

Meeting Minutes

7th Meeting of the National Aquaculture Drug Research Forum Friday, August 01, 2008 9:00 am – 12:30 pm

Held in conjunction with the
14th Annual Aquaculture Drug Approval Coordination Workshop
Bozeman, Montana

The 7th meeting of the National Aquaculture Drug Research Forum (Forum) was well represented by aquaculture drug researchers, research coordinators, chemical and pharmaceutical sponsors, and members of CVM's Aquaculture, Biometrics, and Environmental Teams.

The following agenda items were covered:

1. Status of a survey to identify primary protozoan ectoparasites. Mark Gaikowski (USGS UMESC) led the development of a survey to solicit information from fish health professionals regarding external and internal parasites that cause substantial disease or fish health concerns at hatcheries 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 can be accessed on UMESC's website at http://www.umesc.usgs.gov/aquatic/drug_research/cap_parasite_survey/parasite_survey.html.

Mark briefly showed and described some survey responses and is encouraged by the preliminary responses. The survey has since been disseminated through the National Association of State Aquaculture Coordinators, the American Fisheries Society's Fish Health Section (through Jerri Bartholemew's weekly FHS update) and the American Veterinary Medical Association.

Mark characterized development of the survey as relatively quick and easy, and easy to compile survey responses (data) into Excel. The survey development and design experience could be readily be applied to the development of other surveys.

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.

Discussion ensued regarding:

- a. Whether survey results will be compiled and sent out to respondents (they will);
- b. If the survey is being sent out in a manner to reach 100% of the target audience is being reached

- c. If a reply is being sent out immediately to respondents thanking them for taking the time to fill out and return the survey (a reply email is being sent out indicating that the survey was received and thanking the respondent);
 - d. That efforts should be made not to send different surveys to the same group (we'll focus on getting surveys into the hands of a specific target audience);
 - e. That requests such as that drafted by the DAWG go to State Hatchery Chiefs rather than State Fish Chiefs (it's more likely that there will be follow-through from requests sent to Fish Chiefs);
 - f. When the summary report of describing the parasite survey results is disseminated, ensure that the members of the AFWA Fishery and Water Resource Committee (this committee is comprised of State Fish Chiefs) are included in the distribution list;
 - g. A comment was made regarding OMB review of information collection activities; at present it is unclear if distribution through the DAWG requires OMB review or not. This requirement will be clarified before future information collection activities are initiated.
2. Overview of the parasite round table discussions (see attachment). Jim Bowker started the discussion that focused on (1) designing an experiment to address the label claim (i.e., use to control mortality or to control parasite infestations), (2) how to standardize sample collections, wet mount examinations, and enumerating parasites on a microscope slide, (3) development of a null hypothesis to address reduction of fish parasite load, and (4) identifying clinical signs associated with parasites (specific vs general clinical signs).

Discussion ensued regarding:

- a. Jen Matysczak (CVM Aquaculture Team) announced that Dr. Sarah Poynton, a fish parasitologist from John Hopkins University who teaches in Germany part time will be leading a course through CVMs Staff College on parasites. The course will be on August 28, and will focus on, among other things, parasite enumeration. All interested in attending via webinar should email Jen at jennifer.matysczak@fda.hhs.gov
- b. Utility of the survey to help identify parasite-specific clinical signs, coordinate definitions for use in protocol, and more effectively coordinate protocol development and submission.
- c. Whether CVM can provide those developing protocols (1) how many parasites need to be collected and identified for confirmation, and (2) how parasites should be ID, i.e. to family, genus or species
- d. How to deal with disease complexes (situations exist where parasites in the genus *Gyrodactylus* are causing fish health problems, but fish also may have Tichodinid with various intensities.
- e. Roz Schnick asked whether a general white paper should be developed on lumping parasite genus that could subsequently be used to support lumping parasite genus for any potential parasiticide ("to set the table for all parasites").
- f. Whether it's possible to group parasites by genus because therapeutic mode of action is typically not species (or even genus) specific, but is more likely family or order specific.
- g. Don Prater (CVM Acting Director Division of Therapeutic Drugs for Food Animals) indicated that a precedent for "lumping" has already been established relative to the Saprolegniasis claim. He suggested searching the literature for sound biological justification for lumping and determine whether or not there is a

- “disease” that is linked/associated with specific genera. He further commented that it’s important to know drug mechanisms and how it would affect a family, etc.
- h. Renate Reimschuessel asked that if species response is the same to a therapeutant, to what level does a parasite identification need to be?
 - i. Whether the parasite survey asked for information about infections with multiple organisms. Mark G. indicated that some respondents have commented about seeing co-infections at some of their hatcheries.
 - j. Ron Phelps (Auburn University) indicated that he has often seen epistylis (ectoparasite) and Aeromonas (Gram - bacteria) together and that they one rarely sees them separate. How should such a disease complex be handled?
3. NADRF white paper review process – proposal: Renate Reimschuessel drafted a proposal to review draft documents generated by the NADRF. The proposal suggests that draft documents be submitted to by an author to each of the co-chairs, and each co-chair chose 1 – 2 reviewers from their organization (or those outside the organization with the relevant expertise) to provide (anonymous) comments. Leaders then consolidate comments from their reviewers, meet in conference (phone/email) to discuss comments, consolidate comments from other reviewers, and return document author for final revision.

Discussion ensued regarding:

- a. Mark G. asked that if a white paper is developed (under JSA, DAWG, etc.), is it possible for a “group” to submit this paper to CVM? Or does it need to be submitted to CVM under a specific INAD/agency?
- b. Don P. responded that the document can be made public, and that any group can submit a document as a “general correspondence” submission;
- c. Jen M. commented that it would be easier to submit such a document to a specific INAD (thus, one agency should make the submission);
- d. Mark G. asked whether such a document can be submitted to a publically disclosed INAD data file (he further commented that this submission would be specific to a drug and would probably not happen very often);
- e. Don P. threw out the idea that such white papers may be used to create Guidance for Industry. He further commented that the NADRF is creating guidance for users, which are very valuable and “easier” to do than for CVM to create GFI’s (it is a long process for CVM to come out with formal guidance).

Jim suggested that the four co-leaders get together within next month or two to finalize the draft review process and to apply the process to the next document that is developed from this group.

4. The value of round-table discussions such as the parasite discussion The group discussed the value of round-table discussions, and agreed that bringing in a relatively large group representing different groups and experiences is of great value. Dave Lovetro (Eka Chemical) supported the idea of an informal round table format to draw a lot of people from a variety of backgrounds, that such a format should be kept broad to attract more people, and that such a format is a powerful tool.

Additional discussion included:

- a. Whether such discussions can be widely distributed ;
- b. Whether such discussions (in the form of training) can count for continuing education credits;

- c. Any time discussion focuses on experimental design, somebody from CVM's Biometric Team should be present;
- d. Whether future round-table discussions should be held in conjunction with larger annual meetings (e.g., Aquaculture America) as a recruiting tool (to recruit others to either get involved in aquaculture drug approval research or conduct their research in a manner more acceptable to CVM review teams).

Mark G. commented about that at the recent AFS – FHS meeting there was an 8-hr training session on designing clinical field trials (primary focus was on clinical field trials at net pen farms). He suggested that we pick pieces of their curriculum, develop our own (shorter) training session and focus on the needs of our “group.” The training course would be mostly presentations, with sufficient time built in for discussion, and would include real-life scenarios/problems that class could “work out”.

Jim B. asked whether CVM could be instructors (would there be a conflict). Ron P. asked whether the training would be general or would be set up in a manner to recruit other researchers into the aquaculture drug approval research arena, and further asked whether this training is need for current researchers and therefore should address specific training needs (group thought that more specific training needs would be of greater value).

5. New home for the NADRF – With the sunseting of the JSA Working Group on Drugs, Biologics, and Pesticides in the format that it has operated for years (participation by federal and non-federal participants), there has been some discussion about the future of the NADRF. It is and has been unanimous that this group continues to be functional and productive and that it should continue to function. The main question has whether the NADRF needs (or should have) a home, and if so, where the home should be.

Mark G. offered the following as potential NADRF homes:

- a. Become a subcommittee of the DAWG
- b. Become a AFS subcommittee or sub-working group
- c. Become a separate entity (no home required)
- d. Fall under the AFS Aquaculture Chemicals Subcommittee (ACS)

Agreement was nearly unanimous that the NADRF would have more “weight” and leverage if it was part of a larger entity. There was discussion that the NADRF would be a good fit in the following:

- a. As part of the DAWG because this group focuses on public aquaculture.
- b. Under the AFS ACS

Comments relative to finding a home under the AFS ACS included:

- a. That NADRF meetings would not have to be held at AFS meetings only; that meetings could still be held in conjunction with Aquaculture America meetings or Aquaculture Drug Approval Coordination Workshop meetings.
- b. That if the NADRF finds a home under the ACS, then that leadership must come from within the NADRF group.
- c. Curry Woods (current AFS FCS president) commented that the infrastructure is already set-up within AFS, that aquaculture drug approvals are an extremely important area to FHS and FCS membership, that AFS provides a “location” for people to have access to resources, that there are no structural impediments to

get things done, and that links between US Aquaculture Society (WAS) and AFS-FCS are established.

- d. Curry W. further commented that associate membership to a section is available to non-AFS members (e.g., for those that want to participate in FCS, but not the rest of the society).
 - e. Don P. commented that the NADRF would benefit from an association with AFS, that it would be best for CVM if some of the meetings are scheduled to coincide with national meetings such as AFS, AA, or the Aquaculture Drug Approval Coordination Workshop, and that the NADRF co-chairs need to make sure that AFS is willing to support this group.
6. Providing statements of aquaculture drug needs to the JSA National Research and Technology Task Force – Renate R. requested that the NADRF participate in providing aquaculture drug needs (e.g., information requested in surveys such as the parasite survey, zero-withdrawal anesthetic, approved drugs) information to help revise the JSA NR and TTF Strategic Plan for Aquaculture. She further commented that:
- a. What goes into this document will be important for subsequent funding cycles
 - b. Priorities for research are part of the strategic plan
 - c. That a white paper needs to be developed to describe funding needs for developing and gaining FDA approval of drugs for use in aquaculture
 - d. That JSA had started this document several years ago but it was not completed

Renate R. will contact select group members and request help drafting this document or review the drug research part of the document. She further suggested that group individuals consider contacting Dr. Jeff Silverstein (USDA ARS National Program Leader – Aquaculture) and letting him know that the need for safe and effective aquaculture drugs is a BIG deal in the aquaculture world.

NADRF Participants

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| Tom Bell | USFWS, AADAP Program | thomas_a_bell@fws.gov |
| Jim Bowker | USFWS, AADAP Program | jim_bowker@fws.gov |
| Molly Bowman | USFWS, AADAP Program | molly_bowman@fws.gov |
| Dan Carty | USFWS, AADAP Program | dan_carty@fws.gov |
| Edward Chen | USFDA, CVM | edward.chen@fda.hhs.gov |
| Courtney Coddington | USFDA, CVM | courtney.coddington@fda.hhs.gov |
| Paul Curtis | AquaSolver LLC | paultrout@aquasolver.com |
| Charles Eirkson | USFDA, CVM | charles.eirkson@fda.hhs.gov |
| Richard Endris | Intervet/Schering Plough | richard.endris@sp.intervet.com |
| Dave Erdahl | USFWS, AADAP Program | dave_erdahl@fws.gov |
| Tom Goodrich | TGD Consulting | tdgoodrich@verizon.net |
| Stacey Gore | USFDA, CVM | stacey.gore@fda.hhs.gov |
| Bonnie Johnson | USFWS, AADAP Program | bonnie_johnson@fws.gov |
| Alan Johnson | Iowa DNR, Rathbun FCRF | alan.johnson@dnr.iowa.gov |
| Niccole Lawson | USFWS, AADAP Program | niccole_lawson@fws.gov |
| Dave Lovetro | Akzo Nobel/Eka Chemical | dave.lovetro@eka.com |
| Randy MacMillan | Clear Springs Foods, Inc. | randy@clearsprings.com |
| Jen Matysczak | USFDA, CVM | jennifer.matysczak@fda.hhs.gov |
| Terry Ott | USFWS, La Crosse FHC | terrence_ott@fws.gov |
| Ken Peters | USFWS, Bozeman FHC | ken_peters@fws.gov |
| Ron Phelps | Auburn University | rpphelps@acesag.auburn.edu |
| Don Prater | USFDA, CVM | donald.prater@fda.hhs.gov |
| Renate Reimschuessel | USFDA, Office of Research | renate.reimschuessel@fda.hhs.gov |

Paul Rice
Roz Schnick
Steve Sharon
Eric Silberhorn
Dave Straus
Jesse Trushenski
Curry Woods

Bimeda
NCANADA
Wyoming Game & Fish Dept.
USFDA, CVM
USDA ARS SNARC
Southern Ill Univ/AFS FCS
Univ. of Maryland/AFS FCS

paul.rice@bimedaus.com
rozschnick@centurytel.net
steve.sharon@wgf.state.wy.us
eric.silberhorn@fda.hhs.gov
dave.straus@ars.usda.gov
saluski@siu.edu
curry@umd.edu