

## Meeting Minutes

### 8<sup>th</sup> Meeting of the National Aquaculture Drug Research Forum Monday, February 16, 2009 3:30 – 4:30 pm

Held in conjunction with the  
Aquaculture America 2009  
Seattle, Washington

The 8<sup>th</sup> meeting of the National Aquaculture Drug Research Forum (Forum) was represented by aquaculture drug researchers, research coordinators, chemical and pharmaceutical sponsors, and CVM's Aquaculture Team.

The following agenda items were covered:

1. Status of a survey to identify primary protozoan ectoparasites. Mark Gaikowski (USGS UMESC) provided an update on information collected from fish health professionals regarding external and internal parasites that cause substantial disease or fish health concerns at hatcheries rearing freshwater finfish under their watch. The survey was disseminated through the Association of Fish and Wildlife Agencies Drug Approval Working Group (DAWG) in a letter dated June 24, 2008 and signed by the Steve Sharon, DAWG Chair. The survey tool can be accessed from the following website for any others that would like to add to the database [http://www.umesc.usgs.gov/aquatic/drug\\_research/cap\\_parasite\\_survey/parasite\\_survey.html](http://www.umesc.usgs.gov/aquatic/drug_research/cap_parasite_survey/parasite_survey.html).

Mark provided a short powerpoint presentation describing survey objectives, a summary of responses, and included a number of quotes from survey respondents that further described their experiences with parasites and available chemotherapeutants.

In summary, at least one response was received from 36 states, most survey responses were provided by fish health specialists or fish culturists from Public/Not for Profit production or research facilities. Responses indicate that protozoans and monogeneans appear to be the parasite groups of greatest concern. Protozoans of greatest concern included Ich and Ichthyobodo, and to a lesser extent Trichodina and Chilodonella. The monogeneans of greatest concern were Gyrodactylus and Dactylogyrus.

As mentioned in the notes from the last meeting, Mark will prepare a summary report of the survey to distribute to respondents. Additionally, a follow-up questionnaire may be sent to some of the respondents. The follow-up questionnaire would target collection of specific additional information including (1) treatment strategies and regimens used, (2) triggers to initiate treatment (what clinical signs or parasite loading densities trigger disease treatment), and (3) clinical signs are observed before treatment and when/if treatment resolves those signs.

Results from the survey will help those involved in evaluating the effectiveness of various parasiticides to focus their efforts on ectoparasites of greatest concern. Kudo's to Mark and his staff for their effort to pull together this important information.

2. Use of PROC GLIMMIX to analyze mortality data in efficacy and target animal safety studies. Over the last few years, Mark Gaikowski has been working with CVM's Dr. Todd Blessinger and Intervet/SPAH's Diane Sweeney to develop a better way to analyze binomial data such as mortality. Mark Gaikowski provided a powerpoint presentation that summarized the evolution of analyzing survival data, from ANOVA to PROC GLIMMIX. SAS code, example data sets, and associated output are available to those interested (feel free to contact with Mark or Jim Bowker). For those interested in a little more information about the utility of this statistical procedure, please feel free to contact Mark.
3. Use of INAD data to minimize pivotal efficacy trial requirements. Efforts have been underway for several years to try to conduct one more study on a coolwater fish (other than walleye) to demonstrate the use of chloramine-T to control mortality caused by external columnaris. Because there have been virtually no opportunities to conduct such a study, we're faced with the reality that although the approval for chloramine-T may be to control mortality in all freshwater-reared salmonids due to BGD and all warmwater finfish due to external columnaris, it may be limited to only walleye and not all coolwater finfish. As a result, an effort was initiated to draft a "white paper" argument that based on the chemicals mode of action (as an oxidizing agent), there is sufficient data available in peer-reviewed literature, pivotal studies submitted to CVM, and INAD data to support the position that conducting this one last study should not be required to complete this last remaining effectiveness technical section. Jim Bowker provided an overview of a document being developed by AADAP. Subsequent discussion was focused the utility of creating a broader document that would include information on additional oxidizing agents such as hydrogen peroxide and potassium permanganate. Our goal is to provide CVM with the information they might need to agree to reducing the number of field efficacy trials required to complete an all fish claim based on (1) the mode of action of this type of chemical, (2) the fact that oxidizing agents are effective in disinfecting a substrate, and (3) that the external surface of the fish serves as a substrate. Jim will work with others from the Research Forum to refine the paper's objective, eg. focus on a single chemical situation initially and potentially expand it to a broader discussion of external oxidants, and submit it to CVM's Aquaculture Team.
4. Expert Panel Reports for non-food fish drug Indexing – Recently, several aquaculture drug sponsors have explored Indexing, which provides for the legal marketing of unapproved new animal drugs for use in a minor species that are characterized as non-food animals (e.g., ornamental fish), through an integrated process of agency and expert panel review. The drug sponsor is responsible for establishing a panel qualified experts. The panel is responsible for (1) evaluating all available target animal safety and efficacy information relevant to the proposed use of the new animal drug, (2) preparing a written report summarizing their evaluation, and (3) stating the panels opinion regarding whether the benefits of using the new animal drug for the proposed use outweighs its risk to the target animal. The sponsor is responsible for submitting the written report to CVM and working to obtain Indexing with those in the Office of Minor Use Minor Species.

It is likely that drug sponsors seeking to index a new animal drug may seek out experts associated with the NADRF. Such members are encouraged to participate and help in the effort to gain legal marketing of unapproved drugs for use in non-food fish.

5. New home for the NADRF – Although this issue was not included on the agenda, it was a topic of discussion at the last meeting. The new home for the NADRF is under the AFS Fish Culture Section's newly formed Working Group on Aquaculture Chemicals. The NADRF will remain open to anybody interested in participating, whether they are FCS members or not.

## NADRF Participants

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