

Highlights and Summary of the 2004 Annual NCRAC Meeting
Hilton Milwaukee City Center

February 6-8, 2004

- The Board of Directors, the Industry Advisory Council (IAC), the Technical Committee (TC), administrative staff, Gary Jensen of USDA's Cooperative State, Research, Education, and Extension Service (CSREES), and other guests met at the Hilton Milwaukee City Center hotel in Milwaukee, Wisconsin, from Friday through Sunday, February 6-8, 2004.
- The Board made decisions concerning two projects that had been developed since the last NCRAC Annual Meeting held in East Lansing, Michigan in February 2003: (1) Nutrition (2-year, \$200,000 project) and (2) 17 α -Methyltestosterone (MT) (1½-year, \$223,677 project).
 - ▶ Approved both projects but asked that they be revised taking into account the concerns and comments of the Board, the reviewers, and the Project Review Committees.
 - ▶ The revised projects will be included in a Plan of Work (POW) that must be submitted to USDA/CSREES for their approval. It is hoped that the MT project will be able to begin by no later than June 1 and the anticipated starting date for the Nutrition project will be September 1, 2004.
 - ▶ The Nutrition project will be undertaken by Paul Brown at Purdue University, Chris Kohler at Southern Illinois University-Carbondale, Don Garling at Michigan State University, and Jeff Malison at the University of Wisconsin-Madison. The two objectives for that project are as follows:
 - (1) Develop cost-effective fish meal-free diets for grow out of hybrid striped bass with an initial minimum weight of 100 g (3.5 oz).
 - (2) Develop cost-effective fish meal-free diets for grow out of yellow perch with an initial weight of 10 g (0.35 oz).
 - ▶ The MT project will be undertaken by Terry Barry, Ashok Marwah, and Padma Marwah of the University of Wisconsin-Madison. The six objectives of that project are as follows:
 - (1) Develop a robust and validated high performance liquid chromatography (HPLC) and liquid chromatography-mass spectroscopy (LC-MS) method to measure MT in fish feed.
 - (2) Conduct a series of stability studies on MT in fish feed.
 - (3) Gain acceptance from CVM for the series of stability studies.
 - (4) Review and develop a LC-MS method for detecting MT in water.
 - (5) Conduct a biodegradation study of MT in water.
 - (6) Gain acceptance from CVM for the biodegradation study on MT.
- Oral presentations were made Saturday morning by a variety of speakers on a number of topics which are listed below, many of which are based on the Center's White Papers which are available at <http://ag.ansc.purdue.edu/aquanic/ncrac/wpapers/wpapers.htm>.
 - ▶ NCRAC Overview - Ted Batterson
 - ▶ Status Reports
 - Economics/Marketing - Bill Nelson
 - Yellow Perch - Jeff Malison
 - Hybrid Striped Bass - Anita Kelly for Chris Kohler
 - Walleye - Bob Summerfelt
 - Sunfish - Joe Morris
 - Salmonids - Ron Kinnunen
 - Wastes/Effluents - Steve Yeo
 - Tilapia - Anita Kelly
 - Aquaculture Drugs - Roz Schnick
 - ▶ USDA/CSREES Update - Gary Jensen, National Program Leader for Aquaculture

- Saturday evening the Board approved and set funding levels for several different activities/projects based on a prioritized list by the IAC presented late Saturday afternoon. The Board's decisions were conveyed to everyone Sunday morning. They were as follows:
 - (1) Up to \$50,000 for a MT target animal safety study.
 - (2) Up to \$60,000 for work on Aqui-S.
 - (3) \$10,000 for support of Roz Schnick's position as the National Coordinator for Aquaculture New Animal Drug Applications (NADAs).
 - (4) \$2,500 for development of a Marketing white paper.
 - (5) Up to \$225,000 for a 3-year Regional Aquaculture Extension Specialist project. This project would be developed using a Project Review Committee (PRC).
 - (6) Development of a 2-year "base" Extension project predicated on a needs assessment conducted under the direction of Joe Morris, Associate Director of NCRAC and head of Extension Programming.
 - (7) Up to \$170,000 for a Largemouth Bass nutrition project looking at cost-effective diets to grow fish from ¾ lb to market size. This project would be developed using a PRC.
- In regard to the drug-related activities on MT and Aqui-S, they would be coordinated and overseen by Roz Schnick, the National Coordinator for Aquaculture New Animal Drug Applications. All of the drug-related activities would be "fast-tracked" so that efforts may start as soon as possible pending USDA approval.
- On Sunday morning the IAC and TC drafted problem statements and objectives for the drug-related activities, the Regional Aquaculture Extension Specialist project, and the Largemouth Bass nutrition project as well as identified the six members for those projects having PRCs.
- Problem statements, objectives, and PRC members where applicable are as follows:
 - MT Target Animal Safety Study

Problem Statement: MT is needed to manipulate the gender of a variety of fish (e.g., tilapia, hybrid striped bass, trout, percids, sunfish, and esocids) cultured in the North Central Region (NCR). The National Aquaculture NADA Coordinator and the Industry Advisory Council of NCRAC identified the remaining data requirements that are impeding an original NADA approval for MT in tilapia. Once a NADA approval is gained for tilapia, other species can be added through supplemental NADAs that are relatively easy to gain in comparison to an original NADA. In particular, one technical section that remains to be addressed for an original NADA approval in tilapia is a target animal safety study on MT in tilapia. When this study is completed, the researchers need to submit this data package to the Investigational New Animal Drug (INAD) Coordinator (Auburn University) for transmission to CVM for the agency's acceptance as complete. The researchers will be required to answer any questions regarding this study until it is acceptable to CVM.

An initial NADA approval should be gained for the use of MT to manipulate gender in tilapia if CVM accepts as complete the (1) revised product chemistry technical section submission from Rangen, Inc. based on the more accurate analytical method in feed and stability studies that are underway at the University of Wisconsin-Madison, (2) revised environmental assessment from Auburn University based on the development of a more accurate analytical method in water and a biodegradation study that are underway at the University of Wisconsin-Madison, (3) target animal safety technical section on tilapia submission from Auburn University based on the target animal safety study on tilapia to be performed by an entity to be identified, (4) efficacy technical section submission from Auburn University, and (5)

Freedom of Information (FOI) summaries for efficacy and target animal safety technical sections under preparation at Auburn University.

After the initial NADA approval for tilapia is approved, supplemental NADAs for MT could then be obtained more easily for such species as trout, hybrid striped bass, percids, sunfish, esocids, and ornamental fishes.

► *Objectives:*

1. Interact with CVM to determine the study design and protocol.
2. Submit the study protocol to CVM and gain acceptance from CVM for the study protocol.
3. Conduct a target animal safety study using MT on tilapia according to CVM guidelines for a target animal safety study in feed under good laboratory practices (GLP).
4. Write the final study report and submit to CVM through the MT INAD.
5. Provide progress reports to NCRAC.
6. Gain acceptance from CVM for the target animal safety study on MT in tilapia.

► **AQUI-S®**

Problem Statement: There is no legally approved anesthetic with a zero withdrawal time (i.e., time between last treatment and potential consumption or release) available for the many procedures that are used in aquaculture production or fishery management. AQUI-S®, an efficacious broad-spectrum anesthetic that contains isoeugenol as the active ingredient, has the potential to cover the need for a zero withdrawal anesthetic in the culture and management of fish and shellfish. AQUI-S® is an excellent candidate for an approval because it has the research results, an active drug sponsor, and research and development plans in place. To gain the Food and Drug Administration's Center for Veterinary Medicine (CVM) approval of any drug, researchers must prove that it is safe and effective for its intended purpose. The technical sections required for a new animal drug application (NADA) approval include (1) product chemistry, (2) environmental safety, (3) mammalian safety, (4) human food safety, (5) target animal safety, and (6) efficacy. A consortium of interested private and government agencies are providing funds to address the above technical section requirements of AQUI-S® for aquaculture and fishery management purposes.

The strategy to gain NADA approval for all fish starts with an initial approval for salmonids, both freshwater and marine. The only funds needed to complete the initial approval for salmonids involves the human food safety research to demonstrate to CVM that this drug can be declared and approved as a zero withdrawal anesthetic. The funding is needed for the purchase of radiolabeled material for a total residue depletion study on rainbow trout (surrogate for all salmonids). These data will ensure that no residues of concern will be present in edible tissues of salmonids produced for direct consumption through commercial aquaculture or for immediate release to rebuild depressed commercial, recreational, or subsistence salmonid fisheries.

Without this study, the approval process stops. The anticipated impact of an approval of a zero withdrawal anesthetic will be great on all commercial salmonid culture and salmonid restoration efforts. Researchers and producers will be able to use, for the first time, a legal, safe, and effective anesthetic that allows immediate consumption or release for all salmonids, and other fish can be easily added to the approval after that initial approval.

- ▶ *Objectives:*
 1. Purchase radiolabeled material in conjunction with sponsor contributions and through the sponsor, AQUI-S New Zealand, Ltd.
 2. The material will be used by the Upper Midwest Environmental Sciences Center, La Crosse, Wisconsin to complete a pivotal total residue depletion study (TRDS) on rainbow trout as a surrogate for all salmonids.
 3. Results of the TRDS to be submitted to CVM to help complete a portion of the human food safety technical section for an initial approval of AQUI-S® on salmonids.
 4. Provide progress reports to NCRAC.

- ▶ National Coordinator for Aquaculture NADAs

Problem Statement: The National Coordinator for Aquaculture New Animal Drug Applications (National Aquaculture NADA Coordinator) position depends solely upon voluntary monetary contributions from agencies, organizations, and companies. Contributions have dropped to the point where the position is now at three-quarter time, and these contributions are in danger of dropping the position below that. This is at a critical time when the National Aquaculture NADA Coordinator is finalizing the NADA packages with the sponsors and guiding the sponsors through the approval process for a number of drugs of priority for public and private aquaculture. Without her involvement, the approval process would stop. In addition, critical projects have been started that need coordination (e.g., 17 α -Methyltestosterone (MT) and AQUI-S®).

The National Aquaculture NADA Coordinator provides valuable experience and essential services to facilitate aquaculture drug approvals by the U.S. Food and Drug Administration, Center for Veterinary Medicine (CVM). Because of the unique, non-governmental nature of the position, the National Aquaculture NADA Coordinator is well positioned to provide assistance that cannot be obtained through any other source. CVM strongly supports the position and its independence. The National Aquaculture NADA Coordinator is the only person who has an established, working relationship with all the current sponsors of drugs and who is in the position to complete the final processes toward approval.

- ▶ *Objectives:*
 1. Complete the initial or supplemental NADA packages for a number of drugs that are close to approval (e.g., chloramine-T, copper sulfate, florfenicol, formalin, hydrogen peroxide, and oxytetracycline).
 2. Continue to coordinate and oversee ongoing projects that will lead to aquaculture drug approvals (e.g., MT and AQUI-S®).
 3. Continue to draft white paper documents on big-picture issues, such as solicitation of additional funds for drug approval research, minor-use minor-species legislation, hatchery effluent issues, and antimicrobial resistance issues.
 4. Continue to give presentations at conferences and meetings to advocate to as wide an audience as possible the benefits of supporting those involved in trying to gain CVM-approval of drugs for use in aquaculture.
 5. Provide written and verbal progress reports to NCRAC.

- ▶ Regional Aquaculture Extension Specialist

Problem Statement: There are a limited number of extension full-time equivalents (FTEs) in the region to address the needs of the aquaculture industry. To reduce this problem, a regional aquaculture extension specialist is needed. The goals for

- the extension specialist will be: (1) provide leadership for the aquaculture industry in the North Central Region (NCR), and (2) enhance information transfer.
- ▶ *Objectives:*
 1. Provide leadership for the aquaculture industry in the North Central Region (NCR)
 - ▶ Liaison among current Extension specialists
 - ▶ Liaison among state associations and the industry
 - ▶ Provide leadership training for the industry as requested
 2. Enhance information transfer
 - ▶ Work with the Aquaculture Regional Extension Facilitator (AREF) Project and NCRAC Associate Director's Office
 - ▶ Develop appropriate Extension deliverables (i.e., hands-on workshops, fact sheets, CDs, newsletters, Web sites)
 - ▶ Disseminate information (i.e., telephone, mail, electronic...)
 - ▶ *Project Review Committee:*
Curtis Harrison (IAC), Bill Lynch (IAC), Bill West (IAC), Joe Morris (TC), Bill Nelson (TC), Bob Pierce (TC)
 - ▶ Largemouth Bass
Problem Statement: Growers in the North Central Region (NCR) have not been able to consistently raise largemouth bass to 1.5 lb in ponds on formulated feed only. It appears that the problem lies in the slowing of growth when the fish reach about 0.75 lb in size. Culturists currently provide live forage to increase growth to 1.5 lb, which is a very expensive option. It has been speculated that this problem is nutritional, but that has not been verified. A cost-effective formulated feed is needed to potentially overcome this cultural growth barrier.
 - ▶ *Objectives:*
 1. Assess diet and environmental factors that affect growth and health of largemouth bass raised to 1.5 lb in ponds with formulated feed.
 2. Develop cost-effective finisher diets that enhance health and growth of largemouth bass.
 3. Conduct a region-wide workshop on raising largemouth bass to 1.5 lb in ponds based at least in part on the results of the research activities in Objectives 1 and 2.
 - ▶ *Project Review Committee:*
Bill Blythe (IAC), Brad Farber (IAC), Paul Wills (IAC), Tommie Crawford (TC), Jeff Gunderson (TC), Gary Whelan (TC)
 - The problem statement and objectives for the Regional Aquaculture Extension Specialist and Largemouth Bass projects will be developed into Calls for Statements of Interest that will be distributed by mail in early March to all those in the region that are in the NCRAC database. At the same time, it will also be posted on the NCRAC Web site at: <http://ag.ansc.purdue.edu/aquanic/ncrac>.