U.S. Fish & Wildlife Service

The Aquatic Animal Drug Approval Partnership Program

"Working with our partners to conserve, protect and enhance the Nation's fishery resources by coordinating activities to obtain U.S. Food and Drug Administration approval for drugs, chemicals and therapeutants needed in aquaculture"

Volume 6-2

AADAP NEWSLETTER

July 2010

Arches National Park, Utah USA

TABLE OF CONTENTS

SLICE® INAD finally received: On 21 May 2010 (and after more than 5 years since we started down this path) AADAP received an Investigational New Animal Drug (INAD) exemption for SLICE® (emamectin benzoate) with slaughter authorization. The INAD allows for use of SLICE® to control infestations of ectoparasites on all life stages of freshwater finfish. Click here to view the authorization letter from FDA/CVM, and for additional details refer the "FINS & TAILS, BITS & BOBBERS" section of this news letter (click on the appropriate page number in the Table of Contents above).

WHAT'S SHAKIN'

16th Annual USFWS Aquaculture Drug Approval Coordination Workshop to be held 3-5 August 2010 in Bozeman, Montana, USA: It's almost here! The agenda has been set, key-note speakers and Workshop sponsors have committed, picnic supplies have been purchased, the river rafts are inflated, the fun run/walk course has been set and we are ready for the best Workshop yet!

Sooooo, if you haven't made your hotel reservations nor registered for the Workshop, now is the time to do it! Given the timing of the Workshop being a few days before Bozeman's Sweet Pea Festival, hotel rooms at the moment may be scarce. Check the Workshop webpage for a list of hotels close to the Workshop venue; there are also other hotels within Bozeman and nearby (9 miles via the freeway) Belgrade as well.

Workshop registration is easy and can be completed online. The cost of registration is US$20 (cash only, we can not accepts personal checks or credit cards) and is payable at the door. When registering online, please take the time to inform us whether or not you will be attending any of the extracurricular activities, and how many will be in your party for each of the activities (we encourage you to bring your spouse and children if they have accompanied you on the trip to Bozeman). Costs for participating in the Workshop-associated extracurricular activities have already been included within your registration fee.

Speaking of extracurricular activities, for the first time this year the Workshop will host a 1/3/5 mile fun run/walk. This year's fun run/walk (aka the "Trout Trot") is being sponsored by Western Chemical, Inc. and will take place late Wednesday afternoon (4 August 2010). For more details and to register for the fun run/walk contact Dan Carty (dan_carty@fws.gov or 406-994-9912). Don't forget to bring your running, walking or hiking shoes!

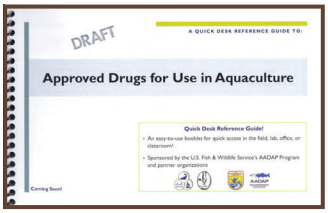
If you should decide that you have heard enough talk about fish drugs for any given day and choose to discretely slip out a little early on your own, you should find plenty of outdoor activities (other than those associated with the Workshop) to keep you happy. So bring your rod & reel, your golf clubs, your binoculars, and/or you hiking boots (and some sunscreen). Just ask any of the AADAP crew for recommendations and directions.

Last, but not least, the American Fisheries Society Fish Culture Sections' Working Group on Aquaculture Drugs, Chemicals, and Biologics (WGADCB) will be holding a meeting in conjunction with the Workshop. The WGADCB meeting will be held Wednesday, 4 August 2010, from 3:00 - 4:30 pm at the Workshop venue.

We look forward to seeing you here in Bozeman.

Update on "Sedative Challenge": In the last issue of the AADAP Newsletter (March 2010), the Association of Fish and Wildlife Agencies' (AFWA) Drug Approval Working Group (DAWG) issued a challenge to the aquaculture community. The "Sedative Challenge" was intended to encourage aquaculturists to "field test" either (or preferably both) of the two immediate-release candidate sedatives (eugenol and benzocaine), by enrolling in the AADAP-administered INADs for these drugs. The goal being to obtain real-life input as to the pros and cons for each of the sedatives to help the DAWG focus its concerted efforts on one or the other. The response to the "Challenge" has been encouraging. To date, 22 facilities have enrolled in the eugenol INAD and 23 in the benzocaine INAD. Most importantly, 18 facilities have signed up for both INADs, and hence, should be able to conduct side-by-side trials. Watch for a report on "Challenge" results in the next issue of the Newsletter and on AADAP's website.

New information aid on aquaculture drug-use progressing well: A companion tool to the AADAP - AFS "Approved Drugs for Use in Aquaculture" poster, is in the final stages of development. The desk-reference booklet (also a partnership project of the American Fisheries Society and AADAP) will contain the same information as the poster, as well as suggested guidance on "How to Calculate" the proper dose or concentration of approved drugs as per label instructions. We plan to be able to begin distribution in September 2010. Watch for an announcement of availability on AADAP's website.



Biologics Poster on schedule: The publication of the *"Approved Vaccines for Use in Aquaculture"* poster (noted in the last issue of the AADAP Newsletter), which is a joint effort between the USDA's Center for Veterinary Biologics' (CVB), the US Fish & Wildlife Service's Aquatic Animal Drug Approval Partnership Program (AADAP), the American Fisheries Society's Fish Culture (FCS) and Fish Health Sections (FHS) and the American Veterinary Medical Association (AVMA) is on schedule to be printed within the next two months. The poster will be made available, free of charge, from all of the noted sponsors. When the poster actually becomes available for distribution to the public, notice of such will be made on AADAP's website, as well as that of the other sponsors.

Progress update from the American Fisheries Society - Fish Culture Section's (AFS-FCS) Working Group on Aquaculture Drugs, Chemicals, and Biologics (WGADCB): In the last AADAP Newsletter, you read about several WGADCB projects, including revising the "*Guide to Drug, Vaccine and Pesticide Use in Aquaculture"* and developing an AFS Policy Statement on the need for an immediate-release sedative for fisheries critical use. Since then, the WGADCB has made significant progress on both of these projects, and also found time to respond to the FDA's request for public comments on regulation of Veterinary Feed Directive drugs.

During a recent conference call, Jesse Trushenski, Jim Bowker, Mark Gaikowski, Dave Straus, and Maren Tuttle-Lau discussed the WGADCB's objectives for revising the "*Guide to Drug, Vaccine and Pesticide Use in Aquaculture*." What was good about the previous *"Guide?"* What could be done better? What is the most critical information that end-users need to have ready access to? And, most importantly, how can we put it all together in a format that needs little-to-no upkeep? The new *"Guide"* will be as comprehensive as previous editions, covering drugs, biologics, disinfectants, and pesticides—one-stop shopping for end-users. Knowing what compounds are available is important, but so is knowing how to use them—the new *"Guide"* will include sections on application methods and best use practices. Most of this information already exists in one form or another, and WGADCB intends to take advantage of it. The new *"Guide"* will be available in electronic format only, and will link to frequently updated online sources to minimize the need for future revisions. With this game plan in mind, the various responsibilities have been divvyed up and the revision process is well underway.

Thanks to the hard work of all those involved, the draft AFS Policy Statement on the need for an immediate-release fisheries sedative is now nearly complete. The Policy Statement puts this issue in its full, broad context, describing:

- demand for an immediate-release sedative in fish culture, fisheries management and fisheries research;
- limitations of currently available sedatives, MS-222 and CO_2;
- the process for gaining aquatic animal drug approvals;
- effects of candidate immediate-release sedatives, benzocaine and eugenol; and
- the consequences of the continued absence of an immediate-release sedative for use in fisheries.

The Policy Statement concludes with a semi-quantitative risk assessment and recommendations to streamline the process of making an immediate-release sedative available to fisheries professionals. The complete draft will be made available for comments and suggestions at the next WGADCB meeting (see below), and then sent to the AFS Resource Policy Committee for formal review. Because they carry the weight of the 9000+ fisheries professionals that belong to AFS, Policy Statements can be effective tools in informing policy-makers of issues and constraints in the fisheries disciplines. Ultimately, it is hoped the Policy Statement on immediate-release sedatives will help to delineate a strategy to put these critically needed tools in the hands of fisheries professionals as quickly as possible.

FDA is currently undertaking a review of their Veterinary Feed Directive (VFD) drug requirements in an effort to identify ways to make regulating access and use of VFD drugs more efficient. As a part of this review, FDA requested public comments on all aspects of VFD regulations. Jim Bowker, Jesse Trushenski, Randy MacMillan, Mark Gaikowski, and Steve Sharon submitted comments on behalf of the WGADCB, suggesting a variety of strategies to simplify the ways in which end-users access VFD drugs and to increase the efficiency by which FDA regulates their use. Public comment periods are an important way for regulatory entities to interact and communicate with the regulated community, other stakeholders, and the general public. Unfortunately, calls for public comment often go unnoticed or unanswered. To ensure that fish culturists and others affected by VFD regulations were aware of this opportunity to make their voices heard, the WGADCB co-chairs made their comments available to the FCS, U.S. Aquaculture Society, and National Aquaculture Association memberships, along with instructions for how they could provide their own comments to FDA. Quite a few individuals and organizations have used the WGADCB comments as boilerplate in providing their own feedback to FDA. Providing a forum for interaction between the public and private sectors is central to the mission of the WGADCB—engaging stakeholders in the VFD public comment process is a great example of how the WGADCB is serving this purpose.

The next meeting of the WGADCB is scheduled during the 16th Annual USFWS Aquaculture Drug Approval Coordination Workshop, at 3:00 PM on Wednesday, August 4th. The WGADCB has accomplished a lot over the past few months, but there's always more to do. So bring your thinking caps, skill sets, and anything else you'll need to get involved in the WGADCB. See you there!

Text provided by Jesse Trushenski; Fisheries and Illinois Aquaculture Center; Southern Illinois University Carbondale; Carbondale, Illinois USA.

FDA - Center for Veterinary Medicine (CVM) Announces Minor Use/Minor Species Grant Program Request for Applications: CVM recently announced an application period for a second round (in this calendar year) of funds available for studies to generate effectiveness or safety data to be ultimately used in support of a New Animal Drug Application. These funds are aimed specifically at drugs for use on minor species (e.g., fish) or for minor use on major species. The application deadline is 3 September 2010. Additional information can be found on CVM's 8 July 2010 press release. See also the "CVM's NOTES" section in this issue of the Newsletter.

FDA - Center for Veterinary Medicine (CVM) issues draft antimicrobials judicious use guidelines: The CVM recently published (29 June 2010) a Federal Register Notice outlining draft guidelines "...intended to help reduce the development of resistance to medically important [human] antimicrobial drugs used in food-producing animals." The comment period will be open until 30 August 2010. CVM's 28 June press release went on to state "The document [draft guideline] recommends phasing in measures that would limit medically important antimicrobial drugs to uses in food-producing animals that are considered necessary for assuring animal health and that include veterinary oversight or consultation." CVM has provided links to the FR Notice, the draft guidelines and a series of Q&As, all of which can be found in their 28 June press release. Although the FR notice is relatively recent, public comments have been submitted and can be viewed by clicking here. See also the "CVM's NOTES" section in this issue of the Newsletter.

Comment period for suggested revisions to the Veterinary Feed Directive (VFD) regulations extended to 27 August 2010: The FDA's Center for Veterinary Medicine (CVM) has requested (29 March 2010), via the Federal Register (FR), that interested

parties provide comments on new proposed rule-making pertaining to the VFD regulations. In the initial FR Notice, CVM stated: "FDA's VFD regulation, which became effective on January 8, 2001, established requirements relating to the distribution and use of VFD drugs and animal feeds containing such drugs. FDA is undertaking a review of these requirements in an effort to identify possible changes to improve efficiency. Therefore, the agency is requesting public comment on all aspects of the VFD regulation, particularly suggestions relating to improving efficiency." To view the initial entire FR Notice, click here. Originally, comments were due by 28 June 2010, however, FDA extended the public comment period until 27 August 2010. To read previously submitted comments click here. See also the "CVM's NOTES" section in this issue of the Newsletter.

AADAP DRUG UPDATES

General:

Ah, summer time is upon us and that means it's time for the AADAP crew and our partners to get the pivotal field efficacy trial train rolling. This season the research team took conducting/planning studies with our collaborators to a new level. So many studies were planned this season that we decided that each research team member would have to take responsibility for at least two studies (whether studies are conducted in-house or in the field with one of our collaborators). Below is an overview of what's been happening since the last newsletter, including what studies have been completed, what's been submitted to CVM, what we've heard back from CVM regarding previous submissions, and what studies are currently underway.

35% PEROX-AID® (hydrogen peroxide) Update:

Ectoparasitic monogenetic trematodes and rainbow trout efficacy study: In the last newsletter, it was reported that Miranda Dotson and Dan Carty were developing a research protocol under which we would conduct one or more studies to evaluate the effectiveness of hydrogen peroxide to control or reduce infestations of ectoparasitic *Gyrodactylus* spp. in rainbow trout. The protocol was submitted to CVM on 23 April 2010, and on 18 June 2010 we heard back from CVM that they did not concur with the protocol. The primary issue was that we proposed to conduct efficacy trials at the Ennis National Fish Hatchery (Ennis, Montana, USA) only on male rainbow trout broodfish. Males tend to become more heavily infested with *Gyrodactylus* spp. than females. CVM proposed that we conduct the studies using fish from a reference population comprising both males and females. Dan has revised the protocol to address the issues and we plan to resubmit it to CVM for another go-round of reviews in early August. In the meantime, Miranda is working with the crew at the Ennis NFH to identify a suitable population of test fish, and we hope to launch a study in late summer/early fall.

AQUAFLOR® (florfenicol) Update:

Systemic columnaris and warmwater fish efficacy studies: It seems that we are always busy testing the efficacy and safety of AQUAFLOR® and this year is no different. What's exciting is that our efforts are really beginning to pay off as we move towards completing more technical sections, which in turn lead to new approvals. In the last AADAP Newsletter, we reported that a Final Study Report entitled *"Use of AQUAFLOR® to control mortality caused by columnaris in largemouth bass"* was accepted by CVM as pivotal. We also reported that we had submitted a Final Study Report on a similar study that was conducted on bluegill. Although the timeline for review of the bluegill study extends to early August, we are optimistic that this study will also be accepted as pivotal, and that results from both studies will put us one step closer to completing the effectiveness technical section for this claim for ALL warmwater finfish.

Systemic columnaris and channel catfish efficacy study: Although we tend to not bring up planned studies (sometimes things just don't work out), we do have another efficacy study planned with AQUAFOR® at Richloam Fish Hatchery (RFH) in Florida, USA. Niccole Wandelear has been working with Mike Matthews (Florida Bass Conservation Center, RFH) to get things in place to conduct a study to evaluate the effectiveness of AQUAFOR® to control mortality caused by systemic columnaris in channel catfish. We're not entirely sure that this study will be required to complete the effectiveness technical section for this claim for all warmwater fish, but if it is, we want to be ready to roll. Things have been a little quiet down in Florida and Mike has been blessed with healthy fish. However, if things go south with a population of channel catfish that Mike has set aside specifically for this study, then we'll be off and running.

Systemic columnaris and rainbow trout efficacy study: With last year's merger of Bellingham (Washington, USA) Technical College's Fisheries Technology Program (Earl Steele) and Bellingham State Fish Hatchery (Kevin Clark), an ideal situation has been created with a facility to conduct studies and lots of eager students ready to get their hands wet and collect data. Hence, we launched yet another study using AQUAFLOR® to control mortality caused by systemic columnaris in rainbow trout early this month (July 2010). It's too early to tell the outcome, but we're into the post-treatment period now and the study is looking promising. Thanks to Jed Varney (Washington Department of Fish and Wildlife) for collecting fish health data, Terry Ott at the La Crosse

Fish Health Center for running PCR for pathogen confirmation, and Pat Gaunt and Mississippi State University's Thad Cochran National Warmwater Aquaculture Center for doing MIC and disc diffusion work with *Flavobacterium columnare*. Keep your fingers crossed for this study and stay tuned for results!!

Bacterial kidney disease and Chinook salmon efficacy study: On yet another disease front, we have been talking with Doug Munson (Idaho Fish and Game) for over a year about conducting small scale trials at the Eagle Fish Health Lab (Eagle, Idaho, USA) to evaluate the efficacy of AQUAFOR® to control mortality caused by bacterial kidney disease (causative agent, *Renibacterium salmoninarum*) in Chinook salmon. Actually, Doug has been the driving force behind this idea and effort all along. This year, Doug found a couple of candidate populations of spring Chinook salmon for inclusion in efficacy trials. The first trial was conducted May – June 2010 and entailed allocating fish from a single reference population into eight test tanks. Fish in four randomly selected test tanks were fed AQUAFOR® at a concentration of 15 mg florfenicol per kg fish body weight per d for 10 d, and fish in the remaining tanks served as controls and were fed non-medicated feed. Preliminary data indicate that mean cumulative mortality at the end of the study was significantly less in treated tanks than in control tanks. This was indeed encouraging news, and Doug "asked" if he could do another study! A second study was launched in early July 2010 using fish from a different reference population of fish, and is scheduled to be completed in mid-August. Preliminary analysis of data collected to date shows that mean cumulative mortality in treated tanks is significantly less than that in control tanks. If the mortality pattern holds steady for the rest of the study, we should have two studies that will likely be accepted by CVM as pivotal. Data from the first study is being audited by Doug, who will then ship it to us where it will be entered into various databases and analyzed. Once the data has been analyzed, the AADAP crew (lead by Molly Bowman) will begin to develop a Final Study Report for submission to CVM. We will follow the same approach with the second study. With any luck, Doug may have helped to generate the data needed to complete the effectiveness technical section for this claim for all Chinook salmon. Many thanks to Doug and the crew at the Eagle Fish Health Lab for conducting these studies. Without fisheries professionals like Doug Munson, progress towards aquaculture drug approvals would come about much more slowly.

Strep infections and sunshine bass safety study: We've also been active in evaluating the safety of AQUAFLOR® on a variety of fish species. Although it seems like a long time ago (it was actually only this past January), we submitted a final study report entitled *"The Safety of AQUAFLOR® (50% Florfenicol; Type A Medicated Article) Administered in Feed to Sunshine Bass, Female White Bass* Morone chrysops *x Male Striped Bass* M. saxatilis*"* to CVM for review. We just heard word back from CVM that not only was the study accepted, but that results from the study were used to support a claim for use of AQUAFLOR® to control mortality caused by *Streptococcus iniae* in sunshine bass. This approval will allow for the use of AQUAFLOR® at a concentration of 15 mg florfenicol per kg fish body weight per d for 10 d. Can you say "HELLO New Label Claim?"

The in-life phase of this study was conducted by Dave Straus and the staff (Cindy Ledbetter, Drew Mitchell, and Bradley Farmer) at the USDA/ARS Stuttgart National Aquaculture Research Center (SNARC) in Stuttgart, Arkansas, USA. We want to thank them, Jeff Silverstein (Agriculture Research Service National Program Leader for Aquaculture), and Don Freeman (SNARC Center Director) for their support of this important work. We would also like to thank Beth MacConnell (USFWS retired) for her help evaluating fish tissues for histological changes.

Yellow perch target animal safety study: Acceptance of the sunshine bass study (noted above) put us on the home stretch to complete the safety technical section to allow use of AQUAFLOR® at a dosage of 15 mg florfenicol per kg fish body weight per d for 10 d for ALL freshwater finfish. We just got one step closer to the finish line when we recently completed an AQUAFLOR® target animal safety study on yellow perch. This study had been more than a little difficult to launch due to uncooperative test fish. However, due to the diligence of Molly Bowman and help from Jason Ilgen (USFWS, Bozeman Fish Technology Center), we finally got all fish on board (i.e., they began to consistently feed aggressively). The in-life phase of the study was conducted 11 February – 8 March 2010. Fish were randomly allocated to 12 test tanks (n = 15 fish per tank), and each tank was assigned one of four treatment conditions. Fish were fed either 0, 15, 45, or 75 mg florfenicol per kg fish body weight per d for 20 d. During the course of the study, there was little mortality, fish fed aggressively, and their behavior was characterized as normal. Feed samples analyzed for dose verification showed that the actual concentration of florfenicol in feed was within ±4% of the target dose. After the last treatment day, all fish were sacrificed for fish health evaluation and tissues were processed for histological evaluation. Much to the dismay of our histopathologist (Beth MacConnell), results of the evaluations were unremarkable and relatively boring (no significant differences between the 75 mg group and the non-treated control group!). Over the years, we've found that boring histology

slides often mean that there were no indications of a toxic dose-response relative to the test article. After data were analyzed, Molly Bowman drafted the final study report (FSR), our Quality Assurance officer inspected the data and FSR for compliance with GLP's and the study protocol. We plan to submit the final report to CVM early August 2010.

AquaFrin® (lauryl methyl pyrifrin) Update:

Basic R&D studies continue: Studies on the photophysical properties of AquaFrin®, as well as *in vitro* studies on a variety of micro-organisms, are continuing. Some toxicity studies with light and in the dark have been completed with trout and trout eggs and safe dosage of AquaFrin® for trout exposure identified. The effect of light intensity and distribution of light wavelengths on the drugs performance on cells is currently under study. Determination of effective treatment protocols for saprolegnia infected trout will be undertaken as soon as infected trout become available. The effects that AquaFrin® has on other aquatic organisms generally found in nature are currently being evaluated. Studies have been and/or are being conduct by Dr. Giulio Jori (University of Padua; Padua, Italy), as well as by AADAP staff and our partners.

Text provided by Jerry Bommer, Frontier Scientific Inc., Logan, Utah USA.

Channel Catfish Pituitary Update:

Waiver sought for reduced data requirements: Following the session on Use of Spawning Aids at Aquaculture America 2010 (held in San Diego, 1-4 March 2010), a round-table was convened to talk about some issues relative to the use (and approval) of spawning aids in aquaculture. Perhaps the biggest stumbling block, at least when considering a crude product such as pituitary glands to enhance spawning, is identification of data requirements associated with the Chemical, Manufacturing, and Control technical section. Dr. Chris Green (Louisiana State University Agricultural Center, Aquaculture Research Station) has been working with Roger Yant (Hybrid Catfish Company; Inverness, Mississippi, USA) to try to address this issue for catfish pituitary (CP). In the meantime, AADAP has submitted two packages to CVM requesting no additional data be required to complete the Human Food Safety (HFS) and Environmental Safety (ES) technical sections. The justification and rationale for the requests are consistent with those used previously to complete the HFS and ES technical sections for common carp pituitary as a spawning aid. Without going into the gory details, we argued that treatment with small volumes of CP into mature fish to induce gamete maturation does not pose a concern for HFS or ES.

The reasons behind our premise include, but are not limited to, the following:

- CP is used primarily on catfish broodfish and is injected IP or IM. Whether discrete or diffuse, pituitary tissue is present in all fish species, and injection of additional pituitary hormones will have no lasting effect.
- Treated channel catfish, as an example, are not suitable for harvest for at least 60 d posttreatment. The external fish quality is poor due to mechanical damage associated with aggression displayed during prespawning courtship and competition for mates. As such, a lengthy withdrawal period will be inherent.
- There is no evidence found in the literature to indicate that the active pituitary material is excreted into the aquatic environment. The active pituitary material remains in the broodfish and should be subjected to normal (and rapid) metabolic degradation mechanisms.
- Use of CP does not include direct discharge into the environment. If through some unanticipated mechanism any of the pituitary material were to enter the environment, the levels would be extraordinarily low, and through dilution and natural biodegradation processes would be dissipated.
- If there is CP left over at the end of the spawning season it will not be suitable for use during the next spawning season and will be discarded in the local landfill.
- CP is very similar to common carp pituitary in terms of its preparation, formulation, and projected use-patterns. Hence, CP is considered to be as safe as common carp pituitary when used to treat fish that may eventually enter the human food chain and should be considered to be as safe as common carp pituitary relative to environmental safety.

The information packages and associated letters requesting that no data be required to complete these two technical sections were submitted on 4 May 2010 (Human Food Safety) and 2 June 2010 (Environmental Safety). We anticipate that the review timeline for such submissions is six months. So….we hope to hear some good news by the end of the calendar year. Keep your fingers crossed!

HALAMID® AQUA (chloramine-T) Update:

External columnaris and yellow perch efficacy study: Sometimes it just seems that life isn't fair. As we mentioned in the last AADAP Newsletter, we have been beating the bushes for several years trying to find a collaborator to help us conduct a chloramine-T study on a representative coolwater fish species other than walleye. We stated that if we're able to pull off

such a study, and it gets accepted by CVM, we will have completed the elusive effectiveness technical section for ALL coolwater finfish for this claim.

Well, we've got some bittersweet news. We took Doug Aloisi (Project Leader, Genoa National Fish Hatchery; Genoa, Wisconsin, USA) up on his offer to help us conduct such a study using yellow perch. The study was started in June 2010, and chloramine-T was administered to fish in treated tanks at a dosage of 20 mg per L for 60 min on three alternate days while fish in control tanks received a sham water blank treatment for 60 min on three alternate days. Midway through the study, Doug faxed Miranda Dotson (AADAP point-of-contact) daily mortality data sheets. Mortality data were plugged into one of our databases, summarized, and graphed. You could feel the collective disappointment emanating from AADAP HQ when we found that mean cumulative mortality on virtually every day of the study in treated and control tanks was nearly identical, indicating that the study was not going to demonstrate treatment efficacy. We speculate that possibly the treatments should have been administered every day (this is the INAD treatment regimen typically used at Genoa NFH) or perhaps, we needed to get fish into tanks and begin the study earlier in the course of the disease, before they got too sick. Regardless, we thank Doug and the crew at Genoa NFH for their efforts, and their willingness to conduct another study when test tank space becomes available

Immediate Release Fish Sedative Update:

Eugenol analytical method development: Previously, we've mentioned that we received concurrence from CVM with respect to efficacy study protocols for both AQUI-S® E (active ingredient, eugenol) and BENZOAK® (active ingredient, benzocaine). We also mentioned that there has not yet been an analytical method developed to measure either eugenol or benzocaine using equipment that can be easily transported to, and used in, the field (e.g., spectrophotometer or hand-held colorimeter). Without an analytical method we can't begin to generate the required efficacy or target animal safety data.

Recently, Randal Phillips (General Manager, AQUI-S New Zealand, Ltd.; ANZL) worked with Jim Bowker to submit a package to CVM that supports the use of a UV-Vis spectrophotometric method to measure eugenol in water. The package consisted of (1) a protocol to measure eugenol in water using a spectrophotometer, (2) data generated by AADAP using the method to analyze eugenol in various sources of water (note: we found the method to be simple, accurate, and precise), and (3) protocols for how ANZL will determine product stability in water samples. Accompanying the packet of information was a letter requesting that CVM allow us to use this method to verify concentrations of AQUI-S® E in efficacy and target animal safety studies. It is our opinion that CVM will have to venture outside of their comfort zone to agree to such a request. Regardless, we are hopeful that they will agree that the method is suitable for its intended purpose. As usual, stay tuned.

Benzocaine human food safety genotoxicity component CVM review nearing completion: The genotoxicity battery final study report (FSR) was submitted to CVM late January 2010. In recent correspondence with CVM's Human Food Safety group, we've been informed that the review of the FSR is on schedule to be completed within the 180 day mandated response time. Hopefully by the time of our upcoming Workshop (3-5 August 2010) we may have some good news to share.

SLICE® (emamectin benzoate) Update:

Ectoparasitic copepods and rainbow trout efficacy studies: In a previous issue of the AADAP Newsletter, we stated that our protocol entitled *"The Efficacy of SLICE® Premix (0.2% Emamectin Benzoate) Administered in Feed to Control* Salmincola *spp. on All Freshwater-Reared Salmonids"* was accepted by CVM on 24 March 2010. We also mentioned that now that the difficult part (obtaining protocol concurrence) was out of the way, it was time to have some fun conducting the trials. Well, Dan Carty didn't waste too much time getting things rolling. Our first pivotal efficacy study was launched in collaboration with Jim Schaffer and Tom Van Tassel at Magic Springs Hatchery (SeaPac of Idaho) in Hagerman, Idaho, USA, and a second study was launched in collaboration with Scott LaPatra at Clear Springs Food Research Facility (Buhl, Idaho, USA) - both studies were launched in early June 2010. To date, Dan and Niccole Wandelear have been working with the crews at both testing sites, both studies are progressing smoothly, and it is our plan to terminate the studies the week of 26 July 2010. Study termination will consist primarily of counting the number of *Salmincola* spp. on each fish in all test tanks. It's too early to predict the outcome of the studies, but (as usual) we are optimistic that fewer copepods will be found on fish from treated tanks than on fish from control tanks. We'll find out soon, so as per usual stay tuned!

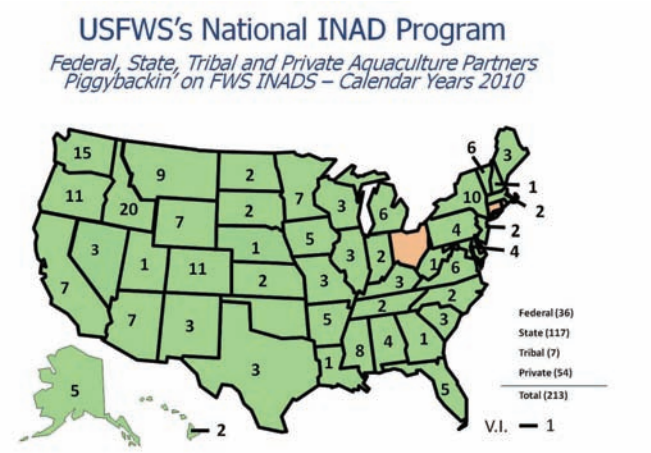
Terramycin® 200 for Fish (oxytetracycline dihydrate) Update:

Systemic columnaris and warmwater fish efficacy study: In the last newsletter, we mentioned that we had developed a research protocol to evaluate the effectiveness of Terramycin® 200 for Fish administered in feed to control mortality caused by

susceptible pathogens in a variety of freshwater finfish. The protocol was submitted to CVM for review on 12 March 2010 and was accepted on 30 April 2010. Niccole Wandelear is currently making plans to work with Mike Matthews and the crew at the Florida Bass Conservation Center to conduct studies under this protocol to evaluate the effectiveness of Terramycin® 200 for Fish to control mortality caused by systemic columnaris in a variety of warmwater finfish. As usual, stay tuned.

FINS & TAILS, BITS & BOBBERS

National INAD Program (NIP) Update: The NIP continues to be a tremendously successful program for the USFWS and partner facilities/agencies. The NIP not only assists fisheries managers in meeting program objectives, but also provides important efficacy and safety data in support of future aquatic species drug approvals. To date in 2010, there are 213 federal, state, private, and tribal facilities located in 45 different states and one U.S. territory participating in the NIP. Currently, 15 different INAD exemptions are open for enrollment.



Calendar year 2009 NIP study submission statistics: Last year was another busy year for conducting studies under INAD exemptions, and with your help, we were able to collect a wealth of very useful/real world data. Here are some of the summary statistics from 2009 studies:

1. Number of completed study reports submitted to the AADAP Office – 563
2. Number of reporting facilities - 145
3. Number of INAD exemptions utilized - 13
4. Number of treated fish – 60.2 million
5. Species of fish treated – 20 salmonid species; 36 non-salmonid species; and 4 marine species
6. Percentage of studies that appeared to result in efficacious treatment = 89%
7. Number of Quarterly Reports submitted to FDA/CVM – 54
8. Number of Annual Reports to be submitted to FDA/CVM – 12

Thank you to everyone for your hard work in contributing data to the AADAP Office, and please remember that these data are being used to support new and/or expanded drug labels.

Attention managers needing to immersion mark fish: If you have been planning on using oxytetracycline hydrochloride (OTC) treatment to immersion mark fry and/or fingerlings this year, you are probably aware that the three FDA-approved OTC soluble powders are either no longer available (2 products) or difficult to administer (1 product). AADAP, FDA's Center for Veterinary Medicine (CVM), and PennField Animal Health (PAH) have worked out a solution! AADAP now has an OTC bath marking INAD (#9033) in place for which PAH is an authorized source of the drug. PAH's product (Pennox® 343) is a generic copy of Pfizer's Terramycin 343®, and hence, it is identical in composition and activity. Currently the label for Pennox® 343 does not include a fish marking claim, but PAH is currently working diligently with CVM to amend their existing label to ultimately include a claim for skeletal marking of finfish.

Until such time that PAH obtains FDA approval for Pennox® 343, or any of the viable approved OTC skeletal marking products again become available, AADAP INAD #9033 will remain in effect and Pennox® 343 (without the fish marking claim on the label) may be used under the INAD to mark fry and fingerlings. Please direct any questions regarding participation in INAD #9033 to AADAP's Bonnie Johnson (bonnie_johnson@fws.gov).

Oxytetracycline immersion therapy (OTIMM) INAD #9033 - New product available: Due to the lack of availability of Pfizer's Terramycin 343®; FDA/CVM has amended the Food-Use Authorization for the use of oxytetracycline hydrochloride soluble powder for immersion – therapy under INAD #9033. This authorization has been changed so that both Terramcyin 343® and Pennox® 343 may be used under the INAD. Please click on the following link for more information on where to purchase Pennox 343: http://www.fws.gov/fisheries/aadap/9033bathmarking.htm.

SLICE® INAD 11-370 authorization received!!!: Some said it could not be done and others turned back; however, the AADAP Office remained determined that someday an INAD exemption for the use of SLICE®-medicated feed for the control of external parasites in freshwater fish would indeed become a reality. The AADAP Office recently received both the food-use and categorical exclusion authorizations for the investigational use of SLICE® under INAD 11-370! Any facility that would like to participate under this INAD will first need to 1) complete and submit a "Facility Specific Effluent-related Treatment Information Sheet" to the AADAP Office (click here to access); 2) receive a facility-

specific categorical exclusion from the FDA; 3) obtain and document approval from your local NPDES Authority (or EPA) for the proposed use of SLICE® at your facility; and 4) send a copy of the approval from your NPDES Authority to the AADAP Office. After all requisite approvals are in place, facilities will be able to participate under the SLICE® INAD 11-370.

Contract for the AADAP's web-based INAD Program Management System (IPMS) finally signed: In the last issue of the AADAP Newsletter, we informed you of the delayed test-launch of the website automation program (on-line data reporting) for National INAD Program participants. We are delighted to say that finally the crucial contract with our webpage and database developers has been completed and signed, and the IPMS development is back on track. Although it is going to take us all a little bit of time to get back to where we left off last fall, it would probably still be safe to say that we should be able to have a beta version up on-line before the end of the calendar year. Stick with us, we will get there!

RELEVANT LITERATURE

The following is a list of journal publications with particular relevance to the broad topic of drugs and aquaculture species. This list comprises citations exclusively from 2009 and 2010. Please note that this list does not include those provided in previous issues of the AADAP Newsletter.

If you have come across literature that you believe would be of interest to the readership of the Newsletter, please forward the citation to Tom Bell (thomas_a_bell@fws.gov) and we will place it in the next edition.

The inclusion of a citation within the Newsletter does not imply: (1) recommendation of the technique to any particular situation, (2) concurrence with a treatment procedure/drug, (3) acceptance by the U.S. Food and Drug Administration's Center for Veterinary Medicine of the drug's safety or effectiveness, nor (4) in any way an endorsement of a product by the U.S. Fish & Wildlife Service.

Antibiotic and Bacterial

Cháfer-Pericás, C, et al. 2010. Immunochemical determination of oxytetracycline in fish: comparison between enzymatic and time-resolved fluorometric assays. *Analytica Chimica Acta* **662(2):177-185**.

Cížek, A, et al. 2010. Antimicrobial resistance and its genetic determinants in aeromonads isolated in ornamental (koi) carp (*Cyprinus carpio koi*) and common carp (*Cyprinus carpio*). *Veterinary Microbiology* **142(3-4):435-439**.

Del Cerro, A, et al. 2010. Genetic diversity and antimicrobial resistance of *Flavobacterium psychrophilum* isolated from cultured rainbow trout, *Onchorynchus mykiss* (Walbaum), in Spain. *Journal of Fish Diseases* **33(4):285-291**.

Fang, M-J, et al. 2009. Isolation, determination and bacteriostasis test of the bacterial septicemia from *Aemibarbus maculates*. *Fisheries Science* **28(12):717-720**.

Gaunt, P, et al. 2010. Efficacy of florfenicol for control of mortality caused by *Flavobacterium columnare* infection of channel catfish. *Journal of Aquatic Animal Health* **22(2):115-122**.

Glover, KA, et al. 2010. Pharmacokinetics of emamectin benzoate administered to Atlantic salmon, *Salmo salar* L., by intra-peritoneal injection. *Journal of Fish Diseases* **33(2):183-186**.

Lee, S, et al. 2010. Chemical composition and antimicrobial activity of the essential oil of *Syzygium aromaticum* flower bud (Clove) against fish systemic bacteria isolated from aquaculture sites. *Frontiers of Agriculture in China* **3(3):332-336**.

Li, H, et al. 2010. *In vitro* antibacterial activities and postantibiotic effects of marbofloxacin against main marine pathogenic Vibrios. *Journal of Fishery Sciences of China* **17(1):97-102**.

Lin, C-Y, et al. 2010. Transgenic zebrafish eggs containing bactericidal peptide is a novel food supplement enhancing resistance to pathogenic infection of fish. *Fish & Shellfish Immunology* **28(3):419-427**.

Liu, W-L, et al. 2010. Supercritical fluid extraction *in situ* derivatization for simultaneous determination of chloramphenicol, florfenicol and thiamphenicol in shrimp. *Food Chemistry* **121(3):797-802**.

Lu, W-H, et al. 2010. Identification and drug sensitive test of the pathogen in acinetobacter disease from hybrid Crucian carp (*Carassius auratus gibelio* female × *Cyprinus carpio* male). *Fisheries Science* **29(3):156-161**.

Nya, EJ, et al. 2010. The garlic component, allicin, prevents disease caused by *Aeromonas hydrophila* in rainbow trout, *Oncorhynchus mykiss* (Walbaum). *Journal of Fish Diseases* **33(4):293-300**.

Rattanachaikunsopon, P, and Phumkhachorn, P. 2010. Use of Asiatic pennywort *Centella asiatica* aqueous extract as a bath treatment to control columnaris in Nile tilapia. *Journal of Aquatic Animal Health* **22(1):14-20**.

Samuelsen, OB. 2010. A single-dose pharmacokinetic study of emamectin benzoate in cod, *Gadus morhua* L., held in sea water at 9°C. *Journal of Fish Diseases* **33(2):137-142**.

Zilberg, D, et al. 2010. Dried leaves of *Rosmarinus officinalis* as a treatment for streptococcosis in tilapia. *Journal of Fish Diseases* **33(4):361-369**.

Zong, H, et al. 2010. Research on florfenicol residue in coastal area of Dalian (Northern China) and analysis of functional diversity of the microbial community in marine sediment. *Bulletin of Environmental Contamination and Toxicology* **84(2):245-249**.

Parasite and Fungus Control

Harikrishnan, R, et al. 2010. Effectiveness and immunomodulation of chemotherapeutants against scuticociliate *Philasterides dicentrarchi* in olive flounder. *Experimental Parasitology* **124(3):306-314**.

Leibowitz, MP, et al. 2010. Treatment development for systemic *Tetrahymena* sp. infection in guppies, *Poecilia reticulata* Peters. *Journal of Fish Diseases* **33(6):473-480**.

Mitchell, A, et al. 2010. Comparison of percent hatch and fungal infestation in channel catfish eggs after copper sulfate, diquat bromide, formalin, and hydrogen peroxide treatment. *North American Journal of Aquaculture* **72(3):201-206**.

Roque, A, et al. 2010. Physiological stress response of sea bass (*Dicentrarchus labrax*) to hydrogen peroxide (H_2O_2) exposure. *Aquaculture* **304(1-4):104-107**.

Sampaio, FG, et al. 2010. The combined effect of copper and low pH on antioxidant defenses and biochemical parameters in neotropical fish pacu, *Piaractus mesopotamicus*. *Ecotoxicology* **19(5):963-976**.

Sedation or Anesthesia

Azpeleta, C, et al. 2010. Melatonin reduces locomotor activity and circulating cortisol in goldfish. *Hormones and Behavior* **57(3):323-329**.

Hegyi, Á, et al. 2010. Investigation of potential stress parameters in rainbow trout (*Oncorhynchus mykiss*). *Acta Biologica Hungarica* **61(1):24-32**.

Pramod, P, et al. 2010. Comparative efficacy of MS-222 and benzocaine as anaesthetics under simulated transport conditions of a tropical ornamental fish *Puntius filamentosus* (Valenciennes). *Aquaculture Research* **41(2):309-314**.

Pramrod, P, et al. 2010. Effects of two anesthetics on water quality during a simulated transport of a tropical ornamental fish, the Indian tiger barb, *Puntius filamentosus*. *North American Journal of Aquaculture* **72(4):290-297**.

Robertson, DR, and Smith-Vaniz, WF. 2010. Use of clove oil in collecting coral reef fishes for research. *Marine Ecology Progress Series* **401:295-302**.

Skeletal Marking

Brooke, S, and Young, CM. 2010. *In situ* measurement of survival and growth of *Lophelia pertusa* in the northern Gulf of Mexico. *Marine Ecology Progress Series* **397:153-161**.

Ebert, TA. 2010. Demographic patterns of the purple sea urchin *Strongylocentrotus purpuratus* along a latitudinal gradient, 1985-1987. *Marine Ecology Progress Series* **406:105-120**.

Herrmann, M, et al. 2009. Growth estimations of the Argentinean wedge clam *Donax hanleyanus*: a comparison between length-frequency distribution and size-increment analysis. *Journal of Experimental Marine Biology and Ecology* **379(1-2):8-15**.

Michels, J, and Büntzow, M. 2010. Assessment of Congo red as a fluorescence marker for the exoskeleton of small crustaceans and the cuticle of polychaetes. *Journal of Microscopy* **238(2):95-101**.

Pierce, SJ, and Bennett, MB. 2010. Validated annual band-pair periodicity and growth parameters of blue-spotted maskray *Neotrygon kuhlii* from south-east Queensland, Australia. *Journal of Fish Biology* **75(10):2490-2508**.

Smith, JE, et al. 2010. An osmotic induction method for externally marking saltwater fishes, *Stigmatopora argus* and *Stigmatopora nigra*, with calcein. *Journal of Fish Biology* **76(4):1055-1060**.

Torao, M, et al. 2010. Seasonal timing of downstream migration and migrating speed of the hatchery and wild pink salmon, *Oncorhynchus gorbuscha*, fry in the Tohoro River, eastern Hokkaido, Japan. *Scientific Reports of the Hokkaido Fish Hatchery* **64:7-15**.

Walsh, CT, et al. 2010. Growth, episodic recruitment and age truncation in populations of a catadromous percichthyid, *Macquaria colonorum*. *Marine & Freshwater Research* **61(4):397-407**.

Spawning Hormones and Gender Manipulation

Belanger, R, et al. 2010. Methyltestosterone-induced changes in electro-olfactogram responses and courtship behaviors of cyprinids. *Chemical Senses* **35(1):65-74**.

Correia, TG, et al. 2010. Aluminum as an endocrine disruptor in female Nile tilapia (*Oreochromis niloticus*). *Comparative Biochemistry and Physiology, Part C: Toxicology & Pharmacology* **151(4):461-466**.

Garber, AF, et al. 2009. Hormonal induction of ovulation and spermiation in Atlantic cod (*Gadus morhua*). *Aquaculture* **296(1-2):179-183**.

Hulak, M, et al. 2010. Morphological sex change upon treatment by endocrine modulators in meiogynogenetic tench (*Tinca tinca* L.). *Aquaculture Research* **41(2):233-239**.

Kuzminski, H, and Dobosz, S. 2010. Effect of sex reversal in rainbow trout (*Oncorhynchus mykiss* Walbaum) using 17-alfa-methyltestosterone and 11-beta-hydroxyandrostenedione. *Archives of Polish Fisheries* **18(1):45-49**.

Murata, R, et al. 2010. Precocious sex change and spermatogenesis in the underyearling Malabar grouper *Epinephelus malabaricus* by androgen treatment. *Aquaculture Research* **41(2):303-308**.

Noori, A, et al. 2010. LHRHa-induced ovulation of the endangered Caspian brown trout (*Salmo trutta caspius*) and its effect on egg quality and two sex steroids: testosterone and 17 alpha–hydroxyprogestrone. *Aquaculture Research* **41(6):871-877**.

Sugni, M, et al. 20101. Chemical fate and biological effects of several endocrine disrupters compounds in two echinoderm species. *Ecotoxicology* **19(3):538-554**.

Sun, P, et al. 2010. Steroid sex hormone dynamics during estradiol-17 beta induced gonadal differentiation in *Paralichthys olivaceus* (Teleostei). *Chinese Journal of Oceanology and Limnology* **28(2):254-259**.

Miscellaneous

Harnisz, M, and Tucholski, S. 2010. Microbial quality of common carp and pikeperch fingerlings cultured in a pond fed with treated wastewater. *Ecological Engineering* **36(4):466-470**.

Oplinger, RW, and Wagner, EJ. 2010. Effect of potassium permanganate treatments on New Zealand mud snail behavior and survival and rainbow trout growth and condition. *North American Journal of Aquaculture* **72(3):207-212**.

Pizzolon, M, et al. 2010. When fathers make the difference: efficacy of male sexually selected antimicrobial glands in enhancing fish hatching success. *Functional Ecology* **24(1):141-148**.

Mudryk, Z, et al. 2010. Detection of antibiotic resistant bacteria inhabiting the sand of non-recreational marine beach. *Marine Pollution Bulletin* **60(2):207-214**.

USGS's CORNER

Chloramine-T: To address one of the remaining data needs for the approval of Halamid® (chloramine-T), the Upper Midwest Environmental Sciences Center (UMESC) staff modified the analytical method for para-toluenesulfonamide (ρ-TSA), the marker residue of chloramine-T. UMESC staff completed all laboratory assays for this body of work. An 864-page comprehensive final report has been compiled and is currently undergoing Quality Assurance review. Data generated during this study will be reviewed by the FDA to determine if the data support a method detection limit of less than or equal to 20 parts per billion, the FDA proposed tolerance limit for ρ-TSA in fish fillet tissue. Contact Jeff Meinertz, jmeinertz@usgs.gov for more information.

17α-Methyltestosterone: The UMESC, in collaboration with Maxxam Analytics (formerly CANTEST Ltd.), is coordinating an analytical method transfer study to complete the Chemistry Manufacturing and Controls Technical Section for 17α-methyltestosterone. The laboratory portion of the familiarization phase was completed in early 2010. The definitive method transfer phase was completed in June. A comprehensive final report is under development. This study was funded through grants from the North-Central and Western Regional Aquaculture Centers. Contact Jeff Meinertz, jmeinertz@usgs.gov for more information.

Hydrogen Peroxide: UMESC will initiate the study *"Efficacy of 35% PEROX-AID® to control mortality caused by* Saprolegnia parasitica *or* Saprolegnia diclina *in walleye* Sander vitreum" in early August 2010. The walleye study is being funded through a grant provided by the Food and Drug Administration. A final study report in under development for the study *"Efficacy of 35% PEROX-AID® to control mortality caused by* Saprolegnia parasitica *or* Saprolegnia diclina *in rainbow trout* Oncorhynchus mykiss*."* Contact Maren Tuttle-Lau, mttuttle@usgs.gov for more information.

Sedatives: Work to develop an analytical method to detect eugenol residues in the fillet of freshwater fish is complete. The data generated during this body of work indicate that the method developed by UMESC staff will accurately and precisely determine eugenol concentrations in fish fillet tissue ranging from about 0.01 to 100 µg per g. A comprehensive final report is

under development. This study is being funded through a Multistate Conservation Grant from the Association of Fish and Wildlife Agencies. Contact Jeff Meinertz, jmeinertz@usgs.gov for more information.

Iodophor disinfection: Two studies were completed in April and May 2010 to determine the safety of Ovadine® (PVP-Iodine) (product of Western Chemical, Inc.)

administered as a surface disinfectant to walleye *Sander vitreum* and hybrid striped bass *Morone chrysops* x *Morone saxatilis* eggs. The study objective was to determine the safety of iodophor surface disinfection at target doses of 0, 1, or 2x the recommended dose rate (100 mg/L) for multiple exposure durations at various times post fertilization and for 1 or 2 disinfection events. The second disinfection event was administered between fertilization and the first cell division for both fish species tested. The safety studies involved agency collaboration with USFWS Garrison Dam National Fish Hatchery and Oklahoma Wildlife Department Byron State Fish Hatchery. Contact Maren Tuttle-Lau, mttuttle@usgs.gov for more information.

Text provided by Mark Gaikowski, Fisheries Management Chemical and Aquaculture Drug Team, U.S. Geological Survey, Upper Midwest Environmental Sciences Center, La Crosse, Wisconsin, USA.

USDA's CORNER

17α-methyltestosterone Target Animal Safety (TAS) Study: In June we completed the long-awaited, in-life phase of the GLP TAS study to evaluate the safety of 17α-methyltestosterone administered in feed to tilapia. This is another FDA-required study that we have done in partnership with the folks at AADAP. The fish tissues have been sent to AADAP to be processed and evaluated histologically. We are presently awaiting results of a data audit by our Quality Assurance group and will work with AADAP on the final study report. Future collaborations with the staff at AADAP are being discussed and the benefits are obvious for the overall drug approval project.

Copper sulfate TAS Technical Section complete: Good news! A "Technical Section Complete" letter was received in May for the $CuSO_4$ target animal safety study on channel catfish eggs. Also, see AADAP's good news about the AQUAFLOR® and sunshine bass TAS.

Copper sulfate and saprolegnia effectiveness study: A final study report for the effectiveness range-finding (supportive) studies of $CuSO_4$ on saprolegniasis of channel catfish eggs was submitted by our partners at Freeport-McMoRan to FDA/CVM in June and we are anxiously awaiting the verdict. Pivotal dose-confirmation final study reports of the effectiveness technical section are being delayed for work on the environmental assessment for $CuSO_4$ in ponds.

Catfish eggs and fungus studies: The catfish spawning season is over. This year we continued our studies on water molds (i.e., fungus) that grow on catfish egg masses. A trial with peracetic acid was completed and low doses seem to work well.

Drew Mitchell (USDA/ARS/SNARC) compared three hydrogen peroxide treatments for effectiveness against fungi and their ability to increase egg survival. The treatments (all at 250 mg/L) were: (1) immersion, (2) flush treatments applied once daily, (3) twice daily and (4) a 15 minute static treatment applied once daily. Preliminary results indicate that the static treatment outperformed the others in terms of egg survival and fungal growth.

Text provided by Dave Straus, Disease & Drug Approval Section, Harry K. Dupree – Stuttgart National Aquaculture Research Center (SNARC), Agricultural Research Service, U.S. Dept. of Agriculture, Stuttgart, Arkansas, USA.

MEETINGS, ETC.

Recently held meetings

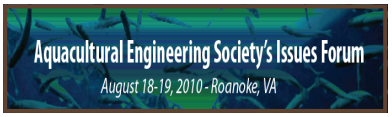
35th Annual Eastern Fish Health Workshop; 24-28 May 2010; Shepherdstown, West Virginia USA: As noted in the Workshop Program "Although the title of the workshop appears to be exclusive for fish..." there was represented "...broad participation in all aspects of aquatic animal health from invertebrates to mammals." Abstracts from the weeklong workshop can be viewed by clicking here. Any questions regarding the workshop can be directed to Rocco Cipriano (rcipriano@usgs.gov).

2010 Western Fish Disease Workshop; 23-24 June 2010 ; Corvallis, Oregon, USA: For those of you unable to attend and are interested in what was discussed at the Workshop, we have just heard word that the complete set of abstracts from this year's meeting will be up on the American Fisheries Society Fish Health Section web page very soon. Their web page can be accessed by clicking here.

Upcoming meetings

World Aquatic Veterinary Medical Association Conference; 14-19 July 2010; Athens, Greece: This year's conference is being held at the Divani Palace Acropolis Hotel in Athens. The conference theme is: "Integrated Disease Diagnostics, Control & Treatment in Aquatic Veterinary Medicine - from koi, to cod, to sushi." Conference sessions include those on: integrated management systems, emerging diseases, zoonoses, biosecurity and economics and clinical topics. In addition the conference organizers have arranged a tour day of Athens, as well as a 4-day Continuing Education & Professional Development/ Family Cruise of Greek and Turkish Islands. For more information see the conference webpage at: http://www.wavma.org/index.cfm/id/2482.

Aquaculture Engineering Society Issues Forum; 18-19 August 2010; Roanoke, Virginia USA: This conference is being held at The Hotel Roanoke and Conference Center and is immediately proceeding and at the same venue as the Conference on Recirculating Aquaculture (see below). The 2-day forum focuses on three special topics: 1) biofloc, 2) advanced oxidation processes (AOP) in recirculating aquaculture systems and 3)marine aquaculture systems. Other information, including online registration can be found on the conference webpage: http://www.recircaqua.com/aesforum.html.



8th International Conference on Recirculating Aquaculture; 20-22 August 2010; Roanoke, Virginia USA: Like the Aquaculture Engineering Forum noted immediately above, this conference is being held at The Hotel Roanoke and Conference Center. It is being held immediately following the above Forum. The conference will comprise the following topics sessions: recirculating aquaculture systems (RAS) in penaeid shrimp culture, culture of algae as an alternative fuel source, recirculating systems for salmonids, sustainable RAS, innovative feeds for RAS, the application of RAS technology for mollusk culture, RAS process control I: PLCs or other types of control applications, RAS process control II: commercial vendor showcase. For more information, including online registration, refer to the conference webpage: http://www.recircaqua.com/icra.html.

6th International Symposium on Aquatic Animal Health; 5-9 September 2010; Tampa, Florida USA: Next year's symposium, like those in the past, is being sponsored by the American Fisheries Society - Fish Health Section, with additional support from the International Association for Aquatic Animal Medicine, the National Shellfisheries Association, the Japanese Society for Fish Pathology, the European Association of Fish Pathologists, and the Aquatics Committee of the American Veterinary Medical Association.

The symposium will provide a stimulating and inclusive forum for exchange of current information on research, management and policy issues related to health and diseases of aquatic animals, whether wild, farmed, or held on exhibit. The broadest range of animals is considered, from invertebrates, to fish, amphibians, chelonians, and marine mammals. This important international gathering will be used to facilitate discussion and action on issues of international importance. Key themes of the symposium will include (i) infectious diseases in aquaculture, (ii) planning and emergency response for aquatic animal health emergencies, (iii) interaction of diseases between wild and farmed stocks, and (iv) outcomes of environmental stress including effects of contaminants, and regional and global habitat alteration. For more information refer to the conference website: http://aquaticpath.epi.ufl.edu/isaah6/

International Symposium on Infectious Salmon Anaemia; 13-15 September 2010; Oslo, Norway: The symposium, sponsored by the World Organisation for Animal Health (OIE), is being held at the Thon Hotel Opera which is located close to the Airport Express Train Terminal at Oslo Central Station. The goal of this conference is to provide updates on infectious salmon anaemia (ISA) research, biosecurity and disease control strategies. Sessions or presentation will include: OIE's historical perspective; pathology and pathogenesis; virus characterisation and host interactions; epidemiology; diagnostic methods and procedures; vaccination and disease control; strategies for biosecurity and risk management in industrial aquaculture; summary of strategies and experiences on ISA prevention, control and eradication in the respective countries; classification of fish farms and surveillance of ISA from an EU perspective; ISA control/eradication strategies from an industrial perspective; and challenges associated with different prevention/control/eradication strategies. Further information including registration, accommodations, etc. can be found on the conference webpage: http://www.vetinst.no/nor/Forskning/Aktuelle-tema/Fiskesykdommer/Infeksioes-lakseanemi-ILA/ISA-OIE.

Workshop on Biosecurity in Aquaculture; 16-17 September 2010; Oslo, Norway: This workshop scheduled to immediately follow the ISA Symposium (noted above), at the same venue, has been cancelled due to lack of registrants. CANCELLED

NCRAC Baitfish Production and Health Workshop; 21 September 2010; Onalaska, Wisconsin, USA: The USDA's North Central Regional Aquaculture Center (NCRAC) is holding a 1-day baitfish production workshop on 21 September 2010 at the La Crosse Fish Health Center in Onalaska, Wisconsin USA. The workshop is designed for individuals interested in commercial baitfish production and fish health, existing producers, researchers, and extension personnel.

Workshop presentations include:

- Updates on baitfish production in the South and North Central Regions of the US
- Fish health and baitfish disease treatments
- Pond and RAS production of baitfish
- Results from recent research projects focusing on intensive production of golden shiners, spotfin shiners, and hornyhead chubs.

Experts from across the region will also be available to answer questions. There is no cost to attend; however, advanced registration is required. For more information, including registration, hotels, agenda, etc. go to: http://www.ncrac.org/roadmap/webinfo/pdf_downloads/pdf_events/baitfish_flier.pdf.

Aquaculture Europe 2010; 5-8 October 2010; Porto, Portugal: The European Aquaculture Society is the organizing body for next year's conference. The conference is being held at the Centro de Congressos da Alfândega (web address: www.amtc.pt) – the old customs house on the quay of the Douro River in the heart of Porto and just opposite the famous port wine cellars that are synonymous with this lively city. The theme for the 2010 conference is "Seafarming Tomorrow." Further information can be found on the Society's website at: http://www.easonline.org/.

2nd International Congress on Aquatic Animal Health Management & Diseases; 26-27 October 2010; Tehran, Iran: This year's congress is being held in Tehran, Iran and is being organized by the Veterinary Council I.R. Iran. The congress will includes presentations by international researchers, organized in several session topics including:

1. Diseases, Prevention and Treatment,
2. Nutritional Health Management,
3. Water Quality Management, and
4. Health Management in Farms

For more information refer to the congress website: http://www.icahmd.com/index.php.

VIII International Symposium on Fish Parasites; 26-30 September 2011; Viña del Mar, Chile: This year's Symposium will be an important forum for the discussion and distribution of new findings in this rapidly expanding field. The theme of the conference is "Fish Parasitology: from Classical Taxonomy to Holistic Approach". The organizers hope to develop an exciting scientific program that will provide an update in our field of research. They are sure that the diversity of themes in the dynamic field of fish parasitology will be the most favorable platform for strong and positive collaborations between fish parasitologists. An intense program is scheduled to include preliminary talks, mini symposiums, and oral presentations. Poster sessions will be an important aspect of 8th ISFP. Competitive awards for students and postdoctoral scientists from developing countries will be offered. In addition, a diverse and enjoyable program of social activities will also be provided in order to showcase the best of Chilean traditions and culture. See the conference website at: http://www.8isfp.com/.

Symposium organizers note on their webpage that the Symposium venue, and all tourist facilities and attractions were only minimally affected by the February earthquake and are now operating normally.

71st Midwest Fish & Wildlife Conference; 12-15 December 2010; Minneapolis, Minnesota, USA: The natural resource professionals of the US Midwest have organized this year's annual meeting and have set it to take place at the Hyatt Regency Minneapolis. Examples of the 18 symposia taking place during the conference include: Influencing Shoreland Conservation Behavior; Trout and Trout Angler Symposium; Examining the Risk of Aquatic Invasive Species Transfer by Inland Waterway Transportation; Shallow Lake Ecology and Management; and Ongoing and Emerging Issues in Wildlife Health and Disease. Complete information on the conference can be found at the conferernce webpage: http://www.midwest2010.org/index.php.

CVM's NOTES

Public Workshops: The Center for Veterinary Medicine 's Division of Manufacturing Technologies this summer put on a successful three-part webinar series on Question-based Review of Chemistry, Manufacturing, and Control Submissions.

On October 21, 2010, CVM is planning a webinar that will introduce "e-submitter." E-submitter is a new tool that will allow submissions to be submitted electronically to the Office of New Animal Drug Evaluation starting in March 2011.

The American Academy of Veterinary Pharmacology and Therapeutics (AAVPT) "Veterinary Drug Regulatory Life Cycle (A to Z) Training Course" is planned for February 28- March 4, 2011, in the Washington D.C. metropolitan area. The purpose of this intensive 5-day training course is to provide training in the areas of development, approval, and post-approval surveillance/compliance of a new animal drug (the entire drug life cycle) in the U.S. This course will provide a comprehensive overview of the Center for Veterinary Medicine's (CVM) evaluation, approval, and surveillance of animal drugs, food additives, feed ingredients, and animal devices. Course material will be presented by CVM staff from across the entire Center. This event will provide a scientific forum for interaction between academia, industry and CVM and foster the development and approval of safe and effective new animal drugs. More information can be found on the AAVPT website (http://www.aavpt.org/VeterinaryDrugLifeCycle.shtml).

Grants: Applications for designation grants are being accepted now through September 3, 2010. The grants support safety and effectiveness testing of drugs intended for minor use or minor species (which includes fish!) Only new animal drug products that have been designated by the Office of Minor Use and Minor Species are eligible, and there must be protocol concurrence from the Office of New Animal Drug Evaluation. Detailed information is available on this website link (http://grants.nih.gov/grants/guide/rfa-files/RFA-FD-10-001.html). Please contact Dr. Joan Gotthardt (joan.gotthardt@fda.hhs.gov) if you have any questions.

Opportunities for public comment: FDA is Soliciting Comment on: 1) VFDs and 2) a Draft Guidance on the Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals.

VFDs: FDA has extended the comment period on the Advanced Notice of Proposed Rulemaking (ANPRM) for the veterinary feed directive (VFD) program for an additional 60 days. The agency is taking this action after receiving comments that the current 90-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to the ANPRM. Now until August 27, 2010, interested persons may submit comments. The ANPRM was originally announced in the Federal Register on March 29, 2010, with a 90-day comment period. Please see the Federal Register (http://edocket.access.gpo.gov/2010/pdf/2010-6872.pdf) for more information and directions on how to submit comments.

Judicious Use: FDA is also asking for public comment on a Draft Guidance on the Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals. The purpose of the draft guidance is to:

- Discuss FDA's public health concerns about how certain uses of medically important antimicrobial drugs in food-producing animals may impact antimicrobial resistance;
- Summarize some of the key scientific reports on the use of antimicrobial drugs in animal agriculture; and
- Outline FDA's recommendations on how to make sure that medically important antimicrobial drugs are used judiciously in food-producing animals and remain effective for animals and people.

In summary, FDA believes that in order to minimize the development of antimicrobial resistance, steps need to be taken to ensure the judicious use of medically important antimicrobial drugs in food-producing animals. Steps outlined include phased-in measures that 1) limit medically important antimicrobial drugs to uses in food-producing animals that are considered necessary for assuring animal health, and 2) limit such drugs to uses in food-producing animals that include veterinary oversight or consultation.

To implement the recommendations for judicious use, FDA will actively work with drug companies; the veterinary, public health, and animal agriculture communities; and other stakeholders. FDA wants the recommendations to be implemented in a way that protects the health of animals and people. FDA does not want the recommendations to negatively impact animal health or disrupt the animal agriculture industry.

FDA is interested in hearing from the public and stakeholders on this draft guidance and is encouraging comment. The draft guidance is available online (http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM216936.pdf) along with a Questions and Answers page (http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/ucm216939.htm).

Text provided by Dr. Jennifer Matysczak, Aquaculture Drugs Team Leader; Office of New Animal Drug Evaluation; Center for Veterinary Medicine, Food and Drug Administration; Rockville, Maryland USA.