

Legal Use of Drugs and Therapeutants in Aquaculture

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Drug and Therapeutant Use in Aquaculture



Once upon a time...and not all that long ago.....

- Fisheries manager's access to drugs and chemicals was limited only by their active and inventive imaginations
- If you could get your hands on it, you could use it!!
- Home and Ranch, Chemical Supply Companies, local discount stores, hardware stores, etc. were all “fair game” in the quest for needed drugs and chemicals



However, in the early 1990's a decree went out that changed everything.....and feast became famine

- FDA...who had very conveniently been looking the other way....decided the time had come for aquaculture to be regulated
- FDA's decision left aquaculture with only 3 therapeutants and a single anesthetic that were “approved” for use...and use of these drugs was severely restricted by species, life stage, specific pathogen, and use-pattern



Drug and Therapeutant Use in Aquaculture



"Mechanisms" currently available for legal use of drugs in aquaculture

- FDA-approved drugs
- Low Regulatory Priority Compounds
- Compounds with Deferred Regulatory Status
- For use on specific Federally-listed T & E species
- Extra-label drug use policy
- Veterinary Feed Directive Drugs
- Compassionate INAD exemptions



Drug and Therapeutant Use in Aquaculture



Approved Drugs

Tricaine methanesulfonate (MS-222)

- Temporary immobilization (i.e., anesthetic)
- All finfish
- 21-day withdrawal period before fish can be released, stocked, or harvested



Approved Drugs

Formalin

- Control of external parasites - all finfish
- Control of fungi - eggs of all finfish



Approved Drugs

Terramycin (OTC) for Fish (in feed)

- Control of bacterial hemorrhagic septicemia and pseudomonas disease in catfish
- Control of ulcer disease, furunculosis, bacterial hemorrhagic septicemia, and pseudomonas disease in salmonids
- Marking of skeletal tissue in Pacific salmonids



Approved Drugs

Romet 30 (in feed)

- Control of enteric septicemia in catfish
- Control of furunculosis in salmonids
- ✓ Unfortunately, Romet 30 has always had some relatively major palatability issues



Approved Drugs

Romet TC

- Control of enteric septicemia in catfish
- Control of furunculosis in salmonids
- ✓ Top coat feed at facility
- ✓ Improved palatability issues



Approved Drugs

Chorulon

(Human Chorionic Gonadotropin -HCG)

- Spawning aid in broodfish (i.e., induced gamete maturation)
- All finfish



Drug and Therapeutant Use in Aquaculture



Approved Drugs

Oxytetracycline (immersion) (recent approval)

- Skeletal marking of all finfish
- 4 products available (Phoenix Scientific, Alpharma, Inc., Pfizer, Inc., and Cross Vetrpharm Group, Ltd.)



Approved Drugs

35% PEROX-AID[®] (hydrogen peroxide) (recent approval)

- Control mortality caused by fungal infections in freshwater finfish eggs
- Control mortality caused by BGD in freshwater-reared salmonids
- Control mortality caused by external columnaris in coolwater finfish and channel catfish



Approved Drugs

AQUAFLO[®] (florfenicol) (recent approval)

- Control mortality caused by ESC in catfish
- Control mortality caused by columnaris in catfish
- Control mortality caused by CWD in freshwater-reared salmonids
- Control mortality caused by furunculosis in freshwater-reared salmonids



Approved Drugs - Summary

-although we are making progress, obviously there remains a critical shortage of approved drugs.....particularly if you are feeling poorly and you are not a salmonid or a catfish!!



Low Regulatory Priority (LRP) Compounds

- Consideration for LRP status originates from a request from outside of CVM
- Candidate compounds are typically quite innocuous (e.g., salt, ice, onion, etc.)
- FDA makes determination based on review of all available data
- 17 compounds are currently on the LRP list



Low Regulatory Priority (LRP) Compounds

- LRP status does not mean “carte blanche” use of a particular compound
 1. Must be used for indication listed
 2. Must be used according to good management practices
 3. Must be used at the prescribed level
 4. Must be of appropriate grade for use in food animals
 5. Only if an adverse effect on the environment is unlikely
- LRP drug use is not considered to be “approved” drug use, but rather low enforcement priority....regulatory action unlikely (??)



Drug and Therapeutant Use in Aquaculture



Deferred Regulatory Status

- Very little specific, written guidance available
-verbal translation is that FDA chooses not to regulate....period!..... at this time
- Copper sulfate and potassium permanganate only 2 such compounds
- For all practical purposes.....this is “carte blanche”



Use of Unapproved Drugs on Federally Listed T & E Species

- CVM letter dated Dec. 4, 1995
- Includes FWS and Collaborators
- Use of unapproved drugs in T & E species will be considered to be of low enforcement priority
- Requires completion and submission to AADAP:
 - Drug receipt form
 - Drug use inventory form



Drug and Therapeutant Use in Aquaculture



T & E Species

regulatory action will not ordinarily
be considered if:

- Treated species are not subject to legal harvest
- Service assumes responsibility with NEPA compliance
- Used only as conservation action necessary for protection and recovery of listed species
- CVM's enforcement discretion will apply to the Service and contract facilities utilized by the Service



Drug and Therapeutant Use in Aquaculture



Extra-label Drug Use Policy

- Is a low enforcement priority documented in FDA Compliance Policy 7125.06
- Is a reflection of FDA's recognized need for veterinarians to be able to treat disease conditions for which there may not be an effective, approved drug
- It is directed at the actual or intended use of an approved drug in a manner not in accordance with label directions



Drug and Therapeutant Use in Aquaculture



Extra-label Drug Use Policy

- Extra-label drug use is limited by the following very specific restrictions:
 1. Applies only to drugs approved for use in other species (fish or otherwise)
 2. Available only thru practicing veterinarians, and mandates a valid veterinarian/client/patient relationship
 3. No effective approved drug is available for use in target animal
 4. Does not permit the use of drugs to prevent disease, or for enhanced production (e.g., growth promotion, induced spawning)
 5. Does permit (at least in fish) the use of drugs mixed in feeds. *However, VFD drugs (e.g., Aquaflor®) are excluded from this provision.*



Drug and Therapeutant Use in Aquaculture



Veterinary Feed Directive (VFD) Drugs's

- Drug classification established by FDA to more closely control new therapeutic products (primarily antibiotics) and their use in food animals
 - New classification that applies only to new therapeutants approved after 1999 and administered in feed. All products approved before 1999 will remain available as “Over-the-Counter” drugs
- VFD drugs are obtained through normal feed distribution channels – BUT orders require a signed VFD from a licensed vet
- VFD drugs likely fall somewhere between Over-the-Counter and prescription drugs...but probably closer to a prescription drugs
- VFD drugs cannot be used under extra-label provisions



Drug and Therapeutant Use in Aquaculture



Steps to obtain and feed VFD drugs

- Contact veterinarian for diagnosis and treatment recommendation
- Vet works within vet/patient/client relationship to determine need for VFD drug
- Vet issues a signed VFD form to hatchery & feed mill
- Hatchery uses VFD form to order medicated feed
- All parties retain copies of signed VFD order for 2 years



Good ol' INADs

"The Downside"

- Not just “use permits” like many folks initially believed
-a bit....ok, maybe more than a bit...of paperwork (and accountability) necessary for ALL involved
- Cost to participate....in either \$\$'s and/or time
- Under constant scrutiny by FDA.....as many within “The Big FDA” would like to see them go-away



Good ol' INADs

"The Upside"

- Contribute valuable efficacy and target animal safety data that can be used to support new approvals
- Treatment objectives written to be as inclusive as possible (e.g., “.....to control mortality caused by bacterial pathogens in freshwater fish”)
-we have been able to assemble quite a few!!
- INADs are providing access to a variety of drugs...and drug uses....that we would otherwise not have at our disposal



Summary of Legal Drug Use Options



- ...thankfully, the utility of the sum is greater than that of the individual parts
-a variety of options do exist
-but we still need to continue our efforts to obtain more **approved drugs**

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AADAP Website

<http://www.fws.gov/fisheries/aadap/home.htm>



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