



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”



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WHAT’S SHAKIN’

Update from the Association of Fish and Wildlife Agencies’ Drug Approval Working Group (AFWA-DAWG): The Drug Approval Working Group of the Association of Fish and Wildlife Agencies ([AFWA-DAWG](#)) met recently on 12-13 September 2011 during the annual AFWA meeting in Omaha, Nebraska USA. The DAWG convened twice during the AFWA meeting; first prior to the [Fisheries and Water Resources Policy Committee](#) (FWRPC) meeting, in preparation to update

the FWRPC committee members on the progress of the eight AFWA project drugs, and secondly directly after the FWRPC meeting to finalize action items and respond to direction provided by the FWRPC. As with recent past DAWG gatherings, the approval activities surrounding AQUI-S[®] 20E and chloramine-T (the top priority drugs for the FWRPC) dominated DAWG’s discussions.

The path towards approval for AQUI-S[®] 20E (eugenol) as an immediate-release sedative received a major boost as the [U.S Army Corps of Engineers - Northwestern Division](#) (USACOE) invested \$300,000 to assist in the completion of study activities (for further details refer to the notes on the [Pacific Northwest Fish Sedatives Task Force](#) in this issue of the Newsletter). The USACOE donation was much appreciated by the DAWG, especially during these times of fiscal austerity, and will assist greatly in completing required residue chemistry studies under the Human Food Safety Technical Section of the ultimate [New Animal Drug Application](#). A BIG THANKS from all involved in the immediate-release sedative approval process!

The level of priority and focus of activities for future drug approvals was another topic at the Omaha meeting. The eight priority drugs originally outlined by the AFWA project (circa 1995) were evaluated based upon (a) what approvals have been accomplished to date, (b) if additional/expanded label claims are needed, (c) if there is the opportunity to apply extra label use for a specific drug(s) (outside of VFD antibiotics), and (d) to develop a tiered priority system for new approval or additional/expanded label claims. During the DAWG’s discussions it was decided (and ultimately approved by the FWRPC) to remove potassium permanganate from the priority list since its field use is typically as a water treatment versus a drug and approval activities have been minimal. In the near future, the DAWG will canvass the public and private aquaculture communities with respect to what pathogens of concern still need to be addressed and if these actions require a new drug approval or can they be accomplished under extra label use.

The DAWG is also in the process of developing a new Memorandum of Agreement between AFWA, U.S. Fish and Wildlife Service, U.S. Geological Survey, and the National Oceanographic and Atmospheric Administration relative to our concerted efforts for aquatic species drug approvals. This renewed five year agreement will ensure continued strong and

coordinated activities between the agencies. Our only challenge, as it relates to the MOA *per se*, is to obtain a final draft agreeable to all the agency solicitors.

In the near future the DAWG will reinitiate the [National Public Fish Production Survey](#) last completed in 2005. The results from this new survey, as with the 2005 survey, will serve as a reference for the Food and Drug Administration regarding public production levels in coolwater, warmwater and coldwater species. At the same time, public resource agencies will also be asked to provide a sampling of information on such items as rearing densities and water flows. These latter inquiries, formulated with assistance from the Center of Veterinary Medicine (CVM) will assist the DAWG (and CVM's Environmental Safety Team) to more accurately assess data requirements for the completion of the Environmental Assessment component of a New Animal Drug Application (NADA). The last survey was a great success; 100% of the public resource agencies participated. We hope to see the same level of response this time around as well!

The next DAWG meeting is tentatively scheduled for 28 February 2012 at Aquaculture America (AA) 2012 in Las Vegas, Nevada USA. The AA meeting provides us a great opportunity each year to meet with drug sponsors and many others involved in virtually all facets of aquaculture, allowing us to discuss our shared challenges and how these can best be addressed together. DAWG members are hoping that we will be able to meet individually with each drug sponsor to address ongoing issues and future needs. Success can only be accomplished if all parties are actively involved and well informed, so we are looking forward to a very successful meeting!

Text provided by Steve Sharon; Chair DAWG; Wyoming Game and Fish Department; Casper, Wyoming USA

AADAP staff member moves on: Miranda Dotson, a valuable member of the AADAP team since 2004, has moved on. She and her family left Montana this past September for a new life in northern New Mexico USA. Miranda filled two important roles at AADAP; our administrative officer and an active member of our research team.



Although we were all sorry to see her leave, we are confident that she is doing what is best for her and her family, and that's good. We wish her the best of luck and will most certainly miss her.

The 17th Annual USFWS Aquaculture Drug Approval Coordination Workshop is history: This past August 1st through 4th the Workshop and associated meetings were held in Bozeman, Montana USA. By all accounts, this year's Workshop was a great success. As in

previous years, there was a broad spectrum of representatives from all of the major sectors of the aquaculture community. Attendees included those from private and public producers, resource agencies, academia, pharmaceutical companies, non-governmental organizations and FDA's Center for Veterinary Medicine (CVM). In addition to the normal Workshop sessions *per se*, three other special sessions were held.

On Monday, 1 August, AADAP hosted a "Discussion Session with CVM to Develop Strategies to Resolve Drug Approval and Post Approval Issues." This all-day meeting (less formally referred to as a "listening session") was well attended by representatives from CVM, other federal agencies, state resource agencies, pharmaceutical companies, universities, private aquaculturists and non-governmental organizations. As the name of the session would suggest, numerous issues/impediments relating to the aquaculture drug approval process were brought to the attention of the CVM staff present and on a conference phone line. Potential solutions were discussed and several small *ad hoc* working groups were formed to further investigate in greater detail the critical issues and their potential solutions. All attendees concurred that the session was a good first step. Further details of the meeting are outlined in this Newsletter's [EDITORIAL](#). Future "listening sessions" are in the offing.

The second and third special sessions were offered during the Workshop's normally scheduled time period. The second was the meeting of the American Fisheries Society - Fish Culture Section's (AFS-FCS) Working Group on Aquaculture Drugs, Chemicals & Biologics (WGADCB). Draft minutes from the meeting are posted on the AFS-FCS webpage; included within their Summer 2011 Newsletter (<http://tinyurl.com/3pqkd6a>). Additional current updated information from the WGADCB can be found in this issue of the Newsletter by [clicking here](#).

The third was a special session focused on advances in and new information on biologics for finfish. The session was chaired by Dr. Phil Klesius from the U.S. Department of Agriculture's [Aquatic Animal Health Research Laboratory](#) in Auburn, Alabama USA.

All the presentations from the biologics special session, as well as all the other presentations from the Workshop, have been archived on AADAP's website at <http://tinyurl.com/6gfphm2>.

Update on the Approved Aquaculture Drugs - Quick Desk Reference Guide: As we noted in the [last AADAP Newsletter](#) the first 1000 copies of the AADAP-AFWA-AFS's *Quick Desk Reference Guide To: Approved Drugs for Use in Aquaculture* was "sold out" by Tuesday 31 May 2011 (only a week after being first made available). Unfortunately, a second printing has



yet to occur. What's new is that in the interim, we have come to understand, from a pharmaceutical sponsor, that a new claim will soon be added to their existing approved drug. Hence, we have decided to wait for that to happen, such that we can include this update in the

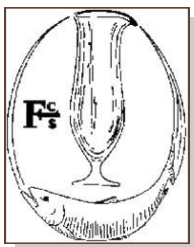


next printing. To those waiting for your copy(ies), please accept our apologies for the long wait. We hope that you will find the wait worth it. Please check the [AADAP website](#) for availability information.

For those unaware of what we are talking about, the “Desk Reference” comprises all the information contained in our “Approved Drugs for Use in Aquaculture” poster, as well as examples of “...how to calculate...” the proper dose or concentration of approved drugs as per label instructions.

The “Desk Reference” can be ordered (free of charge, when it is available) or downloaded via AADAP’s website at: http://www.fws.gov/fisheries/aadap/desk-reference_introduction.htm.

Progress update from the American Fisheries Society - Fish Culture Section’s (AFS-FCS) Working Group on Aquaculture Drugs, Chemicals, and Biologics (WGADCB):



Earlier this summer, the WGADCB organized a “listening session” or stakeholders’ meeting with key representatives of FDA CVM to discuss strategies to improve the approval process for aquaculture drugs. The meeting was held 1 August 2011 in Bozeman, Montana USA and was well-attended, with the public-data generating partners, more

than a dozen FDA CVM staff, drug sponsors, and the WGADCB leadership all coming together to try to address issues related to aquaculture drug research and approval. With the help of Eric Dubbin, a CVM staffer who moonlights as a facilitator, the group worked through the listening session talking points, ranging from data requirements to establish efficacy and safety to the complexities associated with labeling and packaging restrictions. Although minutes were not taken during the listening session itself, the major issues and outcomes were discussed during the WGADCB meeting held later that week during the 17th Annual USFWS Drug Approval Coordination Workshop. As you can see from the [minutes from the WGADCB meeting](#), some substantive progress is being made, though there are still quite a few action items that are as-yet unresolved. What is most important is that the listening session started a dialogue among the aquaculture drug stakeholders, and that everyone came to the table ready to work and open to new ways of

doing business. Over the next few months, it will become clear whether the proposed solutions are workable and if “talking the talk” during the listening sessions is helping us in “walking the walk” towards a more effective aquaculture drug approval process. The WGADCB exists to support the development, and safe and legal use of aquaculture drugs, chemicals and biologics—one way or another, the WGADCB leadership is committed to fulfilling that purpose.

To accomplish our goals, we need the help of knowledgeable people with all kinds of expertise. Biochemistry and pharmacology, fish diseases and pathology, environmental science, risk assessment, and many, many more disciplines are involved in the development, approval, and judicious use of aquaculture drugs. WGADCB participants cover a lot of this ground, but we also recognize the need to expand our ranks to include others with the skills we currently lack. Recently, the WGADCB did a [self-assessment to determine our strengths and weaknesses](#). The good news is that we are strong in many of the areas identified in the survey—fish health, fish culture, efficacy and safety testing, etc. However, we need to identify some individuals to build our knowledge base in histopathology, toxicology and environmental fate, analytical chemistry, genetics, endocrinology, and a few other areas. Do you know someone with expertise in one or more of these areas? Drop them a line or put them in touch with one of the WGADCB co-chairs!

One of the most visible efforts of the WGADCB to date has been the development of the “Guide to Using Drugs, Biologics, and Other Chemicals in Aquaculture” (the “Guide”) and the companion drug treatment calculator. We are proud to announce that new editions of these popular resources are now available via the AADAP and Fish Culture Section websites ([the “Guide” and calculator](#)). The “Guide” has been revised to correct a few minor errors, update some links, and provide contact information for end-users to report mistakes or make recommendations for future editions of the “Guide.” The treatment calculator has been expanded to include calculation worksheets for drugs available under the USFWS National INAD Program, and for those who can’t access the Excel 2007 (.xlsx) version, the original calculator is now available in Excel 97-2003 (.xls) format. Many thanks to the WGADCB leadership and other volunteers for reviewing the “Guide” and treatment calculators and helping to put tools—strike that, NEW and IMPROVED tools—in the hands of fish culturists, fish health biologists, veterinarians, students learning the ropes of fish culture, instructors looking to reinforce the calculations they teach in the classroom, and other end-users of aquaculture drugs.

For more information on current WGADCB activities, please see the [meeting minutes](#), contact one of the co-



chairs, or better yet, come to our next meeting! The next meeting of the WGADCB will be held in conjunction with the [Aquaculture America 2012 conference](#) to be held in Las Vegas, Nevada from 29 February to 2 March 2012. Stay tuned to the AADAP website for WGADCB meeting scheduling announcements.

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

Pacific Northwest Fish Sedative Task Force History and Update: This *ad hoc* group was formed in February 2009 in response to a note in the [October 2008](#) issue of the AADAP Newsletter. The note was an update on activities by members of the [AFWA-DAWG](#) to obtain an immediate-release sedative for fish. The gist of the update comprised a report on an immediate-release sedative “product development meeting” with CVM and a review of the most recent DAWG meeting during which immediate-release sedative activities were the primary focus of discussion. In response to the update, Mr. Ed Larson, employed by the [Nez Perce's Department of Fisheries Resources Management](#), initiated a call to AADAP, asking “...how can we be of assistance?” This led to a meeting of representatives from several Pacific Northwest Native American tribes, state natural resource agencies, the [Bonneville Power Administration](#), the Department of Commerce's [National Marine Fisheries Service](#) (NMFS), the [U.S. Army Corps of Engineers](#) (USACOE), private aquaculture, AFWA-DAWG and FWS-AADAP. The group later became known to its members as the Pacific Northwest Fish Sedative Task Force (herein referred to as the TF). The February 2009 meeting, held during Aquaculture America in Seattle, allowed the DAWG and AADAP to educate the TF member groups on: a) the drug approval process and current CVM regulations regarding approved and prospective fish sedatives, b) recent DAWG-led research activities related to fish sedative approvals and c) the need for TF members' participation and monetary assistance in gaining an approved immediate-release sedative for their specific needs. All participants agreed that the need for an immediate-release sedative in the Pacific Northwest for salmonids was “mission critical.” Attendees were urged to carry this information and a solicitation for assistance to their upper management.

The TF members agreed to meet again, and the DAWG and AADAP were assigned the responsibility of providing to the TF members specifics on (1) which prospective drug was to be the focus of our work, (2) what actual studies needed to be completed and their estimated costs, and (3) a timeline and sequence for all work needed to gain an approval for the selected drug. Additionally, it was agreed that the intended claim

for whichever prospective immediate-release sedative was selected was to be limited to “...for the sedation of salmonids to a handleable stage...”

The next TF meeting was held a year later in Newport, Oregon USA. At that time two of the three DAWG/AADAP assigned deliverables [(1) [study details and cost comparisons for the two prospective sedatives](#); and (2) [a timeline of all required work](#)] were provided to attendees and discussed at length. Although no specific resource commitments of assistance were made by TF members, indications of the desire to do so and the potential benefits of such were shared by the group members.

Shortly following the February 2010 TF meeting, NMFS (Portland Regional Office) provided notice to the TF that they were making \$50,000 available toward funding the required studies. Unfortunately, no other entity stepped-up with a contribution, and hence, the \$50,000 went unspent; NMFS's contribution was insufficient **alone** to cover the cost of one of the required studies (i.e., a study other than one for which a DAWG research partner had already pledged to complete).

In September 2010, after a difficult decision process, the DAWG decided that its efforts from that point forward would be focused on eugenol (the active ingredient in [AQUI-S New Zealand Ltd.](#)'s AQUI-S® 20E product). The TF was somewhat disappointedly inactive (with the exception of the DAWG's decision to focus on eugenol) for the remainder of 2010 and the first half of 2011.

However, in July 2011 things changed big-time! In light of the fact that the DAWG and AADAP had, in all honesty, pretty much written-off the TF as a viable mechanism to assist in expediting the approval of an immediate-release sedative for fish, we were totally unprepared when the [Northwest Regional Office of the USACOE](#) called and said “...we've got \$300,000 available to invest in getting eugenol approved, what should we spend it on?” To make a long story shorter, after consulting with the drug sponsor ([AQUI-S New Zealand Ltd.](#); AQNZ), and the DAWG it was decided that the best strategy was to apply the funds to completing a series of residue chemistry studies comprising part of the Human Food Safety Technical Section. The next step was to find a laboratory to conduct the studies. After comparing the costs and benefits of using either one of several contract research labs or the U.S. Geological Survey's [Upper Midwest Environmental Sciences Center](#) (UMESC) it was decided that the UMESC lab was the best choice. The USACOE and UMESC have since worked out the arrangements and the work is scheduled to be completed by approximately October 2012.

And there is more good news!! The USACOE has another \$300,000 line-item in their Fiscal Year 2012 budget for additional work on eugenol. Of course, one



must consider: (1) these are tough financial times for the USA, (2) the FY2012 budget has yet to be approved by Congress and may not be for several months in spite of the fact that FY2012 began 1 October 2011, and (3) the final approved budget may not include this \$300,000 line-item.

Even though this second round of USACOE funding is not yet a sure thing, the other members of the TF have again been solicited to contribute to the cause. The situation will be much different this time around, assuming the USACOE's second round of funds do become available; i.e., any contribution, no matter how small, can be added to that of the USACOE's and will not go unspent.

We've all got our fingers crossed hoping that those parties positioned to benefit the most from the approval of an "immediate-release" sedative for salmonids can find the wherewithal in these tough times to help us help them. We will keep you posted.

AADAP DRUG UPDATES

General: Summer is waning, our pivotal field efficacy trial season has come to an end (for now), datasets from a slew of fish sedative studies are getting crunched, reports are being developed and submitted to CVM, and we're getting ready to launch a couple of target animal safety studies scheduled for late fall or early winter. It seems that because we are always in the process of submitting Final Study Reports, Research Protocols, and other information packets (e.g., Environmental Assessments and White Paper Arguments) to CVM, we are also often hearing back from CVM reviewers. Sometimes, we're blessed with good news from the reviewers, and sometimes the news is not so good. We hate to think of it as "job-security" but it often seems like there's always one more thing to do. To see what's been happening in the land of AADAP Research, read on.

AQUAFLO[®] (florfenicol) Update:

Anticipated all-fish approval for columnaris: Why not start off with some of the best news we've received in a looong time....but pay attention because it's a twisted tale. As you may know, we have submitted data to CVM that demonstrate the effectiveness of florfenicol to control or reduce mortality in coho salmon, rainbow trout, bluegill, and largemouth bass due to columnaris disease associated with *Flavobacterium columnare*. Unfortunately, we didn't have enough data to complete an effectiveness technical section for salmonids or for warmwater species of freshwater fish.

Earlier this year we submitted another Final Study Report summarizing the effectiveness of florfenicol to

control mortality in rainbow trout caused by columnaris disease in hopes that this would be sufficient to complete the technical section for all freshwater salmonids. The response from CVM stated that the "...study was not acceptable as part of substantial evidence of effectiveness for the proposed claim."

In spite of the aforementioned not-so-good news, by reading CVM's response further (i.e., the fine print) we found that all that was needed to demonstrate effectiveness in controlling columnaris in **ALL** freshwater-reared finfish was a justification supporting the likelihood of limited use of florfenicol in coolwater species. CVM noted that this satisfactory justification along with the previously accepted studies in freshwater-reared salmonids and warmwater species, and the data submitted by the sponsor ([Merck Animal Health](#)), would be adequate to support the proposed indication for **ALL** freshwater finfish. About 30 min after reading the letter, we provided the sponsor with the requested justification, and are anticipating that the claim for AQUAFLO[®] will be expanded to include use on **ALL** freshwater species of finfish to control mortality caused by columnaris disease. This is truly amazing news, and we are encouraged that CVM reviewers are investigating ways to improve the efficiency of the aquaculture drug approval process.

Just one more BKD efficacy study: On another front, in the last [AADAP Newsletter](#) we stated that a third study will have to be conducted to demonstrate the effectiveness of AQUAFLO[®] administered at a dosage of 15 mg florfenicol per kg fish body weight per d for 10 d to control mortality caused by bacterial kidney disease (BKD; causative agent, *Renibacterium salmoninarum*) in Chinook salmon. We also mentioned that CVM's Aquaculture Team would prefer that the study be conducted at a facility other than the Eagle Fish Health Lab EFHL ([Idaho Department of Fish and Game](#)) and by an investigator other than Doug Munson (Fish Health Biologist for the IDFG Anadromous Fish Hatcheries). After some discussion with the CVM Aquaculture Team, they agreed to allow another study to be conducted at the EFHL, but stipulated that the study be conducted by a different investigator. Doug has collected eggs from two "hot" (i.e., with high ELISA optical density values) female Chinook infected with BKD. The resultant fry will be used next year in the 3rd efficacy trial. Doug has looked into lining up another Study Investigator, perhaps a veterinarian intern or Dr. Phil (Mamer) himself. Hence, the game plan is to conduct one more pivotal efficacy study sometime next summer. We'll keep our fingers crossed that the treatment will work as well on this group of test fish as it has worked on previous groups, and that the results from this study will be sufficient to complete the effectiveness technical section for the proposed claim.



AQUAMYCIN® 100 (erythromycin thiocyanate) Update:

Bacterial Kidney Disease efficacy study: Some of you may recall from the last [AADAP Newsletter](#) that in one of the studies conducted by Doug Munson last year to control mortality in Chinook salmon caused by BKD (see above note), groups of sick fish were fed with either AQUAFLO® or AQUAMYCIN® 100 (22.045% erythromycin thiocyanate, ET). As noted in the last Newsletter, a significant difference in cumulative mortality was detected at the end of the study between the replicate groups of fish fed AQUAFLO® and control groups, and the results were summarized and submitted to CVM for review.

At the time it was our understanding that no additional AQUAMYCIN® 100 efficacy data were required to support its approval, so we did not summarize and submit results from the ET part of the study. Now here's where it gets interesting. Have you ever known somebody that you have a difficult time saying "no" to? Well, we do.

Dr. Meg Oeller ([CVM Office of Minor Use Minor Species](#)) recently contacted us and explained that virtually all the data that had previously been submitted to CVM to support the safety and effectiveness for AQUAMYCIN® was generated from studies utilizing the drug that had been incorporated into fish feed. Meg also noted that the current industry standard is now to top-coat the drug onto feed. She went on to explain that to gain approval of this drug for top-coated use, data or information needs to be submitted to CVM to demonstrate bio-equivalency between the two methods of adding ET to feed.

We're guessing that you know how the story ends: yep...we agreed to write up the results from this study and submit it to CVM to support the approval of AQUAMYCIN® 100. AADAP's Dan Carty dove into the dataset, reanalyzed mortality data (a significant difference was detected in mortality at the end of the 42-d study between AQUAMYCIN® 100-treated and control tanks [9% vs. 25%, respectively]), and, of course, found a few quirks in the study that needed to be addressed. The Final Study Report has been submitted to CVM and we hope it's adequate to address the bio-equivalency concern.

As many of you know, Dr. Christine Moffitt ([University of Idaho, Idaho Cooperative Fish & Wildlife Research Unit](#); Moscow, Idaho USA) has been committed to generating data to support an approval for the use of AQUAMYCIN® 100 in aquaculture, and after many years of effort the approval is oh-so close to the finish line. We're glad that we could play a very minor role in helping her gain approval of this much needed aquaculture drug.

AQUI-S®20E (eugenol) and BENZOAK® (benzocaine) Update:

Pivotal and high quality supportive (HQS) effectiveness trials: In the last [AADAP Newsletter](#), we told you that we were ready to launch into a field season full of sedative effectiveness trials. Well, launch we did. Jim Bowker and Niccole Wandelaar took their act east to Carbondale, Illinois USA and worked with Dr. Jesse Trushenski and several of her students on the [Southern Illinois University](#) campus. After spending a day or two at home, they then hustled east again to La Crosse, Wisconsin USA to work with Jeff Meinertz and staff at the [U.S. Geological Survey's Upper Midwest Environmental Sciences Center](#) (UMESC). Over a 2-wk period, Niccole and Jim conducted 23 separate pivotal and HQS trials to evaluate the effectiveness of AQUI-S®20E and BENZOAK® to sedate nine different fish species to the handleable stage of sedation.

Although study plans were focused only on the conduct of pivotal efficacy studies, as it turned out, sufficient numbers of hybrid striped bass and yellow perch were available to allow for the completion of a number of HQS trials. Some of these HQS trials were designed to investigate the effect of life-stage, water temperature, or sedative concentration on time to sedation and recovery from sedation. Other HQS trials were designed to investigate the effect of "group sedation" versus individually sedated fish on times to sedation and recovery..

As you can imagine, they generated a mountain of data, and we hope that these data will be sufficient to complete the effectiveness technical section for sedation to handleable for all freshwater finfish for these two drugs. All these studies could not have been conducted without help from Jesse, John Bowzer, Brian Gause, and Bonnie Mulligan (SIU graduate students) and Jeff, Aaron Cupp, Karina Hess, Steve Redman, and Sue Schleis (UMESC staff).

Before Jim and Niccole said goodbye to their study cooperators, they went through all the data, made sure everything was signed and incorrect data entries were correctly corrected (don't ask...it's what we do), and boxed all the data notebooks up for shipment home. Once the data made it home, AADAP's Molly Bowman dove into it, entered it into databases, and has been doing some data-snooping to get a better idea of what we have. We've come up with a game-plan to write up the Final Study Reports for both the pivotal and HQS trials, as well as plans to begin to submit them one-at-a-time to CVM for review within the next couple of months. This should keep the CVM reviewers more than a little busy given we've already sent in five Final Study Reports summarizing the



effectiveness of AQUI-S®20E and/or BENZOAK® on rainbow trout, Arctic char, cutthroat trout, and walleye.

Extra coldwater species eugenol efficacy studies: Sometimes we can't help it, but when we have fish available at our home base, the [Bozeman Fish Technology Center](#) (BFTC), we almost always end up conducting one more study. As it turns out, the BFTC had two sizes of rainbow trout available (large fingerlings and adults), and with the help of the BFTC hatchery staff, a couple of systems were fired up where we could test the rainbow trout at two different water temperatures (9°C and 16°C). So testing began and Niccole and Molly have been generating data to evaluate the effectiveness of 25 and 75 mg per L eugenol to sedate rainbow trout to a handleable stage. The purpose of these studies is to investigate whether fish size and/or water temperature has an effect on sedation and/or recovery times for rainbows.

Eugenol Dose confirmation methods: Lastly, we submitted the following report to CVM to provide further evidence that a UV-Vis spectrophotometric method is suitable for measuring eugenol in solutions of AQUI-S®20E used in field effectiveness and target animal safety studies: *"A Simple UV-Vis Spectrophotometric Method to Determine the Concentration of Eugenol in Water and the Stability of Eugenol in a Solution of AQUI-S®20E."* These data were generated earlier this year, but we waited to submit them until a complementary report had been submitted to CVM by Jeff Meinertz (U.S. Geological Survey, [Upper Midwest Environmental Sciences Center](#); LaCrosse, Wisconsin USA), which confirmed using HPLC that the UV-Vis spec method is specific for eugenol (see [USGS's Corner](#)).

In our study, it was shown that calibration curves (absorbance vs. nominal concentration) from eugenol standards made from six different water sources were virtually identical, and that the concentration of eugenol in 100, 500, and 1,000 mg per L solutions of AQUI-S®20E were stable over a 144-h period. We're hopeful that CVM reviewers will agree that (1) the UV-Vis method is suitable for measuring eugenol in solutions of AQUI-S®20E used in field effectiveness and target animal safety studies and (2) AQUI-S®20E samples can be collected throughout the day and measured after the last sample is collected without concern that eugenol concentrations may decrease over that time period. For more information on the results from these two experiments, visit the AADAP website and read Drug Research Information Bulletins (DRIBs) #20 ["The Robustness of a Simple UV-Vis Spectrophotometric Method to Determine the Concentration of Eugenol in Water"](#) and #24 ["Stability of Eugenol in Solutions of AQUI-S®20E."](#)

Channel Catfish Pituitary Update:

Update on Product Development Meeting with CVM: In the last [AADAP Newsletter](#), we mentioned (1) that AADAP had submitted an Environmental Assessment (EA) for the use of channel catfish pituitary (CP) as a spawning aid in a variety of warmwater finfish species and (2) a product development meeting (PDM) was scheduled with Roger Yant (the drug sponsor; Hybrid Catfish Farm; Indianola, Mississippi USA), his collaborators, and CVM to specifically determine what will be required to complete the remaining technical sections in support of an approval. The PDM was held on 12 October 2011 and the following was discussed: (1) that AADAP will receive an End Review Amendment request for the previously submitted EA, for which we should be able to provide CVM with the requested information within the allotted time period; (2) that CVM's Environmental Team will help us to make sure we get the EA correct this next go-round; (3) that Roger Yant and Dr. Chris Green (Assistant Professor of Aquaculture, [Louisiana State University, Aquaculture Research Station](#)) will begin a dialog with CVM's Division of Manufacturing Technologies Biotherapeutics Team to determine the course of action to take to complete the Product Chemistry (PC) requirements for this crude product; and (4) the details relative to conducting studies to demonstrate that CP is effective and safe to target animals. Wrapping up the EA and developing efficacy and target animal safety protocols and conducting the studies should be relatively straightforward. The upshot of the PDM was that completing the Product Chemistry requirements with the limited analytical capabilities available to the sponsor will likely be the biggest stumbling block, but that we're hopeful that alternative approaches can be used to get around such stumbling blocks.

SLICE® (emamectin benzoate) Update:

Status of ectoparasite efficacy studies: In the last issue of the [AADAP Newsletter](#), we reported that we had submitted three Final Study Reports (FSRs) to CVM. These FSR's summarized each of the efficacy studies we conducted last year to evaluate the effectiveness of SLICE® administered in feed as a means to reduce infestations of the ectoparasite *Salmincola californiensis* in female populations of rainbow trout. Although we met our statistical objective (i.e., the mean abundance of *S. californiensis* on fish in treated tanks would be significantly lower than that in control tanks) in all three studies, in only 1 of 3 studies did we meet our reduction threshold (i.e., the mean abundance would be >90% lower on fish in treated tanks than in control tanks). For more information on these studies, see DRIB #23 ["Efficacy of SLICE® Premix \(0.2% emamectin benzoate\) to Control Infestations of](#)



[Salmincola spp. on Freshwater-reared Rainbow Trout](#)"; and DRIB #25 "[Efficacy of SLICE® \(0.2% Emamectin Benzoate\) to Control Natural Infestations of Salmincola californiensis in Freshwater-Reared Rainbow Trout.](#)"

In CVM's review of our submissions, they requested that we conduct at least one additional study to demonstrate the effectiveness of SLICE® to reduce an infestation of *S. californiensis* on a mixed-sex population of fish. We concurred with their request, and decided that in this next study, we would extend the posttreatment to 42-d. This is the same posttreatment period duration as that used in the study conducted last year (at [Clear Springs Food Inc.](#), Snake River Research Facility, Buhl, Idaho) where we achieved >90% reduction in abundance.

In response to the aforementioned CVM request, AADAP's Nicole collaborated with Wesley Swee and the staff at the [Missouri Department of Conservation's Maramec Spring Hatchery](#) (St. James, Missouri USA), to conduct a mixed-sex SLICE®/*S. californiensis* study on rainbow trout. The results of the Meramec study demonstrated that SLICE® was once again effective in reducing an infestation of *S. californiensis*. SLICE® treatment resulted in a significant decrease in mean abundance of *S. californiensis* between treated and controls, and also resulted in >90% reduction in mean abundance. The Final Study Report summarizing results from this last study has been submitted to CVM for review. At this time we are working to assemble some additional information to submit with a letter requesting that the effectiveness technical section be considered complete for this claim. As always, we're optimistic that we're finished conducting efficacy trials in support of this claim, but you never know until you hear back from CVM. So, please check back in six months.

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

Ectoparasite pivotal efficacy study: Let's wrap up the Research Program update with a little more good news – an update on another acceptance letter from CVM. Reviewers in CVM's Aquaculture Team accepted the study we conducted to evaluate the effectiveness of 35% PEROX-AID® when administered at a dose of 50 mg per L hydrogen peroxide per day on two alternate days for the treatment and control of the ectoparasite *Gyrodactylus salmonis* in freshwater-reared rainbow trout. We've forwarded the acceptance letter from CVM to Mark Gaikowski ([USGS UMESC](#)) for inclusion in a letter/request that Mark will submit to CVM in 2012 requesting that the effectiveness technical section be considered complete to control and/or reduce *G. salmonis* infestations in all freshwater-reared salmonids.

FINS & TAILS, BITS & BOBBERS

New Treatment-Use Authorizations received for AQUAFLO®: With prior approval from the AADAP Office, salmonids can now be treated under INAD #10-697 at 15 mg florfenicol per kg of fish per day for coldwater disease! Please note that if you intend to treat at this dose, you must provide to the AADAP Office signed documentation from a licensed veterinarian verifying the need for treatment at the 15 mg per kg dose. For additional information, please contact Bonnie Johnson (bonnie_johnson@fws.gov).

The AADAP Office has also recently established AQUAFLO® INAD #12-061, which is only for use in lobster. The treatment regimen is for use at 10 or 15 mg per kg body weight per day for 10 consecutive days.

2012 INAD enrollment: We once again apologize for the delay in launching the INAD Program Management System (IPMS) - Online Data Reporting database. Although we are keeping our fingers crossed, the current plan is for all facilities and monitors to be able to create their accounts in the IPMS mid-December 2011, and subsequently all 2012 INAD data (study requests, drug receipts, reports, and INAD drug inventory) will be entered directly into the IPMS. Once the IPMS is ready to be used, an email will be sent out to all current INAD participants with more detailed information and instructions for using the IPMS.

End of the Year INAD Forms due: If you have not already done so, please send in all Form 2's (Drug Inventory Form) and Form 3's (Results Report Form) for each of the INAD drugs that were used at your facilities for INAD Year 2011. Note: If your facility was signed-up on an INAD, but the INAD drug was not actually used, a Form 2 is still required showing either the amount of drug on hand or that no use occurred.

EDITORIAL

AADAP's Perspective on a Recent "Listening Session" with FDA's Center for Veterinary Medicine: Part 1 - Objective Observations

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Editor's note: The views expressed by Drs. Bell and Erdahl are not necessarily those of the U.S. Fish & Wildlife Service (USFWS).

Introduction and Objectives

This past August a "listening session" was held the day before the U.S. Fish & Wildlife Service's (USFWS's) [17th Annual Aquaculture Drug Approval Coordination](#)



[Workshop](#) in Bozeman, Montana USA. The session was formally entitled the “*Listening Session with FDA’s Center for Veterinary Medicine to Develop Strategies to Resolve Drug Approval and Post Approval Issues.*” The all-day session was well attended with approximately 60 present. All sectors of the aquaculture community were well represented, including those from FDA’s Center for Veterinary Medicine (CVM), other federal agencies, state natural resource agencies, universities, non-governmental organizations and private aquaculture companies. Although the genesis of this meeting goes back several years, it was only recently brought to some level of fruition via the initiative of several folks in the American Fisheries Society’s [Working Group on Aquaculture Drugs, Chemicals and Biologics](#) (WGADCB). The “talking points” for the session were the result of topics assembled, by the WGADCB, from a large number of interested and involved individuals from all segments of the aquaculture community, including input from CVM.

The overall objective of the session was to initiate formal discussion and actions that will hopefully lead to increased efficiencies in the drug approval process for aquaculture drugs. In its present form the process is extremely inefficient, and in many respects has become even more so over time. The part of the [Federal Food Drug and Cosmetic Act](#) (the law governing the approval process for human and animal drugs) and its accompanying [Federal Regulations](#) that address animal drugs were not written with any aquaculture species in mind. Hence, the Regulations pertaining to major animal species (e.g., cows, chickens, pigs, horses; all of which are terrestrial) in many, if not most, cases can not be extrapolated to aquatic species. In most instances, one of CVM’s tenets, as exemplified by this statement “a horse is a horse is a horse” is not applicable to aquatic species; hence, “a fish is not a fish is not a fish.” Consequently, detailed requirements for the approval of an aquatic species drug may be “borrowed” from that for terrestrial species or are developed and established on a case-by-case basis. In both cases, such action typically leads to additional studies being included in the required workplan, but with little or no scientific merit or justification that the results will add appreciably to the “critical mass” of knowledge necessary to demonstrate that the prospective drug is safe and/or effective.

So, to reiterate, the purpose of this session was to start a concerted course of action to identify these inefficiencies and the means to eliminate or minimize these impediments to more expeditiously obtaining new aquatic animal drugs. Obviously, it was understood by all that this must be accomplished without jeopardizing human, animal or environmental health.

Major Action Items Identified

Although numerous topics were discussed, at the end of the day it was agreed that a number of *ad hoc*

committees should be formed to head-up efforts to find a solution(s) for a select subset of the identified issues. The consensus opinion of the attendees was that each committee formed should comprise 2-3 individuals, with at least one person from CVM and one person from other than CVM. In many cases, committee members were identified prior to the meeting being adjourned.

The following are brief summaries of the issues for which in many cases *ad hoc* committees were, or are being, formed. They are listed in no particular order of importance.

- **Sharing of discoveries or breakthroughs:** It was noted that the community of entities working toward gaining new aquaculture drugs is very small. Further, to bring new experts into the process, our achievements need to somehow be disseminated to a broader audience. In so doing, our collective expertise (and progress) has the potential to be significantly enhanced. Several thoughts were shared: (a) conduct a discoveries/breakthroughs session at the USFWS Annual Aquaculture Drug Approval Coordination Workshop, (b) include such information on AADAP’s website, and (c) have CVM generate a list of “lessons learned” based on the comments provided by CVM to sponsors’ submissions. Some current and past efforts by CVM to address this issue were brought to the attention of the meeting attendees.
- **Data-mining to determine the most influential study variables:** It was observed that certain variables may contribute relatively insignificant information to the outcome of a drug approval-related study. Consequently, it may be a wasteful use of resources to monitor and report the measurement of such to CVM; this information may not help CVM determine whether the reported study results could be used to support safety or effectiveness claims for the prospective drug.
- **More effective use of peer-reviewed or grey literature:** To date peer-reviewed or grey literature has contributed little to the required documentation of effectiveness and/or safety to obtain a new drug approval for aquatic species. The committee will define the critical elements that need to be in such literature as a part of the “body of evidence” necessary to help support a drug’s safety and/or effectiveness claim.
- **More effective use of efficacy (and safety) data generated under Investigational New Animal Drug (INAD) exemptions:** To date the results of thousands of production-site efficacy studies conducted and documented under strictly regulated INAD exemptions have contributed negligibly to the “body of evidence” required to demonstrate a prospective drug’s effectiveness and/or safety.



These studies, *in toto*, represent the myriad of conditions and environmental parameters under which aquaculture drug use actually occurs. Hence, they provide real-life data demonstrating the robustness of a drug and its prescribed treatment regimen. The intended course of action for the committee is to develop a rubric containing the critical elements necessary for an INAD study (or collation of studies) to be used as part of the required “body of evidence.”

- **Modify the Index Drug required label content:** Currently, under the [Minor Use and Minor Species Animal Health Act of 2004](#) one of the new procedures available to drugs companies to legally market their products for minor uses in major species or for minor species is entitled “indexing.” In essence, indexing allows a third-party panel to review all safety and effectiveness information available and make recommendations to FDA-CVM as to whether or not the drug should be added to the “Index.” If added to the Index by CVM, the drug can be legally marketed only by the particular company bringing the proposed indexing to CVM. Technically the index drug is not “approved” (as is a drug being approved via the conventional New Animal Drug Application process), but instead has only been deemed by CVM to be legally marketable. As one of the conditions for the drug to be marketed, its label must clearly contain the following statement “NOT APPROVED BY FDA.” Therein lies the problem, understood now by both those inside and outside of CVM. Although this may be the only brand of this drug in the marketplace to have gone through the indexing review process, the required statement is a clear deterrent to prospective purchasers. Unfortunately non-indexed brands of the same drug are often perceived by the public to be “approved by FDA” by virtue of their not having the previously noted required statement on their label. CVM is currently working to find an appropriate fix to this problem.
- **Identification of a “worst-case scenario” to streamline residue-depletion studies and subsequent determination of a withdrawal time:** This committee will try to determine if there is such a thing as a “worst-case scenario” and, within the context of such, if a conservative withdrawal period can be established to minimize the number of residue depletion studies required to be completed. **Editors note:** Identification (and/or removal) of “worst case scenario” logic is a recurring theme/ problem with respect to other technical section requirements as well.
- **List of questions a naïve drug sponsor should ask CVM at their product development meeting(s):** In general, to get the best advice on what needs to be done to gain the approval of a new aquaculture drug by a naïve drug company, the company must ask the correct questions during their meetings with CVM. A complete list of potential questions to be asked could expedite the approval process, especially for drug companies unfamiliar with how to gain an approval for an aquatic animal drug. CVM is investigating as to whether a CVM staffer can actually participate in a committee to address this issue.
- **The conduct of drug method transfer studies by other than CVM’s Office of Research:** Both a “determinative” and a “confirmatory” detection method must be developed by the prospective drug’s sponsor to gain a new animal drug approval. One of the purposes of these methods is to allow FDA to be able to legally test for residues of the drug in animals so treated. It must be demonstrated, via transfer trials, that the method is robust enough that any properly equipped laboratory can successfully conduct the assay. CVM has responded to this issue, by stating that their Office of Research (OR) normally is used to test one or both of the determinative and confirmatory methods. However, there is usually a large backlog at OR significantly extending the time to complete the transfer trials, especially if the sponsor has more than one drug method awaiting testing (terrestrial drugs being of higher priority to the drug company; thus, relegating their method for aquatic species closer to the bottom of the queue). CVM has responded further that it is possible to have the transfer trials for the determinative method be completed totally by non-CVM labs. However, the confirmatory method must include testing at a government lab (usually CVM’s OR). It appears that a committee to further address this issue will not be formed.
- **CVM’s Environmental Safety Team needing background information:** CVM’s Environmental Safety Team would like to obtain information on various parameters pertaining to fish culture procedures. They note that this is needed to assist them in reviewing Environmental Assessments submitted to CVM. Examples of such parameters could include: water flow vs. fish density; water flow through typical raceways, tanks, etc.; and the number of systems treated at a time. The committee will investigate the development of a survey to compile such information.
- **Decision-tree template:** Such a tool could be valuable in increasing efficiencies in completing either safety and/or effectiveness technical sections. The example of a decision-tree based on preliminary data used to potentially minimize the



number of tissues examined (in target animal safety studies) was cited as an example.

- **New fish species grouping strategy:** Currently the strategy relative to trying to minimizing studies for both target animal safety and effectiveness is to test one or two representatives from cold-, cool- and warmwater cultured species. It was suggested that possibly another strategy may be adequate and allow for the reduction of the number of studies needed. CVM suggested that it might be worth proposing a salmonid/non-salmonid strategy at the next Product Development Meeting for which an “all freshwater fish” claim is being sought.
- **Scientific justification for pathogen grouping:** A CVM staffer, a representative from a commercial aquaculture facility and a representative from a non-governmental organization volunteered to form the committee to investigate this strategy. The purpose being to potentially reduce the studies required for a broadened label.
- **Required documentation for deviation from requirements in a Good Laboratory Practices (GLP) study:** Specific types of studies must be conducted in compliance with GLP guidelines. However, at times a study may be unintentionally less than 100% GLP-compliant. In general, it was noted by CVM that results from these studies can still be acceptable, given that all deviations from GLP-compliance be fully documented and justified as to how such non-compliance did not affect the results of the study in any appreciable manner.

The August 2011 “Listening Session” was understood by all present to be just the beginning of an extended dialogue. Although no specific date was set, plans are now being made to schedule the next session.

This editorial is being presented in two parts. This first installment is an objective documentation of what actually was discussed. The second installment, which will be published in the next edition of the AADAP Newsletter (early 2012), will outline AADAP’s subjective take on what took place at the first “Listening Session” *per se*, as well as what has transpired in the interim. Keep your radio dial set right where it’s at, we’ll be back real soon.

If you have further questions regarding the “listening session” or related topics, please contact Jesse Trushenski (Past-President American Fisheries Society - Fish Culture Section; saluski@siu.edu) or Jim Bowker (President AFS-FCS; jim_bowker@fws.gov).

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 2011, with the exception of a single paper from 2009. 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

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- Bowker, JD, et al. 2011. Chloramine-t margin-of-safety estimates for fry, fingerling, and juvenile rainbow trout. *North American Journal of Aquaculture* **73(3):259-269.**
- Faroongsarn, D, et al. 2011. A toxicokinetic study of oxytetracycline antibiotics in farmed white shrimp, *Penaeus vannamei*. *Journal of the World Aquaculture Society* **42(4):484-493.**
- Harikrishnan, R, et al. 2011. Impact of plant products on innate and adaptive immune system of cultured finfish and shellfish. *Aquaculture* **317(1-4):1-15.**
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- Immanuel, G, et al. 2011. Antibacterial effect of medium-chain fatty acid: caprylic acid gnotobiotic *Artemia franciscana* nauplii against shrimp pathogens *Vibrio harveyi* and *V. parahaemolyticus*. *Aquaculture International* **19(1):91-101.**
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contents. *Journal of Applied Ichthyology* **27(1):57-60**.

Mousavi, SM, et al. 2011. Antibacterial activities of a new combination of essential oils against marine bacteria. *Aquaculture International* **19(1):205-214**.

Ndi, OL, and Barton, MD. 2011. Incidence of class 1 integron and other antibiotic resistance determinants in *Aeromonas* spp. from rainbow trout farms in Australia. *Journal of Fish Diseases* **34(8):589-599**.

Oh, E-G, et al. 2011. Antimicrobial resistance of *Vibrio parahaemolyticus* and *Vibrio alginolyticus* strains isolated from farmed fish in Korea from 2005 through 2007. *Journal of Food Protection* **74(3):380-387**.

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Vaseeharan, B, et al. 2011. Antibacterial activity of *Allium sativum* against multidrug-resistant *Vibrio harveyi* isolated from black gill-diseased *Fenneropenaeus indicus*. *Aquaculture International* **19(3):531-539**.

Zounkova, R. 2011. Complex evaluation of ecotoxicity and genotoxicity of antimicrobials oxytetracycline and flumequine used in aquaculture. *Environmental Toxicology and Chemistry* **30(5):1184-1189**.

Parasite and Fungus Control

Foster, B, et al. 2011. Copper exposure affects hemocyte apoptosis and *Perkinsus marinus* infection in eastern oysters *Crassostrea virginica* (Gmelin). *Fish & Shellfish Immunology* **31(2):341-349**.

Chen, MF, et al. 2011. Isometamidium chloride reduces mortality of adult Chinook salmon due to *Cryptobia salmositica*. *North American Journal of Aquaculture* **73(3):304-310**.

Jussila, J, et al. 2011. Peracetic acid (PAA) treatment is an effective disinfectant against crayfish plague (*Aphanomyces astaci*) spores in aquaculture. *Aquaculture* **320(1-2):37-42**.

Liu, T-H. 2011. The acute toxicity of copper sulfate to scallop *Chlamys farreri*. *Fisheries Science* **30(6):317-320**.

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Akbulut, B, et al. 2011. Use of clove oil to anaesthetize larvae of Russian sturgeon (*Acipenser gueldenstaedtii*). *Journal of Applied Ichthyology* **27(2):618-621**.

Bowker, J, and Trushenski, J. 2011. Guest director's line: AFS policy statement regarding the need for an immediate-release anesthetic/sedative for use in the fisheries disciplines. *Fisheries* **36(3):132-135**.

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(*Cyprinus carpio* L.) in comparison with pre-slaughter CO₂ stunning chilling and asphyxia. *Turkish Journal of Fisheries and Aquatic Sciences* **11(1):141-150**.

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Devaux, A, et al. 2011. Reproduction impairment following paternal genotoxin exposure in brown trout (*Salmo trutta*) and Arctic charr (*Salvelinus alpinus*). *Aquatic Toxicology* **101(2):405-411**.

Lochet, A, et al. 2011. Detection of chemical marks for stocking purposes in sturgeon species. 2011. *Journal of Applied Ichthyology* **27(2):444-449**.

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USGS's CORNER

Sedatives: The [Upper Midwest Environmental Sciences Center](#) (UMESC) completed a request by AADAP to evaluate the performance of a spectrophotometric method that was planned to be used to verify AQUI-S® 20E (active ingredient - eugenol) concentrations during animal safety and efficacy trials. The spectrophotometric method was accurate (>92%) and precise (<0.52%) when determining eugenol concentrations in AQUI-S® 20E solutions that are representative of solutions that will be used in AQUI-S® 20E target animal safety and efficacy studies. A final study report was submitted to FDA's Center for

Veterinary Medicine (CVM) for their review. Contact Jeff Meinertz, jmeinertz@usgs.gov, for more information.

UMESC hosted AADAP during the conduct of pivotal and high quality supportive efficacy trials with AQUI-S® 20E, BENZOAK® (active ingredient - benzocaine), and MS-222 (active ingredient - tricaine methanesulfonate). UMESC retrofitted a series of raceways and a wet lab with flow-through rearing and recovery capabilities to accommodate 7 different groups of fish (6 species including brown trout *Salmo trutta*, common carp *Cyprinus carpio*, fathead minnow *Pimephales promelas*, lake trout *Salvelinus namaycush*, walleye *Sander vitreus*, and yellow perch *Perca flavescens*) at 2 different water temperatures. UMESC personnel served as the principal investigator, provided expert technical assistance while fish were being exposed to various concentrations of the 3 sedatives, and provided the analytical support using the UMESC validated spectrophotometric method to verify the sedative concentrations in the exposure baths. Contact Jeff Meinertz, jmeinertz@usgs.gov, for more information.

35% PEROX-AID® (active ingredient - hydrogen peroxide): UMESC received notification that CVM had accepted the data generated by UMESC to demonstrate the effectiveness of 35% PEROX-AID® to control mortality in all freshwater-reared finfish due to saprolegniasis associated with fungi in the family Saprolegniaceae. The CVM accepted the laboratory-model study UMESC completed in walleye, along with previous laboratory-model studies completed by UMESC in rainbow trout and channel catfish, as demonstrating sufficient information to consider the Effectiveness Technical Section as complete. While obtaining this technical section complete letter is a major step forward, the drug is not yet approved for this use until the drug sponsor, [Eka Chemicals, Inc.](#), submits an amended new animal drug application to CVM. Contact Maren Tuttle-Lau, mtuttle@usgs.gov, for more information.

AQUAFLO® (active ingredient - florfenicol): UMESC received notification that CVM's Office of Minor Use Minor Species selected to fund our proposed study to fulfill the following objectives: (1) determine the depletion rate of the florfenicol amine (FFA) residues from the fillet tissue of rainbow trout dosed with florfenicol (FFC)-medicated feed in a recirculating aquaculture system, (2) determine the FFC concentrations in the water of the recirculating aquaculture system during and after dosing rainbow trout with FFC-medicated feed, (3) determine FFA residue concentrations in the fillet tissue of non-dosed rainbow trout sharing a recirculating aquaculture system with rainbow trout dosed with FFC-medicated feed, and (4) determine the depletion rate of FFA from the fillet tissue of rainbow trout dosed with FFC-medicated feed in a flow-through aquaculture system. The test fish have now been stocked into a recirculating aquaculture system and a separate flow-through system to acclimate to study conditions. Florfenicol dosing is



scheduled for early November with the in-life phase scheduled for completion by mid-December. Contact Jeff Meinertz, jmeinertz@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.

MEETINGS, ETC.

UPCOMING MEETINGS

3rd International Symposium on Cage Aquaculture in Asia; 16 - 19 November 2011; Kuala Lumpur, Malaysia: This year's symposium will be held at the [Putra World Trade Centre](#) in conjunction with Malaysian International Seafood Exposition 2011. The symposium



is scheduled to include topics/sessions covering: site selection and environmental management (including adaptation to climate change); species selection and seed production; feeds and feeding; biosecurity and health management; production

technology and systems; economics, markets and certification; and policy and regulations. Additionally there will be a special sessions on seafood trade and certification and farmers' day. For additional information visit the symposium website at: <http://tinyurl.com/48lkyac>.

8th Symposium on Diseases in Asian Aquaculture; 21-25 November 2011; Mangalore, India: The DAA8 is being held at the [Hotel Moti Mahal](#) in the heart of



Mangalore, India. The conference is being sponsored by several groups including the [Asian Fisheries Society](#) (AFS) and the [Fish Health Section](#) of AFS. For more information refer to the conference website: <http://www.daa8.org>.

62nd Annual Northwest Fish Culture Conference; 6-8 December 2011; Victoria, British Columbia, Canada: This year's



conference is being sponsored by the [Freshwater Fisheries Society of BC](#) and [Fisheries and Oceans Canada](#). The theme this year is "Spawning New Ideas - Thinking Outside The Hatchery" and conference

activities are being held at the [Victoria Conference Center](#). Official conference accommodations are [The Fairmont Empress Hotel](#). Although the deadline has been passed for submission of papers, online

registration is open and can be accomplished online at: <http://tinyurl.com/67fd3wr>. The conference organizers are soliciting presentations, in particular, on the following topics: 1) stocking, recreational fishery development, and marketing - How do we build angler participation?; 2) water recirculation, reuse and energy conservation; 3) fish health, disease, and physiology; 4) economic evaluation and socio-economic justification; 5) new fish culture technologies; 6) sustainable fish culture; 7) alternative species for fish culture; 8) optimizing stocking programs - How well do fish perform after release?; and 9) pen session on topics related to fish culture, management, and biology. More information on the conference can be obtained at the conference website: http://www.gofishbc.com/nwfcc_2011.htm.

Aquaculture America 2012; 29 February - 2 March 2012; Las Vegas, Nevada USA: This is the annual international conference and exposition of the [U.S. Chapter of the World Aquaculture Society](#), the [National Aquaculture Association](#) and the [Aquaculture Suppliers Association](#).



This year's conference is being held at the [Paris Hotel](#) in amazing [Las Vegas, Nevada](#). The conference currently has scheduled 18 special sessions, and will probably have more. For detailed information regarding the conference, including registration and accommodations, refer to the conference website: <http://tinyurl.com/3r38vp6>.

International Seminar on Marine Science & Aquaculture 2012; 13-15 March 2012; Kota Kinabalu, Sabah, Malaysia: The [Universiti Malaysia Sabah](#) is the host and organizer of this annual meeting, the theme of which is "Sustainable Development and Management of Aquatic Resources in a Changing Climate." The conference is being held at the [Promenade Hotel](#) in [Kota Kinabalu](#). Planned topics in aquaculture include: management of aquatic environments, sustainable integrated aquaculture, diseases and biosecurity, issues and challenges in breeding and species hybridization, current status of feed and nutrition, and aquatic husbandry. Topics in marine science include: research and development in the coral triangle, harmful algal blooms, biodiversity and conservation of marine resources, sustainable marine tourism, environmental management, and impacts of climate change on the marine environment. For detailed information on registration, etc., please refer to the conference webpage by clicking on the following link: <http://tinyurl.com/6m7g5hn>.



37th Annual Eastern Fish Health Workshop; 23 - 27 April 2012; Lake Placid, New York USA: This year's Workshop, as in the past, is being organized by Dr. Rocco Cipriano of the U. S. Geological Survey's National Fish Health Research Laboratory in Kearneysville, West Virginia USA. The Workshop is being held at the [High Peaks Resort and Conference Center](#) in Lake Placid. The organizers are still accepting titles for the General Session, and already have 10 Special Sessions scheduled with a wealth of presentations in each. Additionally, a Continuing Education Opportunity is planned for the last day of the Workshop. For more information on the Workshop accommodations, registration, important dates, and program content [click here](#) or contact Dr. Cipriano (rcipriano@usgs.gov).

Skretting Australasian Aquaculture 2012; 6-10 May 2012; Melbourne, Victoria Australia: The 2012



international conference is hosted by [Asian Pacific Chapter of the World Aquaculture Society](#) and the [Australian National Aquaculture Council](#). The naming rights sponsor is [Skretting](#), while the sponsors are [Australia's Fisheries Research and Development](#)

[Corporation](#) and [Melbourne Australia](#). The theme for this year's meeting is "The Next Ten Years" and in the words of the organizers "Whether it be genetic improvement of farmed species, advances in health management, increased production efficiency, or higher product quality for consumers - the aquaculture industry continues to develop innovative and sustainable practices" the theme is apropos. The conference *per se* will be held at the [Melbourne Convention and Exhibition Centre](#), with [several conference hotels](#) close nearby. For additional information refer to the [conference website](#).

Aquaculture UK 2012 Conference and Trade

**AQUACULTUREUK
2012**

Exhibition: 23-24 May 2012; Aviemore, Scotland UK: This year's conference and exhibition is being held at the [Macdonald](#)

[Aviemore Highland Resort](#) situated at the foot of the Cairngorm Mountains in the heart of the [Cairngorms National Park](#). Details of conference sessions are scheduled to become available late in 2012, but are planned to fill two full days with a broad array of aquaculture topics. Detailed information, including registration, etc. can be found on the conference webpage at: <http://www.aquacultureuk.com/index.php?c=home>.

AQUAVET[®] I; 27 May - 23 June 2012; Bristol, Rhode Island USA: The course will be presented at [Roger](#)

[Williams University](#) in Bristol, Rhode Island. Arrival and the start of classes is May 27th and departure is June 23rd. The fee for the 4-week course INCLUDES tuition and room and board. It is \$1,975 for full-time veterinary students and \$3,375 for veterinarians. Through the generosity of a program benefactor, a \$200 scholarship will



be applied to partially offset the fee for all full-time veterinary students resulting in a net tuition of \$1,775 for the accepted full-time veterinary students this year. The program is diverse, incorporating many topics relating to aquatic organisms, their environment, and the application of traditional veterinary disciplines to aquatic animals. To deal with this breadth of subject matter, faculty members are enlisted from a variety of backgrounds and fields of interest, and a broad range of learning situations are used. In addition to lectures, laboratories, student seminars and discussions, there are field trips, practicums and films. Applications for admission are due by 14 January 2012. For more information, please refer to the AQUAVET[®] I web page: <http://www.vet.cornell.edu/aquavet/one.cfm>.

AQUAVET[®] II; 27 May - 9 June 2012; Bristol, Rhode Island USA: The course will be presented at [Roger](#)



[Williams University](#) in Bristol, Rhode Island. Arrival and the start of classes is May 27th and departure is June 9th. The fee for the 2-week course INCLUDES tuition and room and board. It is \$1,125 for full time veterinary students, and \$1,850 for veterinarians. Applications for

admission are due by 14 January 2012. AQUAVET[®] II is a natural extension of the AQUAVET[®] I. While similar in organization, the focus of AQUAVET[®] II is narrower, allowing a more detailed look at specific areas of aquatic animal medicine for students and veterinarians interested in continuing in the field. Recently AQUAVET[®] II has been presented as a two-week course on the pathology and histopathology of selected aquatic invertebrate and vertebrate species of importance as biomedical research models. Completion of the AQUAVET[®] I course, or adequate equivalent preparatory work is a prerequisite for admission to any AQUAVET[®] II course. In addition, it is generally assumed that applicants will have completed the basic science courses in the veterinary curriculum or have graduated prior to attending. For more information, please refer to the AQUAVET[®] II web page: <http://www.vet.cornell.edu/aquavet/two.cfm>.

9th International Conference on Recirculating Aquaculture; 24-26 August 2012; Roanoke, Virginia



USA: The 2012 annual meeting is being sponsored by



[Aquacultural Engineering Society](#), [Freshwater Institute](#), [U.S. Department of Agriculture](#); [Virginia Tech's College of Agriculture and Life Sciences](#), [College of Engineering and Center for Organizational and Technological Advancement](#) (COTA). The conference is being held at the [Hotel Roanoke and Conference Center](#) and includes sessions covering the following topics: algae culture, animal health and biosecurity, aquaponics, cool and cold water culture, commercial RAS case studies, economics, emerging species, hatchery, marine culture, nutrition and feeds, ornamentals, quality assurance, salmonid culture, shrimp culture, system design and engineering, warm water culture, and waste management. Additional information, including accommodations and registration can be found on the conference website: <http://www.recircaqua.com/icra.html>.

Aqua 2012; 1-5 September 2012; Prague, Czech



Republic: This conference, like that in 2006, is the combined meeting of the [World Aquaculture Society](#) and the [European Aquaculture Society](#), with organizational assistance from the [South Bohemian Research Center of Aquaculture and Biodiversity of Hydrocenoses](#); and the [Faculty of Fisheries and Protection of Waters, University of South Bohemia České Budějovice](#). Numerous sessions

and special sessions are being planned, as well after hour and tours. The conference theme is “*Global Aquaculture – Securing our Future*”. For more information refer to the conference website at: <http://tinyurl.com/3fgzads>.

CVM's NOTES

Greetings! Here are two items of mention from CVM.

A “new” member of the Aquaculture Drugs Team:

Dr. Eric Landis, who for the past two years has been working with the Aquaculture Drugs Team as a FDA Commissioner's Fellow, has joined the team as a reviewer. Prior to his fellowship at FDA, Eric was a Post-Doc at [NOAA's Northwest Fisheries Science Center](#); his efforts there focused on identification of genetic differences between environmental and clinical strains of *Vibrio parahaemolyticus*. Eric obtained his PhD. from the [University of Maryland, Baltimore](#), by studying the immune response of rainbow trout to IHNV. Early in his career he worked in the aquaculture industry

as a research scientist at a commercial hybrid striped bass operation.

New Guidance Document now available: After an open comment period, the [Office of New Animal Drug Evaluation](#) has finalized and made available a Guidance for Industry (#215) entitled, “[Target Animal Safety and Effectiveness Protocol Development and Submission](#).”

The purpose of this document is to provide sponsors guidance in preparation of study protocols. The recommendations included in this guidance are intended to reduce the time to protocol concurrence.

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

