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The Association of Fish and Wildlife Agencies—the organization that represents North America’s fish and wildlife agencies—promotes sound management and conservation, and speaks with a unified voice on important fish and wildlife issues..

FINAL DAWG MEETING NOTES
Association of Fish and Wildlife Agencies – Drug Approval Working Group
Seattle, Washington
15 February 2009; 0800-1400 hr

Prepared by Thomas Bell on 2 April 2009

Attendees: Kevin Amos (NOAA), Thomas Bell (FWS), Jim Bowker (FWS), Dave Erdahl (FWS), Mark Gaikowski (USGS), Jen Matysczak (CVM), Roz Schnick (NCANADA), Steve Sharon (Chair; WY GFD), Dave Straus (USDA).

Attachments: Roz Schnick’s drug status summary hand-out
Mark Gaikowski’s Parasite Survey hand-out

- Steve S. called the meeting to order
- Steve S. noted that Kevin Amos had been asked to attend representing NOAA Fisheries, but it has yet to be determined as to whether Kevin will ultimately be the representative for NOAA.
- Dave E. asked how it was NOAA was now being asked to join the Working Group.
 - Steve S. stated that to his knowledge NOAA has always been a member of AFWA.
- Steve S. also stated that he had asked John Kerwin (Washington State Department of Fish and Wildlife) to become a member as a representative of the Pacific Northwest States and representing anadromous fish.
- Steve S. asked if there were any comments, corrections, etc. to the minutes from the last DAWG meeting.
 - No corrections or comments were noted.
- Discussion of Action Items from the last meeting.
 - Hydrogen peroxide Fact Sheet – tabled for discussion later in the meeting.

- New Fact Sheets - tabled for discussion later in the meeting.
- Carbonic acid
 - Steve S. will do later and will possibly submit to CVM a request for LRP status.
 - Jen M. asked whether or not a letter from AFWA had already been sent in requesting that the LRP list be retained and includes carbonic acid as the source of CO₂ gas. The answer was no, and Jen M. then suggested that AFWA might model their letter after the National Aquaculture Association's (NAA) earlier letter, but being sure to include the AFWA-specific requests regarding NAA CO₂ gas.
 - It was noted that comments made today were essentially the same as that made at the previous meeting; that CO₂ gas is more reflective of actual use patterns.
- Letters to states regarding pivotal work
 - Dave E restated that he was not for going back too far chronologically.
 - Jim B. suggested that a list be put together by each AFWA member representative that identifies all folks/facilities that have contributed no matter how far back.
 - Mark G. suggested that for older products, we wait until the approval is acquired to acknowledge all entities that had contributed, and in the case of newer products, we send out acknowledgements as soon as it happens. He also reiterated that letters should be sent to high authorities and to allow for acknowledgement to trickle-down to the actual researchers.
 - It was noted that this should be for pivotal and high quality supportive studies only.
 - Steve S. stated that all will assemble a list for all drugs and provide to Steve S. by the end of February and draft letters (for formalin, H₂O₂, OTC, OTC HCl and Aquaflor) by the end of March. The DAWG will assemble a database with tracking for sending out the letters.
 - Dave S. suggested that announcements be made at AFWA meetings where all resource agency directors are present.
 - Tom B. suggested that maybe during the same venue a certificate of appreciation be handed out.
 - Steve S. will check on the rest of this with Ron Regan.
- Illegal drug-use letter
 - AADAP did not do this yet as promised, but will provide draft to Steve S. by mid-March.
 - Steve S. asked whether an annual letter should be sent out to Fish Chiefs asking for help conducting pivotal field efficacy trials using chloramine-T or H₂O₂.
 - Jim B. suggested that these are probably already taken care of.
 - Therefore, Steve S. recommended that we not do this activity this year.
 - Jim B. suggested that maybe we target facilities by using the AADAP INAD list.
 - Steve S. reiterated not sending them this year, but tabled the topic for further discussion until next fall.
- Immediate-release catchability study
 - Preparatory activities completed by UMESC

- Mark G. noted that UMESC and partnering Universities in the La Crosse area are already working on it.
- AFWA brochure – tabled until later in meeting
- Sedative/anesthetic selection process
 - Mark G. submitted protocol to CVM for first-feeding (catchability study) and requested a phone conference (week of 9 March) to discuss all aspects of conducting these studies. Viterbo University (La Crosse) and University of Wisconsin – La Crosse are the two universities subcontracted to participate in the study. Mark will get back to the DAWG on exactly when the phone conference is scheduled.
 - Mark G. noted that the protocol was basically provided to CVM as background information for their proposed phone conference.
 - Mark G. also stated that the \$20-22K previously allocated for this work, with UMESC in-kind funding, will fully fund the project.
 - Mark G. stated that the total residue depletion study for eugenol is scheduled to be initiated by Jeff Meinertz this summer, with actual in-life exposures scheduled to begin early FY2010.
 - Tom B. said that the 6 quotes from contract laboratories had been received for the benzocaine genotoxicity battery, all but one of which was within the allotted \$80K. Further, AADAP had initiated the bidding/contracting with our Washington Office, but we had received extremely poor support so far from the WO. AADAP would continue to pursue this with the WO. Tom also noted that he had discussions with Martha Moore at NCTR about their conducting the genotoxicity battery and was told that 1) such work would have to be placed in their queue (hence postponing completion quite some time), and 2) NCTR is a research lab and consequently the required work, if it were to be done there, would not be conducted under GLP. Therefore, NCTR was eliminated from consideration. However, Martha M. did offer her services to help us review bids, etc.
 - Tom B. noted that AADAP had worked with NTP to obtain all reports and data that NTP had generated on their eugenol toxicity study(s). All study reports were finally acquired and submitted to CVM (directly to the Human Food Safety group) the week prior to the DAWG meeting.
- Coordination of anesthetic activities since the last meeting.
 - Roz S. commented, based on her hand-out, page 6
 - The question was asked and she stated that she does not know if ACD has sought MUMS designation for benzocaine, and that we would have to question their representative, George Kohan (who was attending AA2009).
 - She stated that AQUI-S New Zealand has a eugenol based product called AQUI-S[®]E that is approved in several countries (one country in the EU) and for which the company just recently received MUMS designation for 8 separate claims. Any other questions regarding this product needed to be posed to their representative, Tom Goodrich, who likewise is in attendance at AA2009.
 - Tom B. provided an overview of the NOAA-initiated anesthetic meeting to take place on the following Tuesday (2/17) at Aquaculture America 2009.

- Nez Perce Tribe (NPT) of Idaho approached AADAP as a result of reading the immediate-release anesthetic activities article in the October AADAP Newsletter. The NPT informed AADAP that fisheries resource managers in the Columbia River basin are faced with a serious dilemma without a legal immediate-release anesthetic. The NPT noted that NOAA was planning an early spring meeting with Columbia basin agencies/entities to discuss this issue and inquired if AADAP and the DAWG would be interested in facilitating/attending the meeting to present what the DAWG is working on and provide an overview of the regulatory process. Perhaps most importantly, the NPT asked the question "...is there anything that we can possibly do to help the process move along?"
- Steve S. indicated that the NOAA meeting was essentially by invite only (AFWA; Columbia River Inter-Tribal Fish Commission; Idaho Fish and Game; NAA; Nez Perce tribe; NOAA; Northwest Indian Fish Commission; Oregon Dept. of Fish and Wildlife; U.S. Army Corp of Engineers; U.S. FWS, AADAP, Idaho Fish Health Center and Washington Dept of Fish and Wildlife), and he would report back to the DAWG on the results of the meeting.
- Steve S. stated that he would have further discussion, during AA2009, regarding eugenol and benzocaine with the sponsor representatives.
- Jim B. asked if there was to be a selection of one company for benzocaine? (no recorded response)
- Kevin A. explained his and NOAA's role vis-à-vis the DAWG and otherwise
 - He is NOAA's aquatic animal health coordinator and NOAA's liaison with the NOAA Fisheries (i.e., the old National Marine Fisheries Service), which includes health aspects associated with: "new" marine species, salmon restoration and other species such as shellfish.
 - He stated that NOAA could conceivably bring funds to the table.
- Drug-specific reviews
 - Chloramine-T
 - See Roz S.'s hand-out.
 - Roz S. noted that there have been no red flags raised relative to Axcentive's CMC package submitted to CVM, but there are still some components that need to be provided by Axcentive to complete the CMC technical section. There will not be a final acceptance by CVM until all components of the CMC technical section have been submitted (and accepted).
 - Mark G. stated that the previously accepted *p*-TSA method (developed with the understanding that the working tolerance was 1 ppm) has a limit of quantitation of approximately 35 ppb. UMESC has been notified by CVM that a new tolerance has been established at 20 ppb. Therefore, their method will have to be tweaked to deal with the new tolerance. Mark further stated that a late-eluting peak is causing some analytical problems and that the cause of this late-eluting peak is being investigated. Mark said that validation, on several species, of the new tweaked method should be completed and submitted by the next DAWG meeting.

- Roz S. stated that we should expect an approval for chloramine-T approximately 6 months after UMESC's submission of the revised method, and that all minor technical sections will be submitted prior to the review of the UMESC submission.
- Jen M. suggested that the sponsor not wait until the end to submit the AOI.
 - Roz S. stated that the AOI would be submitted this spring.
- Jim B. noted that the largemouth bass and bluegill studies were submitted, but as of the DAWG meeting there has been no formal response from CVM. However, the largemouth bass study report is being revised after informal consultation with CVM.
- Jim B. also stated that there may be an opportunity coming up for the completion of a striped bass study at Richloam SFH in Florida, and that AADAP is in a position to possibly complete other studies also at Richloam.
- Roz S. said that she would like to have a decision by fall as to what is going to be the label, and would like to have Jim B. keep her informed of research activities. She also stated that Axcentive is willing to pursue amendments to their NADA.
- CuSO₄
 - See Roz S.'s hand-out.
 - Dave S. stated that there is an anticipated submission of the EA on or about August 2009.
 - Dave S. further noted that it is possible that there could be a late 2009 or early 2010 approval.
- Florfenicol
 - See Roz S.'s hand-out.
 - Jim B. described activities regarding upcoming target animal safety studies for label expansion to use at 10 or 15mg/kg. He informed the group of AADAP having to go through an ERA (End Review Amendment) exercise relative to the protocol submissions for both yellow perch and sunshine bass.
 - Yellow perch study (to be conducted under full GLP) to take place in Bozeman probably in summer. Rather stringent fish import restrictions by Montana Fish, Wildlife and Parks are slowing down overall process, but it appears to be a workable situation. Bozeman Tech Center staff has experience in hatching/culturing perch.
 - Sunshine bass to be completed by AADAP and SNARC. SNARC to conduct day-to-day activities with oversight and assistance by AADAP. To be conducted under near-GLP in early spring.
 - Dave E. noted that SPAH has data for all freshwater-reared salmonids and other fish, which will allow the above noted TAS studies to be the only other studies needed to expand label to all freshwater-reared finfish at 10 or 15mg/kg.
 - Jim B. also briefly discussed the most recent florfenicol/largemouth bass study at Richloam, noting that feed analyses revealed OTC contamination and lack of florfenicol homogeneity. The jury is still out as to how the study will be designated by CVM (i.e., pivotal vs. high quality supportive vs. supportive), but in all likelihood, this study will not be accepted by CVM.

- Mark G. stated that the pivotal streptococcus/tilapia study has been submitted to SPAH for review prior to submission to CVM. Also he noted that UMESC is working to complete the marker residue study in tilapia.
- Formalin
 - See Roz S.'s hand-out.
 - Roz S. noted that Western Chemical for sure would pick up the new claims.
 - Kevin A. asked whether or not CVM was more strictly regulating the industry relative to the industry's use of non-approved products. The question was in the context of the terrestrial animal husbandry industry using commodity formalin (non-approved) as opposed to extra-labeling the approved aquatic animal product.
 - Jen M. indicated that CVM's Office of Surveillance and Compliance would be better to answer that question than she would.
- H2O2
 - See Roz S.'s hand-out.
 - Jim B. reviewed AADAP activities
 - AADAP expects to submit the request for efficacy technical section complete to control mortality caused by columnaris in all cool- and warmwater finfish by the end of the month.
 - Jim can't get any hatchery personnel to confirm that BGD is an issue in cool and warmwater finfish.
 - Mark G. discussed UMESC' work (refer to Roz S.'s handout)
 - Noted that in the saprolegniasis studies on rainbow trout and walleye (item #4 in Roz's handout) there were two fungal pathogens.
 - Mark also stated, regarding the efficacy trial at Jake Wolf State Fish Hatchery, that the study would probably be considered supportive, at best.
- OTC dihydrate
 - See Roz S.'s hand-out.
 - Jim B. stated that the protocol has been accepted (12 January 2009) by CVM for the pivotal marking study. Only one study in any salmonid will be required to expand the label from Pacific salmon to an "all freshwater-reared salmonids." Further, the study has already been initiated and the exposure phase would be beginning later in the week (approximately 24 February 2009).
- OTC hydrochloride
 - See Roz S.'s hand-out.
 - Mark G. stated that since the last DAWG meeting no additional progress has been made at UMESC.
- CuSO₄
 - See Roz S.'s hand-out.
 - Dave S. said that two pivotal and one supportive study have been completed but have yet to be submitted to CVM.

- Dave S. also indicated that their studies have shown that CuSO_4 is better and cheaper than formalin for use on channel catfish eggs.
- Additionally, Dave S. stated that the Environmental Assessment (EA) is on the back burner until other studies have been completed and submitted.
- Florfenicol (as it relates to the NCRAC funded project)
 - See Roz S.'s hand-out, in particular discussion on motile aeromonas septicemia (MAS).
 - Mark G. asked Dave E. if he could have Molly Bowman database [sic; Bonnie Johnson's INAD database] to pull information out on MAS occurrence. Dave responded that he would.
 - The issue of florfenicol use against bacterial kidney disease (BKD) was brought up for discussion
 - Dave E. stated that he did not have much new information to add to the discussion other than the fact that there has been a little bit of interest expressed by Doug Munson in Idaho.
 - Dave suggested that we take BKD off the florfenicol list until such time as there is more definitive data indicating it may be efficacious or that somebody in the field takes the initiative to conduct such a study – there were no objections.
 - Mark G. said that UMESC is involved in a USGS/FWS Science Support Project proposal to look at florfenicol and enrofloxacin to combat BKD in Chinook salmon in the Great Lakes.
 - The proposal was accepted and will be funded
 - The study will be using Chinook salmon as a surrogate species for the T&E coaster brook trout.
- H₂O₂
 - See Roz S.'s hand-out.
 - Mark G. discussed the Iron River National Fish Hatchery study on external parasites.
 - UMESC went ahead and conducted the study in spite of the fact that their protocol revision (with incorporated CVM-recommended changes) had yet to be approved by CVM.
 - Study demonstrated that treatment had a significant impact on the reduction in parasite load; reduced from 60-100 parasites per in² down to 0-2 per in².
 - Mark indicated that this study should help to establish the correct sample size needed to accurately assess treatment effectiveness.
- KMnO₄
 - See Roz S.'s hand-out.
 - Dave S. noted that item #2 on Roz's handout could be eliminated as it will be part of the EA.
 - Dave S. is trying to do a mass challenge (immersion) model rather than use the model developed by UMESC in which one fish is abraded at a time using a Dremel tool.

- Steve S. stated that he would be talking with Randy MacMillan regarding Clear Springs' plan to do something to ensure that they not lose the use of KMnO₄ at Clear Springs.
- Dave E. noted that he had previously suggested to Randy that Clear Springs request a product development-type meeting with CVM to discuss this, but Randy recently expressed a desire to somehow obtain authorization for the use of KMnO₄ as an “oxidizer of organic material” as opposed to either a drug or pesticide.
- It was noted that Mike Mason had previously agreed to look into the use of KMnO₄ in coolwater species.
- Roz S. suggested that a letter should go to the public sector asking their needs and informing them of the probable loss of the product altogether (as indicated by the Sponsor, Carus Chemical, stating at the August 2008 Aquaculture Drug Approval Coordination, in so many words, that they planned to pull their support).
 - Dave E. said that it is not our responsibility to threaten possible doom at this point in time; however, our responsibilities might be different if CVM were to tell us that the “deferred regulatory status” of KMnO₄ will be pulled unless folks start using it under the INAD and generating data, and/or for whatever reason they identify.
 - Roz S. suggested that we go back to the original “needs” survey and use that to target individuals (that indicated a need) to inform them that they should step up to help if it is still a priority of theirs.
 - Roz S. will get to Steve S. with a list of the states that indicated that approval of KMnO₄ was a priority to them.
- AFWA Drug Approval Brochure
 - Steve S. commented that the last review process resulted in way too many versions/comments such that incorporation would far exceed the size limitations of the tri-fold format.
 - Steve S. rhetorically asked “...where do we go from here?” and offered some options to consider in lieu of the current concept:
 1. Produce a “factoid” sheet, presumably much more condensed
 2. Dispense with the entire idea; it may have been a good idea at the time, but now it does not have the same merits, if any.
 3. Produce a “web-based” (only) version.
 - Tom B. and Steve S. will work with Laura McLean if option #3 proves to be the accepted option.
 - Steve S. will send out all the revisions that he received as reference materials.
- Drug Fact Sheets
 - It was noted that Roz S. developed the first one on H₂O₂ and the purpose was to inform readers [of the fact sheet] about what the DAWG has accomplished
 - Roz S. and Mark G. will use the H₂O₂ fact sheet to create the actual format to be used on all other drug fact sheets, and will provide to all the DAWG members for review prior to the September 2009 meeting.
- Parasite Survey

- Mark G. provided a hand-out explaining it and describing the results.
- Refer to hand-out for descriptions.
- Steve S. stated that the Memorandum of Agreement (MOA) be placed on the agenda for the next meeting.
 - The MOA is due to expire in 2010 and there will be changes, if for no other reason than Roz. S. will be retiring in April, 2010.
- Next DAWG meeting is scheduled to take place in Austin, Texas
 - During the fall AFWA meeting being held in the week of 14 September 2009.
- Steve S. will be providing Virgil Moore (Chair, AFWA Fisheries and Water Resources Policy Committee) with a written synopsis of this DAWG meeting for presentation at the March North American Wildlife and Natural Resources Conference. Steve will not be attending this meeting.