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 7-1

AADAP NEWSLETTER

March 2011

The Bridger mountain range northeast of Bozeman, Montana USA

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WHAT'S SHAKIN'

17th Annual USFWS Aquaculture Drug Approval Coordination Workshop: Mark your calendars; 2 - 4 August 2011 are the dates for this year's Workshop. This year the Workshop will once again be held in Bozeman, Montana USA, and will (as per usual) focus on a comprehensive review of ALL ongoing aquaculture drug approval activities. Even though it is rather early in the planning process, we already know that the American Fisheries Society - Fish Culture Section's Working Group on Aquaculture Drugs, Chemicals and Biologics is also planning to meet in Bozeman during the same week. As is always the case when the Workshop is held in Bozeman, the Sweet Pea Festival activities are scheduled for the same week and the following weekend. Hope to see you'all here in Bozeman! Check the AADAP website for more details as they become available.

Vaccines poster 2nd printing NOW AVAILABLE: At publication time of our last issue of the AADAP

Newsletter (November 2010), the *"Approved Vaccines for Use in Aquaculture"* poster was temporarily out of print. However, since then we have arranged for a second printing, and posters are now available and still free-of-charge. To obtain your copy or copies, either click here or go to the following webpage on the AADAP website: http://tinyurl.com/4ar44yq. The AVMA likewise plans to make the Poster available, details of which can be found on AVMA's website (http://www.avma.org).

Chorulon® is still available: A couple months ago word began to spread rapidly that the manufacturer of Choruon®, the only FDA-approved human chorionic gonadotropin (hCG) product for fish, was going to stop production of the drug. Since that time, AADAP has spoken directly with the manufacturer about this issue. Palma Jordan (Marketing Director, Global Aquatic Animal Health; Intervet/Schering-Plough Animal Health; A subsidiary of Merck & Co., Inc., Whitehouse Station, NJ, USA) provided the following official statement.

> *"Intervet/Schering-Plough Animal Health is planning to continue to provide Chorulon® for the aquaculture market through 2013, based on our best estimate of the usage of the product. Our current supply source for hCG, the active ingredient in the product, will be able to meet our production needs until this time. After 2013, we plan to use an alternative supplier and will work with the FDA to validate the new supplier according to the standards and rules of the agency."*

Association of Fish and Wildlife Agencies' Drug Approval Working Group update: The Drug Approval Working Group (DAWG) of the Association of Fish and Wildlife Agencies (AFWA) met recently on 28 February 2011 in New Orleans during Aquaculture America 2011. Approval activities for all eight AFWA project drugs were discussed and reviewed, with AQUI-S® E, chloramine-T, and AQUAFLOR® as the highlighted meeting priorities.

As has been the case at other recent DAWG meetings, the DAWG's pursuit of an immediate-release fish sedative for field use garnered most of the discussion. As reported in the previous issue of the AADAP Newsletter, in September 2010 the DAWG selected AQUI-S® E (active ingredient eugenol) as the product/ compound upon which the DAWG will focus all future immediate-release sedative approval activities. As such, we have a minor correction to report! Instead of focusing efforts on AQUI-S® E (50% eugenol), the DAWG has decided that AQUI-S® 20E (10% eugenol) is a better candidate product/compound for approval, primarily as it relates to ease of use in the field (e.g., requires no mixing/dilution/vigorous shaking prior to use). None-the-less, the DAWG's main objective over the next six months is the development of a survey for dissemination to state, federal and tribal agencies on sedative use-patterns in the field. A draft survey will be developed in April 2011 after a Product Development Meeting (PDM) in March 2011 with the FDA's Center for Veterinary Medicine [**editor's note**: see next article for an update on the PDM] to assist us in collecting information needed to address potential human food safety concerns. Although the anticipated approval of AQUI-S® 20E is still likely several years down the road, the coordination between AQUI-S New Zealand Ltd. (the drug sponsor) and the DAWG is greatly appreciated; one of the most open and collaborative experiences to date with a sponsor. The DAWG is optimistic this relationship will reduce the time line for approval.

The DAWG also plans to coordinate with several western states and AADAP in the months to come in order to develop an AQUAFLOR® treatment summary portfolio for the control of mortality caused by coldwater disease in freshwater-reared salmonids. More specifically, the portfolio will help to document that the 10 mg per kg treatment dosage may not be efficacious under certain treatment conditions. These data will hopefully support further consideration for inclusion of a 15 mg per kg dosage for effectively combating *Flavobacterium psychrophilum* under all freshwater conditions.

Since our last meeting in September 2010, the DAWG has increased its membership to include Mr. Brian Wisner of the Pennsylvania Fish and Boat Commission to represent the eastern states. Welcome aboard Brian!

In addition to Brian, the DAWG consists of the following members: Mike Mason, Iowa Department of Natural Resources; Kelly Winningham, Arkansas Game and Fish Commission; Steve Sharon (Chair), Wyoming Game and Fish Department; John Kerwin, Washington Department of Fish and Wildlife; Dave Erdahl, Aquatic Animal Drug Approval Partnership, U.S. Fish & Wildlife Service; Mark Gaikowski, Upper Midwest Environmental Sciences Center, U.S. Geological Survey; Dave Straus, Stuttgart National Aquaculture Research Center, U.S. Department of Agriculture - Agriculture Research Service; and Kevin Amos, National Marine Fisheries Service, National Oceanographic and Atmospheric Administration.

AQUI-S® 20E Product Development Meeting: On 21 March 2011, representatives from AQUI-S New Zealand Ltd. (AQNZ; the drug sponsor), USGS's Upper Midwest Environmental Sciences Center, USFWS's Aquatic Animal Drug Approval Partnership program and Brock Scientific Consulting LLC met with members of all the major divisions of FDA's Center for Veterinary Medicine (CVM) to discuss specifics of AQNZ's product development plan for AQUI-S® 20E as an immediate-release sedative. AQNZ had previously provided CVM with a series of specific questions addressing technical section data requirements for chemistry and manufacturing, effectiveness, target animal safety, human food safety and environmental safety. Although CVM could not provide definitive answers to all questions (which is to be expected as the approval process is oftentimes a step-wise process that is dependent upon review of previously submitted data) the PDM most certainly provided us with a MUCH clearer path forward. Thank you to CVM for their guidance! All parties would encourage AQUI-S® 20E INAD participation to supplement efficacy and safety data that can be used to support future registration of the product.

New Oxytetracycline Soluble Powder approved for skeletal marking: PennField Animal Health (Omaha, Nebraska USA) was recently (6 December 2010) notified by FDA's Center for Veterinary Medicine that their oxytetracycline hydrochloride (OTC) soluble powder (PENNOX® 343) has been approved for use to mark skeletal tissue in finfish fry and fingerlings. For more information click here. Currently, PENNOX® 343 is the only approved OTC soluble product available for purchase or easily/safely administered when used for skeletal marking.

Approved Aquaculture Drugs - Quick Desk Reference Guide: Due to unforeseeable delays, printing of the AADAP - AFWA - AFS's Quick *Desk Reference Guide To: Approved Drugs for Use in Aquaculture* has been rescheduled for completion in April 2011. The "*Desk Reference*" comprises all the information contained in the "*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. Watch the AADAP website for notice of its availability. As is the case of the complementary poster, the "*Desk Reference*" can be ordered (free of charge) or downloaded via AADAP's website at: http://www.fws.gov/fisheries/aadap/desk-reference_introduction.htm.

USDA's Stuttgart National Aquaculture Research Center (SNARC) scientists receive national award: Dave Straus, Drew Mitchell and Ray Carter of SNARC, along with Jim Steeby of Mississippi State University received the

'Excellence in Technology Transfer' award from the Federal Laboratory Consortium (FLC). The award was presented at the recent annual meeting of the FLC's Mid-Continent Region, and was in recognition of the team's work in developing copper sulfate as an effective treatment for fungal infections in catfish eggs. Dave Straus and Jim Steeby accepted the award for the team. For more information, click here to view the complete article reprinted with permission from the October 2010 issue of *The Catfish Journal*.

Progress update from the American Fisheries Society - Fish Culture Section's (AFS-FCS) Working Group on Aquaculture Drugs, Chemicals, and Biologics (WGADCB): The WG met on 28 March 2011 in New Orleans, Louisiana USA, in conjunction with Aquaculture America 2011. The meeting of roughly 24 stakeholders was led by WG co-chairs Jesse Trushenski, Jim Bowker, Mark Gaikowski, Lester Khoo, Randy MacMillan, and Steve Sharon. During the meeting, status updates were provided on several WG projects. Provided below is a synopsis of what was presented and discussed:

- The *Guide to Using Drugs, Biologics, and Other Chemicals in Aquaculture* and companion Treatment Calculator are now available on the FCS and AADAP websites. Numerous fisheries professionals, including aquaculture extension agents, contributed to or reviewed *The Guide* before it went 'live', and Jessie Trushenski thanked everyone involved in the process. The positive feedback really began to roll in once *The Guide* and Treatment Calculator were launched, and it's clear that both products are going to be useful tools for fish culturists. It was mentioned that *The Guide* will be periodically revised, and that readers/users should send suggested revisions to either Jesse Trushenski or Jim Bowker. It was also mentioned that since *The Guide* is only available in electronic format, it will be easy to revise on an "as-needed" basis.
- The *AFS Policy Statement on the Need for an Immediate Release Sedative/Anesthetic in Fisheries* will be available to AFS members for comment within the next few weeks. A summary of the *Policy Statement* will be published in March issue of the AFS *Fisheries* magazine, and then AFS members will have 60 days to comment. After the public comment period, the *Policy Statement* can be brought again before the AFS Governing Board and full membership for a vote to approve. Based on positive feedback from those who have reviewed the *Policy Statement* to date, it is not anticipated that there will be any major revisions suggested. For those that can't wait, the DRAFT *Policy Statement* is available on the AFS FCS website.
- *Involvement of the U.S. Aquaculture Society and other professional societies within the WG* was proposed for discussion. There is a misconception that to participate in the WG, you have to be a FCS member, and that members of other professional organizations can't join in the discussions. It was noted that when the WG co-chairmanship was established, it focused on ensuring that relevant disciplines - public hatcheries, private aquaculture, the veterinary community, and the public data-generating entities involved in drug approval research - were represented, but other professional organizations weren't specifically targeted. However, formally recognizing a U.S. Aquaculture Society (USAS) board member as a co-chair of the WG might encourage broader participation and help to dispel the perception that WG "membership" is restricted. The WG is officially housed as an ad-hoc committee within the FCS, so the Section President can appoint co-chairs at his/her discretion. It was decided that Jesse Trushenski would contact incoming USAS President Michael Schwarz, and ask him to identify a USAS board member willing to serve within the WG.
- There was considerable discussion relative to the *WGADCB response to FDA's request for public comments on Guidance Document #209 ("The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals") and Unapproved Animal Drugs*. The majority of the discussion was about concerns

regarding the content of the comments, and whether or not they reflected the position of the co-chairs (and their respective agencies), the WG as a whole, or simply the individuals who submitted comments. Despite these issues, all recognized that the WG's involvement in encouraging public response to Federal Register notices has not only made people more aware of opportunities for public comment, but also provided valuable context for Federal Register notices so that individuals can better understand the issues and provide their own substantive feedback. It is not, of course, the role of the WG to dictate comments to the public. Other points of discussion included (1) misuse of the term "boilerplate"—comments prepared by WG members should not be referred to as such; (2) whether comments should be general and intended to help raise awareness or more specific to better help FDA resolve an identified issue; and (3) WG co-chairs need to explore ways to distribute comments without making it appear that all co-chairs support comments that they may in fact not fully agree with, or that might put them in a difficult situation with their employer, agency, etc.

- Whether it's time to *Reengage the MUMS Coalition and revisit Minor Use Minor Species Act (MUMSA)?* Several members of the WG have been discussing the possibility of AFS hosting a congressional briefing on the issues related to the drug approval process. More specifically, they have been working to assemble information on aquaculture drug access/use/importance in the public and private sector, and to identify ways to improve/enhance the drug approval process to allow for greater drug availability while still ensuring public safety and animal health and well-being. There was concern that rewriting the MUMSA would require an inordinate amount of time, money, and people (even perhaps hiring a lobbyist). The focus of discussion then turned to (1) what could be accomplished through less sweeping changes, i.e., small revisions to the existing statutes, regulatory change, etc.; (2) what should we recommend; (3) how do we do it; and (4) who on Capitol Hill would be best to speak with? All agreed that the briefing should provide information on things Congress can actually help with; we should present achievable goals, nothing too broad. We also need to be specific, propose solutions, and clearly articulate to the congressional staffers how they can help. All meeting attendees were made aware that key WG participants had been invited to a planning meeting (1 March 2011) to discuss emerging ideas to refine MUMSA, perhaps through the context of a congressional briefing.

For more information on current WGADCB activities, please see the meeting minutes (click here to view 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 17th Annual USFWS Aquaculture Drug Approval Coordination Workshop, 2 - 4 August 2011 in Bozeman, Montana USA. Stay tuned to the AADAP website for WGADCB meeting schedule announcements.

Text provided by Jim Bowker; U.S. Fish & Wildlife Service, Aquatic Animal Drug Approval Partnership Program; Bozeman, Montana USA.

AADAP DRUG UPDATES

General: In last newsletter, we described how the 2010 AADAP pivotal field efficacy trial train got rolling, that there were a few hiccups along the way, that some studies rolled on without a hitch, some required us to do a little 13th-hour head-scratching, and some planned studies simply never "left the gate." Here it is a few short months later, and we're putting the final touches on the last of the 2010 field study reports before we package them up and submit them to CVM for review. Below is an overview of recent research happenings including what data/reports have been submitted to CVM and what we've heard back from CVM regarding previous submissions. In addition, we've included the status of some preliminary tests that we have recently completed with AQUI-S®20E. Hopefully, these data will ultimately be useful towards the approval of AQUI-S®20E as an immediate-release sedative for use on fish.

17α-Methyltestosterone Update:

Approval status meeting: At the Aquaculture America 2011 meeting in New Orleans, Louisiana USA, parties involved in efforts towards the approval of17α-Methyltestosterone (17MT) medicated-feed for use to produce all-male populations of tilapia met. The primary purpose of this 17MT "mini-session" was to update each other on progress relative to all specific assigned activities. Although progress oftentimes appears to be excruciatingly slow, take heart - we are in fact getting close! To view the updated status report of 17MT activities, click here.

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

***Gyrodactylus* efficacy study:** In the last newsletter, we described a study that was conducted to evaluate the efficacy of 50 mg per L hydrogen peroxide administered for 60 min on two alternate days to control an infestation of *Gyrodactylus salmonis* in rainbow trout brood fish. The study was conducted at the Ennis National Fish Hatchery and results

conclusively demonstrated that treatment knocked infestation levels down to pretty much zero. The Final Study Report (FSR) was submitted to CVM for review on 7 February 2011. As usual, we're optimistic that the study will be accepted by CVM, and will be considered in the body of evidence to complete the effectiveness technical section for this claim. For more information about other studies conducted to complete the effectiveness technical section for this claim, see USGS's Corner in this Newsletter.

AQUAFLOR® (florfenicol) Update:

We're amped-up: We get pretty amped-up when we've got a busy summer efficacy-study season planned or when we get close to submitting the last of the previous summer's efficacy-study final study reports (FSRs) to CVM for review. First things first of course, and that's where we're at now – wrapping up the last of the 2010 reports to send to CVM.

BKD - Chinook salmon efficacy studies: In the last AADAP Newsletter, we stated that two studies were conducted in collaboration with Doug Munson (Idaho Department of Fish and Game) to evaluate the efficacy of AQUAFLOR® 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. A FSR summarizing the results from the first study was submitted to CVM for review on 8 October 2010, and based on our experience we anticipate that it will be accepted (mean treated vs. untreated cumulative mortality; 14.8% and 24.3%, respectively). In the second study, mean cumulative mortality in the treated tanks (12.1%, range, 11.4-12.7%) was significantly different (P = 0.0003) than the mean cumulative mortality in untreated control tanks (20.5%, range, 17.3-22.9%). The FSR summarizing results from this study was submitted to CVM on 29 December 2010. In anticipation that both studies will be accepted, we submitted a letter to CVM on 29 December 2010 requesting that the effectiveness technical section for the use of AQUAFLOR® to control mortality caused by BKD (at the above-referenced treatment regimen) be considered complete for Chinook salmon. When we hear back from CVM, we hope that we'll have some good news to share, so don't touch that dial!

Yellow perch target animal safety study: Speaking of good news, the study that was conducted to demonstrate the safety of AQUAFLOR® (50% florfenicol; Type A medicated article) administered in feed to yellow perch *Perca flavescens* was accepted by CVM on 10 February 2011. Yeeha! Results from this study clearly demonstrated that the florfenicol margin of safety extends to at least 75 mg florfenicol per kg fish body weight per d when administered for 20 d to yellow perch (i.e., 5X the proposed dose and 2X the proposed duration). Acceptance of this target animal safety study has completed AADAP's efforts to demonstrate that this proposed treatment regimen is safe to fish. However, the safety technical section to allow use of this treatment regimen (i.e., 15 mg/kg per day for 10 days) on ALL freshwater fish is not quite complete. Fear not, because the last remaining study has been completed. Briefly, this last study was conducted on tilapia, the results indicate that the margin of safety extends to a dose much higher than 15 mg florfenicol per kg body weight per d, and the FSR has been submitted to CVM for review. Acceptance of this last study will complete the target animal safety technical section for 15 mg florfenicol per kg fish body weight per d for 10d on ALL freshwater fish. Whew!

Systemic columnaris - rainbow trout efficacy study: Lastly, we may have some good news with respect to a collaborative study conducted with the Bellingham Technical College's Fisheries Technology Program (Earl Steele), Bellingham State Fish Hatchery (Kevin Clark), and the Washington Department of Fish and Wildlife (Jed Varney) to evaluate the effectiveness of AQUAFLOR® to control mortality associated with systemic columnaris in rainbow trout. In the last AADAP Newsletter we reported that this study was completed last summer; mean cumulative mortality in treated tanks was lower than that in untreated control tanks, analytically verified concentration of florfenicol in feed was within 80 – 100% of the target concentration, and the pathogen associated with mortality was confirmed by polymerase chain reaction as *Flavobacterium columnare*. In addition, the (1) 24 h minimum inhibitory concentration for isolates of this pathogen ranged from 0.5 to 1.0 µg per ml florfenicol, and (2) pharmacokinetic information from the literature indicates that the maximum florfenicol concentration in rainbow trout fed florfenicol at a dosage of 10 mg per kg fish body weight per d for 10 d was 3.23 ± 0.51 µg per ml. In spite of the fact that some of the raw data sent from Bellingham never arrived at AADAP HQ, AADAP's Molly Bowman is busy drafting the FSR for what we hope will be the last study required to complete the effectiveness technical section for this claim. We may need some help convincing CVM reviewers that sufficient data has been submitted to support the claim of efficacy, so if you have some spare karma laying around, please send it our way. Thanks! ☺

Channel Catfish Pituitary Update:

Requested Environmental Assessment Waiver: In the last AADAP Newsletter, we mentioned that we submitted a "white paper" to CVM with documentation to support an argument that no additional data be required to complete the Environmental Safety

technical section for catfish pituitary (CP). On 29 November 2010, we received a letter from CVM's Division of Scientific Support stating that under the National Environmental Pollution Act, all applications or petitions requesting Federal agency action require the submission of an Environmental Assessment (EA) or a claim for a categorical exclusion. CVM stated that the white paper we submitted for CP could not be used "...as a substitute for the formal submission of an EA...". In addition, there were comments asking us to address specific issues, such as providing a more complete list of hormones in a teleost pituitary, describing the half-life of peptide hormones once they are released into the environment, and the likelihood of possible fish escapement. Jim Bowker has been working with Roger Yant (Hybrid Catfish Company, Inverness, Mississippi USA), Dr. Chris Green (Assistant Professor of Aquaculture, Louisiana State University, Aquaculture Research Station, Baton Rouge, Louisiana USA), and Dr. Nagaraj Chatakondi (Research Geneticist in the U.S. Department of Agriculture/Agriculture Research Service's Catfish Genetics Research Unit, Thad Cochran National Aquaculture Research Center, Mississippi State University, Stoneville, Mississippi USA) to address these issues and develop an EA for submission to CVM for review. We had not previously submitted an EA to CVM for review, and are treading in relatively unfamiliar territory. However, we would like to thank CVM's Environmental Team for helping us through this process. We hope that next time we have something to report relative to the EA for CP, it's to inform you that the EA has been accepted by CVM. As usual, stay tuned!

AQUI-S®20E

Analytical method development: In the last AADAP Newsletter, we discussed generating data to verify that a UV-Vis spectrophotometric method developed by AQUI-S New Zealand Ltd. to determine the concentration of eugenol in water is specific for eugenol, and that the linearity of the standard curve can be reproduced using various types (i.e., sources) of freshwater. We prepared standards from six different water sources collected from three locations (Fish Breeders of Idaho, Hagerman, Idaho USA; Miles City State Fish Hatchery, Miles City, Montana USA; Bozeman Fish Technology Center, Bozeman, Montana USA) and found that the method is reproducible and robust. We concluded that the methodology should be considered adequate for measuring the concentration of eugenol in water during pivotal efficacy and target animal safety studies. For more information on this study, please see Drug Research Information Bulletin 20 entitled "The Robustness of a Simple UV-Vis Spectrophotometric Method to Determine the Concentration of Eugenol in Water."

AQUI-S® 20E (10% eugenol) stability studies: While the spectrophotometer was fired up, we thought we'd try to address another issue that came up a couple years ago while we were conducting studies to evaluate the effectiveness of AQUI-S® (50% isoeugenol) to sedate freshwater finfish to handleable. That is, how long does the concentration of the active ingredient remain stable in a sedative working solution? Hence, we prepared three solutions of AQUI-S®20E (10% eugenol), one each at 10, 50, and 100 mg per L eugenol in 1 gal plastic buckets. Buckets were left on the lab counter without covers for the duration of the trial. Five aliquots from each were measured at Time = 0, 2, 4, 6, 8, 12 and 24 h post-preparation, and then once daily for the next 6 d. A fresh set of standards were prepared and used before each sampling period to establish the calibration curve. Briefly, we found that the concentration of the (1) 10 mg per L eugenol solution ranged from 10.0 to 10.7 mg per L, (2) 50 mg per L eugenol solution ranged from 47.1 to 50.0 mg per L, and (3) the 100 mg per L eugenol solution ranged from 92.4 to 97.1 mg per L, over the entire 7 d study period! Analytically verified concentrations of eugenol on day 6 for the 10, 50 and 100 mg per L solutions were 10.4, 49.7, and 95.3 mg per L, respectively. We hope to use this data (along with data being generated by Jeff Meinertz, U.S Geological Survey, Upper Midwest Environmental Sciences Center, La Crosse, Wisconsin USA) to confirm that the concentration of eugenol will remain stable in solution for at least an 8 h period.

Pilot safety study comparing isoeugenol to eugenol products: Lastly, we conducted a preliminary safety study to evaluate the effects of overexposing fingerling rainbow trout to AQUI-S® (50% isoeugenol), AQUI-S® E (50% eugenol), and AQUI-S® 20E (10% eugenol). The objective of this study was to demonstrate that pathologies (or more accurately, the lack of pathologies) are consistent (1) regardless of whether fish are exposed to isoeugenol or eugenol, and (2) regardless of whether fish are sampled immediately after exposure or at some time postexposure. All working sedative solutions were prepared to have the same concentration of active ingredient (i.e., either 20 mg per L isoeugenol or 20 mg per L eugenol). Groups of 20 fish were exposed in separate exposure containers to one of the sedative solutions for one of two time periods [T1 - longest time of exposure and still have 100% survival or T2 - mean time in which a few fish did not recover from sedation]. Following exposure, groups of fish were transferred to separate recovery tanks. Three fish were collected from each recovery tank at Time = 0, 24 or 96 h postexposure and processed for histological evaluation. Tissues are currently being evaluated by Beth MacConnell (Headwaters Fish Pathology, LLC), and preliminary results indicate that there is virtually no evidence of dose-related toxic effect. We hope to

use results from this study to convince CVM to allow us to conduct target animal safety studies in which (1) fewer tissues are required for histological evaluation, (2) a shorter post-exposure sampling period is appropriate, and (3) perhaps conduct fewer studies in which histology is required (i.e., establish margins of safety based primarily on mortality). This is a new approach, and is being explored in an effort reduce overall data requirements necessary for the completion of the target animal safety technical section. This approach is stepping a "good distance" outside of the traditional data-box, and of course we would not begin to attempt to complete technical sections with less data without the support of CVM reviewers. However, we believe our data/argument is sound, and as always, we're optimistic that at the end of the day we'll get the answer we're looking for (i.e., reduction in data requirements!). Until then, stay tuned..

SLICE® (emamectin benzoate) Update:

Ectoparasite efficacy studies: We've been very busy the last few months writing up results from three field efficacy studies that were conducted to evaluate the efficacy of SLICE® administered in feed at a dosage of 50 µg emamectin benzoate per kg fish body weight per d for 7 d to reduce infestations of *Salmincola californiensis* in rainbow trout. One study was conducted in June 2010 at SeaPac of Idaho's Magic Springs Hatchery in Hagerman, Idaho USA, with the help of Jim Schaffer and Tom Van Tassel. The other two studies were conducted in June and October 2010 at Clear Springs Foods' Snake River Research Facility in Buhl, Idaho USA, with the help of Scott LaPatra, Bill Shewmaker, and Robin Burkhart. Briefly, at the end of the 30 or 42-d posttreatment period, a significant difference ($P < 0.001$) was detected in the mean abundance of parasites in treated and untreated control tanks. However, the 90% reduction threshold in parasite infestation level currently required by CVM to demonstrate efficacy) in treated tanks compared to control tanks was achieved in only one study. In the two June studies, we observed a 79% and 83% reduction in parasite infestation level at the end of the 30-d posttreatment period. In the October study we observed a 96% reduction in infestation level at the end of the 42-d posttreatment period. In spite of the fact that we did not meet the percent reduction threshold outlined in the study protocol, final study reports for all 3 studies have been developed and submitted to CVM for review. In addition, we have submitted a letter to CVM requesting that the effectiveness technical section for this claim be considered complete for all freshwater rainbow trout. We don't know exactly how CVM reviewers will interpret the data results – so, as we are fond of saying, stay tuned!

FINS & TAILS, BITS & BOBBERS

End of the Year INAD Forms due 1 April 2011: Thank you very much if you have already sent in all Form 2's (Drug Inventory Form) and Form 3's (Results Report Form) for each of the INADs in which your facilities was enrolled for INAD Year 2010.

If you have not done so, you will be forgiven if you provide the completed forms to Bonnie Johnson (phone 406-994-9905, FAX 406-582-0242) no later than 1 April 2011. **Note:** If your facility was signed-up to use an INAD, even though the INAD drug was not actually used, a Form 2 is still required showing either amount of drug on-hand or that no drug use occurred.

AQUI-S® 20E (not AQUI-S® E) available: AQUI-S New Zealand Ltd. has notified us that the final formulation for their prospective eugenol-based "immediate-release" anesthetic/sedative is called AQUI-S® 20E. AQUI-S® 20E differs from the original formulation (AQUI-S® E) in that AQUI-S® 20E contains only 10% eugenol (compared to 50% in AQUI S® E). Although this new final formulation will require more product to be used to achieve the same concentration of eugenol in your treatment water, a major concern about the use of AQUI-S® E has been eliminated; i.e., difficulty in measuring out a specific quantity of the product and getting it to go into solution. The U.S. source of the drug, Western Chemical Inc., has informed us that AQUI-S® 20E will be available for INAD use beginning the last week in March or the first week in April 2011. At that time, AQUI-S® 20E will be available only in a 100 mL and a 1.0 L container. The next AQUI-S® 20E production run, possibly available for distribution as early as June 2011, will include 100 mL, 500 mL, 1.0 L and 4.0 L volume containers. The price schedule for the various sizes are:

Size	Cost ($US)
100 mL	32.00
500 mL	95.00
1.0 L	173.00
4.0 L	640.00

See the AQUI-S® 20E fact sheet for details on its use, where to purchase, etc.

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 2010 and 2011. 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

Chalupnicki, MA, et al. 2011. Efficacy and toxicity of iodine disinfection on Atlantic salmon. *North American Journal of Aquaculture* **73:124-128**.

Darwish, AM, et al. 2010. Evaluation of the therapeutic effect of potassium permanganate at early stages of an experimental acute infection of *Flavobacterium columnare* in channel catfish, *Ictalurus punctatus* (Rafinesque). *Aquaculture Research* **41(10):1479-1485**.

Gaunt, PS, et al. 2010. Determination of florfenicol dose rate in feed for control of mortality in Nile tilapia infected with *Streptococcus iniae*. *Journal of Aquatic Animal Health* **22(3):158-166**.

Gaunt, PS, et al. 2011. Preparation of ormetoprim-sulfadimethoxine-medicated discs for disc diffusion assay. *North American Journal of Aquaculture* **73:17-20**.

Geng, Yi, et al. 2010. *Stenotrophomonas maltophilia*, an emerging opportunist pathogen for cultured channel catfish, *Ictalurus punctatus*, in China. *Aquaculture* **308(3-4):132-135**.

Stuart, KR, et al. 2010. Efficacy of formalin and povidone-iodine disinfection techniques on the eggs of three marine finfish species. *Aquaculture Research* **41(11):e838-e843**.

Sun, Y-X, et al. 2010. Tissue distribution and elimination of florfenicol in crucian carp (*Carassius auratus cuvieri*) after a single dose intramuscular or oral administration. *Aquaculture 309(1-4):82-85*.

Parasite and Fungus Control

Kouba, A, et al. 2010. Artificial incubation of noble crayfish (*Astacus astacus*) eggs in a partially recirculating system using formaldehyde as an antifungal treatment. *Aquaculture Research* **41 (10):e618-e623**.

Matsche, MA, et al. 2010. Observations and treatment of *Nitzschia sturionis* on Atlantic Sturgeon from Chesapeake Bay. *Journal of Aquatic Animal Health* **22(3):174-181**.

Saksida, SM, et al. 2010. The efficacy of emamectin benzoate against infestations of sea lice, *Lepeophtheirus salmonis*, on farmed Atlantic salmon, *Salmo salar* L., in British Columbia. *Journal of Fish Diseases* **33(11):913-917**.

Sedation or Anesthesia

Bilbao, A, et al. 2010. Efficiency of clove oil as anesthetic for abalone (*Haliotis tuberculata coccinea*, Revee). *Journal of Shellfish Research* **29 (3):679-682**.

da Cunha, MA, et al. 2010. Essential oil of *Lippia alba*: a new anesthetic for silver catfish, *Rhamdia quelen*. *Aquaculture* **306(1-4):403-406**.

Huang, W-C, et al. 2010. Combined use of MS-222 (tricaine) and isoflurane extends anesthesia time and minimizes cardiac rhythm side effects in adult zebrafish. *Zebrafish* **7(3):297-304**.

Suquet, M, et al. 2010. Anaesthesia and gonad sampling in the European flat oyster (*Ostrea edulis*). *Aquaculture* **308(3-4):196-198**.

Skeletal Marking

Dong, Z, et al. 2010. A fluorescent method for marking the cuttlefish, *Sepiella maindroni* de rochebrune. *Journal of Zhejiang Ocean University* **29(2):120-127**.

Fujiwara, K, et al. 2010. Multiple marking of alizarin complexone for the otolith of nigorobuna *Carassius auratus grandoculis* and estimation of individual size-at-release. *Nippon Suisan Gakkaishi* **76(4):637-645**.

Honeyfield, DC, et al. 2011. Dietary calcein marking of shovelnose sturgeon and the effect of sunlight on mark retention. *North America Journal of Aquaculture* **73:129-134**.

Linard C, et al. 2011. Calcein staining of calcified structures in pearl oyster *Pinctada margaritifera* and the effect of food resource level on shell growth. *Aquaculture* **313:149-155**.

Morales-Nin, B, et al. 2010. Marking of otoliths, age validation and growth of *Argyrosomus regius* juveniles (Sciaenidae). *Fisheries Research* **106 (1):76-80**.

Verreault, G, et al. 2010. First record of migrating silver American eels (*Anguilla rostrata*) in the St. Lawrence Estuary originating from a stocking program. *Journal of Great Lakes Research* **36 (4):794-797**.

Spawning Hormones and Gender Manipulation

Luo, Y-S, et al. 2010. Molecular cloning and mRNA expression pattern of Sox9 during sex reversal in orange-spotted grouper (*Epinephelus coioides*). *Aquaculture* **306(1-4):322-328**.

Targonska, K, et al. 2010. Controlled reproduction of asp, *Aspius aspius* (L.) using luteinizing hormone releasing hormone (LHRH) analogues with dopamine inhibitors. *Aquaculture* **306(1-4):407-410**.

Miscellaneous

Broughton, EI, and Walker, DG. 2010. Policies and practices for aquaculture food safety in China. *Food Policy* **35(5):471-478**.

Ducrot, V, et al. 2010. Modeling effects of diquat under realistic exposure patterns in genetically differentiated populations of the gastropod *Lymnaea stagnalis*. *Philosophical Transactions of the Royal Society of London, Series B: Biological Sciences* **365(1557):3485-3494**.

Gates, KW. 2010. Fishery products—quality, safety and authenticity. *Journal of Aquatic Food Product Technology* **19(3-4):318-325**.

Harikrishnan, R, et al. 2010. Immune enhancement of chemotherapeutants on lymphocystis disease virus (LDV) infected *Paralichthys olivaceus*. *Fish & Shellfish Immunology* **29(5):862-867**.

Kim, HY, et al. 2010. Monitoring of veterinary drug residues in foods produced in Korea. *Korean Journal of Food Science and Technology* **42(6):653-663**.

Lauzon, HL, et al. 2010. Microbiota of Atlantic cod (*Gadus morhua* L.) rearing systems at pre- and posthatch stages and the effect of different treatments. *Journal of Applied Microbiology* **109 (5):1775-1789**.

Merrifield, DL, et al. 2010. Probiotic applications for rainbow trout (*Oncorhynchus mykiss* Walbaum) II. Effects on growth performance, feed utilization, intestinal microbiota and related health criteria postantibiotic treatment. *Aquaculture Nutrition* **16 (5):496-503**.

Rambla-Alegre, M, et al. 2010. Analysis of selected veterinary antibiotics in fish by micellar liquid chromatography with fluorescence detection and validation in accordance with regulation 2002/657/ EC. *Food Chemistry* **123(4):1294-1302**.

Ribeiro, RV, et al. 2010. Incidence and antimicrobial resistance of enteropathogens isolated from an integrated aquaculture system. *Letters in Applied Microbiology* **51(6):611-618**.

USGS's CORNER

17α-methyltestosterone: UMESC, in collaboration with Maxxam Analytics (Burnaby, British Columbia), coordinated an analytical method transfer study to move the Chemistry Manufacturing and Controls (CMC) Technical Section one step closer to completion for 17α-methyltestosterone (MT). UMESC submitted (17 December 2010) to U.S. Food and Drug Administration's Center for Veterinary Medicine (CVM) the final report describing the analytical method transfer study determining the ability of naïve investigators to quantify MT concentration in feed using the present analytical method. UMESC created a generic standard operating procedure describing the analytical method for review by CVM. That procedure was provided to Rangen Inc. for submission with their CMC data. This study was funded through grants from the North-Central and Western Regional Aquaculture Centers. Contact Jeff Meinertz, jmeinertz@usgs.gov, for more information.

Chloramine-T: To address the remaining data requirement to complete the Human Food Safety Technical Section for the approval of Halamid®, UMESC staff modified the analytical method for para-toluenesulfonamide (p-TSA), the marker residue of chloramine-T. UMESC submitted to CVM a comprehensive final report (1 September 2010) containing the data that was expected to allow CVM to conclude that the analytical method to quantify p-TSA at concentrations <20 ng per g (the CVM tolerance limit for p-TSA in fish fillet tissue) is acceptable. UMESC received a letter from CVM indicating that the data marginally supports a tolerance of 20 ppb and that additional work needed on the method should be delayed pending other studies that CVM's Office of Research may conduct that could result in the assignment of a higher tolerance. Contact Jeff Meinertz, jmeinertz@usgs.gov, for more information.

Sedatives: A comprehensive final report describing research completed by UMESC staff to develop an analytical method to determine eugenol concentrations in the fillet of freshwater fish was submitted to the Association of Fish and Wildlife Agencies (AFWA). The

method can be used to accurately and precisely determine eugenol concentrations in fish fillet tissue ranging from about 0.01 to 100 µg per g. This method will be used to support total residue depletion studies planned for eugenol – the total residue depletion study will allow CVM to select the marker residue of eugenol administration. Once the marker residue is selected (presumably eugenol), the analytical method will be modified to confirm its accuracy, precision and

quantitation limits in order for CVM to accept the method as the analytical method of record for the eugenol marker residue. This work was funded through a Multistate Conservation Grant from the Association of Fish and Wildlife Agencies. Contact Jeff Meinertz, jmeinertz@usgs.gov, for more information.

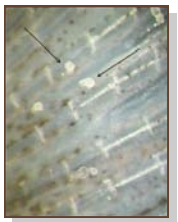
A comprehensive final report describing the availability of freshwater fish to anglers following sedation by either eugenol or benzocaine was submitted to AFWA. The data indicate that though hatchery-reared fish will eat soon after sedation, there is minimal risk of capture of recently sedated fish by anglers. This report will be used to support a broader risk assessment of the potential for anglers to capture recently sedated fish – the risk assessment is intended to provide information to CVM to support the consideration that the risk of consuming a recently sedated wild fish is better modeled as an unlikely, acute, single day consumption rather than the chronic exposure models typically used. This work was funded through a Multistate Conservation Grant from the Association of Fish and Wildlife Agencies. Contact Jeff Meinertz, jmeinertz@usgs.gov, for more information.

UMESC received CVM concurrence for two protocols designed to support the initial studies required to address the eugenol Human Food Safety Technical Section. The first protocol is designed to determine exposure parameters that maximize eugenol residues in the fillet tissue and determine the sample times that will adequately characterize the depletion of eugenol residues from the fillet tissue of rainbow trout exposed to AQUI-S® E 20. The second was to characterize eugenol total residue depletion from the skin-on fillet tissue of rainbow trout. Funds must be acquired to support the purchase of the radio-labeled eugenol before the total residue depletion study may be initiated. Contact Jeff Meinertz, jmeinertz@usgs.gov, for more information.

UMESC was asked by AADAP to participate in an evaluation of a simple analytical technique to determine eugenol concentrations in water. UMESC developed a protocol and is preparing to conduct a study to compare the accuracy, precision, specificity, and sensitivity of the spectrophotometric method developed by AADAP with a high pressure liquid chromatography method developed by UMESC to determine if the spectrophotometric method is suitable for dose verification while conducting animal safety, efficacy, and environmental assessment work with AQUI-S® 20E. Contact Jeff Meinertz, jmeinertz@usgs.gov, for more information.

Hydrogen Peroxide: UMESC submitted two proposals to determine the efficacy of 35% PEROX-AID® to reduce *Gyrodacytlus* sp. infestation density on cool and warmwater fish for consideration for funding through the competitive grants program of the CVM Office of Minor Use Minor Species (OMUMS).

Eric Leis, U.S. Fish & Wildlife Service's (FWS) La Crosse Fish Health Center, completed parasite



enumeration from a pivotal efficacy study conducted in collaboration by UMESC and the FWS Iron River National Fish Hatchery (IRNFH) to control *Gyrodactylus salmonis* on lake trout. The final study report is presently in preparation for submission to CVM. Review of these data, when combined with data previously accepted by CVM with coaster brook trout at IRNFH and data generated by AADAP on rainbow trout will likely complete the Effectiveness Technical Section for hydrogen peroxide to control *G. salmonis* on all freshwater-reared salmonids.

UMESC submitted (27 January 2011) a final study

report "Efficacy of 35% PEROX-AID® to control mortality caused by *Saprolegnia parasitica* or *Saprolegnia diclina* in rainbow trout *Oncorhynchus mykiss*" to CVM. UMESC also completed a pivotal efficacy study to assess the effectiveness of 35% PEROX-AID® to control mortality from saprolegniosis in walleye. This latter study was completed in December 2010 and the final study report is presently in review by the UMESC Quality Assurance Officer prior to submission to CVM. Work completed on walleye was funded through a grant from CVM OMUMS. Contact Maren Tuttle-Lau, mttuttle@usgs.gov, for more information.

Florfenicol: UMESC received CVM concurrence for a protocol to (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. Subsequently a proposal was submitted for consideration for funding through the competitive grants program of the CVM Office of Minor Use Minor Species. Contact Jeff Meinertz, jmeinertz@usgs.gov, for more information.

UMESC re-submitted a pivotal efficacy study protocol in February 2011 to CVM for review for comments leading to concurrence with its study design to evaluate the effectiveness of FFC- or oxytetracycline-medicated feed to control mortality from motile aeromonas septicemia, or MAS, in cool and warmwater fish due to *Aeromonas* sp. An End Review Amendment (ERA) was received on 9 March 2011 and responses submitted to CVM.

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

Aquaculture America 2011: The "Aquaculture Drug Research and Drug Approval Status" special session (formerly the "Therapeutic Drug Research" special session) was a big hit again with 12 presentations and plenty of discussion. The session was organized and moderated by Jim Bowker and Dave Straus. This was the 9th year we have held this special session focused on research in aquaculture therapeutants.

17α-Methyltestosterone: As mentioned in earlier AADAP Newsletters, we collaborated last summer with AADAP on the 17α-methyltestosterone tilapia target animal safety study. We have finally completed the painstakingly thorough quality assurance audit to provide AADAP with an 'in-life study' report. The histopathology examinations are almost complete and when completed we will assist AADAP with the final study report (FSR). Funding from the U.S. Department of Agriculture's Western Regional Aquaculture Center helped defray the costs of the study and we thank them.

FDA stuff: In December 2010, the FDA's Center for Veterinary Medicine accepted our copper sulfate efficacy FSR. The FSR described the supportive effectiveness range-finding studies testing copper sulfate against fungus (of the family Saprolegniaceae) on channel catfish eggs. As time allows, we will complete the complementary pivotal dose-confirmation study and prepare its associated FSR to complete the effectiveness technical section. As AADAP would say, "stay tuned."

Miscellaneous studies: We recently completed a study with a natural outbreak of columnaris in catfish and used our low-flow aquarium system to test the effectiveness of potassium permanganate ($KMnO_4$) and copper sulfate ($CuSO_4$) in controlling the outbreak. The duration of the experiment was 7 d, and the survival on day 7 was 38.5%, 72.7% and 52.3% for the control, $CuSO_4$ and $KMnO_4$ treatments, respectively. Only copper sulfate was significantly different from the control ($P \leq 0.05$). This research will be presented at the 2011 Eastern Fish Health Workshop.

Transitions: We are sad to say that Drew Mitchell retired from our USDA Stuttgart National Aquaculture Research Center (SNARC) this past January. We will

miss his valuable contributions to disease research and his endearing ways. We had a fantastic retirement reception for him with many great pictures of Drew in his different phases over the years. Drew worked at SNARC for 34 years and was our walking encyclopedia on fish diseases, any trivia about Stuttgart or whatever else. He will be sorely missed, but is only a phone call away (if he decides to answer!).

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

6th International Symposium on Aquatic Animal Health; 5-9 September 2010; Tampa, Florida USA: Last year's symposium hosted over 300 participants, representing 24 nations - the most geographically diverse attendance at any of the Symposia. Including plenary sessions and sponsor perspectives, the Symposium comprised approximately 220 oral and poster presentations, covering 37 sessions. Abstracts from the entire Symposium, photographs and other information are now available online at: http://aquaticpath.phhp.ufl.edu/isaah6/index.html.

UPCOMING MEETINGS

36th Eastern Fish Health Workshop; 28 March - 1 April 2011; Mount Pleasant, South Carolina USA: The 2011 Workshop will be held at the Holiday Inn Charleston-Mount Pleasant. As always, the Workshop will provide a diverse group of Special Sessions, including those ranging from "The evolution of Herpesviridae and fish disease" to "The Aquatic Detective: Unusual and Perplexing Case Reports." In addition to the Special Sessions, there will be a continuing education day; Histopathology, Part II: Finding and Interpreting the Overlooked. For more information refer to: *http://tinyurl.com/4c4xcpj*.

Aquaculture Canada^{OM} 2011; 8 - 11 May 2011; Québec City, Québec, Canada: This year's conference is being held at the Loews Hôtel Le Concorde, which is located in center of Québec City. Numerous technical sessions are scheduled, including those on: freshwater, certification, mussels, scallops, nutrition, communication, risk, and engineering. For more information on the conference, including registration, agenda, etc. refer to the conference's website: http://tinyurl.com/4uqqt3m.

World Aquaculture 2011; 6-10 June 2011; Natal, Brazil: The 2011 annual conference of the World Aquaculture Society (WAS) will be held at the Natal Convention Center, and is being jointly hosted by the World Aquaculture Society (WAS), the Latin American & Caribbean Chapter of WAS and the Associação Brasileira de Criadores de Camarões. WA2011 is being held in conjunction with Fenacam 2011. World Aquaculture 2003 was one of the most highly attended WAS meetings ever. In 2011, WAS will once again hold WA 2011 in Brazil. This time, it will be held in Natal, Brazil and located in the midst of many kinds of aquaculture. In 2003, aquaculture in Brazil was doing well, but now the aquaculture industry is doing even better. Aquaculture now has it's own Ministry in the Brazilian Federal Government – meaning there is a lot of government support for expansion of aquaculture in Brazil. The conference comprises over 75 sessions in 9 general topic areas, including the major topic area "Aquaculture and Human Health." For more information, refer to the conference website at: https://www.was.org/WasMeetings/meetings/Default.aspx?code=WA2011.

8th International Conference on Molluscan Shellfish Safety; 12-17 June 2011; Charlottetown, Prince Edward Island, Canada: The conference will be held at the University of Prince Edward Island. conference program will primarily feature the following topics: epidemiology; risk assessment; pathogen and toxin monitoring; analytical methods in microbiology and biochemistry; consumer health protection; management of production and harvesting areas; post-harvest processing; and other topics. For more information, refer to the conference website: http://tinyurl.com/4647fb9.

52nd Western Fish Disease Workshop; 14-16 June 2011; Nanaimo BC, Canada: The Workshop is being held as a joint meeting with the American Fisheries Society's Fish Health Section. The joint meeting is being held at the Nanaimo Conference Center. A full day continuing education session is scheduled for 14 June. For more information click here.

OIE Conference – Aquatic Animal Health Programmes: their benefits for global food security; 28 - 30 June 2011, Panama City, Panama: The conference will provide a forum for OIE Members and other participants to exchange the latest information on a science-based approach to the management of aquatic animal health and food safety at the production level. Participants will be able to share valuable experience in the prevention, detection and control of aquatic animal diseases, safeguarding food safety, and related contributions to sustainable management of the aquatic environment. Topics to be addressed will be: analysis of the global aquatic animal health situation; the roles and responsibilities of Aquatic Animal Health Services and Veterinary Services, including OIE national Delegates and focal points, in aquatic animal health management; the roles and responsibilities of national and international laboratories for disease diagnosis and reporting and related scientific research; effective communication amongst all concerned sectors; understanding the OIE role and mandate and the relationships between authorities where there is a shared responsibility for aquatic animal health; OIE Members' experiences in aquatic animal health management, including the challenges and priorities of developing countries; awareness of the OIE standards and recommendations for aquatic animals and practical advice on how to comply with the standards; requirements for aquatic animal feed and for the use of veterinary products in aquatic animals; the education of veterinarians and aquatic animal health professionals in the public and the private sector on their role and responsibilities; improvement of governance of Veterinary Services and Aquatic Animal Health Services using the OIE PVS pathway; and future needs and priorities to support decision makers, international organisations and donors with the objective of strengthening the governance and management of the aquatic animal production sector especially as this relates to animal heath, food safety at the production level, and relevant contributions to safeguarding the environment. For more information refer to the conference website: http://tinyurl.com/4whwa2b

1st Australiasian Scientific Conference on Aquatic Animal Health; 5-8 July 2011; Cairns, Queensland, Australia: The conference, being held at the Pullman Reef Hotel, provides a forum for presentation of diagnostic, research, management and policy issues encompassing all areas of aquatic animal health and bio-security. Previously, the Aquatic Animal Health Subprogram (AAHS) of the Fisheries Research Development Corporation of Australia has organized national scientific conferences (in 2003, 2005, 2007 and 2009) featuring presentations on aquatic animal health research in Australia and an international aquatic animal health expert as the keynote presenter. While the format of the 2011 conference is likewise being hosted by AAHS, it is expected to be similar to previous conferences with an international keynote speaker, presentations on a range of aquatic animal health topics, prize for best student presentation etc., a recent decision was made to expand the conference to encompass the Australasian region, attracting participants from New Zealand, SE Asia and beyond. To receive the second conference announcement which will include the draft program, registration (registration fee will be Aus$330) and abstract forms and further accommodation details please provide Joanne Slater, FRDC Aquatic Animal Health Subprogram Coordinator (email: joanne.slater@csiro.au) with an expression of interest indicating whether you plan to attend and/or make a presentation (please indicate topic). Please provide the following details: your name, institution, postal address, email address, fax and telephone numbers. Also your area(s) of interest: research/management/policy and regulation; finfish/crustaceans/molluscs/reptiles/amphibians; viral/bacterial/parasitic/fungal pathogens; and/or diagnostic test development and diagnostics.

Salmon Disease Workshop; July 11-22, 2011; Corvallis, Oregon USA: This workshop is designed for professionals working in the fish health field and will emphasize recent advances and developments in our understanding of salmonid diseases. Specifically, the workshop will include sessions covering: current immunological and molecular techniques; sampling for pathogens in wild populations; new and emerging fish pathogens; cell culture techniques, including maintenance of cultures and viral identification; histopathology associated with salmonid diseases; current status of important viral, bacterial, and parasitic pathogens; salmonid disease treatment practices in Pacific Northwest hatcheries; and epidemiology. The workshop is limited to 20 participants on a first come, first served basis. For more information, including lodging, registration, etc. refer to the following: http://tinyurl.com/47mfuuw.

Coral Tissue Slide Reading Workshop; 31 July - 5 August 2011, Mote Marine Laboratory; Summerland Key, Florida USA: This 5-day workshop focuses on the histology or microscopic anatomy of scleractinian corals, gorgonians, and other Cnidaria to support studies on their ecology, physiology, reproduction, biochemistry, systematics, molecular biology, genetics, immunology, embryology, and pathology. For more information refer to the course description webpage: http://tinyurl.com/4u8jbu6.

Diseases of Corals and Other Reef Organisms; 6 - 14 August 2011; Mote Marine Laboratory; Summerland Key, Florida USA: This course will introduce students to the field of pathobiology of marine organisms. The focus of lectures, dives, and laboratory sessions will be on diseases affecting hard corals, but diseases of other reef organisms will also be discussed. Methods of studying diseases will include collection of field monitoring data and physiological, histological and microbiological techniques. The course will provide students with a state-of-the-art overview of reef pathobiology, experience with relevant techniques, and an understanding of the need for a multidisciplinary approach to its study. For more information refer to the course description webpage: http://tinyurl.com/4827knc.

Health and Colony Management of Laboratory Fish; 15-19 August 2011; Mount Desert Island, Salisbury Cove, Maine USA: This is a novel short course to help technical staff, graduate students, postdoctoral fellows, junior faculty and investigators monitor the health of a colony of aquatic organisms. For more information refer to the course description at: http://tinyurl.com/28oamuo.

2011 International Aquaculture Biosecurity Conference and Workshop; 14 - 17 August 2011; Trondheim, Norway: The 2nd International Aquaculture Biosecurity Conference (14 - 15 August) will be followed by the 1st International Aquaculture Biosecurity Workshop (16 - 17 August). The Conference will cover the following topics: components of ideal biosecurity plans and programs; determining and mitigating critical control points and risks of disease introduction; surveillance, monitoring and determining disease status/freedom; diagnostic testing, veterinary and farm record keeping; national and international biosecurity strategies; contingency plans for the control and eradication of disease; immunoprophylaxis in biosecurity plans and programs; use of biosecurity manual for aquaculture (practical benchtop exercise); and biosecurity check list. The Workshop will allow for on-site review of the biosecurity practices throughout

the entire value chain of seafood production, based on the current standard of the salmon aquaculture industry. For more information, including agenda, registration and lodging refer to their website: http://tinyurl.com/4m8zrsy.

AQUA NOR FORUM 2011; 17-18 August 2011; Trondheim, Norway: The European Aquaculture Society (EAS) in cooperation with the Nor-Fishing Foundation, SINTEF and CREATE, organizes this meeting that provides a forum for science, industry, consumers and policy makers to review developments in the aquaculture sector and to discuss the key issues that affect those developments. For more information please refer to the conference website: http://tinyurl.com/6hcmofo.

141st Annual Meeting of the American Fisheries Society; 4 - 8 September 2011; Seattle, Washington USA: The theme of this year's meeting is "New Frontiers in Fisheries Management and Ecology: Leading the Way in a Changing World," and is being held at the Washington State Convention Center. The official hotels for the meeting are the Seattle Sheraton, the Grand Hyatt Seattle and the Hyatt at Olive 8. The meeting will feature a broad range of technical, social, and legal topics that are of national and international interest, including measures to recover from massive man-made and weather-related catastrophes and to ensure the long-term sustainability of fisheries resources. Regional topics will highlight efforts to protect and clean up Puget Sound and address emerging issues related to the Columbia River, salmon recovery, and watershed management. For further information, please refer to the meeting's website: http://afs2011.org/.

AQUACULTURE EUROPE 2011; 18-21 October 2011; Rhodes, Greece: The conference, organized by the European Aquaculture Society in cooperation with the Federation of Greek Maricultures (FGM), and Hellenic Centre for Marine research (HCMR) will address vital questions affecting the development of Mediterranean aquaculture over the next decade, with reviews of the importance of aquaculture in EU food production; the sustainability of aquaculture feeds and the implementation of selective breeding strategies in aquaculture. A review of current EU-funded research programmes will highlight their relevance to the current and future production practices. The conference will include an international trade show, a Farmers' Day and a student workshop. It will also provide a platform to showcase European initiatives in aquaculture. For more information, please refer to the conference website: http://tinyurl.com/4q8dvbr.

VIII International Symposium on Fish Parasites; 26-30 September 2011; Viña del Mar, Chile: Next 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/.

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.

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.

CVM's NOTES

Editor's note: Due to a communications error, there will not be information provided by FDA's Center for Veterinary Medicine this issue. We sincerely apologize for the error.