

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



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

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



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**
Approved November, 2002
- **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 ($\geq 9^{\circ}\text{C}$)
- Marking of skeletal tissue in Pacific salmonids



Approved Drugs

Romet TC (in feed)

- Control of enteric septicemia in catfish
- Control of furunculosis in salmonids
- ✓ Palatability issues associated with Romet have been resolved (?)



Approved Drugs

Aquaflor (in feed)

- To control mortality in catfish due to enteric septicemia (ESC) – **Approved Nov, 2005**



Approved Drugs

Sulfamerazine for Fish (in feed)

- Control of furunculosis in rainbow trout, brook trout, and brown trout
- ✓ *Unfortunately Not Available.....oh well!!*



Approved Drugs

Oxytetracycline (immersion marking agent)

- Skeletal marking of all finfish
- 3 products available
 - IVX Animal Health
 - Alpharma, Inc.
 - Pfizer, Inc.



Approved Drugs

Chorulon

(Human Chorionic Gonadotropin -HCG)

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

- All finfish



Approved Drugs - Summary

-obviously, there is an extreme 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 (??)**



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”



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



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
 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. Permits the use of approved over-the-counter drugs mixed in feeds
(veterinarian order to treat a different fish species than that described on the label or for a different disease condition)
 5. Does not permit the use of drugs to prevent disease, or for enhanced production (e.g., growth promotion, induced spawning)



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 safety data that can be used to support broadening 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



Use of Unapproved Drugs on 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



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



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 certainly have a long way to go with respect to our goal of **approved drugs**



Final Exam - Drug Use

Question: Your fish are feeling poorly and have requested a cure-all treatment to get them back on their fins. Unfortunately, you are a bit uncertain as to how best to proceed. What **should** you do first? If necessary, what **could** you do second?

✓ Answers: Call your local fish health expert first.....and if any drug-use questions remain, please feel free to give AADAP a holler.



Questions??



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