proscribed diseases, at proscribed dosages for fixed lengths of time, and they must be purchased from an approved source (JSA 2004).

INAD

Drugs are administered under an investigational new animal drug exemption (INAD). The first requirement for use of an INAD in the USA is that the use of the drug must have an official sponsor or study monitor. In addition there must be records addressing Drug Accountability, Proper Disease Diagnosis, Protocol Adherence, Prescribed Application Rates and Withdrawal Periods, and finally Documentation of Use and Response. Expectations are that the use of unapproved new animal drugs will result in the collection of data that will support decisions on drug approvals (JSA 2004).

Unapproved New Animal Drugs of Low Regulatory Priority

Neither approved animal drug applications nor an INAD exemption is required for these compounds. Regulatory action is unlikely, if an appropriate grade is used, Good Management Practices are followed, and local environmental requirements are met (JSA 2004).

Extra Label Use of an Approved Animal Drug

Extra label use of an approved animal drug is allowed under the guidance of a veterinarian, but is limited to when the health of the animal is threatened, or when suffering or death may occur if not treated. These drugs must be prescribed only in accordance with the Animal Medicinal Drug Use Clarification Act. Extra label use of certain drugs for food animals is prohibited: (e.g., chloramphenicol, clenbuterol, diethylstilbestrol, dimetridazole, ipronidazole, other nitroimidazoles, furazolidone, nitrofurazone, sulfonamide drugs (except approved use of sulfadimethoxine, sulfabromomethazine, and suflaethoxypyridazine),

fluoroquinolones, and glycopeptides [example is vancomycin] and phenylbutazone (FDA 2005, JSA 2004). In the USA, therapeutic extra label use of approved animal drugs in medicated feed for aquatic species can only be used under the direction and written recommendation of a veterinarian (veterinarian-client patient relationship). It must also have been approved for use in another aquacultured species, and its use should be consistent with all established regulations and policies (JSA 2004).

Record Keeping

Records must be kept in each area of chemotherapeutic antibiotic use. Records on treatment status of animals and culture facility must be kept, as well as records on dosage rates and withdrawal times. Producers must also keep records to demonstrate that all drugs and chemicals are used properly under the direction of a veterinarian and have been properly disposed. For INAD exemptions, records must be kept in several areas (see the paragraph on INAD use) (JSA 2004).

World Aquaculture Drug and Vaccine Progress

The drug approval process varies by country and continent. Vaccine approval process also varies by country and continent.

Chemotherapeutics

Aquaculture production companies and exporting countries must be aware and comply with the drug and vaccine use requirements of the importing country. It is incumbent on the exporting country to ensure that the laws of the importing country are met and that the use of chemotherapeutics is kept to a minimum and used only under the direction of a veterinarian . (JSA 1997) Use of chemotherapeutics can be minimized by following and implementing aquaculture GAqPs.

Approvals by Country or Continent

Africa-Most countries do not have regulations on drug or vaccine use;

Asia-Varies from no regulations to restrictive regulations;

Japan-Controlled by Pharmaceutical Affairs Law;

Philippines-Enforced by the Dept. of Agriculture;

Thailand-Controlled by the Dept. of Fisheries;

China-Approved for use by the Animal Drugs Examination Commission, Ministry of Agriculture

Australia-Applications are submitted to the National Registration Authority to seek exemptions from the need for registration;

Europe-Old and new substances defended by a sponsor, data is required to establish Maximum Residue Limits (MRL);

North America-In the USA, the FDA Center for Veterinary Medicine (CVM) regulates animal drugs. The USA drug approval process is similar to Canada, which requires approval of manufacturing, human food and target species, safety and efficacy sections

South America-Little information is available, however, in Chile the agency responsible for approvals is The Fisheries Health Department, National Fisheries Service

References

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