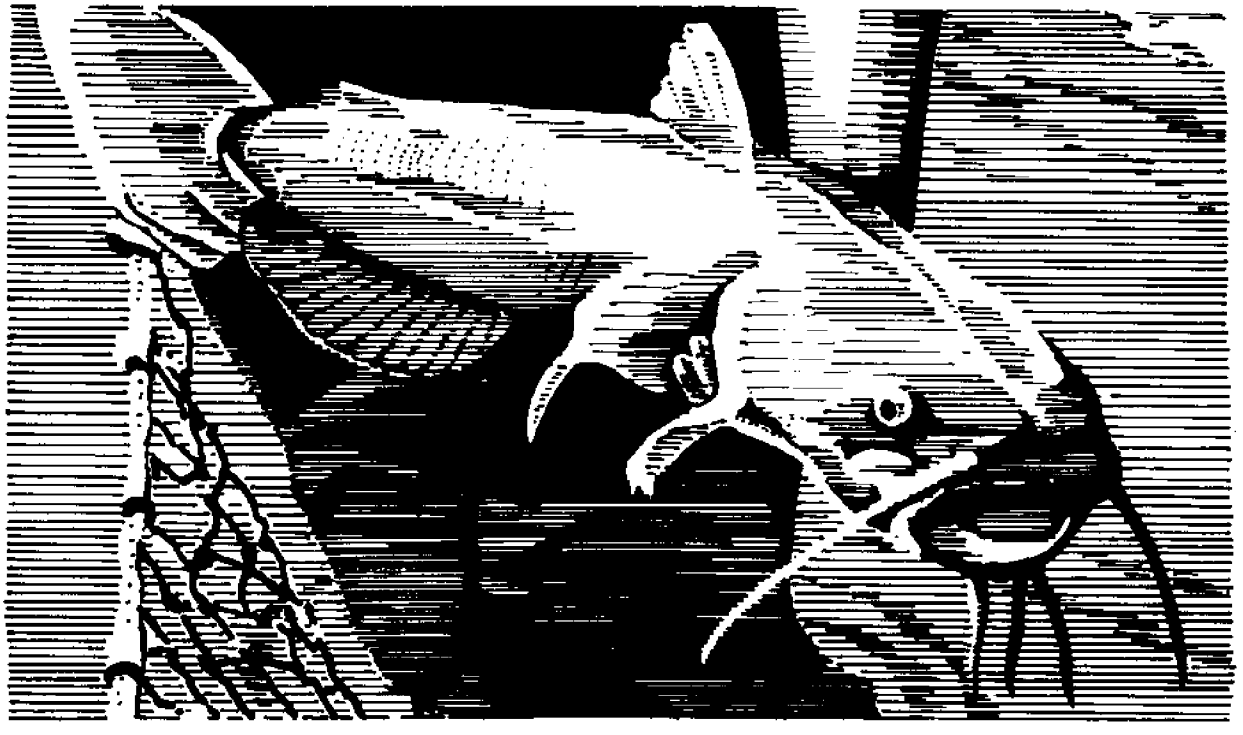
The Alabama Cooperative Extension Service
AUBURN UNIVERSITY

Southern Regional Aquaculture Center

SRAC

AQUACULTURE PRODUCTS SAFETY FORUM



PROCEEDINGS

June 1993

PROCEEDINGS

of the

AQUACULTURE PRODUCTS SAFETY FORUM

February 2-4, 1993
Auburn University Hotel and Conference Center
Auburn, Alabama

Forum Chairman,
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Completed in partial fulfillment of:

Southern Regional Aquaculture Center
Food Safety and Sanitation for Aquacultural Products - Microbial
Aquaculture Products Processing Forum
C.S.R.S. Grant Numbers
89-38500-4516 and
90-38500-5099 (Prime)

June 1993

This publication was supported in part by grants from the United States Department of Agriculture, Numbers CSRS 89-38500-4516 and CSRS 90-38500-5099 (Prime), sponsored jointly by the Cooperative State Research Service and the Cooperative Extension Service.

Issued in furtherance of Cooperative Extension work in agriculture and home economics, Acts of May 8 and June 30, 1914, in cooperation with the U.S. Department of Agriculture. The Alabama Cooperative Extension Service, Auburn University, Ann E. Thompson, Director, offers educational programs and materials to all people without regard to race, color, national origin, sex, age, or handicap and is an equal opportunity employer.

ACKNOWLEDGEMENTS

It takes the support and assistance of many individuals to plan, develop, and conduct a professional meeting like the **Aquaculture Products Safety Forum**. This **Proceedings** of the Forum likewise required a significant amount of input and assistance from many people. Grateful appreciation is expressed to the following individuals and groups:

- **Mr. Charles G. "Jerry" Shepherd**, Director of the Southern Regional Aquaculture Center (SRAC), for originally developing the concept of the Forum, and for providing project funding.

- **Dr. Ann E. Thompson**, Vice President for Extension and Extension Director at Auburn University, for having the vision to host the Forum on the Auburn Campus, and for providing matching funds.

- **Dr. E. Wayne Shell**, Professor and Head of the Auburn University Department of Fisheries and Allied Aquacultures, for his advice, guidance, and encouragement throughout the Forum project.

- **Dr. James I. Jones**, Director of the Mississippi-Alabama Sea Grant Consortium, for his continuous long-term financial support of my Advisory/Extension efforts in seafood technology, and for allowing me the flexibility to expand into this new area.

- **Dr. William Hosking**, Coordinator of Marine Programs at the Auburn University Marine Extension and Research Center, for his guidance during Forum proposal and budget preparation and for gaining the administration's support and approval.

- **Dr. R. O'Neal Smitherman**, with the Auburn University Fisheries Department and **Mr. Gary Jensen**, with the U.S.D.A., who helped flesh out many Forum details.

- **Dr. Larry Wilson**, with The University of Tennessee and **Dr. George Lewis**, with The University of Georgia, for their overall leadership with the Microbial and Residues Working Groups.

- **Dr. W. Steven Otwell**, of The University of Florida, for his assistance with development of the Forum proposal.

- **Dr. Thomas R. Elliott**, Extension Assistant Director at Auburn University, and his staff, particularly **Tasha J. Worden** and **Donna J. Wynn**, for making the many business details associated with the Forum proceed with ease.

- **Ms. Elizabeth E. Peel**, Facilitator at the Auburn University Hotel and Conference Center, and her staff, for assuring that all on-site necessities during the Forum were adequately addressed.

- **Ms. Karen J. Belcolore**, our Secretary at the Auburn University Marine Extension and Research Center, for her expert work in preparing this Proceedings manuscript for publication and for taking care of the endless array of details associated with the Forum project.

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INTRODUCTION

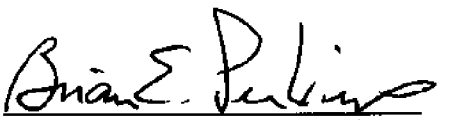
The history of the Aquaculture Products Safety Forum and this resultant Proceedings actually predates that rainy day in Memphis during February 1991, when I first presented my proposed ideas to the Southern Regional Aquaculture Center (SRAC) Technical Committee. It goes without saying that I could not have responded to SRAC's Request for Proposals if Jerry Shepherd, the SRAC Board, and the Technical Committee had not made the decision to address the subject of aquaculture products safety.

The first objective of the Forum project was to draw upon expertise from the Southern Region to review, interpret, condense, and report the current information related to the food safety of aquacultured products. Judging from the caliber of participants listed in the Appendix of this Proceedings, there can be no doubt that the requisite talent was present to accomplish that objective.

The second objective was actually two-fold. On the one hand, SRAC wanted to provide an appropriate forum for its Microbial Project principal investigators to present the results of their first-year projects. In addition, they desired to include industry, agency, and academic representatives from outside the SRAC "fold" to cross-pollinate and, thereby, expand our horizons. A brief review of the diversity and quality of the individual papers that comprise this Proceedings demonstrates that objective was likewise met.

The third objective was to develop a consensus of opinion about possible directions the Southern Region might take with future aquaculture product food safety and sanitation research and extension efforts. The Microbial and Residues Working Groups' reports found near the end of this Proceedings should provide an invaluable tool in that regard. The Working Groups not only defined intermediate and long-term needs and objectives, but charted appropriate courses to achieve those goals.

It is my hope that this document will prove useful to those working in this rapidly evolving and exciting area of aquaculture product safety. I likewise hope that we can come together again at some point in the future to share our accomplishments, note our progress, and, if need be, readjust our course to provide the aquaculture industry with the appropriate degree of support.



Brian E. Perkins
Forum Chairman and
Editor of the Proceeedings

WELCOME TO AUBURN UNIVERSITY

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Thank you. As I looked at the list of people here, I think some of you may have been to Auburn before. It is always a pleasure for me to welcome a group like this to Auburn and to Alabama. On behalf of President Muse and all of us here at Auburn, we hope you will enjoy your stay in the conference center. Mayor Dempsey would say "We are real glad you are here, and remember we have shopping in Auburn and Opelika," and "Our name is from Oliver Goldsmith's *The Deserted Village - Auburn, the Loveliest Village of the Plains.*"

We are a land-grant institution. One of our distinctions is that Auburn is the largest university in the state. There are approximately 21,000 students here and 6,500 at Auburn University at Montgomery. We have about 13 colleges and schools on campus. At lunch, if you have a speaker's podium, it will have one of the Auburn seals on it. Our seal represents Instruction, Research, and Extension. We do support the interchange of these educational efforts. We have outstanding graduates from astronauts to fisheries experts. You know more about research because fisheries is one of our nationwide and world-known programs. We have alumni all over the world from that area as well as other areas. We have over 100,000 living alumni somewhere in the United States at this point in time.

The reason Brian wanted me to give you a welcome was to give you a little bit more about Auburn University's spirit, philosophy, concept, and belief that the extending of knowledge to application for use has for education. I will start by talking about this conference center. The idea was introduced by President Jim Martin, one of his ten goals. That goal was to have a visible symbol of the importance of life-long learning, professional learning, and learning for a life time on campus. We consider this conference center as a laboratory and symbol of useful professional life long learning. Over 150,000 individuals have taken part in conferences and workshops at this facility.

The Vice President's office and the Alabama Cooperative Extension Service seek to identify the state as our campus and even broader. Our major focus is to be user friendly with constituents who want to take part and to facilitate the exchange of education with people.

We have campus and field offices connected through an ACENET computer electronic mail system.

The other part of being accessible is by linkage through uplinks and downlinks from campus to county offices. When Brian and I started talking about this forum, we were hoping you would have some of your colleagues, students and others elsewhere seeing some of the experiences you are involved in this week. I don't know how many of you may or may not have watched the *Trouble in the Henhouse* live uplink from this facility this week. This uplink from here by public television was broadcast throughout the state. This exchange reached more people than we could put in our conference auditorium. The delightful part is viewers could tape for later review. We have the Cooperative Extension Service and University Extension units that are primarily connected with colleges and schools; and stand-alone units, such as the conference center. The Satellite office, Center for Governmental Services, and Continuing Education assist with conferences and workshops on and off campus.

We are delighted to have you. The sounds and symbols of Auburn are many. We are one of the few institutions that has two mascots, the eagle and a tiger. We also have a War Eagle yell. The major idea is we believe in the learn model, that is land-grant stands for Teaching, Research, and Extension putting everything together for knowledge use, and for "R" is resources to get it done and "A" is an attitude and spirit of Auburn that permeates everyone who has a part in an Auburn conference. People like you help us to have the largest alumni community in the nation and world. We have networks of working together and exchanging communication and fostering the type conference that you all are about here. I know Brian and Dr. Shell can assist you with your needs. We thank you for being in Auburn.

AQUACULTURE PRODUCTS SAFETY FORUM OVERVIEW

Dr. E. Wayne Shell
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Thank you Brian. I really don't know if we planned that we would have this conference on Groundhog Day, but I heard this morning that they expect the groundhog in Pennsylvania to see his shadow and go back into his den. I would hope that after we finish this conference that we won't go back into a den somewhere, but we will get busy and try to do something about this aquacultural product safety matter.

Let me also add a word of welcome. I know it takes a lot of time out of busy schedules, and we certainly are pleased that you would take time to share with us some of your ideas about product safety. Without your support we couldn't do it. You have to get people to work together to put on something like this.

When you put on a conference like this, even with only 35 or 40 people involved, it still takes an awful lot of effort. Let me start at the beginning to thank some people who have really helped us put this thing together. First, Jerry Shepherd whose leadership through SRAC helped to develop this idea and finally get it approved by Washington. Vice President Thompson, of course, who you just heard from, provided a substantial amount of matching funds for the forum for the development of the proceedings, which we will talk about a little later; and for the teleconference, which we will have later on. She will also provide a substantial amount of money to match the SRAC of USDA funding.

Neal Smitherman at Auburn and Gary Jensen at USDA helped flesh out this idea of having this conference. They provided input in what they thought should be included in the program. Larry Wilson of the University of Tennessee and George Lewis of the University of Georgia are serving as the breakout leaders in this conference.

We thank Steve Otwell of the University of Florida for assisting with the development of this proposal. He was extremely helpful in getting it together and getting it submitted. And finally the Conference Center staff. They do an awful lot of things for us to help put on a conference like this.

For many years, those of us familiar with the product quality assurance program of the poultry and livestock industries have known that sooner or later we were going to have to do the same thing. It's just a matter of time until the consumers demand that we have an equally strenuous or maybe more strenuous program in aquaculture products.

So, we were pleased about three years ago to see that SRAC had made the decision to develop a major initiative on the quality of aquaculture products. We knew that it needed to be done, but were never able to see how all this might be pulled together until SRAC took the leadership position. We knew that Tom Lovell would probably be involved in this project because he has worked in seafood processing at LSU, and he has continued to work in that area some since he has been at Auburn.

But we also have another resource that is kind of unique for the Fisheries Department, and that is to have a Sea Grant group as an integral part in our Department. We have done a lot of work through Brian Perkins in seafood processing and seafood product safety. So it seemed to be a natural to have Auburn involved and to request part of the SRAC program funds to be allocated to the development of a forum where we can share the information about the programs that are already in place in seafood processing and then to provide us with information and guidance on where we might go with our program in aquaculture products in the future.

This situation reminds me of a story about a coon dog man we have in Lee County. He's well-known far and wide for his coon dogs and also to be able to sell a coon dog to anybody. No matter who it is, if he decides he's going sell that dog, you might as well go ahead and buy it, because he's going to sell it to you. Well he advertised a coon dog, the best in the world, at a good price. And, one of the professors on campus went out there to look at his dog to see whether he wanted to buy it or not, and the man showed him the dog and he went through all his tricks and all those things he had learned to do. Then he says "You wait until

tonight and I'll take you out hunting with that dog," and so they went hunting way down in the swamp on the edge of the Chattahoochee River. Late at night, the dog finally hit on a trail and started off yowling across the swamp and the owner said "He's after a big one, let's go follow him." So they followed the dog for about a half hour and finally came to kind of an open place in the swamp and there was a little ole sweetgum tree about 30 feet high out in the middle of that clearing out there, and there wasn't a leaf on that thing. The dog went up to the base of that tree and started yowling and just making a tremendous noise. The coon dog man went up there with the professor and the professor says "What in the world kind of dog is this? There is no coon up in that tree; you can't sell me a dog like that," and the coon dog man said "Professor, you got it all wrong, this dog is so good that it has beat the coon to the tree." So, that's what we want to do now. We want to beat the coon to the tree in this meeting.

We know sooner or later we are going to have a mandatory program. If we can get ahead of the coon and beat him to the tree, I think we will be waiting for it when he gets there and this will be to our advantage in this whole process. If we can beat the coon to the tree, we are going to be ahead of the game, and certainly we are going to build a lot of confidence in our consumers.

We have four objectives in the forum. The first thing we are going to do is receive information on the current status of aquaculture product safety. We are going to do this essentially in a lecture format, and we have invited several people to talk to you about various aspects of this subject. We will get reports on industry-based quality assurance programs, an overview of regulatory and compliance matters relating to aquaculture product safety, and research updates from the SRAC microbial contaminants project. We will have sessions this morning and tomorrow morning to receive this information in lecture format.

The second objective of the forum is to provide participants with an opportunity to discuss, in breakout sessions, material presented during the morning sessions. In the discussion sessions we will have this afternoon, we want to discuss types and levels of microbes and residues associated with aquaculture products, discuss goals of levels of microbes and residues and contaminants in our products, and then try to develop some kind of a mechanism or some kind of recommendations for achieving those desired goals.

The third thing that we would like to do is to collect the shared information for the development of a formal proceedings. All of this material is going to be recorded. We encourage those of you who are making formal presentations or lecture presentations to get your manuscript to Brian Perkins by the first of March.

Finally, the fourth objective is to obtain information and some video materials to be used in a 30-45 minute satellite teleconference later this year. These are a lot of things to be accomplished in such a short period of time, but if we are going to try to beat that coon to the tree, now is the time to get started. So, let's have at it Brian.

SOUTHERN REGIONAL AQUACULTURE CENTER: PHILOSOPHY AND FUNDING PROCESS

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Thank you, Brian. Speaking on behalf of the Southern Regional Aquaculture Center (SRAC), we feel this Aquaculture Products Safety Forum provides an opportunity to actively involve Sea Grant, Land Grant and other institutions and agencies in cooperative efforts to address an area of utmost importance to the aquaculture industry. This type approach was the intent of legislation passed to establish the Regional Aquaculture Centers. What I would like to do is make a few comments giving background on activity that brought us to this point.

In the Southern Region, to develop the SRAC programs we followed structural procedures used by the land grant systems in our region and this has been helpful. Regional Aquaculture Center programs were established to foster cooperative and collaborative efforts between Sea Grant, 1862 and 1890 Land Grant institutions, and other organizations that have demonstrated aquaculture research and extension expertise. Non-profit private research programs are also eligible to participate in these programs. In each of the five regions, it takes from one to two years for priorities to be identified and steering committees to subsequently develop regional projects using the work group method.

Each Regional Aquaculture Center has a Board of Directors, a Technical Committee and an Industry Advisory Council. SRAC priorities are identified by our Industry Advisory Council and Technical Committee and these are jointly recommended to the Board of Directors which makes final selection of priorities to be funded.

When food safety issues were first discussed by our Industry Advisory Council, the concern most producers expressed was the need for additional assistance to get needed antibiotics and similar materials approved for use in aquaculture production. Regional Center programs alone don't have the level of funding to achieve this, but it was felt that certain research and extension efforts could provide useful information to assist in this area. Initially, this priority was presented with a rather general approach to encompass several segments of food safety. Our Board requested we separate efforts into the more specific categories, "residues" and "microbial." After much work by our steering committees and work groups, we now have active projects underway in each of these important areas. While these projects were very difficult to put together, I feel they're now moving along well, and useful information will be obtained. Activities of these two projects will be the main focus of this Forum.

Brian and Dr. Shell, we appreciate all the efforts everyone here at Auburn has made to develop the program for this Forum. In my opinion, the key challenge to those in attendance as well as to all participants working on the SRAC projects is to clearly identify benefits achieved from conducting the Forum as well as the work outlined in the projects. Our Steering Committees realized from the beginning that we really don't know exactly how much information is currently available on aquaculture food safety and that there may be gaps in the information that is available. Hopefully, from this Forum and other activities in the projects, we will be able to identify deficiencies and move forward with providing information to correct these.

Obviously, initial SRAC projects focused primarily on catfish, which constitutes about half of U. S. aquaculture. We are beginning to see other species included in our projects now, and future projects will very likely consider work on potentially successful emerging species. We have initiated 14 SRAC projects and 7 of these have been completed, most of which have produced a number of publications. The SRAC extension projects have been very productive and the resulting fact sheets and videos are requested from throughout the U.S. and other countries. SRAC publications are distributed nationwide through the Regional Center network. Also, the National Ag Library currently distributes approximately 1500 copies per month of these SRAC publications. Each year SRAC prepares a four-page project summary which is distributed to Extension

specialists throughout the region for distribution to their clientele. In addition, a detailed Report of Progress for all active SRAC projects is also prepared and distributed. Thus, there are several means by which results from our projects can be made available to the aquaculture clientele.

As mentioned earlier, our major challenge from this conference will be to identify significant accomplishments from these efforts. Each year I coordinate congressional testimonies for the five Regional Centers, and it will be very helpful to be able to provide documentation of successful results.

Brian, I appreciate the opportunity to make these comments and look forward to visiting with members of the Forum for the next few days. Thank you.

SOUTHERN REGIONAL AQUACULTURE CENTER: MICROBIAL PROJECT UPDATE

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When Brian asked me to make a presentation at this meeting, my first question was, "What do you want me to talk about?" He responded by suggesting that I give an up-to-date report on the progress of the project. And now as I look at the program, I realize that the meeting itself will be the best update, since many of the project participants are on the program. So, basically what I want to do is to give you a little background information and a few highlights of our first year's work. But before I begin, I want us to recognize Brian and the yeoman's job he has done in putting everything together. He has done a lot of planning, so I expect the next two days will be very productive.

The title *Food Safety and Sanitation for Aquacultural Products: Microbial* came as a result of downsizing and subdividing a larger project proposal which was designed to address the entire issue of aquacultured product safety. After several discussions, it was evident the task needed to be split into "microbial" and "residues" components. The microbial portion seemed to be a little bit more defined, so we were able to get started a little bit quicker. The basic frame of reference at which we are looking is after the product gets to the processor, and from that point to the consumer. George's project on residues has a broader base, and he will fill you in on that.

Basically, the microbial work was proposed as a three-year project. We had interested people that came to the original work group session, and from those, 21 people committed as participating scientists; these scientists represent 9 institutions. The total project is $570,000 over the three-year period. We got started oficially on April Fool's Day last year (hopefully that doesn't relate to the way the work has been going) and are scheduled to run through March 31 of 1995.

There are four main objectives in the project. If you will look at the project, you will see them numbered 1a - 1e, and 2, 3, and 4. The first objective was to gather all relevant food safety data from outside the industry to establish a database from which to work. Steve Otwell (Florida) is compiling all of this and has already made considerable progress. The second part of the objective was to

get "all knowledgeable persons together" and assess the current status of aquacultured food product safety. This forum is a result of that effort, and getting this off the ground has been a very long and hard job. Again, I commend Brian and all the folks that have been instrumental in putting this together.

That basically is what we have been doing during Year 1. Now along with the Year 1 activities, we have had other folks that have been gearing up for research studies for the remaining objectives. Some will be working on the identification and detection of those pathogenic and spoilage organisms that we find on aquacultural products. Others will be looking at different types of reduction methods, whether in modified atmosphere packaging or mechanical/ chemical means of reducing bacterial loads.

Another area is to look at the microbial quality of catfish, crawfish, and trout throughout the processing operations. There will be food safety HACCP audits to see if this approach would be cost effective and result in increased product safety. The HACCP audits will be done in a catfish and a crawfish processing situation in Years 2 and 3.

In addition to the research activities, we will have an outreach and dissemination (Extension) objective. There will be published articles, fact sheets, and videos in addition to the products from the Forum and database searches. It is essential that we get the information out to our clientele so it can benefit the industry. There will also be a bibliography (sort of a wrap-up) finalized in Year 3 that will compile everything that comes out of the project. In addition to the hardcopy, we are going to have a satellite teleconference on food safety issues; Brian is putting that together for later this spring.

As you can see, it has been quite a busy year in terms of our activities. I would just like to point out that I think this Forum is going to be the benchmark for food safety information. People are going to look back and say that the Forum at Auburn was when we got a real grasp of the existing food safety issues and where the gaps are. Hopefully, by defining those gaps, we will be better prepared to plan for future research studies.

I'll be glad to address any questions, although many of them probably will be addressed in subsequent papers and presentations. And then in our breakout sessions, we will be doing some planning and additional information gathering and dissemination for the group so we can move through the next two years of the project. Thanks again, Brian, and I am looking forward to the remainder of the meeting.

SOUTHERN REGIONAL AQUACULTURE CENTER: RESIDUES PROJECT UPDATE

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The Residues Project was authorized in late September. We have begun, but it's just three or four months into the project. I don't have a lot of good, solid information to convey to you. I hope that a year from now we do.

This project is a three-year effort concerning residues associated with species aquacultured in the Southern Region. The concept really developed about three years ago, but I won't go into that. Larry and Jerry already mentioned the difficulties we had getting the Residues and Microbial Projects going.

The Residues Project involves the University of Georgia, Florida, Auburn, Tennessee Tech, Mississippi State, Louisiana, and Texas. The project includes both research and extension components. Funding is at $356,000 for three years. Basically, there are six objectives.

The first objective involves Mississippi State taking the lead to look at existing residues databases. There is some information available on pesticide residues, metal residues, and some other residues in catfish. In the early discussions, there was a perception that some of that data may not be useable because it does not differentiate between wild fish and aquacultured fish. While we feel this is the case, we don't know whether or not that perception is true at this point. We really haven't gotten in and finished sorting and sifting through this issue. Therefore, early on in the project, we will be looking at what these databases are and whether they are relevant to what we are trying to do.

The second objective, which is currently underway, is to develop protocols for sampling so that we have consistency among the institutions. Charlie Santerre shared the draft of those protocols with me, and I have them with me today. The draft protocols are also being mailed to the participating institutions for review. The species that we are investigating are the channel catfish, rainbow trout, and crawfish. There was a lot of discussion early on about including other species. The reason we are not looking at other species at this time is due purely to expense.

We feel there is a need to look at some of the other aquaculture species. We won't argue with that, but when you consider the costs of residue analyses, you can appreciate that limited funds can only do so much. We hope that this work will help focus or indicate if there is a need to include other species. That may be, but it remains to be seen. That is the primary idea behind the second objective.

The third objective, which I think is very important, is to develop educational materials for quality assurance and food safety in aquaculture. We were criticized a little bit on this. I know that the Microbial Project is also developing educational materials. Ours, of course, will be slanted toward the residue issues. The reason that we were not very specific in our objectives for developing educational materials was because the results of the Residues Project will help us to focus on the audience for whom those materials need to be developed, and where and how those materials need to be sent. There are some, I realize, that can and will be generic in their development, but others will result from the project itself. Most of them, of course, will be directed to producers.

The fourth objective, which is really part of a current trend, is to develop a recordkeeping system for farmers. It will include both a hard copy and a computerized system. This effort will start in Year 2, and I believe it will be an adaptation of existing recordkeeping systems. I am not sure how generic our proposed recordkeeping system can be. For example, rainbow trout are primarily cultured in raceways, whereas catfish and crawfish are raised in ponds. There will be some differences, but we'll try to keep it as generic as possible. Possibly, we will end up with two or three recordkeeping systems, depending on the species.

The fifth objective is to determine the fate of residues from the farm through the processing plant to the consumer. Again, I don't perceive any problems here, but I may be wrong. We really haven't gotten far enough into this project to decide whether we do or not.

The final objective, which is another open-ended objective, is to conduct additional sampling near the end of the project to fill in the holes, to fill in the gaps. We don't know if we will have those holes or gaps, but inevitably we will. The intent of this objective is to improve our database toward the end of the overall Residues Project.

That is where we are. Like I said, the protocols are going out. The project is really just beginning to get on its feet and go, being just three or four months into it. I'd be happy to answer some questions.

FISHERIES, AQUACULTURE AND DRUGS/CHEMICALS: A PERSPECTIVE FROM THE CENTER FOR VETERINARY MEDICINE

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Good morning! And thank you for inviting me to meet with you this morning. During the past two years I have had the opportunity to work closely with representatives of Federal and State agencies and the aquaculture industries on animal drug issues. FDA's interaction with these groups has increased substantially over that time as a result of the Agency's concern over the use of unapproved animal drugs in aquaculture production facilities, in general, and in food fish facilities, in particular. The overall response of these parties has been positive and constructive. Across the board, there has been a genuine effort to do what is necessary to position aquaculture so that facilities and firms will be able to be in full compliance with all FDA requirements. We recognize that this has not been an easy time for you, that there are still many unknowns that remain to be addressed, and that a final resolution of many problems is not yet at hand.

This morning I would like to briefly review some of what has been accomplished during this time and to provide some insight into what you may expect from FDA in the coming months. My remarks primarily will address the enforcement side of FDA's regulation of animal drugs.

Let me begin by talking about the Agency itself. The FDA's mission is to assure the American consumer that foods are pure and wholesome, safe to eat and produced under sanitary conditions; that drugs and medical devices are safe and effective for their intended uses; that cosmetics are safe and made from appropriate ingredients; and that labeling and packaging for all these products is truthful and

not deceptive. The guidance on how to do this is provided by the Federal Food, Drug, and Cosmetic Act (FFDCA) and its accompanying regulations. The Act was passed by Congress and the regulations were promulgated by the Agency through public rulemaking procedures. The law and regulations clearly define what is required and/or permitted regarding products that fall under the FDA's jurisdiction. Animal drugs, animal feeds, animal feed additives, and veterinary devices are among the products that are subject to these requirements. The FFDCA applies to government agencies as well as private industry.

The claims made for a product (or the way in which it is actually used) determine whether it is a drug. By definition, a drug is an article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man and other animals; and articles (other than food) intended to affect the structure or any function of the body of man or other animals.

According to the Act, a new animal drug is unsafe unless there is in effect an approval for that drug; and its labeling and use conform to an approved new animal drug application. An approval can only be obtained by submitting to FDA data showing, among other things, that the drug is safe and effective for its intended use. Safe means the product is safe for the animal, the person administering the drug, persons eating food products derived from the animal, and the environment. Effective means that a drug product will do what it is claiming to do consistently and uniformly.

As you are undoubtedly aware, there are five drug products approved for use in aquaculture species. That is the good news. The bad news is that there are many disease conditions and many species for which there are no approved compounds available.

How to deal with those situations is the dilemma facing the industry and the FDA. On one side, is the fact that Congress has passed laws which make the use of unapproved compounds illegal. The primary emphasis of these laws is on drugs used in food producing animals. On the other side, is the concern that a very strict interpretation of the requirements of the FFDCA could severely affect the ability of both public and private aquaculture facilities to function or even to continue to operate.

The FDA chose a course of action that it feels protects public health without placing an unreasonable burden on either public or private aquaculture. The Agency wants all aquaculture production facilities to be in full compliance with all FDA requirements, but we realize that we are dealing with a complex problem. Therefore, a multifaceted approach has been implemented.

Part of the reason that individuals may have may have been using unapproved products is because of misinformation that has been available. To help correct this situation, the Agency has been utilizing an intensive educational initiative to reach all segments of aquaculture production to provide accurate information on proper drug use and the status of compounds permitted for use in aquaculture species. The Working Group on Quality Assurance in Aquaculture Production was established to assist in this effort. The Working Group is composed of representatives from the Federal Government, the states, industry and academia. Examples of Working Group activities are a coordination of efforts to develop:

Educational initiatives;
Data to support animal drug approvals;
Industry quality assurance programs.

Another reason that individuals may have been using unapproved compounds is that some of the compounds are innocuous and commonplace. They meet the definition of a new animal drug but no one ever submitted data to support a formal approval because financially they could never recover their investment by selling an approved product. These are compounds like sodium sulfite and calcium chloride. To address this situation, the agency uses a policy known as regulatory discretion to allow the use of some compounds without requiring an approved new animal drug application. A decision to exercise regulatory discretion must be supported by information related to the use of the compounds as well as the nature of the compound themselves. The following compounds have been designated of low regulatory priority if they are used under certain specified conditions: Sodium Chloride, Sodium Bicarbonate, Sodium Sulfite, Carbon Dioxide Gas, Acetic Acid, Calcium Chloride and Povidone Iodine, Calcium Oxide, Garlic, Ice, Onion, Potassium Chloride, and Magnesium Sulfate.

The Agency adopted its compassionate INAD policy which allows producers to have access to some unapproved compounds under certain conditions. One aspect of this policy is the decision to allow producers access to investigational compounds if they participate as clinical investigators.

The Agency encouraged both public and private aquaculture representatives to prioritize the compounds for which approvals are needed. CVM staff scientists then reviewed this list and ranked the compounds as to the amount of data needed to support an NADA approval. In this way resources can be devoted to those compounds that are in the greatest need and require the least data to obtain formal approval. A list of those compounds is available today.

The Agency has encouraged the various industry production organizations to develop their own Quality Assurance Programs. Adoption of such programs will assist their producers in implementing proper drug use practices on their forms and recording data when using an investigational drug as a clinical investigator. Both Federal and State hatchery personnel would benefit from the adoption of similar guidance.

That is a brief summary of some of the things which have been occurring. As the Agency addressed each of these areas, questions arose as to how various issues would be handled. I would like to share with you the position the Agency has taken on a number of these issues.

An especially significant issue is the question as to whether a particular species is "food" or "nonfood." Enforcement policies for food and non-food species and populations are likely to differ in important ways because the public health considerations for the two groups are different.

A species or population will be considered "food" if it is **reasonably likely** to be consumed for food either by humans or food producing animals. This excludes the occasional or incidental use of a nonfood species for food. A major discriminator will be the traditional or known use of the species involved. We will use recognized classification lists wherever possible for this purpose.

If a species is a food species, then it will, as a general rule, be considered food at all life stages. This has been and will continue to be a controversial issue, because in aquaculture "life stages" encompasses eggs, free-swimming states, etc. Our concern is that, to routinely classify particular stages as "nonfood" would arbitrarily eliminate from human food safety evaluation even the most persistent (and potentially dangerous) compounds used in these stages. On the other hand, a situation by situation evaluation (which we are willing to make) would permit the Agency to conclude that use of a particular drug in a particular species for a particular life stage is, for example, of low regulatory priority. Or, we may conclude that, for purposes of a new animal drug application, very little or no human food safety data are required.

We have looked at four categories of fish from the standpoint of food/nonfood classification.

Baitfish - Following the "reasonably likely" guideline, we have identified three species of baitfish that we have tentatively classified as **nonfood:** Golden Shiners, Fathead Minnows and Goldfish. Additional species will be added to the list as their baitfish classification is documented. However, I should caution that a given population of baitfish, even a population consisting of one of the listed species, could subsequently become classified as "food" depending on its intended use.

Ornamental and Aquarium Fish - In general, such fish are considered to be **nonfood fish.** However, we are not aware of a comprehensive list of species that are considered to be ornamental or aquarium fish. In addition, there are apparently some "crossover" species, i.e., species that are sometimes used as ornamentals and in other instances may be consumed by humans. Such species, or specific populations of those species, are likely to be classified as "food."

Endangered Species - By law, endangered populations may not be harvested. Currently, the majority of endangered populations consist of species that are ordinarily considered to be nonfood species.

Broodfish - Based on the information that we have received as to their use, we have concluded that, in general, broodfish of food species should be considered food. However, individual populations of broodfish might be considered "nonfood" on a case-by-case basis.

We will continue to review our positions with respect to food/nonfood distinctions, and are willing to consider making revisions based upon scientific data, and documentation as to industry practices. Please note that unless the Agency specifically identifies a compound for a particular use as "low priority" or it is used under an INAD exemption, it needs to be formally approved by FDA. Just because a drug is only intended for use in a nonfood fish doesn't mean it is free to be marketed without approval.

Historically, the Agency has focused its animal drug regulatory activities on the manufacturer and distributor of the drugs, rather than on the individual who uses the drugs. For drugs administered through feeds, the Agency has also maintained a program to inspect feed mills. On-farm regulatory visits have generally been limited to investigations resulting from reports of illegal residues found by USDA in meat and poultry products.

However, there are some things that are unique to aquaculture that might cause the Agency to focus its regulatory attention more directly on the producer:

The lack of a drug residue monitoring program similar to that for meat and poultry;

The relatively few approved drugs for aquaculture and the resulting pressure for aquaculture producers to use unapproved drugs; and

The use in aquaculture of general purpose chemicals that are not labeled for drug use, making regulation at the manufacturer/distributor levels difficult.

Nevertheless, the Agency hopes to be able to continue to emphasize education and voluntary quality assurance programs for producers, with regulatory actions being limited to those brought on a "for cause" basis. (The Agency has conducted several onsite surveys of aquaculture producers during the past three years, but these visits were for the purpose of gathering information, e.g., as to drug use, and were not for regulatory purposes.)

At the present time, the primary emphasis of FDA's regulatory efforts in aquaculture will be to limit the manufacture and distribution of unapproved drugs to those for which the Agency has little or no regulatory concern or to those used within the terms of an INAD exemption. However, if we are not able to control the problem this way and farmers misuse drugs, we might have to focus more on producers.

Determination of enforcement priorities for individual drugs will be based on a number of factors. As I mentioned, there are five drug products approved for use in aquaculture species. There are 13 additional compounds which have been designated as having low priority for enforcement purposes, if they are used under specified conditions. All other drugs will be expected to have approvals, or be used under provision of an investigational new animal drug application. The manufacture, distribution or use of unapproved compounds will be subject to regulatory action based on a case-by-case review. Criteria that will be used to determine regulatory priority for taking such actions include:

Scientific/Medical: This includes human food safety (toxicity and residues), target animal safety, effectiveness and environmental concerns. Certain factors, such as suspect carcinogen status, will cause a drug to be identified as high priority for regulatory action.

Intended Use: Species, indication for use, dosage, life stage when used, etc.

Approval Status of the Active Ingredient: If, for example, FDA has withdrawn approval of a drug for human food safety reasons, we would place high priority on actions against the marketing of drugs containing the same active ingredients. Also, unapproved generic versions of approved drugs have high priority.

Misuse Potential: The potential for diversion, for example, to human use and the potential for harm from such diversion.

Examples of drugs that we have identified as high priority for regulatory action include: Chloramphenicol Nitrofurans Malachite Green
Fluoroquinolones Quinolones
Central nervous system stimulants and depressants

Perhaps you have heard or read about FDA's Extra-Label Use Policy. According to the Federal Food, Drug, and Cosmetic Act, if a new animal drug is used for an unlabeled purpose, it may be deemed unsafe and in violation. "Extra-label use" refers to the actual or intended use of a new animal drug in a food-producing animal in a manner that is not in accordance with the drug labeling. This includes, but is not limited to, use in a species or for indications (disease or other conditions) not listed in the labeling, use at dosage levels higher than those stated in the labeling, and failure to observe the stated withdrawal time. The

Extra-Label Use Policy permits veterinarians to prescribe approved drugs in a manner that is not in accordance with the drug labeling under ceratin specified circumstances. This policy applies only to licensed veterinarians.

Another issue that I would like to address is that of pesticides which may have a concurrent benefit that would meet the definition of a drug use. FDA has taken the position that if a registered pesticide is being use properly [i.e., the labeled conditions in fact exist in the facility at the time the pesticide is used, and the compound is not misued under the requirements of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)] FDA will not object to that proper use even though the pesticide may have a potential, incidental, concurrent drug use.

If a registered pesticide is not being used properly under FIFRA and also has a potential drug use, then FDA may consider regulatory action. If a compound that is not registered as a pesticide (or not exempted from registration as a pesticide) is promoted or used both as a pesticide and a drug, regulatory action will be considered.

A final area I would like to discuss today is that of communication between FDA and the aquaculture community. I believe, and I hope you agree, that in the current era good communication between the aquaculture community and regulators such as FDA is absolutely essential. Or philosophy at the Center for Veterinary Medicine is to be as open and forthright as we can, consistent with our mission as a regulatory agency.

We believe in two-way communication. In aquaculture, especially, we need to be educated about the industry, just as the industry needs to learn about our regulatory requirements. To accomplish this we have:

Had two consultants spend a total of eight weeks with us last summer - Dr. O'Neal Smitherman of Auburn University and Dr. Pete Taylor of the USFWS Laboratory in Marion, Alabama;

Have had a number of staff members visit aquaculture facilities, both public and private;

Made arrangements to have two additional consultants during this year - a cold water species expert, as well as an ornamental species expert;

Tried to appear on as many programs, such as this one, as we could;

Developed an aquaculture mailing list for rapidly disseminating information to all segments of the aquaculture community.

We would like to do more, but we do not have the staff or resources. But YOU can help, and I would like to offer a few suggestions as to how. By YOU, I mean everyone involved in or associated with aquaculture in any way.

- Make every effort to understand FDA's aquaculture policy statements, and communicate them accurately to others.

- Participate when we offer an opportunity to comment on our policy development, and take the initiative to comment or raise questions in other circumstances.

- Provide the Agency scientific and factual information and well-reasoned arguments to support your position.

- Invite us to speak and/or participate in your meetings.

That concludes my remarks. Thank you.

FDA SE REGION FISH AND SEAFOOD COMPLIANCE OVERVIEW - FY'91

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FDA's SE Region covers 8 southern states plus Puerto Rico and the Virgin Islands. Our SE Regional office is located in Atlanta, GA. The region is broken down into 5 districts. Atlanta District covers NC, SC and GA. The Orlando District covers the state of Florida. The Nashville District covers TN and AL. The New Orleans District covers LA and MS. And the San Juan District covers Puerto Rico and the Virgin Islands. As you can see, all of these districts have significant coastal areas.

What I want to share with you is a overview of the seafood activities within the SE Region. Most of the statistical data is based on data compiled from our seafood efforts in Fiscal Year 1991. This is significant because the entire seafood industry in the SE Region was examined for a wide range of problems at that time.

According to our FY'91 data there were approximately 5,516 active seafood establishments identified nation wide. The SE Region's inventory of active seafood firms at that time was 1,643 or about 32% or the national total. The breakdown of the seafood firms in the SE Region was 65% manufacturers, 6% repackers, 3% growers, 20% warehouses, 3% shippers, and 3% others. In addition to the active firms, the SE Region also has a substantial number of firms which did not meet our requirements for coverage, but have the potential for becoming active in the future. These would include firms, usually small firms, that do not currently receive or ship products in interstate commerce, which is a requirement for FDA jurisdiction. These firms would normally be covered by the states.

In FY'91 FDA **nation wide** inspected a total of 3,541 seafood firms, or about 64% of the industry. The SE Region inspected basically 100% of their seafood firms, plus some reinspections. Our total for FY'91 was 1,728 inspections or about 49% of that total number of inspections made nation wide. The breakdown by districts shows:

ATL-DO with 272 inspections
NSV-DO with 232 inspections
NOL-DO with 834 inspections
ORL-DO with 404 inspections
SJN-DO with 35 inspections

In addition to FDA inspections, there were 801 inspections were done for FDA by state officials nation wide. 155 of these inspections were done in the SE Region. Our region is second only to FDA's Pacific Region which had 406 inspections completed by state officials.

What is more important than just the numbers of inspections is the results or findings of these inspections. FDA classifies their inspections in a variety of categories and I have combined them into 3 major groups to try and simplify them for you. The first is NAI or No Action Indicated. These are the firms where the investigators did not find significant observations or violations requiring further follow up. Of the seafood firms inspected nationally, 2,288 or 65% of them were classified NAI. The SE Region classified 1,164 or 67% of the seafood firms we inspected as NAI. This means that approximately 2/3rds of the seafood firms across the country are doing business under acceptable conditions and many of these are doing business under outstanding conditions, with good sanitation and good control of their processes!

The second group is that portion of the industry that had limited problems. These would be firms where some significant objectionable conditions or violations were documented but were judged by our compliance staff to be conditions where the firms, through voluntary action, could and most likely would correct the problems themselves. Of the seafood firms inspected nationally, 1,049 or 30% of them were classified in this group. In the SE Region 494 or 29% were in this group.

The third group is the bad actors. Those firms determined to be in violation of our laws our operating under violative conditions that either require official action by FDA to get the conditions corrected or require immediate follow up. Of the seafood firms inspected nationally, only 98 or 3% of them were classified in this group. And only 13 firms or .8% of the seafood firms in the SE Region fell in this group !

Those are real small numbers, 3% nationally and .8% in the SE Region, but the problem is this third group is where FDA expends most of their efforts! Generally we have to reinspect these firms, sometimes several reinspections, and these are indepth inspections with extensive sample collections. The follow-up for just one violative firm can easily take several hundred hours of inspection time and several hundred hours of laboratory and compliance review time. In dollars, your tax dollars, it can easily be thousands of dollars in sample costs, analytical supplies and salary for the FDA employees.

What is clear from an inspectional standpoint is that the violation rate is low for the seafood industry, including the seafood firms in the SE Region. The next question is what kind of things were wrong in the firms where violations were identified. With a limited review of the inspection reports the major problem areas appear to be poor employee practices leading to product contamination; filthy or insanitary conditions; time and temperature abuses; misuse of chemicals (primarily STP and sulfites); and economic problems such as short weight and overglazing.

Nation wide there were 2,326 samples of domestic seafood collected during FY'91. The SE Region collected 914 domestic seafood samples or about 39% of the national total. 110 seafood samples were found violative by SE Region laboratories but this does not relate directly to the number of samples collected in our region because samples are frequently sent to laboratories in other FDA regions and vice versa. Decomposition heads the list with the violative samples, followed by filth problems exhibited through E. coli and fecal coliform contamination. Exclusive of oysters, the primary health hazards found in domestic products were in Listeria and histamine contamination. In oysters there are continuing problems with the Vibrios and in illegal harvesting from closed waters, although these would not necessarily be revealed through sample analysis. Crabmeat, shrimp and oysters led the list of violative products, followed by mahi mahi and fresh tuna. There were 31 different domestic seafood products found to be violative.

So far the figures have only address the domestic seafood firms. What did FDA do with imported seafood during this same time period? To start with let me give you a brief overview of how FDA approaches imports. The paperwork for all lots of imported food, including seafood, is routinely reviewed by FDA. Importers are required to file papers for each entry with FDA before Customs will let the products into the country. We either examine the lots when they reach the dock, this is called a Wharf Examination; we collect samples from the lots; or we let the products enter the U.S. without examination. Keep in mind that imported products must always be in compliance with FDA laws and regulations even though they may have been examined, sampled, or just released without examination when they entered the county.

In FY'91 a national total of 4,094 wharf examinations were made of seafood products and 7,116 import samples of seafood products were collected and examined. The number of import samples collected is 3 times as many as domestic samples. The wharf examinations and sample collections resulted in 3,432 detentions of imported seafood nation wide. The SE Region conducted 278 of those wharf examinations, 1,263 of the samples and had 484 detentions.

Of the 1,263 import samples collected by the SE Region, 198 were found to be violative. Like the domestic samples, decomposition was the most predominant violation, accounting for almost 30% of the violations. A close second was insect and rodent filth (24% of the violations), a problem not frequently found in domestic samples. Labeling was also a very significant problem with imported seafood, accounting for 18% of the violations. The primary health hazards found in imported samples were salmonella and undeclared sulfites and these were found significantly more in imported than domestic samples. Conversely, Listeria and E. coli did not appear as significant problems in imported samples. The imported products most frequently found violative in the samples collected in the SE Region were Shrimp and Lobster. Shark (fins and fillets), crabmeat and canned tuna also made a strong showing. There were 28 different imported seafood products found violative.

In summary, it is obvious from the numbers of inspections and the sample results that most of the seafood industry in this country is doing a good job. It is very important to remember that samples collected and analyzed by FDA generally do not represent a cross section of the products on the market because most of our sampling efforts are selective, that is they are usually collected because

the product was suspect in the first place. This holds for import samples as well as domestic samples. So we need to be very careful not to use the percent of violative FDA samples as an indication of the level of violations in the seafood industry. This would be a significant misuse of our findings.

As the SE Regional Seafood Specialist I feel it is an important part of my job to make sure FDA and the seafood industry are properly represented to the general public. Quite frankly I'm tired of hearing the media and other critics say that no one is inspecting seafood! We all need to work very hard to correct this misconception.

FY91 Data

5,516	Active seafood firms in U.S.
1,643	In SE Region or 31.9% of U.S.

65%	manufacturers
6%	repackers
3%	growers
28%	warehouses
3%	shippers
3%	others

3,541	Seafood Inspections in U.S.
1,728	In SE Region or 48.8% of U.S.

222	Atlanta District
232	Nashville District
834	New Orleans District
404	Orlando District
35	San Juan District

801	Inspections by state officials in U.S.

155	in SE Region
406	in Pacific Region

2,288	Inspections in U.S. classified NAI - 65% of firms inspected
1,164	NAI in SE Region - 67% of firms inspected
1,049	Group 2 in U.S. - 30% of firms inspected
494	Group 2 in SE Region - 29% of firms inspected
98	Group 3 (bad) in U.S. - 3% of firms inspected
13	Group 3 in SE Region - .8% of firms inspected
2,326	Domestic Samples U.S.
914	Domestic Samples SE Region - 39.3% of US (31 dif. products)
110	Violative Samples in SE Region ** selective
4,094	Wharf Exams in U.S.
278	Wharf Exams in SE Region
7,116	Import Samples in U.S.
1,263	Import Samples in SE Region - 198 violative (28 dif. products)
3,432	Import Detentions in U.S.
484	Import Detentions in SE Region

METHOD DEVELOPMENT FOR DRUGS AND OTHER CHEMICALS IN AQUACULTURE PRODUCTS. THE ROLE OF TISSUE DISTRIBUTION AND METABOLISM STUDIES

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The Gulf Coast Seafood Laboratory (GCSL), U.S. Food and Drug Administration (FDA), is located in Dauphin Island, AL. The primary mission of this laboratory is to conduct research on the safety and wholesomeness of fishery products from wild and aquaculture sources. Research areas include investigations of the microbiological safety of seafood, marine biotoxins, chemical indicators of seafood decomposition, and chemical (e.g., drug) residues in aquaculture products. This presentation will review research activities and regulatory concerns regarding drug residues and their determination in aquaculture products.

Research on drug residues at GCSL has three major objectives: (1) to establish the tissue distribution and persistence of residues in aquatic food animals, (2) to establish the pharmacokinetics and metabolism of these compounds, and (3) to provide analytical methodology for residue identification and determination. Most of the aquaculture drug research at GCSL has focused on the channel catfish, a species that represents the largest aquaculture product in the United States. The amount of catfish processed annually in this country has grown from 6 million pounds in 1970 to 457 million pounds in 1992. Other aquaculture species of notable production in the United States are crawfish, rainbow trout, tilapia, hybrid striped bass, and shrimp. In the past ten years, the annual production of farm-raised fish and shellfish in the United States has increased by more than 300%. Despite the advances in aquaculture practices and continued growth of the industry, disease continues to be a major cause of mortality and economic losses in these operations. Consequently, the need for safe and effective therapeutic agents for use in aquaculture has increased.

At present, only five drugs are approved for use in aquatic food animals in the United States. Oxytetracycline first became available for use in 1970. In the mid 1980s, the combination drug sulfadimethoxine/ormetoprim was approved by FDA. Two additional chemicals, the anesthetic tricaine methanesulfonate (MS-222) and formalin, have more recently gained approval. Sulfamerazine is no longer available for use. The drug nifurpirinol is approved for aquarium (non-food) fish only. These approved drugs can only be used under very specific conditions and indications (e.g., disease application, species, administration rate, withdrawal time).

The number of drugs available for aquaculture use in the United States has not kept pace with the growth of the industry. Thus, the potential exists for the illegal use of unapproved drugs as well as misuse of approved compounds. There is also concern about drug residues in imported aquaculture products. Drugs that are available in many countries are not allowed in the United States. For example, in Japan, approximately two dozen drugs are approved for use in aquatic food animals compared to five in the United States.

The public health concerns associated with the use or misuse of aquaculture drugs and chemicals may be grouped under two categories: toxicological concerns for residues and concerns regarding the development of pathogen resistance. These concerns have been the impetus for the development and validation of analytical methods for monitoring drug residues.

The development of analytical methods for drugs and other chemicals in aquatic food animals requires some knowledge of their tissue distribution and metabolism. Tissue distribution and metabolism studies are valuable in that they identify sites of localization, accumulation, and persistence of chemical residues. They identify the appropriate analyte to serve as a marker for total residues in the edible flesh. Additionally, the ratio of marker residue to total residues (parent compound and metabolites) at a given withdrawal time can be determined. Unless proven otherwise, the FDA considers the toxicity of a drug to be due to all of its residues and not just the parent compound.

To conduct tissue distribution and metabolism studies, one must first develop procedures for dosing and sampling of animals. Aquaculture drugs are typically administered in the feed or through waterborne exposure. In the laboratory, dosing with radiolabeled chemicals often increases sensitivity and

facilitates identification and determination of metabolites. Ideally, techniques are developed for the collection of blood, urine, and other tissues and fluids. By monitoring blood or plasma levels of the parent compound, pharmacokinetic models can be developed for describing and predicting drug levels in the tissues. Urine and bile are useful excretory fluids for examining metabolism; however, the edible flesh is the primary focus from the food safety standpoint. At GCSL, surgical techniques have been developed to enable serial collection of blood and continuous collection of urine in the channel catfish (Stehly and Plakas, 1993; Plakas et al., 1992a). These techniques are intended to decrease disturbance to the animals during sampling and to minimize the number of animals needed in a given study. We have used these techniques to conduct tissue residue and metabolism studies and to develop analytical methods for a variety of chemicals, including drugs (Plakas et al., 1988; Plakas et al., 1990; Plakas et al., 1991a), toxins (Plakas et al., 1991b), and pesticides (Barron et al., 1991; Plakas et al., 1992b) to which cultured animals may be exposed.

Research with the mycotoxin aflatoxin B_1 (AFB_1) provides a good example of the value of tissue residue studies. AFB_1 is a potent toxin and known carcinogen in some animals. It is a common feed contaminant and has been found in fish feeds. AFB_1 is much less toxic in channel catfish than in rainbow trout and several mammalian species (Patterson, 1973; Jantrarotai et al., 1990). Channel catfish could potentially accumulate higher levels of this toxin than do more sensitive species without any signs of toxicity and thus pose a consumer health risk. We examined the uptake, tissue distribution, and elimination of AFB_1 in the channel catfish (Plakas et al., 1991b). After oral dosing, parent (unchanged) AFB_1 was rapidly absorbed with peak levels in the plasma occurring at approximately 4 hr (Fig. 1). However, elimination was also rapid with a half-life of nearly 4 hr. Tissue distribution studies revealed that AFB_1 and its metabolites (total residues) were accumulated in the hepatobiliary system (Table 1). The muscle had the lowest levels of any tissue analyzed. Despite the large dosage (0.25 mg/kg), residue levels in muscle were below the limit of determination (less than 5 ppb) at 24 hr. Tissue residue data and pharmacokinetic modeling demonstrated that the potential for accumulating AFB_1 residues in the edible flesh of channel catfish through consumption of AFB_1-contaminated feeds was very low. Withholding feed contaminated at or below the tolerance level for 24 hr before harvest would ensure negligible levels in the edible flesh of this animal. To assess exposure of channel catfish to this toxin, the bile or liver would be logical matrices for method development and monitoring.

Oxytetracycline is an approved aquaculture drug for control of certain bacterial diseases in catfish, salmonids, and lobster. After treating salmonids or channel catfish with this drug, a withdrawal time of 21 days is required before harvest. The tolerance of oxytetracycline in the edible flesh is 0.1 ppm. As with many xenobiotics, tetracyclines accumulate in the hepatobiliary system and in the excretory kidney of fish (Plakas et al., 1988). In our studies of tetracycline administered orally to channel catfish, the muscle had the lowest levels of any tissue examined (Table 2). At two days after dosing, the level was 0.1 ppm. Through pharmacokinetic modeling, we predicted the concentration in the tissues under multiple dosing conditions (e.g., 80 mg/kg/day for 10 days, water temperature 27°C). Based on these data, a 21-day withdrawal time would be more than adequate to ensure drug levels below 0.1 ppm in the edible flesh. However, in the salmonids, elimination of tetracycline drugs is much slower than in catfish. For example, in a study with chinook salmon (Aoyama et al., 1991), nearly 30 days were necessary for oxytetracycline levels in muscle to fall below 0.1 ppm after oral dosing (80 mg/kg/day for 10 days, water temperature 8-10°C). Water temperature is one factor involved in the differences in elimination rates between these species. These differences in elimination rates emphasize the need for strict adherence to the indications and limitations of approved drug use.

The combination drug sulfadimethoxine/ormetoprim is approved in the United States for treatment of enteric septicemia of catfish (caused by Edwardsiella ictaluri) and furunculosis in salmonids (caused by Aeromonas salmonicida). The withdrawal time is 3 days in catfish compared with 6 weeks in salmonids. The tolerance is 0.1 ppm. We examined the tissue distribution and persistence of ormetoprim in channel catfish (Plakas et al., 1990). After a single oral dose, muscle levels of ormetoprim declined below 0.1 ppm within 2 days (Fig. 2). However, residues persisted in the skin and were eliminated much more slowly. The persistence of residues in the skin is not of tremendous concern because the skin of catfish is not considered part of the edible portions and is not normally consumed. In rainbow trout, elimination of ormetoprim residues from the edible flesh is much slower than in catfish; after a single oral dose (8 mg/kg), approximately 7 weeks were necessary for residue levels in muscle to decline below tolerance (Droy et al., 1990). Persistence of residues in the skin has also been demonstrated in rainbow trout (Droy et al., 1990). In the salmonids, residues in the skin are of concern because skin is typically consumed as part of the edible portions. Nevertheless, if recommended treatment and withdrawal times are adhered to and monitored, residue levels would probably not exceed the tolerance level in the edible portions in these species.

Several factors influence the fate of drugs and other chemicals in aquatic animals and must be considered in pharmacokinetic and metabolism studies. For example, species differences in metabolism and other physiological factors can influence elimination. Environmental factors, drug formulation, and feed components can influence uptake and clearance. All of these factors can ultimately influence the levels and nature of residues in the edible flesh and therefore affect method development.

Species differences in the disposition of drugs and other chemicals are well illustrated by data on the bioavailability of tetracyclines in fish (Table 3). Bioavailability is simply defined as the amount of a drug in a given dosage form which reaches the systemic circulation intact. In humans, the oral bioavailability of tetracycline drugs ranges from 60 to 80% (Benet and Sheiner, 1985). In several fish species (i.e., carp, trout, and catfish) the oral bioavailability is less than 10% (Plakas et al., 1988; Bjorklund and Bylund, 1991; Grondel et al., 1987). The low bioavailability of tetracycline drugs in these fishes also raises questions about their cost effectiveness. Species differences in xenobiotic disposition are provided in the comparative metabolism and excretion of the herbicide 2,4-dichlorophenoxyacetic acid (2,4-D), which is often used to control aquatic vegetation and may be used in aquaculture production. In the channel catfish (Plakas et al., 1992b), 2,4-D is not metabolized and excreted in the urine in its free acid form (Table 4). In other fish species (i.e., lobster, flounder, and dogfish), there are varying degrees of conjugation with the aminosulfonic acid taurine (James, 1982; Pritchard and James, 1979; Guarino et al., 1977). In southern flounder and spiny dogfish, the taurine conjugate comprised 50% and 98%, respectively, of total urinary residues originating from 2,4-D.

Environmental conditions may have a dramatic effect on tissue levels and the elimination of drugs. For example, in a study of oxytetracyline in rainbow trout, a withdrawal time of 92 days was predicted at 5°C compared with 37 days at 16°C (Bjorklund and Bylund, 1990). In the United States, the use of oxytetracycline in food fish is not allowed at water temperatures below 9°C. The rate of elimination of xenobiotics in poikilothermic animals generally increases with environmental temperature. Salinity can also be an important environmental factor that influences the fate of drugs in fishes. The drug oxolinic acid is eliminated much more slowly from rainbow trout acclimated in freshwater than from those acclimated in seawater (Ishida, 1992).

Chemical form and formulation of drugs influence their disposition in fish and shellfish. For example, there is not much difference in the bioavailability of free base and sodium salt forms of the drug sulfadimethoxine in lobster and channel catfish (James and Barron, 1988; Squibb et al., 1988). However, in trout (Kleinow and Lech, 1988), the bioavailability of the sodium salt form is two-fold greater (63%) than that of the free base (34%). Feed components also can influence absorption of orally administered drugs. In channel catfish (Plakas et al., 1988), plasma levels of tetracycline were higher when the drug was administered in a solution than in a mixture with feed (Fig. 3). Physical form of a drug is another factor that influences bioavailability. Particle size of oxolinic acid influenced its oral absorption in sea bream; bioavailability was enhanced with a micronized preparation (Endo et al., 1987).

The FDA has provided funding support for research on tissue distribution and metabolism of drugs and for the development and validation of analytical methods for drug residues in aquatic food animals. Drugs and chemicals have been prioritized for method development, based on toxicity data, approval status, and known or suspected use patterns. Chloramphenicol, malachite green, and the nitrofurans were given high priorities on the basis of toxicological properties. The tetracyclines, quinolones, and fluoroquinolones were also given high priorities. For most of these chemicals, method development and metabolism studies are presently being conducted or completed under projects sponsored by the FDA.

In validating analytical methods for drug and other chemical residues in food animals, several measures of performance should be addressed, including assessment of the useful concentration range of analysis and associated linearity, method sensitivity, accuracy, specificity, and reproducibility. Method validation typically involves the interaction of several laboratories, including a method development laboratory, incurred residues laboratory, and several evaluating laboratories. Incurred residues, which result from exposure of live animals to a given chemical, are essential for evaluating repeatibility and reproducibility of the method with authentic target tissue.

A gas chromatographic method for chloramphenicol residues in shrimp (Munns et al., 1993) was developed by the FDA Animal Drugs Research Center (Denver, CO). The method provides a good example of the role of tissue residue studies in the validation process. Analysis of control muscle revealed no interfering

compounds. Control shrimp were fortified with chloramphenicol at four levels, ranging from 1 to 10 ppb, with five replicates per level. Recoveries were very high, with coefficients of variation ranging from 4.5 to 5.6%. To generate incurred residues, live shrimp were exposed to 25 ppm chloramphenicol in seawater for 4 hr. They were then transferred to clean seawater and allowed to eliminate the drug for various lengths of time before sampling. At the end of the 4 hr exposure period, residue levels in the tail muscle exceeded 300 ppb; after a 24 hr depuration period, the levels were approximately 5 ppb (Fig. 4). By varying the time allowed for drug elimination, incurred residues of chloramphenicol could be provided to the collaborating laboratories at the concentrations desired for method evaluation. For this method, homogenates containing incurred residues at two levels (i.e., approximately 5 and 10 ppb) were distributed to three collaborating laboratories. Reproducibility and repeatability data obtained by the laboratories were within acceptable limits.

For regulatory monitoring, a confirmatory analytical procedure (e.g., alternative chromatographic method or mass spectrometry) is also required. Mass spectrometry is particularly valuable and widely used because it provides a unique fragmentation pattern (mass spectrum) which is characteristic of a given analyte. Mass spectrometry provided a useful and sensitive tool for confirmation of incurred residues of chloramphenicol in shrimp (Bencsath et al., 1993). The gas chromatographic/mass spectrometric method for chloramphenicol residues in shrimp was subsequently used by FDA field laboratories to monitor imported aquaculture products. Within the past year, chloramphenicol residues have been found in imported shrimp products and these products were denied entry into the marketplace.

In summary, method development is critical not only for the approval of aquaculture drugs and chemicals, but also to ensure the food safety of aquaculture products. Knowledge of the tissue distribution and metabolism is critical in determining the target analyte and target tissue for method development. Tissue residue studies are also valuable for determining drug withdrawal times, evaluating the potential for product contamination, and generating incurred residues at desired levels for method validation.

Acknowledgement

The author thanks Kevin Greenlees, Rick Long, Guy Stehly, and Kathleen El Said for their critical review of this manuscript.

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Table 1. Tissue levels of AFB_1 after oral dosing (0.25 mg/kg) in channel catfish

	Time (hr)		
Tissue	2	4	24
		ppb	
Bile	149	640	2019
Plasma	320	596	32
Liver	246	421	53
Muscle	19	40	trace

Table 2. Tissue levels of tetracycline after oral dosing (80 mg/kg) in channel catfish

	Time (hr)		
Tissue/Fluid	4	24	48
		ppm	
Bile	133.6	999.4	356.5
Liver	16.0	7.9	1.5
Trunk kidney	4.3	3.3	1.0
Plasma	1.9	1.4	0.3
Muscle	0.5	0.7	0.1

Table 3. Comparative oral bioavailability (%) of tetracycline drugs

Drug	Species	Bioavailability
Oxytetracycline	Carp	0.6
	Trout	6
	Human	60-80
Tetracycline	Catfish	1-3
	Human	77

From: Plakas et al. (1988)
Bjorklund and Bylund (1991)
Benet and Sheiner (1985)
Grondel et al. (1987)

Table 4. Comparative metabolism of 2,4-D

Species	% Urinary Residues as: Free acid	Taurine conjugate
Channel catfish	100	---
Spiny lobster	100	---
Winter flounder	90	9
Southern flounder	50	50
Spiny dogfish	1	98

From: Plakas et al. (1992)
James (1982)
Pritchard and James (1979)
Guarino et al. (1977)

Fig. 1. Plasma levels of AFB_1 after oral dosing (0.25 mg/kg) in channel catfish

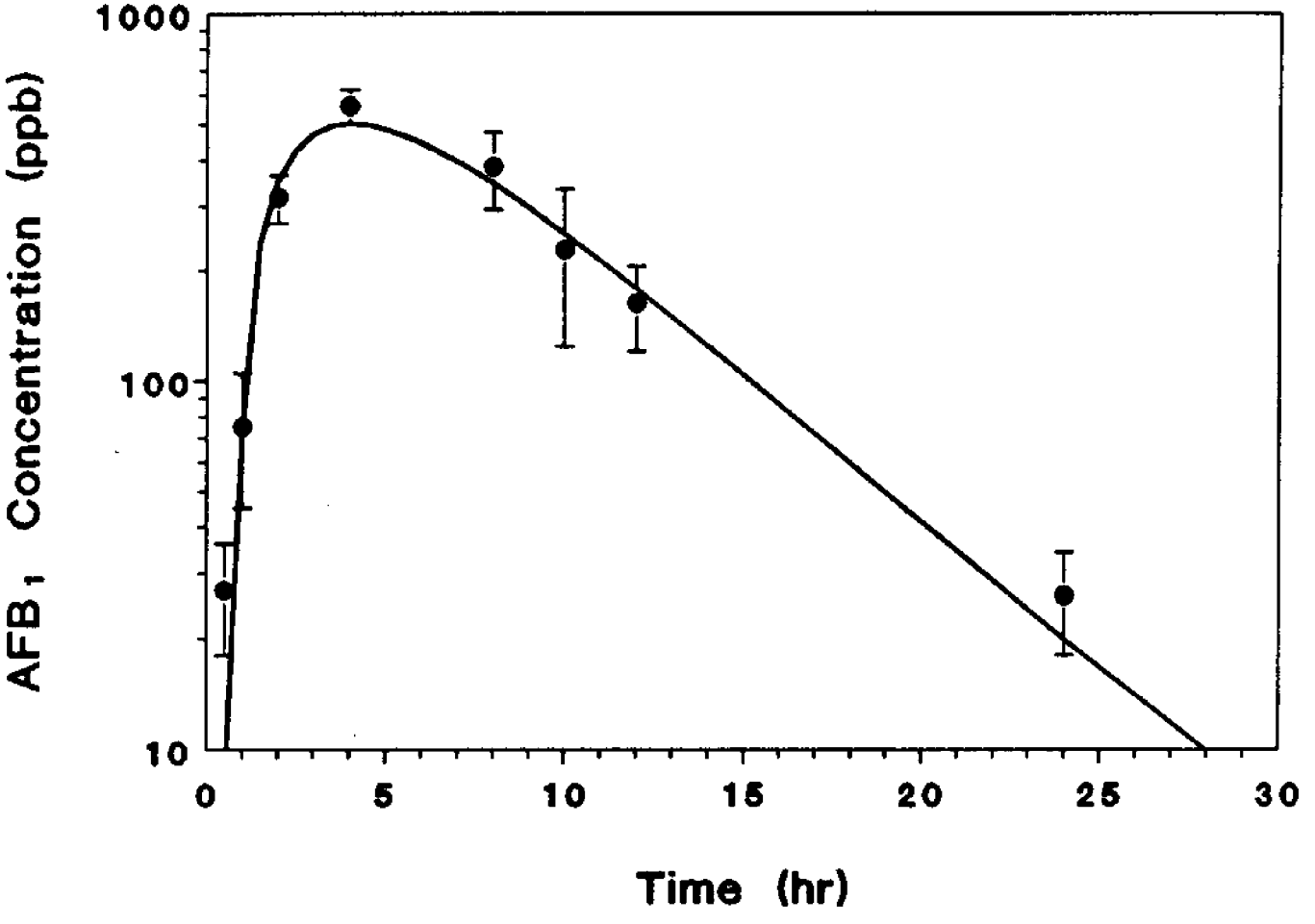


Fig. 2. Tissue levels of ormetoprim after oral dosing (4 mg/kg) in catfish

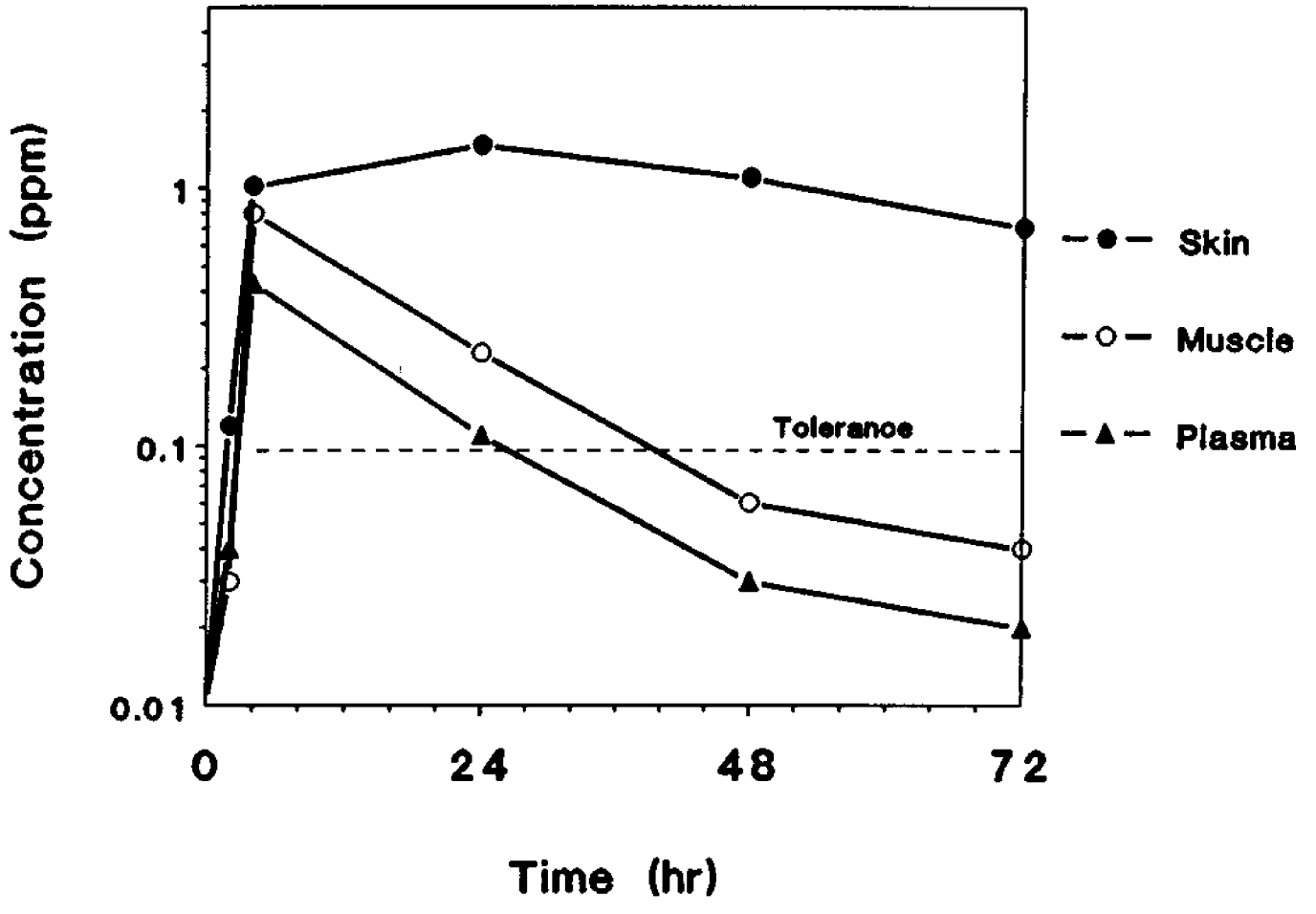


Fig. 3. Plasma levels of tetracycline after oral dosing (4 mg/kg) in catfish

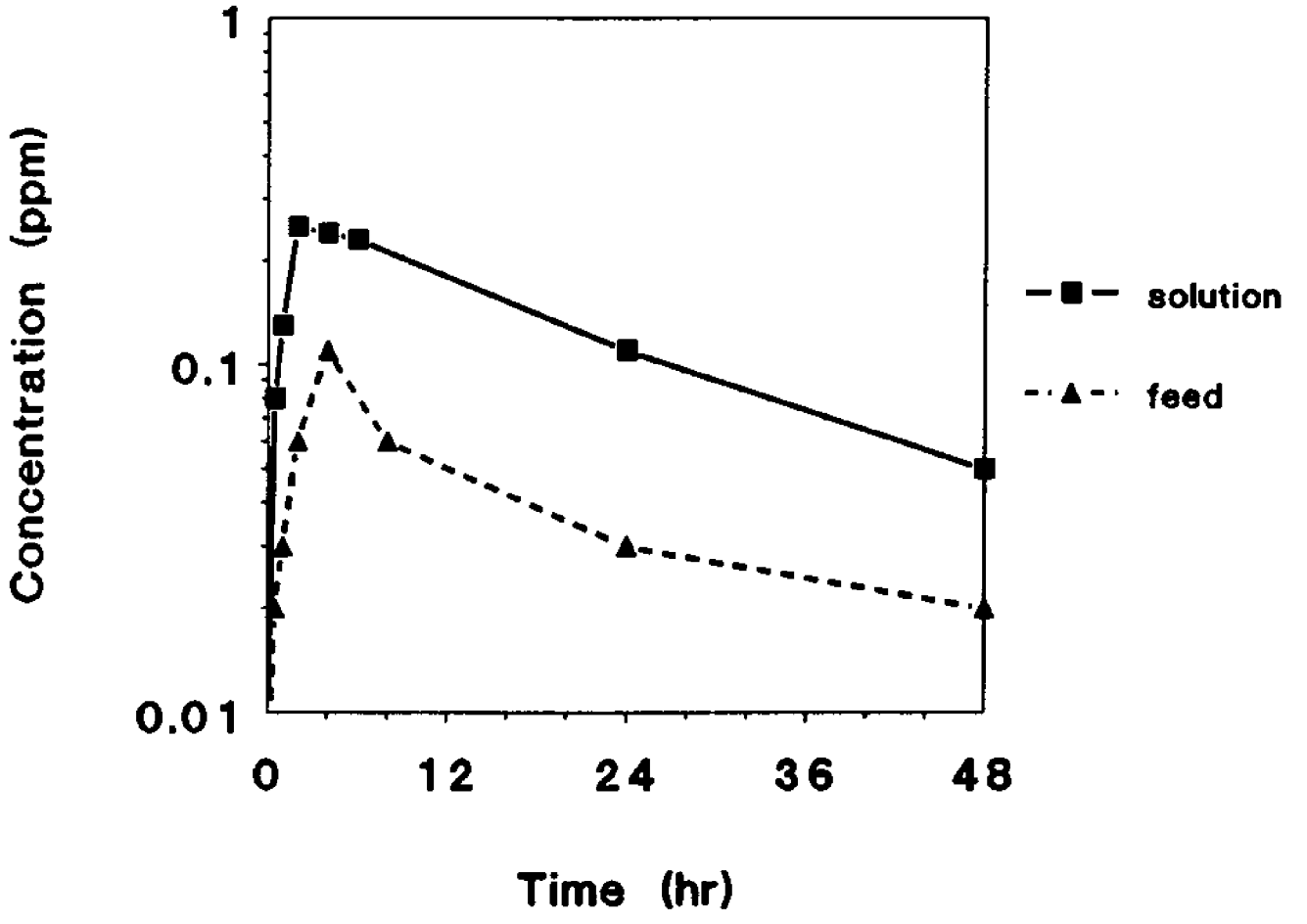
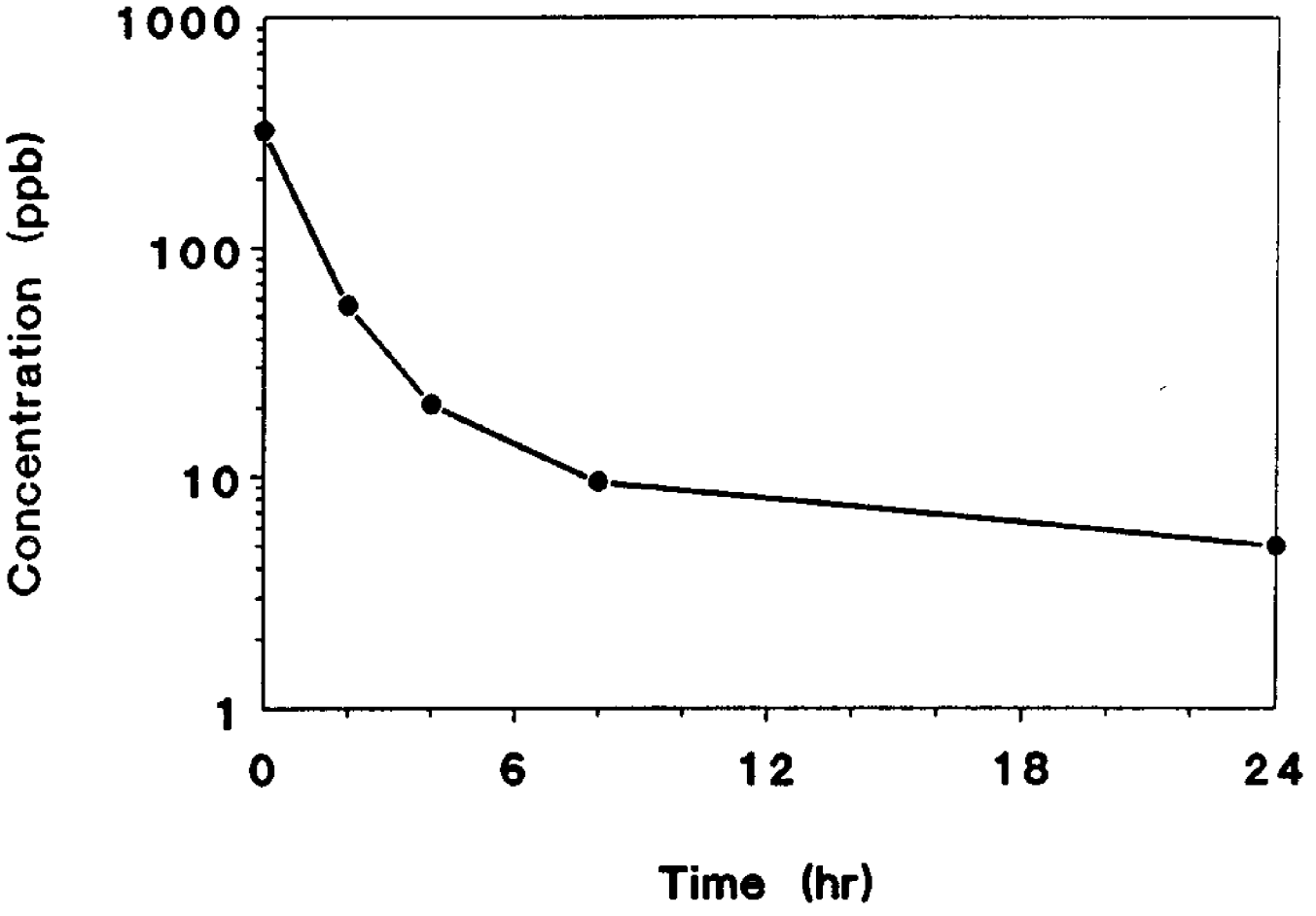


Fig. 4. Chloramphenicol levels in shrimp muscle after exposure to 25 ppm for 4 hr



AQUACULTURE PRODUCT SAFETY: A VIEW FROM THE FOOD SERVICE INDUSTRY

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I just want to thank Brian for inviting me and allowing me to express some of the concerns of the industry, because I will try to voice the viewpoints of the food service industry. However, I would briefly like to tell you a little about Shoney's, Inc. We operate five different concepts under the umbrella Shoney's, Inc. Those are the namesake Shoney's; Captain D's, real seafood, real quick; Lee's Famous Recipe Chicken, a fast food chicken concept; and two specialty restaurants, Pargo's and the Fifth Quarter.

We do sell franchises, and we have approximately the same number of franchises versus company stores in the Shoney's and Captain D's concepts. In the Lee's concept we have a slightly higher than 4 to 1 ratio of franchise stores to company stores, merely because we acquired Lee's in the early 1980s. There are approximately 1800 combined stores of all concepts, company and franchise. We are concentrated mostly in the Southeast region of the country; however, we do have stores reaching to California.

There are many groups or associations working toward the common goal of food service food protection. One of these is the National Restaurant Association (NRA) Quality Assurance Study Group. It includes quality assurance officers like myself from other restaurant companies all across the United States. Several other organizations involving academia, government and industry are the Conference for Food Protection (CFP), the National Environmental Health Association (NEHA) and the Association of Food and Drug Officials (AFDO). The Conference for Food Protection has a memorandum of understanding with the U.S. Food and Drug Administration (FDA), we work with the World Health Organization and the Pan American Health Organization. Currently the CFP is devoted mostly to retail food protection (grocery stores, food vending machines, and the food service/ industry). They are also trying to get the Cooperative Extension Service involved to help spread the word on food safety/food protection education.

One of the other things the industry is doing, we are associated with the joint FDA/NOAA (National Oceanic and Atmospheric Administration) voluntary seafood inspection program. This program involves the Hazard Analysis Critical Control Point (HACCP) plan for seafood, whether it be frozen or fresh product. The program is nearing a closing date and the results should be out by late summer or early fall. The industry is participating in these types of programs, to see which ones work the best to assure overall food safety.

I would like to talk about the six factors needed for bacterial growth; food (high protein), acidity (pH of 4.6 to 7.0), time, temperature (45° F to 140° F), oxygen (presence or absence) and moisture (a_w of .85 or higher) and the multiple barrier concept for controlling their growth. I will talk about some of the issues which are hazards specific to seafood, some of the concerns about the public getting conflicting stories from the media regarding the safety of seafood.

The public's awareness as far as food safety/food protection is way up, due in part to the efforts of the consumer advocate groups. Many of the ways we can address the concerns raised by these groups is through education, such as this forum.

The reason for the multiple barrier concept is to throw as many blockades to bacterial growth as possible. This is especially important to many of you because you will be developing new items or helping others develop new items and as many of these barriers, as are feasible, need to be employed. We cannot change the fact that our product fish (fresh or frozen) is a high protein food with a pH of 6.5, which falls in the middle of the optimal pH range for bacterial growth. However, we can do certain things from a packaging standpoint and for time/temperature controls to assure a safe product. When talking about time/temperature abuse, one of the things which really brought home the importance of time/temperature controls is the shelf life of fresh fish at different temperatures. At 41° F, it takes three days to reach the point of decomposition and at 32° F it takes six days. You can see if fresh fish comes in at 45° F, the current temperature requirement, we have less than a week to use this product before it reaches the decomposition stage.

As I just stated, the current temperature requirement is < 45° F and > 140°F. The seafood pilot project has changed the temperature requirement to < 40° F and > 145° F. The industry is eagerly waiting for the results of the study to determine if these temperatures make a difference in quality and can be adhered

to. The FDA is working on a new food service code where one of the biggest changes may very well be a lowering of the temperature to 40° F. Which may result in new equipment purchases and new equipment purchasing guidelines for the industry.

The presence or absence of oxygen, CAP and MAP (controlled and/or modified atmospheric packaging) is another barrier in the multiple barrier concept. We encourage the development of this type of packaging. Also incorporating moisture or a_w is another method encouraged. One of the many accepted methods is through smoking of the product. Remember the a_w we are concerned with is .85 or higher. Fresh fish has an a_w of .98. As you can see, seafood has many critical areas to watch for, and one of the ways to help control bacterial growth is with the use of the multiple barrier concept. Currently we are using temperature and time as the two most prevalent control factors. Temperature controls will become more difficult as time goes on, due to the Environmental Protection Agency's restrictions on CFCs (chlorofluorocarbons). This is a big concern of the industry and we are diligently working on other refrigerants to use for cooling.

We have special hazards associated with seafoods. Ninety percent of food borne seafood illness is due to ciguatera, scombroid, and shellfish poisonings. Regarding ciguatera poisoning, there are no inspection or purchase guidelines which will prevent this from occurring. This product has been abused further upstream from the restaurant and there is no way of knowing this at the time of purchase. We currently fall under federal, state or local inspection plans now. Don't the inspections need to occur at the point of catch? We are encouraging our suppliers to put HACCP plans in place, because seafood safety must occur at the point of catch until consumption by the consumer.

We are familiar with public outcries on issues ranging from seafood safety to Greenpeace. This is due, in part, to the activities of consumer advocate groups trying to educate the public. The problem stems from the fact these groups all have their special interests and do not convey the entire message. The public must be told and educated that our food supply is safe. I was really surprised by Dr. Becker's speech regarding the number of "bad" aquaculture suppliers found in this region. The percentage is so small, we need to communicate this information to the public. One consumer group will tell you to eat more fish due to the high fatty acid content and then another group talks about anisakiasis, the larvae found in certain species of fish, causing illness when the fish is ingested raw. This is just

an example of the many conflicting reports found. Not to mention, the health advisories associated with eating raw molluscan shellfish (Vibrio, cholera, etc.). However, those individuals who consume this type of product will almost never be persuaded not to consume this product.

We in the industry feel there needs to be a comprehensive product review before it (the product) ever arrives on our doorstep. It must begin at the point of catch all the way to the consumer. A great many of the constraints, currently, are focused on the end purchaser (the food service industry), whereas we are already one of the most regulated of any major food suppliers found. For the most part, we are concerned with doing our jobs right because if we do not, we will not be in business long. I have heard everybody talking about concerns with funding. We get our funding from that customer walking in the front door. If we make people ill, we are not going to have that "funding" coming in. Therefore, we are going to do everything we can to assure product safety.

The industry very much applauds FDA and the U.S. Department of Commerce, and we are very thankful they are including us in the voluntary seafood inspection program. They are trying to get industry input into it to make it a workable program. In this program they are going to use HACCP principles which is a wonderful idea and in theory protects the consumer. One of the problems I have with HACCP-based regulatory programs is no uniformity among regulators, sometimes within their own states. The State of Maryland is a prime example. We submitted one HACCP plan for one county, submitted the same HACCP plan for another county, and it had to be changed. This was in spite of the fact that all menu items were the same. This lack of uniformity makes it difficult for chain restaurants which operate in several states and counties. I know most agencies are working very hard on the uniformity issue and many are making great strides in this area; however, in the mean time we have to work with those conditions.

One of the things I have noticed about HACCP is the fact it seems to be purely microbiological in nature. This totally eliminates chemical and physical hazards. What happens in your HACCP plan if glass is shattered and falls in your food? This issue is not addressed by your critical control points. Another one of these hazards is the risk of dish detergent (or another chemical agent) accidently getting into your food. If HACCP is going to be used, perhaps it should cover more than merely microbiological issues.

One of the biggest problems with HACCP is the documentation, verification and monitoring of things occurring in the back of your house. When these records are kept as part of the critical control plan can they be used against you when the environmentalist comes in and inspects? They jury is still out on this question. This is one of the things which will have to be worked out with time.

Are critical control points being left out because there is no adequate means of measuring them? Hand washing is a good example. How do you monitor if hand washing has taken place? Count the number of paper towels in the trash bin, measure the amount of hand cleanser used, have employees wear buttons which flash when they leave the rest room without washing their hands? There simply is no adequate means to monitor this. The issue of hand washing is addressed through education and management follow-up, not through monitoring.

Remember when developing new products or thinking about changing existing ones, incorporate the multiple barrier concept whenever possible. Control a_w, modify pH, change the packaging, and always keep the product as cold as possible. Education is the key to changing the public's opinion of the food industry (whether it be food processing, food service or retail outlets). We must each do our part to convey the message that the United States has one of the safest food supplies in the world. Many of the regulations including HACCP plans, must be taken throughout the entire industry, from the grower, to the processor, to the consumer.

OVERVIEW OF AQUACULTURE PRODUCT SAFETY

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In keeping with the mission of the Southern Regional Aquaculture Center (SRAC) and the efforts of this conference, I was asked to set the stage for addressing the safety of aquacultured products relative to consumption in the United States. I have chosen a general approach that will supplement many previous presentations on this topic. Likewise, I will lead the audience through a simplified exercise to calculate an informal safety estimate for aquacultured foods in the United States.

Initial reference to production figures, both internationally (Table 1) and in domestic settings (Table 2), reflects the dominance of the catfish industry. This overview focuses on catfish production, but also accounts for the unique safety features associated with crawfish, oysters and other emerging aquaculture species. The food attributes and reported consequences with all species in Tables 1 and 2 will influence the reputation of aquaculture.

Based on 1991 data there were roughly 440 million pounds of whole weight catfish products produced with only 391 million pounds going to processing firms (Table 3). The additional 59 million pounds must have gone through alternative commercial channels. The 1991 wholesale production figure, approximately 200 million pounds, can be used to reflect on amount of product consumed. Assuming a typical serving size of 8 ounces, this wholesale production represents 400 million servings per year. This figure can be used as a benchmark for measuring the safety of the primary U.S. aquacultured products.

Additional information is necessary relative to actual reported foodborne illnesses recorded by the U.S. Center for Disease Control. The CDC is the primary source for annual reported foodborne illnesses. Despite a typical reporting rate of 1 report per every 25 to 100 occurrences, the CDC data still stands as the most reliable source. In contrast to many foods, illnesses due to seafood consumption are more likely to be reported due to the rapid onset of symptoms and typical product suspicion. From 1970 through 1987 reported seafoodborne

outbreaks in the U.S. due to seafood consumption have steadily averaged between 9.2% to 11% of all foodborne outbreaks reported to CDC. During this same period, per capita seafood consumption has increased over 20%. If seafoods and related aquacultured products posed a significant food safety problem then reported illnesses should reflect the increase in consumption. This pattern is not evident. Likewise, in comparing the average annual CDC reported foodborne outbreaks from 1978-87, fish account for only 1.2% of all foodborne outbreaks. This compares favorably against the same averages for beef (4%), turkey (3.7%), pork (2.7%) and chicken (2.6%). These comparisons must also be weighted relative to the average amount of product eaten per person per year. Based on an in-house report (1991) by U.S. FDA and reviewed by CDC, seafoods, particularly fish on a per capita consumption bases, are still considered the safer choice of muscle foods (Table 4).

An estimated ratio of reported illnesses per servings of aquacultured catfish has not been developed. Realizing there are no CDC reported outbreaks due to catfish consumption, one can assume the ratio is smaller, less than one illness per 5,000,000 servings. A conservative guesstimate for catfish could be 1 illness per every 10,000,000 servings.

Now, returning to the estimated 400 million servings of catfish per year, a 1 guesstimated illness per 10,000,000 servings interprets to 40 possible illnesses from aquacultured catfish per year in the U.S. This estimate is unfounded, yet possible, and if it did occur it would involve short term illnesses with mild symptoms typically involving gastrointestinal distress. This analogy is valid realizing no reported illnesses due to catfish consumption and the tendency to not report mild, short term illnesses.

For comic relief one can compare the associated costs involved in assuring aquacultured product safety versus the projected 40 illnesses per year. Accounting for industry efforts, personnel and equipment, regulatory personnel and surveillance, and complimentary research and education programs, a conservative expenditure for assuring aquacultured product safety is $1.0 million per year. These means prevention of one case of possible diarrhea could be valued at $25,000 per case. This estimate offers some entertainment, but it really reflects on the amount of concern expending in assuring aquacultured product safety.

REVIEW OF PRODUCT SAFETY CONCERNS

A review of probable foodborne illnesses which could involve aquacultured products further substantiates the product safety. Starting with natural toxins none of the more common aquatic foodborne natural intoxications involve freshwater species (Table 5). Some of these toxins could involve marine aquacultured products, but there is limited evidence for actually foodborne illnesses vectored through cultured products. Possible occurrence in coastal regions would be site and season specific. Mindful of these natural phenomena, site selection and monitoring programs for toxin precursors could avoid potential problems.

Microbial concerns are more numerous and involved. For simplicity, Tables 6, 7 and 8 represent different categories of microbial concerns. The primary microbial pathogens listed (Table 6) concern bacteria that are noted contributors to annual reported foodborne illnesses. The level of concern for occurrence in aquatic products varies per bacterium and product types. Without detailing all the microbial attributes, it will suffice for this review to note that these common potential microbial pathogens can contaminate fresh and marine water cultured products and pose a potential health threat to consumers. The real concern is for any products destine for raw consumption or any cooked ready-to-eat items that may have been recontaminated. Fortunately, most aquacultured products are cooked before consumption, especially catfish products. Some raw molluscan shellfish may require additional precautions. In fact, microbial concerns for Vibrios and other certain bacteria in raw molluscan shellfish represent a significant limiting factor for the expansion of molluscan culture throughout the world.

The next bacterial group includes potential pathogenic species that are possible or speculative concerns for aquacultured products (Table 7). Although they have not been reported to cause an illness outbreak from aquacultured products they have been found on aquaculture products, and they have caused illnesses with other foods and/or fish. Most of these bacteria are found in freshwater environments. Again concern for these bacteria is significantly reduced by cooking and proper sanitation in processing, handling and storage.

The final 'general' microbial category includes a variety of bacteria species, viruses and parasites (Table 8). Many of these can occur in aquacultured products from fresh and/or marine environments, but they are ubiquitous in terms of our entire food supply, process and preparation settings, and during any period of handling and storage. In other words, their possible or speculative occurrence on

aquacultured products is not unique nor more questioned any more than for many other foods. Some expectations could be noted for certain viruses and parasites, but again most of the general microbial concerns are significantly reduced by proper sanitation in processing, preparation and personnel hygiene, as well as cooking.

Similarly, a review of the chemical concerns vs. aquacultured products reveals a substantial safety record (Tables 9 and 10). The primary chemical contaminants have been found in various aquacultured products depending on the species and location of culture. The contaminant levels encountered or frequency of encounters have not indicated any problems for immediate (acute) or long term (chronic) consequences. The encounters are usually site specific and can be corrected or avoided. Public health advisories on consumption, as used for certain recreational species and/or waters, have not been necessary for aquacultured products in the U.S. Advocates for food safety argue that sampling is inadequate in amount and frequency for all aquatic foods. A similar concern was noted in the 1991 'Seafood Safety Report' by he National Academy of Sciences that called for additional surveillance and control programs for all aquatic products be they harvested or cultured, domestically produced or imported. The NAS report noted the vast majority of seafoods represented a healthy choice, yet some concerns existed per species and specific locations. The species and locations of concern did not include aquacultured products.

A listing of all potential food additives and therapeutics for use with aquacultured products is beyond the intent of this review (Table 10). Two more popular additives, sulfiting agents and phosphating agents are more commonly used with cultured catfish (phosphates) and shrimp. Both agents are U.S. FDA and USDA approved ingredients for use with food. The phosphates influence moisture retention in the edible muscle. They are similar to the natural phosphates in the muscle tissue and do not pose any health threats. The primary regulatory concern for phosphates is excessive moisture addition, or adulteration of the food. In contrast, sulfites (i.e. sodium bisulfite) have caused adverse reactions in certain consumers with advanced or complicated asthmatic conditions. These reactions are usually associated with other foods, but could involve overtreated shrimp. The FDA action level for sulfite residuals on the edible portion of shrimp is 100 ppm. This concentration is adequate to prevent shrimp melanosis (black spot) without exceeding levels that could initiate an allergic type reaction in asthmatic consumers. Likewise, most aquacultured shrimp do not require chemical controls for melanosis due to the rapid access to live product, immediate refrigeration and less tendency for melanin formation in many cultured species.

The list of therapeutics and possible antimicrobial agents for potential use to protect the aquacultured animals continues to increase (Table 10). Subsequent presentations address these concerns in more detail. There inclusion in this review is to note regulatory concern for use of 'approved' substances. Many of these compounds lack formal U.S. FDA approval for application in culture operations or on aquacultured products. The extent of their actual use is in question, particularly in some foreign settings, but there is no current evidence for immediate health concerns for products destine for U.S. consumption. A multitude of regulatory and other government support programs have launched efforts to monitor certain products, review food application status and recommend proper use of these chemicals. The degree of current caution has been cited as an impediment to advancing aquaculture in the U.S., yet aquacultured food safety remains the paramount issue.

PROGRAM RESPONSE

A multitude of programs exist to address and assure the safety of aquacultured products (Table 11). Beginning at the state level, enforcement responsibilities are often shared or implied across various agencies depending on locations, level of commerce, product type and species. Authority can involve Departments of Health, Agriculture, Fisheries, Wildlife, Business and Marketing. The diversities in aquaculture complicate regulatory enforcement more so than in customary land-based agriculture. In contrast, aquaculture has stimulated more interagency cooperation and reevaluation of their respective regulatory roles.

Similarly at the federal level, government responsibility to address safety in aquacultured products is shared by a variety of agencies. The primary agency mandated to assure product safety is the U.S. Food and Drug Administration with it's cast of Offices, Centers and Divisions. FDA's most recent and unique addition is the Office of Seafoods which attempts to coordinate all aquatic food product safety issues within FDA. These safety programs are complemented by the U.S. Department of Agriculture's (USDA) efforts to advance aquaculture and aquacultured product health. The USDA efforts in aquatic food products rely on the Office of Aquaculture. In addition to food safety and quality, USDA programs focus on production, marketing and animal health. Likewise, the National Marine Fisheries Service offers a fee for services inspection program with grading standards for 'North American Freshwater Catfish'. These programs are further complemented by similar production and animal health programs in the U.S. Department of Interior's Fish and Wildlife Service and water quality surveillance

through the Environmental Protection Agency. In total, the multitude of government based support programs is very impressive as listed and will probably grow as aquaculture continues to expand in volume and diversity of production. The government response in terms of programs is not lacking, although financial support and function have been questioned in specific areas.

Future federal programs are being planned for mandatory Hazard Analysis Critical Control Point (HACCP) surveillance. The National Marine Fisheries Services has developed model HACCP programs for aquaculture production of catfish, crawfish, and molluscan shellfish. An FDA proposal for a new mandatory program is anticipated before September 1993. This form of federal overview with industry self-surveillance is the new vogue in food regulation about the world. Likewise, the new international standards for 'Hygienic Practice for the Products of Aquaculture' as drafted (1991) by the Codex Alimentarius Commission (Food and Agriculture Organization of the United Nations) emphasizes HACCP and good manufacturing practices from production through processing.

A variety of working groups and associations help to better coordinate and direct agency efforts (Table 12). Some of their work includes product safety. A good example is the progress of the Joint Subcommittee on Aquaculture's Task Force on Therapeutic Compounds to prioritize chemicals for industry use and regulatory consideration. Also, the new Fish Contaminants Task Force combines the talents of FDA and state experts in the Association of Food and Drug Officials to readdress the continuing concerns for possible contaminants in all fish, harvested or cultured, and how to better communicate this status to the public.

The regional aquaculture centers have emerged as a conduit of expertise and information from the various academic institutes and related industry programs. This National Aquaculture Safety Conference is testimony to the efforts of the Southern Regional Aquaculture Center (SRAC). Similar, supported industry efforts are introducing innovative Total Quality Management programs, HACCP initiatives and other consumer confidence promoting concepts (i.e. 'Mississippi Prime'). Additional center efforts are associated with national and regional communication programs listed in Table 13. These programs are designed to increase communications pertinent to aquaculture production, safety and quality. All of these efforts include, encourage and advance aquacultured product safety.

FUTURE CONSTRAINTS

Aquacultured product safety is not lacking for attention. Studies, government programs, industry initiatives and innovative systems abound and more are emerging. In reviewing these efforts various dominant product safety related concerns are obvious and pose constraints to future aquaculture development in the U.S. (Table 14).

The possibility of *Clostridium botulinum* growth in vacuum packaged products and the concern for *Salmonella* or *Listeria monocytogenes* growth on cooked ready-to-eat products, particularly pre-flavored and smoked items, must be further addressed to allow more use of these and other innovative market concepts for aquacultured products. These problems are not unique to aquacultured foods, but items of freshwater, culture origin can be more prone to exposure and potential cross contamination from these type of bacteria.

Consumers choice to consume raw molluscan shellfish will always pose unique product safety concerns. In addition to culture requirements for proper water quality to avoid fecal related microbial contaminants, certain warm water regions must contend with naturally occurring pathogenic bacteria, i.e. *Vibrio vulnificus.* Since 1975 molluscan shellfish consumption in the U.S. has declined by nearly 50%. This market could be reclaimed with an elevated safety assurance through aquaculture and additional emphasis on markets for cooked or to-be-cooked items. Culture technology is available, yet consumer perception and microbial concerns remain as significant hurdles to development. Incentive for change is based on predictions that molluscan shellfish could be developed into the second largest aquaculture industry in the U.S.

There has been limited studies on the effects of antimicrobial compounds on the microbiology of aquaculture operations and products. The phenomena of generating bacterial strains with resistance to certain antibiotics has been demonstrated in isolated cases, but the significance of these observations remains speculative. Likewise, observations in the culture systems and/or with cultured products do not necessarily indicates threats to consumer health. These unique microbial problems will attract additional studies but there is no current evidence that indicate antimicrobial resistance can persist or proliferate in and beyond the aquaculture environment.

In a related issue, commercial aquaculture demands for effective therapeutants, anesthetics, disinfectants and pesticides exceeds regulatory approval and knowledge of possible consequences in products. This constraint is currently attracting significant regulatory attention, yet the approval process is slow and requires data that is lacking in actual trials. Predictions indicate there will be more frustrated expectations and elevated regulatory scrutiny, particularly for imported items. Detection of illegal practices and/or residues in final products could taint the reputation of certain cultured products.

Product reputation or consumer perception is a potent concern for the future value and expansion of U.S. aquaculture. Our more health conscious society seems willing to pay for the more healthful choices, but they are demanding more safety assurance. In general, public perception is being used to justify the need for more regulatory surveillance or inspection from production through processing and into retail. The anticipated response is a new federally mandatory HACCP (Hazard Analysis Critical Control Point) inspection program. This form of self-regulation with government surveillance will initially impose constraints in efforts to understand and compile with the program, but after the transition it should be obvious that HACCP is the least obtrusive form of government surveillance. HACCP is founded on self-help and self-surveillance. The premise is focus on critical control points, that if violated, compromise the safety of the products. Consumer reaction to HACCP is currently unknown.

Could HACCP and additional constraints imposed on domestic aquaculture producers compromise the competitive positions with imported aquacultured products? This question is typically addressed with regulatory intentions to require 'equivalent' efforts for foreign sources. Additional scrutiny at ports of entry and extending HACCP concepts to foreign settings is ambitious but necessary in respect to the reasoning for additional requirements for domestic firms.

Finally, in the consumers eye quality will continue to be somewhat related to product safety. As for all aquatic products, the cultured items are highly perishable in a readily noticeable manner. Additional work and innovations are necessary to maintain and extend the fresh and frozen shelf-life of aquacultured products. Again, consumer acceptance and confidence are the essential factors to advancing aquaculture in the U.S. More so than in any previous decade, the American consumer expects better quality and product safety in their food supply.

Table 1. World Aquaculture Production, 1992

	lbs. (million)
Shrimp	1,590
Salmon	663
U.S. Catfish	450
U.S. Total	1,120

Source: Aquaculture Magazine Nov./Dec. '92

Table 2. U.S. Aquaculture Production

	$ Million
CATFISH	452
TROUT, RAINBOW	71
OYSTERS	50
SALMON, A & P	84
CRAWFISH	32
CLAMS	14
BASS, H.STRIP	11
TILAPIA	9
SHRIMP	7
MUSSELS	4

Farm income as Reported by Water Farming Journal citing JSA report 1992 for either 1990 or 1991

Table 3. U.S. Catfish Production, 1991

Total Whole Product Weight (million lbs. and $)		Processed Weight
Produced	Processed	Wholesaled
440 lbs	391 lbs	200 lbs
	$247 (farmgate)	$417

Source: David Harvey, USDA, Jan. 1993

Table 4. Estimated Risk of Foodborne Illnesses

Commodity	Est. Individual Illnesses per no. of servings
Chicken	1 per 25,000
All Seafoods	1 per 250,000
Fish (excluding shellfish)	1 per 5,000,000

Source: FDA (1991) Doug Archer

Table 5. Natural Toxins vs. Aquacultured Products

	Aquaculture		Source	
	F water	Marine	Water	Handling
Ciguatera	--	?	✓	
Scombrotoxin	--	?		✓
Paralytic Shellfish Poisoning (PSP)	--	✓	✓	
Diarrhetic Shellfish Poisoning (DSP)	--	?	✓	
Neurotoxic Shellfish Poisoning (NSP)	--	?	✓	
Amnesic Shellfish Poisoning (ASP)	--	?	✓	

-- means not involved

? involvement questionable or unknown depending on species and/or location of culture operation

✓ involvement possible depending on species and/or location of culture operation

Table 6. Microbial Concerns: Primary Pathogens vs. Aquaculture Products

	Aquaculture		Source		
	F water	Marine	Water	Handling	Unique Attributes and concerns
Salmonella	✓	✓	fecal contam.	✓	'0' tolerance; imported shrimp; cook ready-to-eat
Listeria monocytogenes	✓	✓	✓	✓	'0' tolerance; cook ready-to-eat
Vibrio cholerae	✓	✓	✓	✓	sanitation & handling problem; imports from certain countries
Vibrio parahaema.	–	✓	✓	✓	sanitation & handling problem; cross-contamination raw mollusk
Vibrio vulnificus	–	✓	✓	✓	raw mollusk; elevated environ. temperature
Clostridium botulinum	✓	✓	✓	✓	sanitation; vacuum pack.

-- means not involved
? involvement questionable or unknown depending on species and/or location of culture operation
✓ involvement possible depending on species and/or location of culture operation
fecal contam. - water with fecal contamination

Table 7. Microbial Concerns: Speculative (S) vs. Aquacultured Products

	Aquaculture		Source		
Bacteria	F. water	Marine	Water	Handling	Unique Attributes and Concerns
Yersinia enterocolitica	S	S	✓ fecal contam.	✓	
Campylobacter jejuni	S	S	✓ fecal contam.	✓	
Aeromonas hydrophila	✓	?	✓	?	primarily a fish disease
Edwardsiella tarda	✓	?	✓	?	primarily a fish disease
Plesiomonas shigelloides	✓	?	✓	✓	

? involvement questionable or unknown depending on species and/or location of culture operation
✓ involvement possible depending on species and/or location of culture operation
S means 'speculative', associated illnesses are possible but not likely
fecal contam. - water with fecal contamination

Table 8. Microbial Concerns: General Types vs. Aquacultured Products

	Aquaculture		Source		
Bacteria	F. water	Marine	Water	Handling	Unique Attributes and Concerns
E. coli (enteropathogenic)	✓	?	✓	✓	
Pseudomonas aeruginosa	✓	?	✓		
Clostridium perfringens	?	?	✓	✓	
Shigella	?	✓	fecal contam.	✓	import shrimp
Stap. aureus	?	?		✓	
Bacillus cereus	?	?		✓	
VIRUSES	?	✓	✓	✓	raw mollusk
PARASITES	✓	✓	✓		sushi

? involvement questionable or unknown depending on species and/or location of culture operation
✓ involvement possible depending on species and/or location of culture operation
fecal contam. - water with fecal contamination

Table 9. Chemical Concerns: Contaminants vs. Aquacultured Products

Bacteria	Aquaculture		Source		Unique Attributes and Concerns
	F water	Marine	Water	Handling	
Metals					
*Arsenic, *Cadmium, Chromium, Cooper, *Lead, Mercury, Selenium, Zinc	✓	✓	✓		No problem * Shellfish
Specific Organics					
PCB	✓	✓	✓		No problem
BHC	✓	✓	✓		No problem
Dioxin	✓	✓	✓		No problem
Chlorinated Hyrocarbon Pesticides					
DDT, DDD, DDE	✓	?	✓		No problem
Dieldrin, Chlordane, Toxaphene, Heptachlor epoxide, Hexachlorobenzene, DCPA, Mirex	✓	?	✓		No problem

No problem - reference to sampling program reports to date as compiled to date by U.S. FDA, EPA, and various state agencies.
? - involvement questionable or unknown depending on species and/or location of culture operation
✓ - involvement possible depending on species and/or location of culture operation
* - U.S. FDA has recently issued (1992) new Guidance Documents for these metals in Shellfish

Table 10. Chemical Concerns: Additives and Therapeutants vs. Aquacultured Products

Chemicals	Aquaculture		Source		Unique Attributes and Concerns
	F water	Marine	Water	Handling	
Food Additives					
Sulfites	✓	✓		✓	Shrimp only
Phosphates	✓	✓		✓	'GRAS' status only quality concern
Therapeutants, Antimicrobials, Anesthetics, etc.					
Benzalkonium chloride, Benzethonium chloride, Benzocaine, Chloramine-T, *Chloramphenicol, Cooper sulfate, Cytochalasin B, Epinephrine, L-DOPA, Oxytetracycline, Potassium permanganate, Sodium chloride, etc. . .					under speculative investigation

Table 11. Aquaculture Safety Programs: Government

State Agencies

Federal Agencies

Food and Drug Administration (USDHHS)

- FDA - Center for Food Safety & Applied Nutrition
  Office of Seafoods
  Office of Nutrition & Food Science
  Office of Toxicological Science
  Office of Compliance

- FDA - Center for Veterinary Medicine
  Aquaculture Coordinating Committee
  Office of Science
  Office of Surveillance & Compliance
  Div. Animal Feeds
  Office of New Drug Evaluation
  Div. Therapeutic Drugs and Food Animals

U.S. Department of Agriculture

- USDA- Office of Aquaculture
  National Agricultural Library - Aquaculture Information Center
  Agriculture Research Service
  Animal & Plant Health Inspection Service (APHIS)
  Cooperative State Research & Extension Services
  - Natl. Assoc. of State Aquaculture Coordinators
  - Sea Grant Coordinators, Extension Service
  Interregional Research Project No. 4 (IR-4) (based Rutgers Univ.)

U.S. Department of Commerce

- National Marine Fisheries Service
  Voluntary Inspection Program
- National Sea Grant College Program
  Research and Advisory Services

- U.S. Fish & Wildlife Service (USDI)
  National Aquaculture Coordinator
  National Fishery Research Lab - La Cross, WI
  National Fish Health Research Lab - Leestown, W VA
  Fish Farming Experimental Station - Stuttgart, AR

EPA (Environmental Protection Agency)

Table 12. Aquaculture Safety Programs: Interagency and Industry

Joint Subcommittee on Aquaculture
- Working Group on Quality Assurance
- Steering Committee for National Health Strategy for Aquatic Animals
- Task Force on Therapeutic Compounds

AFDO/FDA Task Force on Fish Contaminants
(AFDO - Association of Food and Drug Officials, state and federal)

Regional Aquaculture Centers
- SRAC
- NERAC
- CTSA
- WRAC
- NCSAC

Total Quality Management (TQM) Plans
- Catfish - Catfish Farmers Assoc.
- Trout, Rainbow - U.S. Trout Farmers

Industry Initiatives
- Mississippi Prime
- Southeastern Fisheries Association 'Quality Product Code'

Table 13. Aquaculture Safety Programs: Communications

Electronic Bulletin Board on Seafoods
(New England Fish Development Foundation, Inc.)

FISHNET (Miss. State Univ.) pending (NMFS?)

Aquaculture Resource Center (Univ. Delaware - Sea Grant)

Western Regional Aquaculture Consortium (Univ. Idaho)

Food Animal Residue Avoidance Databank (FARAD)
- Compendium of Food Animal Drugs (Univ. Florida)

Table 14. Future constraints imposed through safety concerns for aquacultured products in the United States

- Certain microbial constraints to advancing value added and alternative processing concepts (i.e. vacuum packaging and convenient cook ready-to-eat products)
- Regulatory constraints imposed by '0' tolerance for Salmonella and Listeria monocytogenes
- Microbial constraints to molluscan aquaculture due to a raw product consumption preference
- Microbial constraints on use of antibiotics relative to concern for elevating microbial resistance
- Biological and regulatory constraints due to the need for effective and legal therapeutants, anesthetics, disinfectants, and pesticides
- Market constraints due to public perception vs. regulatory surveillance
- Regulatory and market constraints imposed by competing imports
- Market constraints due to limited shelflife and consumers equating product quality and safety

DEVELOPMENT OF A FOOD ANIMAL RESIDUE AVOIDANCE DATABANK (FARAD) FOR AQUACULTURE

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At the present time there are only five compounds approved by the Food and Drug Administration for use in aquaculture species, and only four of these are commercially available (Table 1). These compounds are limited to use in approved species (usually catfish and salmonids) for specific indications (Table 1). In addition to FDA-approved products, certain products approved for use on aquatic sites by the Environmental Protection Agency (EPA) have also been used in aquaculture. These products and approved uses have been summarized by Schnick et al. (1989). Rapid growth of aquaculture industries coupled with loss of commercial availability of several approved compound has resulted in a crisis on availability of aquaculture therapeutics (Meyers, 1989).

At the present time extra-label drug use is critical for meeting the therapeutic needs of many aquaculture industries. The Food Animal Residue Avoidance Databank (FARAD) was developed to aid veterinary practitioners and producers in making responsible decisions concerning extra-label drug use in food animals. FARAD programs have been developed for the dairy, pork, and beef industries. These programs are presently being adapted for use by aquaculture industries.

The FARAD system consists of a computerized database which includes information on product name, active ingredient, manufacturer, registration number, approved species, indications, dose, route of administration and relevant pharmacokinetic data. Both FDA- and EPA-approved products are included in the FARAD database. FARAD has been used to gauge withdrawal times for extra-label drug use in food animals. Aquatic food animals are ectothermic and consequently their metabolism is greatly influenced by environmental conditions. It is uncertain how accurate predictions of drug withholding times will be in aquaculture species.

Advantages of the FARAD system include development of a central repository of information on drugs, species, dosage, route of administration and pharmacokinetics. This information can then be accessed by fish health professionals for development of Investigational New Animal Drug (INAD) applications and in addressing concerns such as crop-grouping. The information will also be useful in developing Quality Assurance plans for aquaculture species.

At the present time information on 313 scientific papers and 345 labels of EPA registered products have been entered into the FARAD aquaculture database. This information includes the five FDA-approved products listed in Table 1 and all pesticides approved by EPA for use on aquatic sites. Although 345 products have been approved by EPA for use on aquatic sites, these products represent only 14 different active ingredients.

At the present time there are three regional access centers for FARAD assistance. They are located at the University of California at Davis (916 752-7507), the University of Illinois (717 333-6731), and the University of Florida (904 392-9085). Presently the University of Florida is the only location prepared to answer questions concerning aquaculture species. It is hoped the aquaculture FARAD program will be on line late in 1993 and the program will be distributed nationally through state aquaculture extension specialists and extension veterinarians.

References

Meyers, F. P. 1989. Solutions to the shortage of approved fish therapeutants. *Journal of Aquatic Animal Health.* 1:78-80.

Schnick, R. A., Meyers, F. P., Gray, D. L. 1989. *A guide to approved chemicals in fish production and fishery resource management.* U.S. Fish and Wildlife Service and University of Arkansas Cooperative Extension Service, Little Rock, AR MP-241, 27 pp.

Table 1. Drugs approved for aquaculture use by the Food and Drug Administration.

BRAND NAME	ACTIVE INGREDIENT	APPROVED SPECIES	APPROVED INDICATION
Terramycin	Oxytetracycline	Catfish Salmonids	*Aeromonas sp.* *Psuedomonas sp.* *Hemophilus sp.*
Romet	Sulfadimethoxine + Ormetoprim	Catfish Salmonids	*Edwardsiella ictaluri* *Aeromonas salmonicida*
Paracide-F Formalin-F Parasite-F	Formalin	Catfish Trout Salmon Bass Bluegill Trout Eggs Salmon Eggs	Ectoparasites Fungicide
Finguel	MS-222	"Food Fish"	Anesthetic
Sulfamerazine* in fish grade	Sulfamerazine	Salmonids	*Aeromonas salmonicida*

*No longer available commercially

SCREENING ANTIBIOTICS IN AQUATIC SPECIES

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Thank you Dr. Otwell: Today I would like to look at analytical methods that have potential as residue screening tests for aquaculture products and in particular for screening channel catfish muscle for sulfadimethoxine residues using ELISA tests. There are a number of screening methods that are available for detection of antibiotic residues in red meat and poultry inspection. However, none of these methods are validated or approved for use in aquatic animal tissues. Therefore, existing methods will need to be adapted for use with aquatic animal tissues or new methods developed for screening these tissues for violative residues of the antibacterials used in aquaculture.

The most common antibiotic screening method used in red meat and poultry is the microbial inhibition test. There are a number of other assay methods available and include various colormetric, chromatographic, and receptor based methods. Receptor based assays include bacterial receptor assays such as the Charm II test, radio-immunoassay, and enzyme-linked immunoassays. These tests have relative strengths and weaknesses depending on their intended use and analytical needs.

The topic I would like to focus on for the remainder of this talk concerns immunoassays that may be used for the detection of antibiotic residues in aquatic species. Immunoassays are generally quite specific in their ability to detect individual compounds. Test specificity may be advantageous or not depending on test use. The specificity of immunoassays is particularly applicable to domestic aquatic animal tissues as there are very few compounds approved for use in aquaculture in the US and only two systemic antibacterial agents are currently marketed. This allows one to target a limited number of compounds in a residue monitoring program for US aquaculture products.

There are a number of immunoassays that are commercially available for screening animal tissues for violative residues of the antibacterial compounds used in agriculture. Of interest to the US aquaculture industry are screening tests for the detection of sulfonamides and tetracyclines and in particular assays to detect sulfadimethoxine and oxytetracycline. These are the active ingredients of Romet and Terramycin. There are also a number of immunoassays available for several other classes of drugs that might possibly be used to screen imported fish for residues of drugs that are used in other countries. These include immunoassays for penicillins such as ampicillin; those for aminoglycosides such as neomycin, gentamicin, kanamycin and others.

There are at present several immunoassays that are commercially available for the detection of sulfadimethoxine as a residue in animal derived foods. These tests are marketed primarily for the detection of sulfadimethoxine in milk. Some also have label claims for sulfadimethoxine residue detection in tissue extracts, feed extracts, urine, plasma, and other tissues. However, most are marketed for the detection of residues in milk because this is the largest market. Our interest was whether these tests could be adapted for use as screening methods for detection of sulfadimethoxine at tolerance levels in channel catfish muscle.

We examined four commercially available ELISA tests that are provided in a kit format. The first test we examined was the Signal test which is marketed by SmithKline Beecham Animal Health of Exton, PA. This is actually a test for the detection of sulfamethazine residues. However, we demonstrated that this test cross-reacts with a number of other sulfonamides, including the compound we are interested in, sulfadimethoxine. It can be used quantitatively as a detection method for sulfadimethoxine.

International Diagnostics Systems Corporation of St. Joseph, MI recently introduced a sulfadimethoxine detection test called the Sulfadimethoxine One Step ELISA. Another test, the CITE test marketed by IDEXX Laboratories of Westbrook, ME, is a test for the detection of sulfadimethoxine and two other sulfonamides as residues in milk. Environmental Diagnostics, Inc. of Burlington, NC markets the EZ-Screen sulfadimethoxine test for the detection of sulfadimethoxine residues in a variety of matrices. We will now look at the performance of these four tests for detecting violative sulfadimethoxine residues in catfish muscle.

The first two tests, the Signal and the International Diagnostics Systems assays, are Microtiter-well based assays that have antibody coated to the wall of the well. This is the typical ELISA format that many of you are familiar with. The other two assays, the CITE and the EZ-Screen tests, are membrane-based ELISA's in which the antibody is coated to a permeable membrane instead of to a well surface. All four of these tests are based upon the principle of competitive enzyme-linked immunoassay. We wanted to see if these tests could be used for detection of violative levels of sulfadimethoxine in channel catfish muscle. Since most of these tests are designed to be used with a biological fluid, such as milk, we needed a method of extracting the compound we were interested in, sulfadimethoxine, from the muscle tissue.

I would like to look at a study done at LSU where we extracted the compound from catfish muscle and used the extract to evaluate four enzyme immunoassays as methods for detecting residues of sulfadimethoxine in muscle. So we first needed a means of extracting the drug from catfish muscle. We chose an extraction technique called Matrix Solid Phase Dispersion or MSPD. This is a recently introduced method that performs a simultaneous disruption of tissue structure and dispersion of the sample over a large surface area. It combines the shearing forces generated by grinding the sample with a irregularly shaped particle with the lipid solubilizing effect of a polymer bound to the surface of the particle. This results in a mechanical disruption and dispersion of the tissue and a dissolution of cell membranes with release of cellular contents. This provides a very exhaustive extraction of the tissue including the intra-cellular contents. The resulting tissue-particle blend can be placed in a chromatographic column and the compound of interest eluted from the column using various solvents or solvent sequences. For sulfadimethoxine, eight ml's of dichloromethane was used to elute the compound from the column.

This extraction technique requires no special equipment- A laboratory mortar and pestle for grinding the sample and a column fashioned from a disposable ten ml syringe barrel. The syringe barrel is fitted with a paper filter placed in the distal end of the column and another paper filter placed on top of the tissue-particle blend to secure the blended material in place within the column. The syringe plunger is modified by removal of the rubber tip and is used to pack the column to a volume of about 4.5 ml. A bulb syringe is used as needed to provide positive pressure to the head of the column to maintain flow rate through the column.

The general MSPD procedure uses one-half gram of sample combined with two grams of a particulate material, octadecylsilyl-derivatized silica, which is commonly referred to as C-18. C-18 is a silica particle with a lipid-solubilizing polymer covalently bound to its surface. The silica particle provides solid support and has a very large surface area coated with lipid solubilizing polymer. The tissue and C-18 are blended using a mortar and pestle, the blend transferred to and packed in the syringe barrel used as a column, and the compound we are interested in eluted using a appropriate solvent.

In the case of catfish muscle, one-half gram of muscle is placed on 2 grams of C-18 in a mortar and the two blended with a pestle. A gentle circular motion is used and requires about 1 minute to achieve a homogenous blend of tissue components dispersed uniformly over the particles' surface. Two grams of C-18 has a surface area of around 1000 square meters; so you get a quite exhaustive extraction using small volumes of solvent. The blended material is packed into the column, compressed to a volume of around four and one-half ml's, and sulfadimethoxine eluted using eight ml's of dichloromethane. The dichloromethane is evaporated and the eluent reconstituted in 0.5 ml of buffer appropriate for the particular ELISA used.

Once we have the compound isolated from the muscle and in a buffer solution we can now use this extract to evaluate the performance of the ELISA's for identifying tissues containing illegal residues. In the study to evaluate these tests we examined test performance at five concentrations of sulfadimethoxine in channel catfish muscle. The FDA tolerance for sulfadimethoxine is 100 parts per billion; so we looked at concentrations of 0, 25, 50, 100, and 250 PPB sulfadimethoxine. These concentrations are all close to tolerance. So this was a very rigorous examination of the ability of these tests to identify samples containing 100 PPB or more sulfadimethoxine. Test results were qualitative; either positive or negative for tissues containing sulfadimethoxine at greater or less than tolerance.

The first test we looked at was the Signal test. This is actually a test for sulfamethazine but it also cross-reacts with sulfadimethoxine. This test was used because no Microtiter well based assays were available for sulfadimethoxine at the time. This test is furnished as a kit containing all necessary components. This slide illustrates the Microtiter well format. Results were determined by a comparison of the relative color development of a negative control well to a sample well. The negative control well is on your left and wells containing positive extracts on the right; one at 100 PPB and the other at 200 PPB sulfadimethoxine. An optical density reader was used to provide quantitative results.

The other microtiter well based test we examined was the International Diagnostics Systems test. This test is marketed specifically for detection of sulfadimethoxine residues. The test format and protocol are identical to the Signal test but the relative degree of color difference between the positive and negative wells is much greater than with the Signal test since this is a test specifically for sulfadimethoxine.

Two membrane based ELISA's were also evaluated. The EZ-Screen test is marketed by Environmental Diagnostics of North Carolina for the detection of sulfadimethoxine residues in milk and other tissues. It is furnished as a kit and uses the Quik-Card format. The Quik-Card is a plastic card with two test ports, a control port and a sample port, each containing a membrane coated with antibody. This slide illustrates the visual results obtained with this test. The relatively intense color development of the control port is shown on the left and the sample port on the right exhibits a lack of color development, indicating a positive result from a MSPD extract of catfish muscle containing 250 parts per billion sulfadimethoxine.

The CITE test is marketed for the detection of three sulfonamide in milk. It utilizes the CITE cup test format which contains a membrane filter coated in four discrete areas with antibody to three different sulfonamides and a control spot. This test can detect and differentiate between sulfamethazine, sulfathiazole, and sulfadimethoxine residues at 10 PPB in milk. A negative result is shown in this slide in the cup device on the left. In the cup device on the right the lack of color development of the spot at the 9 o'clock position indicates a positive result for sulfadimethoxine at 250 PPB . So these last two membrane based tests were evaluated visually and the first two tests, the Microtiter well tests, were evaluated by their optical density values.

Once we have the results from these tests we evaluated the ability of the tests to accurately identify samples containing at or above tolerance of sulfadimethoxine in catfish muscle. Performance was evaluated primarily by the tests' sensitivity and specificity. The sensitivity of a screening test is the most important criteria in evaluating it's performance. A screening test should be simple to use and allow one to quickly screen large numbers of samples. It must have the ability to accurately identify samples that are considered positive based on the tolerance for the compound. We define the sensitivity of a screening test as a percentage based on the number of true positive results compared to the total number of known positive samples tested. Known positives includes both true positive and false negative results.

If we look at the overall sensitivity of these four assays we are looking at their ability to identify muscle samples containing sulfadimethoxine at a concentration considered positive in this study; 100 parts per billion and 250 parts per billion. So we are looking at their ability to detect sulfadimethoxine at extremely low levels in catfish muscle. Performance results indicate that all four of these assays have very high sensitivities; that is they could very accurately identify samples containing sulfadimethoxine at tolerance and two and one-half times tolerance. If we look at the individual samples considered positive, again these are samples containing sulfadimethoxine at 100 and 250 parts per billion, we see that all samples containing 250 parts per billion were correctly identified as positive by all four assays. For samples containing 100 parts per billion sulfadimethoxine there were a small number of false negative results (4%) with the two visually determined tests, but these two tests were still very effective at identifying samples containing low levels of sulfadimethoxine in catfish muscle.

Specificity is the ability of an assay to accurately identify negative samples; that is samples that contain sulfadimethoxine at less than tolerance. In this study this included muscle samples containing 0, 25, or 50 parts per billion sulfadimethoxine. Specificity is important mainly from an analytical workload standpoint. If a screening test can not identify samples containing below tolerance with a high degree of accuracy it is of little practical usefulness even if it has 100% sensitivity. This is because all samples identified as positive -including false positives- must be confirmed. False positive results increase the analytical workload and so the screening test provides no advantage over simply using the more rigorous confirmatory methods.

We define specificity as the number of true negative results divided by the total number of known negative results that were examined in the study. Known negative samples includes both true negatives and false positives. If we look at overall specificity we see that three of the assays have quite high specificities. The International Diagnostics Systems, the Signal, and the EZ-Screen tests all had specificities of greater than 90 % for all samples considered negative in this study. That is samples containing 0, 25, or 50 parts per billion sulfadimethoxine. The CITE test had a somewhat lower specificity because of a higher number of false positive results. This could perhaps be a matrix-specific effect as the CITE test is designed for use with milk samples.

If we look at the three individual concentrations that were considered negative in this study- 0, 25, and 50 parts per billion sulfadimethoxine- we see at the two lowest concentrations- 0 and 25 parts per billion- that the International

Diagnostics Systems, the Signal, and the EZ-Screen tests identified 100% of the samples containing below tolerance levels of sulfadimethoxine as negative. However, if you look at specificity of these assays for samples containing the borderline concentration of 50 parts per billion, we see a low number of false positive results; 17 % false positives for the International Diagnostics Systems and EZ-Screen tests and 25% false positives with the Signal test. False positives were especially noticeable with the CITE test with over half (54%) of the samples containing 50 parts per billion sulfadimethoxine incorrectly identified as positive. However, overall these tests can be used to differentiate between blank samples and samples containing violative residues of sulfadimethoxine.

Another indication of the specificity of an assay is it's cross-reactivity with other compounds. Cross-reactivity can be evaluated by a comparison of the concentration causing a 50% inhibition in color development of the sample well when compared to the blank control well. The Signal test, as I said earlier, cross-reacts with a number of other sulfonamides. It has the greatest sensitivity to sulfamethazine with an IC-50 of less than 10 parts per billion, but is also quite sensitive to sulfamerazine and sulfadimethoxine. The IC-50 for sulfadimethoxine is 250 parts per billion.

The International Diagnostics Systems test is marketed specifically for the detection sulfadimethoxine residues and indeed this test is quite sensitive to and specific for this compound. This test exhibited little cross-reactivity with any of the other sulfonamides examined except at concentrations greatly exceeding those expected as tissue residues.

The two visually determined tests, the EZ-Screen and CITE tests, showed no cross-reactivity with any of the other sulfonamides examined. So, three of these ELISA's exhibited no significant cross-reactivity with other sulfonamides and were quite specific for sulfadimethoxine.

We also examined the cross-reactivity of these four tests with 15 other compounds that are either used in aquaculture or have the potential for occurring as contaminants in catfish feed. None of these fifteen compounds exhibited cross-reactivity in any of the assays.

The primary metabolite of sulfadimethoxine, N_4-acetylsulfadimethoxine, was extracted and detected equally as well as the parent compound. The ability of an assay to detect major metabolites is important because the FDA tolerance is based on total residues present, including the parent compound and all metabolites. Therefore, a screening test that can detect parent and metabolites is needed.

In conclusion, I feel we can say that the MSPD procedure provided a relatively rapid, simple, and efficient method for the extraction of sulfadimethoxine residues from channel catfish muscle. Performance results indicate that these commercially available immunoassays can be used to identify channel catfish muscle samples containing violative residues of sulfadimethoxine.

The Signal test exhibited cross-reactivity with a number of other sulfonamides. Therefore, this test should be considered a sulfonamide class assay rather than specific for a single compound. Additionally, these tests may provide variable results at borderline tissue concentrations. This emphasizes that these tests are screening assays and that for regulatory purposes confirmatory methods are required to validate screening test results.

Lastly we feel that on-farm use, especially with the EZ-Screen test, is possible. On-farm use may be a particularly useful application for these assays following extra-label or FDA-IR4 program use by providing a method for screening edible aquatic tissues for violative residues of sulfadimethoxine. Also with the passage of a mandatory seafood inspection program, producers will need a method to determine whether a pond of fish, with a history of drug administration, contains violative residues. Ideally this would be done before the fish are harvested and at the processor to allow additional time for residue depletion. Thank you.

CONTROL OF *LISTERIA MONOCYTOGENES* IN PROCESSED CATFISH AND CRAWFISH

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At LSU, we have been given the directive of looking at pathogens in processed catfish and crawfish meat. We are looking at controlling *Listeria monocytogenes* in these products. Our main objective has been to use multibarrier approaches to inhibit this bacterium in these two food products. Yesterday we heard from an industry spokesperson at our luncheon. She mentioned they were interested in SRAC exploring the use of multibarriers in food products to improve food safety. Some of the barriers LSU has been studying, both individually and in combination, have been citric acid, lactic acid, potassium sorbate, monolaurin, modified atmosphere packaging (MAP), and high and low temperatures. One reason we wanted to look at monolaurin is that we have had a lot of success with it in our laboratories controlling *L. monocytogenes*.

The studies conducted, in an effort to accomplish our major objective, have been: 1) the sanitizing effect of monolaurin and lactic acid on crawfish and catfish meat, 2) the lethal effects of lactic acid and thermal processing on packaged crawfish tail meat. Since this talk was put together, we have done some preliminary work with modified atmosphere in combination with lactic acid and thermal processing, and 3) the effect of low temperature growth of *L. monocytogenes* on crawfish meat treated with citric and lactic acid, potassium sorbate, monolaurin, and MAP.

Brief description of methods:

We were looking at two entirely different products and they were received in different forms. We acquired our crawfish meat samples through local wholesaler/retailers in frozen packages. This is typical of how the product is sold. Samples were brought to the lab and maintained at -20°C until used. We then heated the product to 90°C to reduce as much background microflora as possible before we started working with it.

The catfish was purchased live. In Baton Rouge we have local retailers that "Live Haul" product in from Louisiana, Mississippi or Alabama delta areas on a weekly basis. Catfish were brought into the lab live. As soon as possible the catfish were sacrificed, skinned and then filleted underneath a laminar flow hood. The fillets were then cut into 10 or 20 g samples, placed in sterile packs and frozen at -80°C until used.

Several inoculation methods were used for various samples. For crawfish thermal studies and growth studies a mixed strain *L. monocytogenes* cocktail was blended with the crawfish. One of the reasons for blending crawfish and not dipping is that this product is usually shipped and sold with the hepatopancreas on. An attempt was made to maintain the product as close to that which the processors will eventually be marketing. An additional inoculation method, used in several alternate studies for both crawfish and catfish, was dipping. Samples were dipped in inoculum for five minutes, then drip drained on a sterile cloth.

Treatments of lactic acid, citric acid, or potassium sorbate were sprayed onto previously inoculated samples for thermal studies. Some of the growth studies for crawfish used dip applications to apply treatments.

Results:

The sanitizing effects that we have observed on catfish meat show that as the percent lactic acid increases the effectiveness of the treatment increases (Fig. 1). We observed that treatments exceeding 1.7% lactic acid produced a 1.5 log decrease. An interesting note is that after a 20 to 30 minute time period the sanitizing effects of lactic acid seemed to diminish.

On crawfish meat, the sanitizing ability of lactic acid seemed to be less effective (Fig. 2) We observed less than a 0.5 log reduction of the bacterium when 2% lactic acid was applied to the samples. But again, we see that with this high concentration after about 20 minutes the sanitizing effectiveness of lactic acid seemed to diminish or level off.

The effect of lactic acid in combination with monolaurin is shown in Fig. 3. Monolaurin as a sanitizing agent did not have any effect on the crawfish and catfish meat. When lactic acid was combined with monolaurin we see no additive effect.

We wanted to combine different acid treatments with heat (60°C). Heat is effective on its own in reducing microbial populations. This temperature is effective in reducing *L. monocytogenes* by about 2 logs in 14 minutes (Fig. 4). When we increase lactic acid concentrations, from 0.5% to 1.0%, 14 minute heat treatments produced about a four log increase in lethality of heat. We have determined that this is not a simple pH effect (Fig. 5). The pH of the crawfish tail meat was modified to be equal that of 1.0% lactic acid using hydrochloric acid. An effect of pH was observed, however, there is an additional effect which could be attributed to lactic acid.

Long term storage effectiveness of citric acid and potassium sorbate were examined. They were added to crawfish tail meat at 0.3% levels and the product held at 4°C. There was no observable difference between citric acid and the control; however, with potassium sorbate we observed an extended lag phase. Once exponential growth ensued there was no difference in generation times between that of our controls (data not shown).

We studied the effects of lactic acid at different concentrations up to 3% on crawfish (Fig. 6). As the percent of lactic acid increased, the effectiveness of the treatment increased. Two percent lactic acid halted growth of the bacterium and 3% proved to be lethal to the bacterium. After about a ten day exposure time to 3% lactic acid, the bacterium was below detectable levels. We looked at the inhibitory effect of monolaurin in combination with lactic acid (Fig. 7). We saw an inhibitory effect when 200 micrograms/g of monolaurin was used. This effect was approximately the same as 1% lactic acid. We did observe an additive effect with lactic acid and monolaurin in combination. If percent acid is increased to 2% from 1% and the monolaurin is maintained at the same level, 200 micrograms/g, we were able to create a lethal effect to the bacterium (Fig. 8). It is below the detectable level after approximately 14 days.

The effects of MAP, lactic acid, and monolaurin are shown in Figure 9. The modified atmosphere we used was 75% carbon dioxide, 10% oxygen, and 15% nitrogen. Initial inoculation levels of *L. monocytogenes* for the control, air packaged, and modified atmosphere packaged samples was approximately 3 logs. When we added monolaurin and lactic acid, we saw some inhibition. The most effective combination was MAP, lactic acid and glycerol monolaurate.

Conclusions:

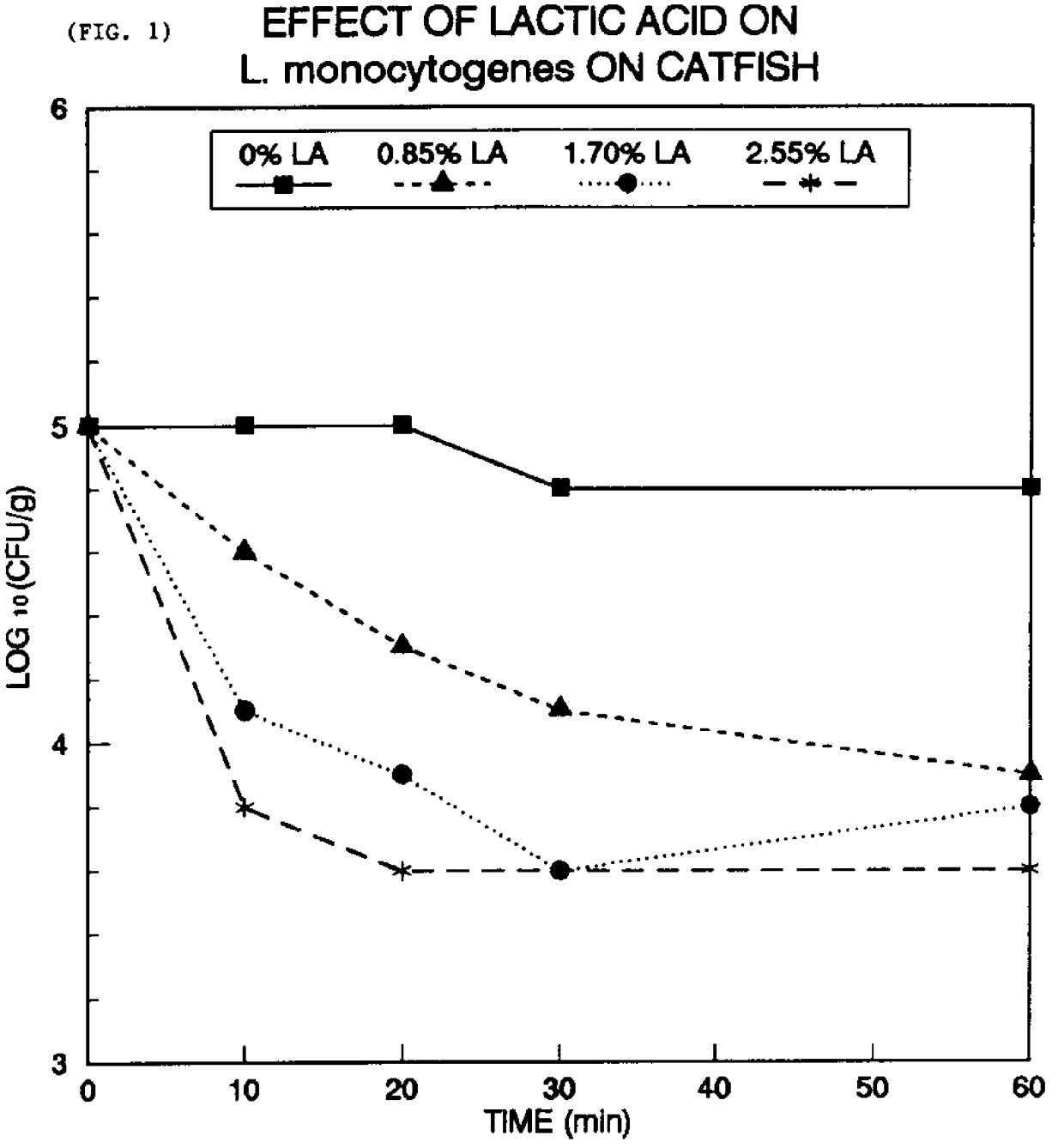
Some conclusions that we have been able to draw thus far from these studies are that glycerol monolaurate used alone had no real sanitizing effect against the organism. Two percent lactic acid reduced *L. monocytogenes* population to approximately one log after 20 minutes of exposure on either crawfish or catfish but we found that it is less effective in crawfish. There was no interaction between lactic acid and monolaurin as sanitizers.

Increasing lactic acid concentrations increases thermal destruction of the organism on crawfish. The effect is independent of pH. Citric acid (0.3%) did not inhibit growth of *L. monocytogenes* on crawfish. Potassium sorbate (0.3%) extended the lag phase of the organism in crawfish, but once exponential growth ensued there was no real difference in generation time.

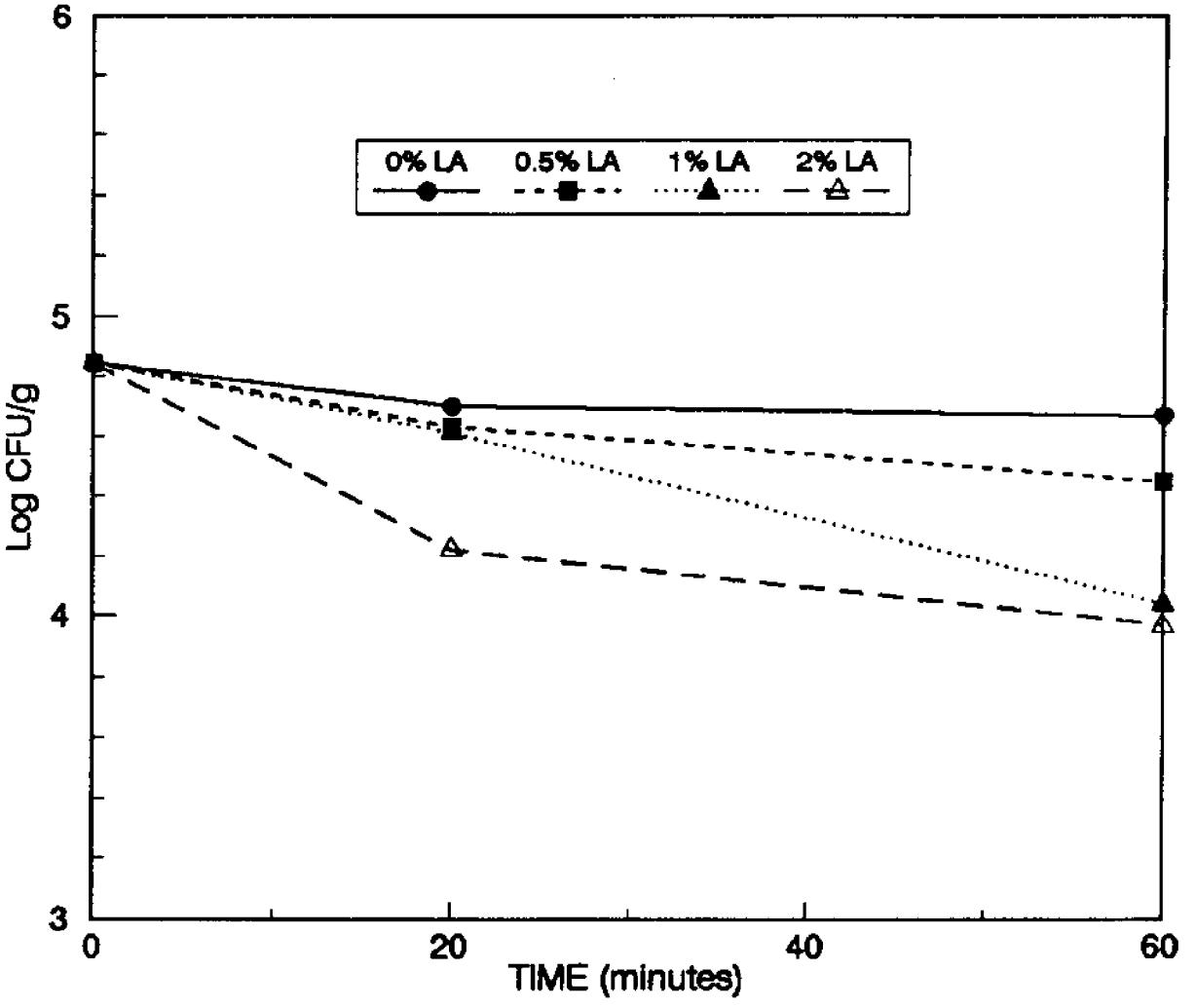
Lactic acid concentrations of 2% prevented growth while 3% killed the organism under cold storage at 4°C. The combination of lactic acid and monolaurin inhibited growth of *L. monocytogenes*. And finally, MAP, lactic acid and monolaurin was the best treatment we've used thus far to inhibit the growth of *L. monocytogenes* in crawfish. A footnote; it appears that if we use heat in combination with MAP and lactic acid, that we will alter the destruction capabilities, to the bacterium, of the above barrier combinations.

Finally, during our research we noted that the generation times on crawfish tail meat for *Listeria* seemed to be relatively short. This would imply that the bacterium grows fairly rapidly. As a result we did a brief scan of the literature and found some interesting facts that need to be addressed in future research projects. For crawfish, a generation time of about 18 hr at 4°C was observed (Fig. 10). An interesting note, when we went through the literature there seemed to be no set protocol for the temperature used in storage studies. We looked at studies done with this bacterium using almost any temperature between 0 to 35°C. It would be nice to come up with a few standards. Four degrees centigrade in addition to 0°C seemed to be the prevalent temperatures used in studies. We see in Figure 10 that crustaceans such as crawfish, crab, lobster, and shrimp, facilitate a relatively short generation time for *Listeria* compared to some of the more traditional food items such as beef, chicken, lettuce, skim milk and yeast extract. A short generation time was also observed in smoked salmon, another aquaculture product. The significance to the seafood industry of this finding remains unknown and warrants our attention.

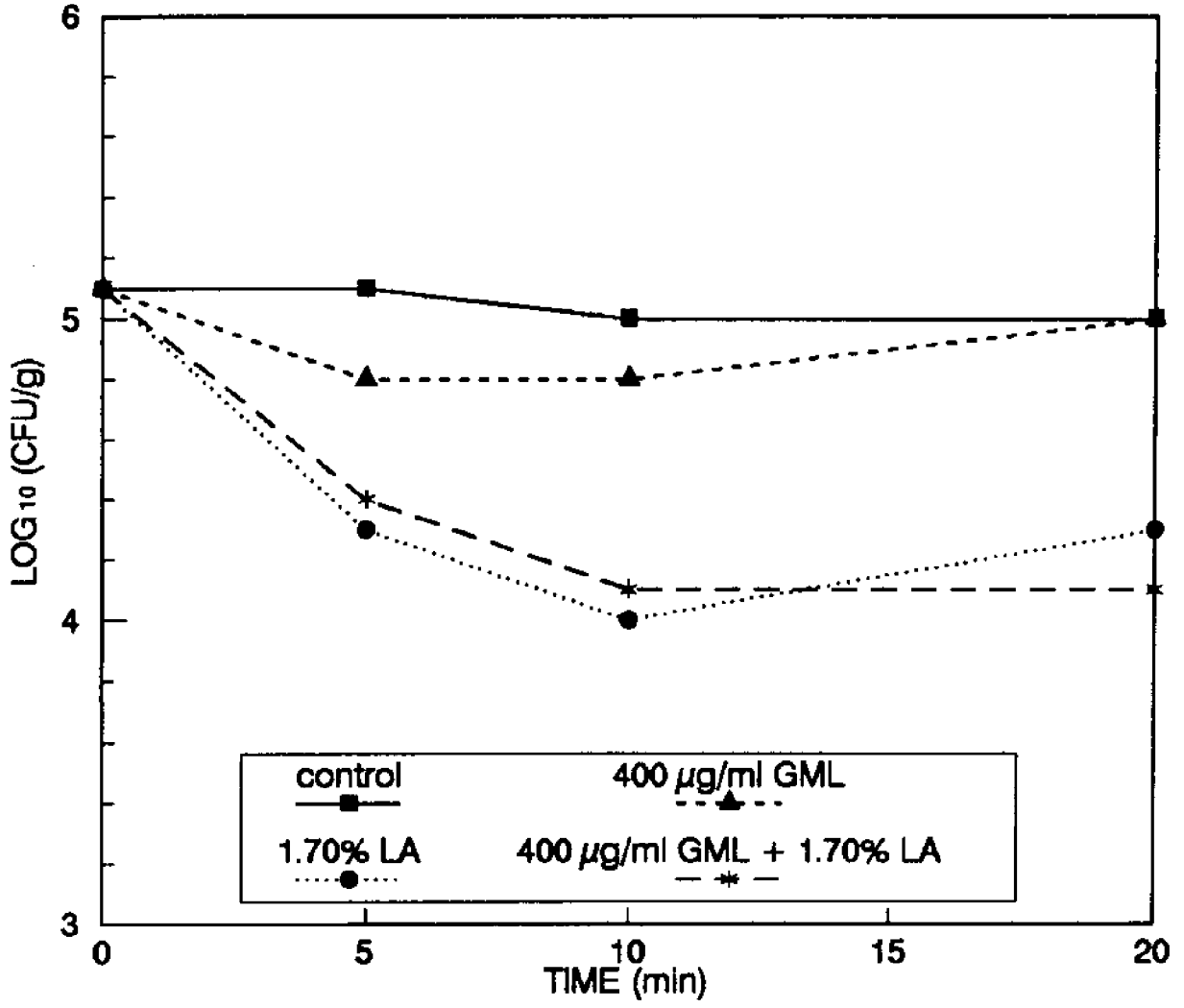
(FIG. 1)


EFFECT OF LACTIC ACID ON
L. monocytogenes ON CATFISH
0% LA
0.85% LA
1.70% LA
2.55% LA
LOG 10(CFU/g)
6
5
4
3
0
10
20
30
40
50
60
TIME (min)

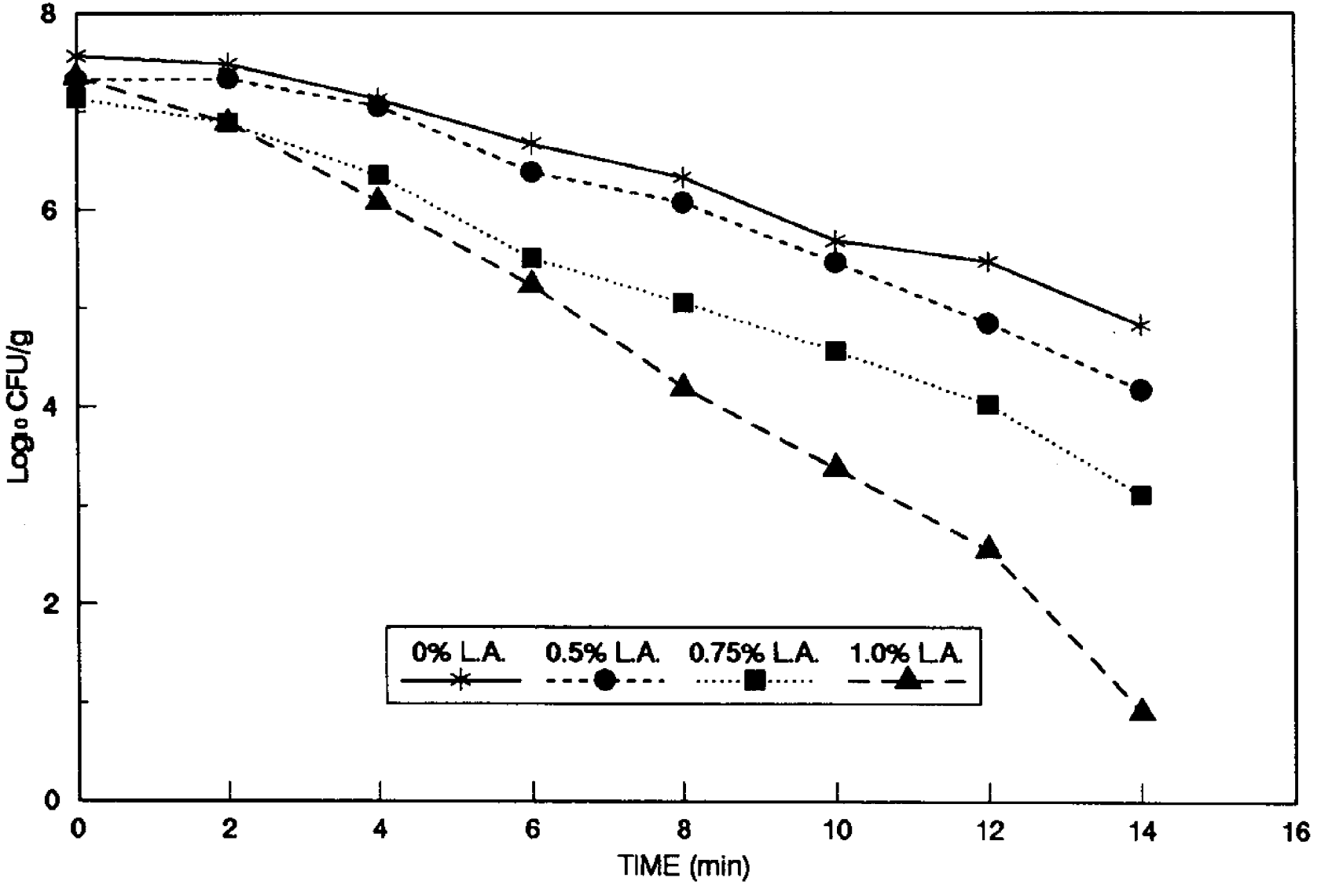
(FIG. 2) EFFECT OF LACTIC ACID ON L. monocytogenes ON CRAWFISH



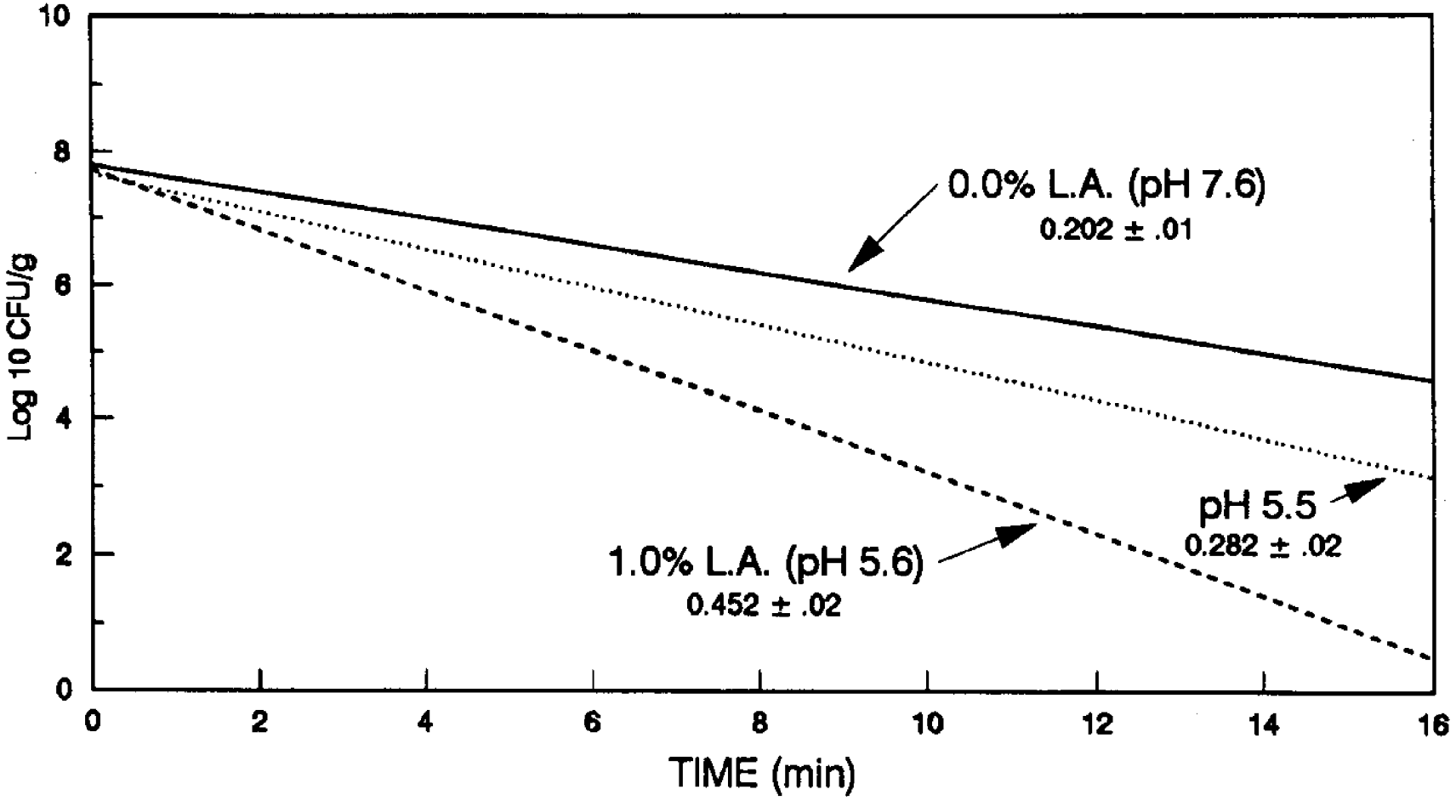
(FIG. 3) EFFECT OF 1.70% LACTIC ACID + 400 μg/ml MONOLAURIN ON L. monocytogenes ON CATFISH



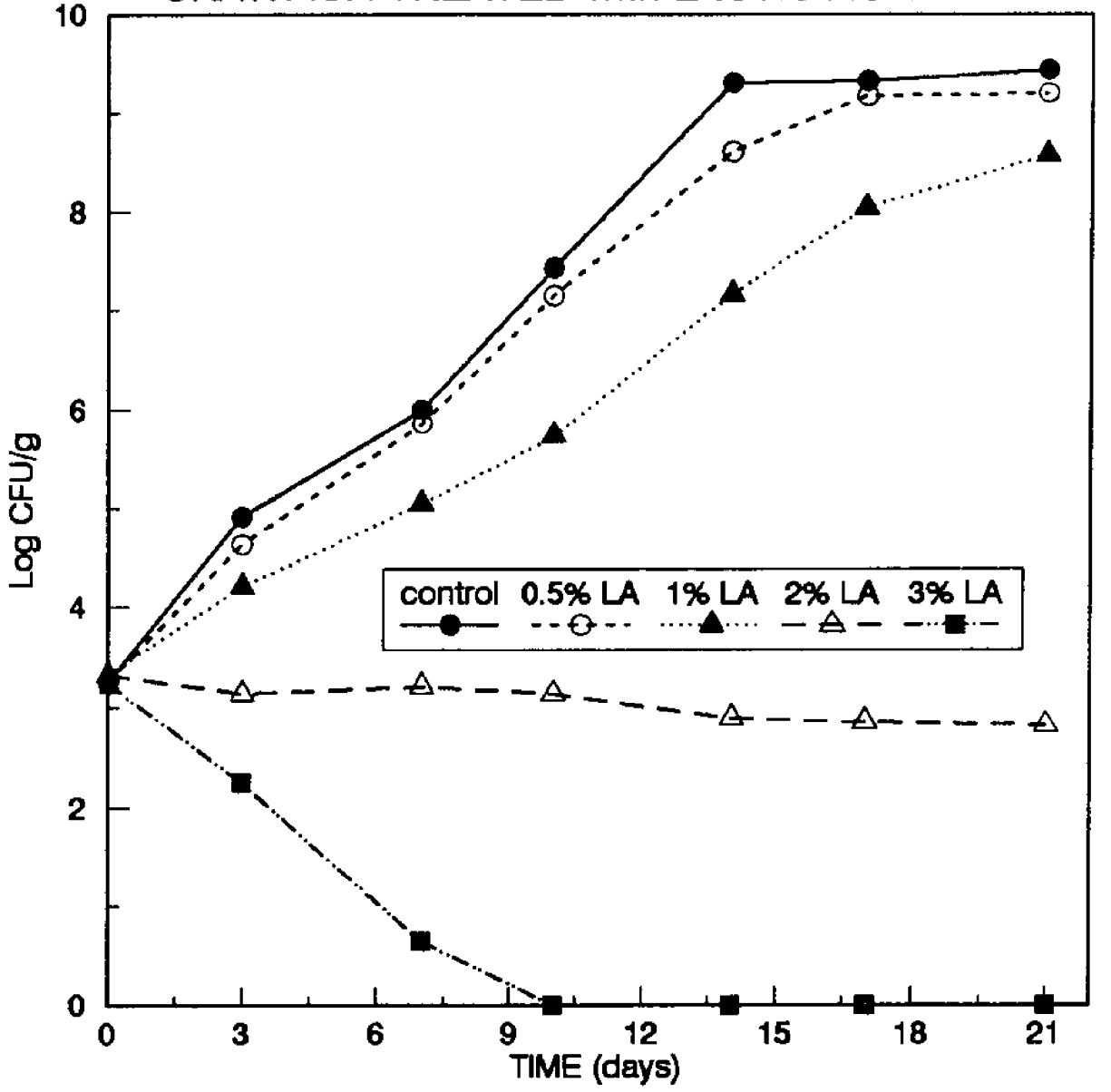
(FIG. 4) **60°C + LACTIC ACID TREATMENTS ON CRAWFISH**



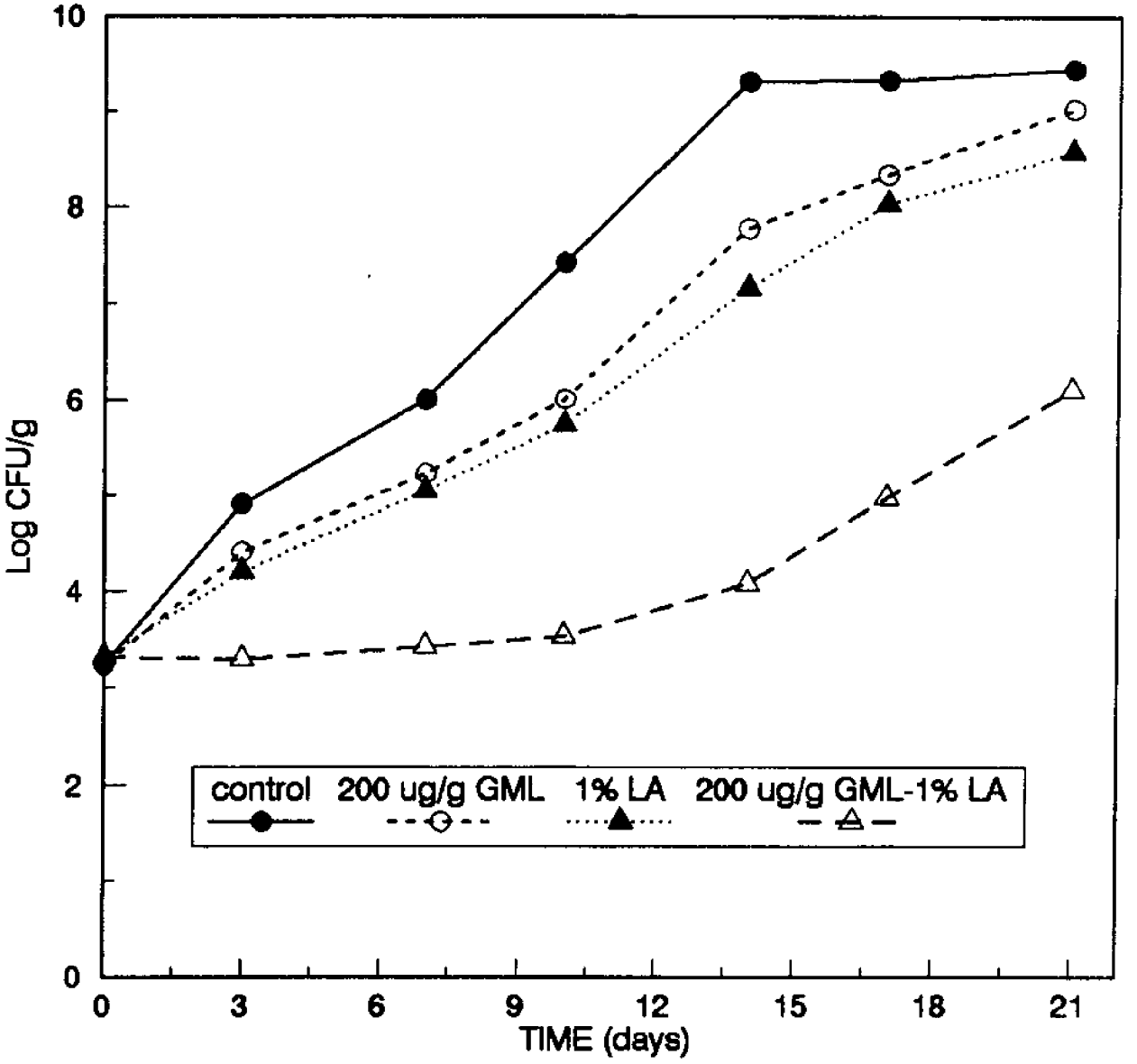
(FIG. 5) **EFFECTS OF L.A. vs pH AT 60°C**



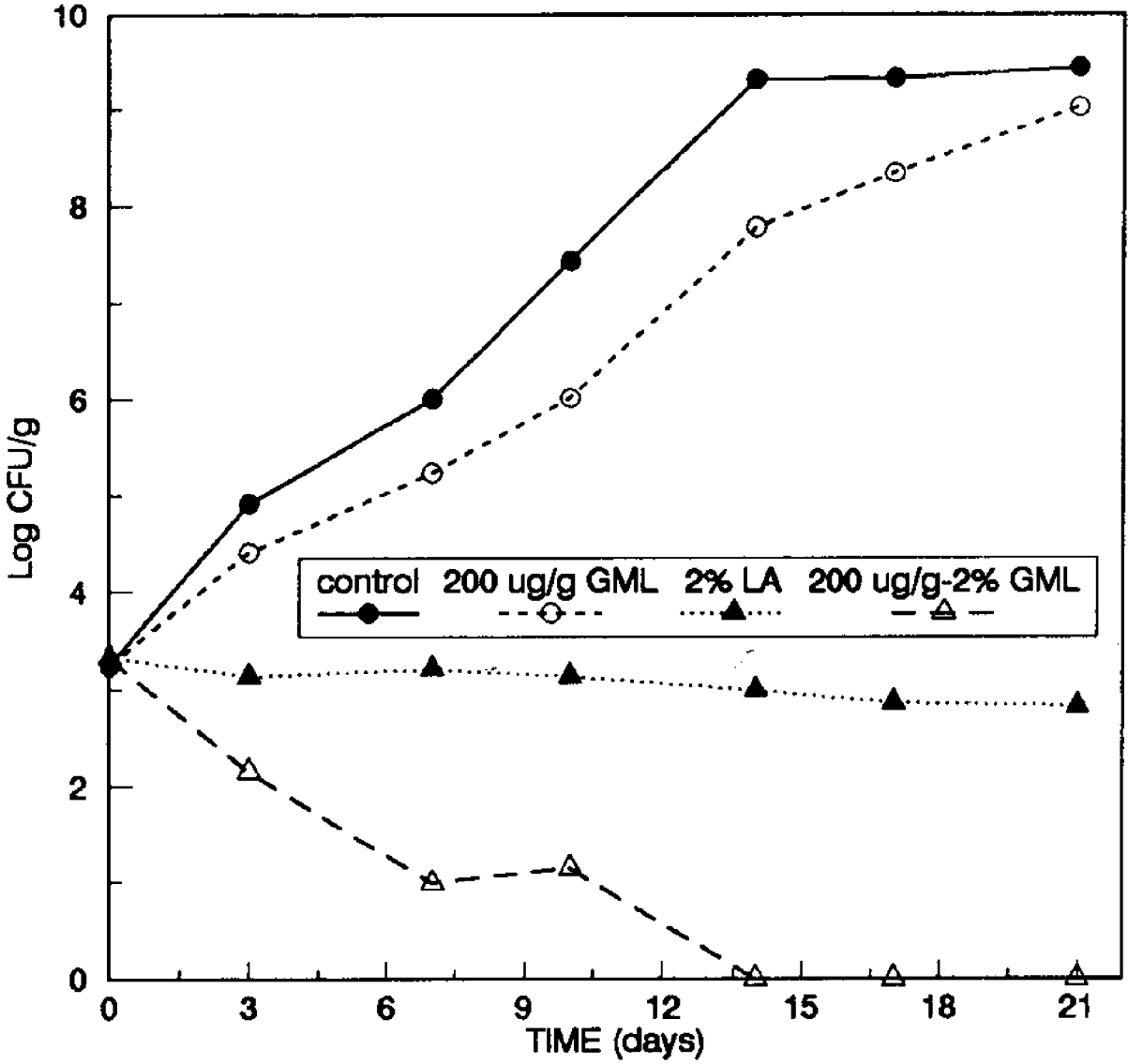
(FIG. 6) GROWTH INHIBITION OF L.monocytogenes on CRAWFISH TREATED with LACTIC ACID at 4°C



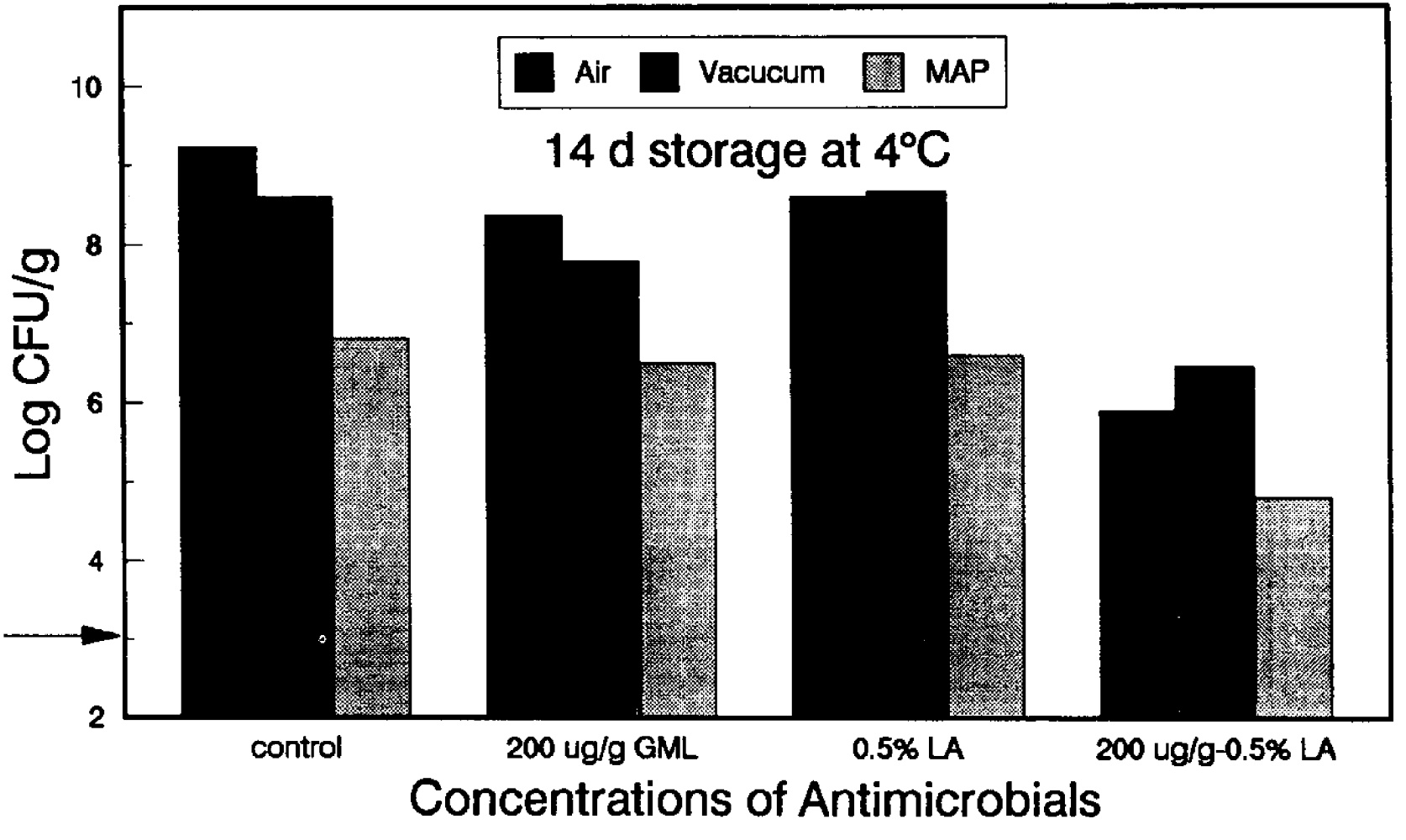
(FIG. 7) GROWTH INHIBITION OF L.monocytogenes on CRAWFISH by COMBINED LA WITH GML at 4°C



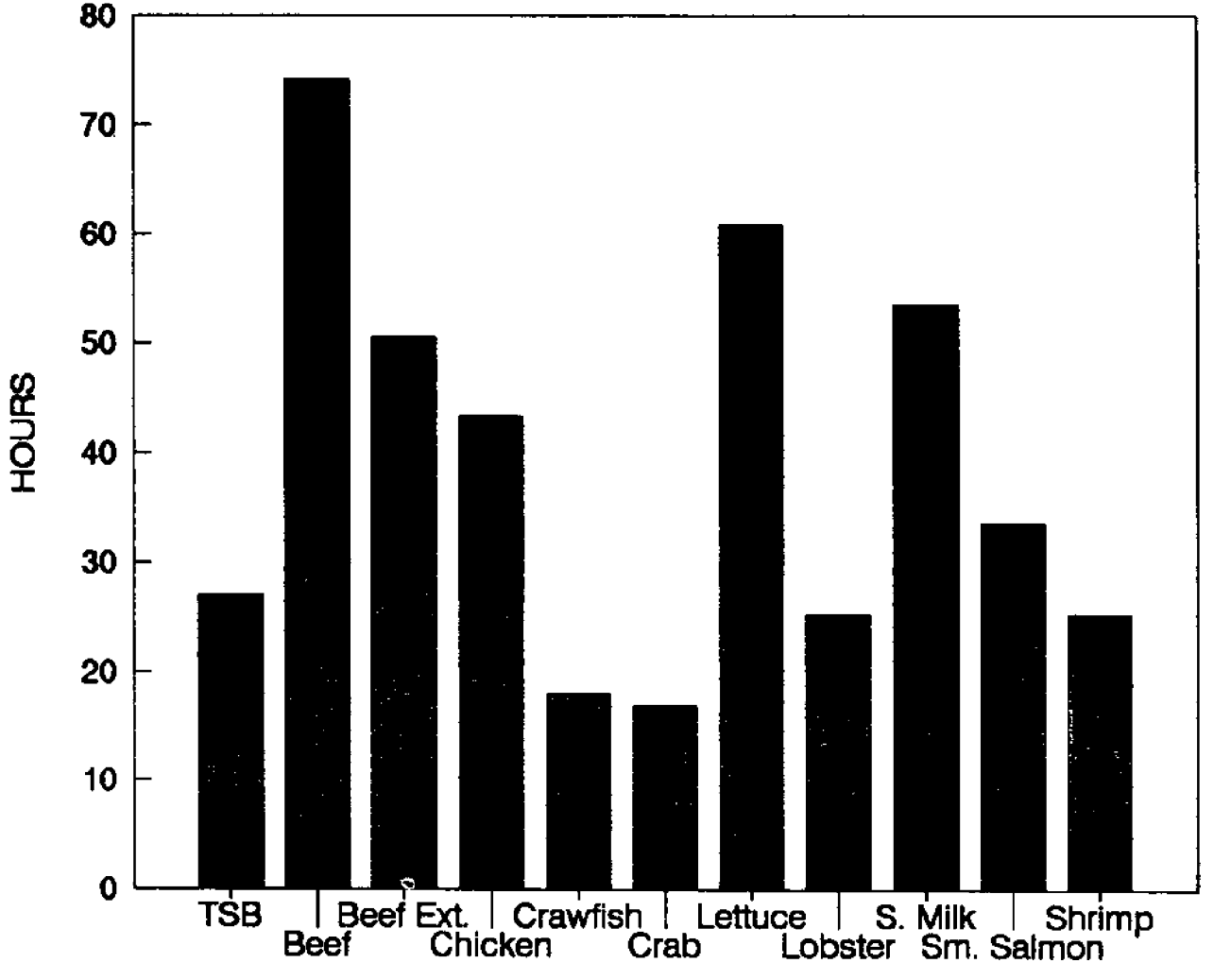
(FIG. 8) GROWTH INHIBITION OF L.monocytogenes on CRAWFISH by COMBINED LA WITH GML at 4°C



(FIG. 9) **EFFECT of MAP, LA, and GML on INHIBITION of L. monocytogenes on CRAWFISH**



(FIG. 10) **GENERATION TIMES FOR L. monocytogenes IN DIFFERENT FOOD PRODUCTS AT 4°C**



USES OF SODIUM LACTATE ON PACKAGED RAINBOW TROUT

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INTRODUCTION

Sodium lactate, a salt of lactic acid, is a Generally Regarded As Safe (GRAS) chemical. It is often used in bakery products including biscuits, cakes and confectionery to keep them moist and give them a soft, crumbly texture, and in cheese to enhance the action of antioxidants. It is also used in jam and marmalade, and margarine to regulate the acidity. In recent years, sodium lactate has been used in meat products as a flavor enhancer and an antimicrobial agent (Shelef and Yang 1991).

Previous studies indicated that sodium lactate inhibited microbial growth and prolong the shelf life of meat products. Duxbury (1990) reported that beef roast injected with sodium lactate resulted in increased shelf life of the roasts. Bacterial growth was inhibited and the microflora came to be dominated by *Lactobacillus* species. Chirife and Fontan (1980) stated that sodium lactate has been shown to decrease the water activity sufficiently to inhibit bacterial growth. de Witt and Rombouts (1990) reported that the antimicrobial effects of sodium lactate may due to the increased permeability of cellular membranes for lactate ion at a high pH. However, feedback inhibition by lactate was proposed as the mechanism of action in the delay of toxin production by *Streptococcus faecalis* (Simpson et al. 1983) and by *Clostridium botulinum* (Maas et al. 1989).

Little information regarding the effect of sodium lactate on seafood was available. Williams and Rodrick (1992) reported that sodium lactate functioned to retard microbial growth, and stabilize color and odor characteristics in the skinned catfish fillets. Total aerobic plate counts of cod fillets were also big reduced when 12% of sodium lactate solution was used to immerse the fillets for 2 min (Anonymous n.d.). However, no study of sodium lactate on rainbow trout has been made. In order to improve the product quality at the retail level, the objectives of this study were to determine the reduction of microbial populations on rainbow trout treated with low concentration of pH adjusted sodium lactate, and to determine the reduction of microbial population on rainbow trout treated with higher concentration of sodium lactate without adjusting pH during refrigerated storage.

MATERIALS AND METHODS

Preparation of Sample

Rainbow Trout (*Oncorhychus mykiss*), harvested from the University of Georgia aquaculture ponds (Cohutta, Georgia). The fish were transported on ice to the University of Georgia, Athens, GA and then headed and gutted. The dressed fish were treated with 0 (pH 7.0), 0 (pH 5.5), 1 (pH 5.5), and 2% (pH 5.5) sodium lactate solutions. The pH of sodium lactate solution was adjusted by using 0.1 N HCl. The live trout were also purchased from the Dekalb Farmers Market (Atlanta, Georgia) for this study. The fish were headed and gutted by store workers and transported on ice to the University of georgia. The fish were then treated with 0, 4 (pH 6.52), 8 (pH 6.15), and 12% (pH 6.13) of sodium lactate solution without pH adjustment. A 2-min dipping in lactate solution was used for all the samples.

Packaging and Storage

All treated fish were packaged by either overwrapping with polyvinylidene films (Saran wrap oxygen transmission rate: 5 cc/m^2/24 hr/atm at 20°C and 43% RH), or vacuum-skin packaging with low density polyethylene films (Surlyn, oxygen transmission rate: 930 cc/m^2/24 hr/atm at 23°C and 75% RH) using a Trigon Intact RM 331 Mark III Mini Intact machine (Trigon Packaging Corp., Redmond, WA). Packaged fish were stored at a 4°C walk-in cooler for up to 20 days and randomly removed from cooler at a 4-day interval for measurement of pH and color and microbial counts.

Microbiological Evaluation

A core section of fish which measured 24.78 cm^2 on both sides of the fish surface and 12.45 cm^2 on the total cavity surface area were collected by using a sterilized hole puncher. The sections were then placed in stomacher bags with 100 ml of 0.1% peptone buffer solution (Bacto) and stomached for 2 min by a Stomacher (Seward model 400, London, England). The aliquots of proper dilution were plated onto plate count agar and incubated at 20°C for 4 days to enumerate a total psychrotrophic bacterial count (Speck 1984). The aliquots were also plated onto trypticase peptone glucose yeast extract agar (TPGY) and incubated at 20°C for 4 days to enumerate total anaerobic plate counts (Speck 1984). The BBL GasPak^R anaerobic chamber with BBL GasPak^R Co_2 gas packs (Becton Dickinsin Microbiology Systems, Boston, MA) were used to create an anaerobic environment for incubation.

Surface pH Measurement

Triplicate pH readings were taken from the surface of each sample fish by using a Fisher Scientific probe (No. 13-620-286) and a Corning pH meter (model 140, Corning Inc., NY, NY).

Color Analysis

The color of fish skin surface was measured prior to removal of the core sample by using a Colormeter (Minolta CR-200, Osaka, Japan). Hunter color values of L (lightness), "a" (redness) and "b" (yellowness) were recorded. Triplicate measurements were taken from each fish.

Data Analysis

Statistical analyses (SAS 1987) were performed on pH, color value and microbiological data by means of PC SAS. The Duncan's multiple range test was used to determine any significant differences among samples from fish with different sodium lactate treatments.

RESULTS AND DISCUSSION

Effects of pH adjustment of sodium lactate solution on microbial counts

Overwrapped rainbow trout treated with 2% sodium lactate had significantly ($p < 0.05$) lower psychrotrophic bacterial counts than control samples (pH 5.5 and 7.0) after 8 days of storage (Table 1). However, no significant difference between 2% sodium lactate treated sample and control (pH 7.0) was found after 16 days of storage. For vacuum skin packaged sample, 2% sodium lactate treated fillets exhibited a significantly lower psychrotrophic bacterial counts on day 16 (Table 2). Although sodium lactate treatment showed to retard bacterial growth, the difference on bacterial count was less than 1 log cycle.

All sodium lactate treated fillets held in overwrapping had significantly lower anaerobic bacteria counts as compared to control samples (pH 5.5) after 12 days of storage (Table 3), however, no significant difference between sodium lactate treated samples and control (pH 7.0) was found after 16 days of storage. No clear evidence on reduction of anaerobic bacteria count among all vacuum skin packaged samples was found throughout the entire storage period (Table 4). Although the shelf life of cod fillets was extended for 4 days by applying sodium lactate to the product (Anonymous n.d), little effect on that of rainbow trout was found in this study. This may be due to the tested rainbow trout had skin on while cod fillets were skinless. The viscous materials on the skin surface may protect the bacteria from sodium lactate solution.

Effects of concentration of sodium lactate on microbial counts

Vacuum skin packaged fillets treated with sodium lactate had significantly lower psychrotrophic bacteria count than control sample after 4 days of storage (Table 5). Fillets treated with 12% of sodium lactate exhibited the lowest count on day 8. For total anaerobic bacterial count, the similar result was found (Table 6), however all the differences in anaerobic bacteria counts were less than 1 log cycle.

Effects of sodium lactate treatment on pH and color changes

No significant difference on surface pH of all samples was found regardless of sodium lactate treatment (Table 7). Results also showed that sodium lactate treatment had no effect on color values of rainbow trout skin.

In summary, fish with lower initial bacterial counts exhibited longer shelf-life. Significant effects on microbial growth were found for fish treated with 2% sodium lactate solution (pH 5.5) or with 4% and higher concentration (without pH adjusting). Since the fish has skin, the immersion time need to be longer.

Q. Your saran overwrap, is that just like you would do it at home, wrap it up in saran wrap, then your vacuum package -were you in a tray with overwrap or ziplock bag.

A. No, it's not a bag - that is a vacuum skin pack and it sealed to the tray directly.

Q. So, you have contact with the skin in both cases.

A. Yes, again, this is an oxygen permeable tray, and the film is also oxygen permeable. We don't want to create anaerobic environment. Again, this is a more sensitive issue, we try to comprise the quality to the safety.

Q. Did you notice any change in the color of the fish or any sensory changes in the packages?

A. No. no changes in color of the fish was noticed by using colormeter. No sensory evaluation of fish was conducted in this study.

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Table 1. **Psychrotrophic bacteria count (logCFU/cm^2) of sodium lactate treated rainbow trout held in overwrapping and stored at 4°C**

Sodium lactate (%)	Days of storage				
	0	4	8	12	16
20					
0[d]	3.43a	2.33a	2.26a	4.07a	5.01b
5.80b					
0[c]	3.10a	2.24a	2.93a	4.17a	5.93a
7.08a					
1[c]	3.32b	2.51a	2.75b	3.85a	5.50a
5.88b					
2[c]	3.29a	2.04a	2.21c	3.65b	4.68b
5.65b					

a,b,c

Means in a column followed by the same letter are not significantly different at level of 0.05

[d]pH=7.0

[c]pH=5.5

Table 2. **Psychrotrophic bacteria count (logCFU/cm^2) of sodium lactate treated rainbow trout held in vacuum-skin packaging and stored at 4°C**

Sodium lactate (%)	Days of storage				
	0	4	8	12	16
20					
0[d]	3.44a	1.95c	2.39b	2.87a	4.19a
5.35a					
0[e]	3.10a	2.57a	2.64b	3.30a	4.56a
5.22a					
1[e]	3.32b	2.08b	2.89a	3.12a	4.18a
5.63a					
2[e]	3.29a	2.40a	3.38a	3.21a	3.50b
4.87b					

a,b,c

Means in a column followed by the same letter are not significantly different at level of 0.05

[d]pH=7.0

[e]pH=5.5

Table 3. **Total anaerobic bacterial count (logCFU/cm²) of sodium lactate treated rainbow trout held in overwrapping and stored at 4°C**

Sodium lactate (%)	Days of storage				
	0	4	8	12	16
20					
0[d]	2.46a	2.04c	3.61a	3.48a	4.52b
5.02b					
0[e]	2.62a	2.31a	2.07b	3.70a	5.24a
6.32a					
1[e]	2.85a	2.16b	2.68a	3.44b	4.47b
5.12b					
2[e]	2.79a	2.34a	1.53c	2.71c	3.90b
4.89b					

a,b,c

Means in a column followed by the same letter are not significantly different at level of 0.05

[d]pH=7.0
[e]pH=5.5

Table 4. **Total anaerobic count (logCFU/cm^2) of sodium lactate treated rainbow trout held in vacuum-skin packaging and stored at 4°C**

Sodium lactate (%)	Days of storage				
	0	4	8	12	16
20					
0[d]	2.46a	2.19a	2.33a	2.55a	4.13a
4.23c					
0[e]	2.62a	2.31a	2.06a	2.70a	3.93a
4.99b					
1[e]	2.85a	2.16a	1.65a	2.59a	3.94a
5.31a					
2[e]	2.79a	2.34a	1.99a	2.34a	3.02b
4.57c					

a,b,c

Means in a column followed by the same letter are not significantly different at level of 0.05

[d]pH=7.0

[e]pH=5.5

Table 5. **Psychrotrophic bacteria count (logCFU/cm²) of sodium lactate treated rainbow trout held in vacuum-skin packaging and stored at 4°C**

Sodium lactate (%)	Days of storage			
	0	4	8	12
0	4.59b	6.01a	9.11a	12.24a
4	3.44c	4.75c	7.88b	12.23a
8	4.92a	5.45b	7.89b	12.15a
12	4.61b	5.52b	7.04c	12.02b

a,b,c Means in a column followed by the same letter are not significantly different at level of 0.05

Table 6. **Total anaerobic bacterial count (logCFU/cm²) of sodium lactate treated rainbow trout held in vacuum-skin packaging and stored at 4°C**

Sodium lactate (%)	Days of storage			
	0	4	8	12
0	2.96a	5.87a	7.57a	12.22ab
4	2.50b	4.61c	7.74a	12.26a
8	2.92a	5.32b	7.02b	12.26a
12	2.75ab	5.60ab	7.07b	12.19ab

a,b,c

Means in a column followed by the same letter are not significantly different at level of 0.05

Table 7. **Surface pH of sodium lactate treated rainbow trout held in vacuum-skin packaging and stored at 4°C**

Sodium lactate (%)	Days of storage			
	0	4	8	12
0	7.08a	6.48a	6.29ab	7.05a
4	6.84b	6.34ab	6.25ab	6.88a
8	6.81b	6.32b	6.38a	6.90a
12	6.53c	6.46ab	6.22b	6.87a

a,b,c Means in a column followed by the same letter are not significantly different at level of 0.05

SHELFLIFE AND SAFETY OF FRESH TROUT

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My topic today is "Shelflife and Safety of Fresh Trout." The work we're doing at Tennessee concerns the use of modified atmospheres to improve safety and shelflife of fresh trout. The scientist from Dr. Marshall's group at LSU has already discussed the growth of *Listeria* in modified atmospheric packaged aquaculture products. Therefore, I would like to concentrate my discussion on basic risk factors associated with modified atmospheric packaged foods and review our current work on microbial quality of trout in retail markets in the Southeast.

The research funded by the SRAC grant provided an opportunity to survey markets in the Southeast to determine the microbial quality of trout currently offered for sale. We have thus far sampled 74 stores. These include the major retail markets such as Kroger, Food City, Winn Dixie, Red Food, Food Lion, Ingles, and some of the higher price upscale specialty groceries such as Fresh Market. Aerobic plate counts (APC) of the fresh trout ranged from log 4.7 to log 8.6/g. Approximately 25% of the fresh trout which we purchased from the 74 stores had microbial counts greater than log 7.5/g (approximately 60,000,000/g) which would be considered spoiled. Several retail markets indicated that they had discontinued selling fresh trout because of the rapid spoilage and losses which they incurred. Our most recent work (April & May 1993), has shown that the problem becomes greater as the seasonal temperatures increase. Over 50% of the fresh trout samples collected in May were "spoiled." Coliform counts ranged from 0 to log 6.9/g with a mean coliform count of log 3.8/g fresh trout. Twenty-one (21) fresh trout samples had coliform counts exceeding log 4.0/g (10,000/g). With the current concern with E. coli 0157, I would consider these counts too high. I believe that the data we have collected point to a great need for improvement in microbial quality of trout. We are currently using carbonic acid dips and a variety of other methods in combination with MAP to reduce microbial counts and improve shelflife of fresh trout. One chain of stores had significantly lower bacterial counts on the fresh trout than the others ($<$log 3.0/g). I'm almost afraid to ask what they've been doing, but it may help us find a solution to the shelflife problems with fresh trout.

Assuming that we can improve freshness and increase shelflife of fresh trout using MAP (our current research shows we can!), will we also increase the chance for growth of hazardous or disease-causing bacteria? This is a question we must answer. Generally, spoilage bacteria compete with pathogenic or disease-causing bacteria in refrigerated perishable foods. Modified atmospheric packaging offers many exciting possibilities for packaging of foods; however, we need to determine if pathogenic bacteria can grow to hazardous levels in fresh trout when shelflife is increased. MAP is definitely the packaging technique of the 90s. The reason for its success is that shelf life can increase anywhere from about 200 to 400%. The bottom line is economics. MAP of fresh trout has been used successfully in Europe for several years. However, the current feeling in the United States is that we do not have a database which shows that MAP of fresh fish products is safe or unsafe and that research needs to be done to correct this deficiency.

The diagram shown below illustrates four possible scenarios which can occur with shelflife extension of fish packaged in MAP.

1. INCREASE PATHOGENIC BACTERIA/DECREASE SPOILAGE BACTERIA
GREATEST RISK

2. INCREASE PATHOGENIC BACTERIA/INCREASE SPOILAGE BACTERIA
SOME RISK

3. DECREASE PATHOGENIC BACTERIA/DECREASE SPOILAGE BACTERIA
LESS RISK

4. DECREASE PATHOGENIC BACTERIA/INCREASE SPOILAGE BACTERIA
LEAST RISK

One of the best indicators of unsafe food is the smell we call spoilage. If we increase pathogenic bacteria and decrease spoilage bacteria such as in #1 above with MAP, this creates a very undesirable and hazardous situation. The third (#3) category is where we would like to be with MAP packaged foods. Ideally, we would wish to *reduce* both spoilage and pathogenic bacteria; thus, ensuring both safety and a long shelflife.

When we discuss modified atmospheric packaging, the major gases of concern ar oxygen, carbon dioxide and nitrogen. Nitrogen is used as an inert gas, primarily as a filler. Oxygen is needed in some products such as vegetables or red meats to preserve quality. Carbon dioxide is the gas which is used to control

microbial growth. There are a number of theories as to why carbon dioxide inhibits growth of microorganisms. Carbon dioxide combines with water and forms carbonic acid and/or bicarbonate ion. These reaction products combine to reduce the pH of the fresh fish. Since the majority of the spoilage bacteria of fish prefer to grow at very neutral pH (pH 7.0), reduction of pH of the flesh slows growth of spoilage bacteria. On the down side, the pH change also affects the structure of proteins in the fish. Too much of a pH change (generally caused by carbon dioxide levels in excess of 60%) causes a release of water from proteins, and the formation of liquid in the package. The liquid is called "drip" and leads to unsightly packages which have less appeal to consumers. Some researchers also report "greying" of fish in excess of 60%.

Another theory about the effect of carbon dioxide on growth of microorganisms is that the bicarbonate ion and carbonic acid ions stick to the outside of the bacterial cell and play havoc with the transport of materials across the cell wall. This theory is highly plausible and helps to explain another phenomena that researchers have discovered. To prevent the growth of anaerobic bacteria (especially *C. botulinum*), some researchers have added oxygen to packaged fish to prevent anaerobiosis. This sounds like a good idea, unfortunately it doesn't work.

Carbon dioxide also affects the enzyme systems of both the fish and the bacteria. Carbon dioxide has been shown to inhibit a certain large group of enzymes called hydrolases which are important for microbial growth. The lack of oxygen also slows enzymatic oxidation of fish. I personally believe that it is probably a combination of the above factors which account for the success of MAP.

In trying to determine the types of microbial studies which need to be done to determine the quality of fresh trout under a variety of packaging conditions, we find in the literature four main types of studies. The first type of study is the most common in which aerobic plate counts are used throughout a storage period at a specific temperature to determine shelflife. The second type of study looks at aerobic plate counts during storage but also monitors growth of pathogenic bacteria. The third type of study is one in which a mathematical model is developed for a product under a variety of conditions. Assuming we know the initial number of cells, the model can predict how fast a particular organism can grow at a specific temperature, pH, NaCl level, etc. The research group at Eastern Regional Research Laboratory which is lead by Dr. Bob Buchanan currently has this program available free of charge on request. Dr. Constantine Geniogeorgis has developed a program for modeling the growth of *Clostridium botulinum* under

a variety of conditions. I am not sure if this is currently available. Dr. Genigeorgis can be reached at Cal Davis. This type of program can be a useful QA tool for companies.

The fourth type of study is the development of a SAFETY INDEX. The number of spoilage bacteria vs. pathogenic bacteria are determined at specific times during storage. The formula is shown below:

$$\frac{\text{CFU spoilage bacteria}}{\text{CFU pathogenic bacteria}} = \begin{matrix}\text{SAFETY} \\ \text{INDEX}\end{matrix}$$

As the denominator gets bigger, the safety index goes down and thus the product becomes potentially more hazardous. This can be a useful tool when used properly. It can quickly help us to identify MAP techniques or treatments which would be considered high risk and possibly undesirable.

In addition to the microbial considerations, there are other advantages to MAP of fish products. Increased market area would be a bonus for the aquaculture industry and would be possible by extending shelflife. MAP improves the appearance of the fish. There is easy separation of product, and less handling and contamination at the retail level. Packages can be submerged in ice without contamination and easily handled by consumers. The biggest disadvantage is the initial cost of capitalizing the processing and the films and the cost of the research required for development of the technology. Some researchers have also reported that high levels of carbon dioxide (>60%) caused undesirable flavor changes in fresh fish.

In a discussion of risk with MAP of fish, the key organism of concern must be *Clostridium botulinum*, since it grows anaerobically (in the absence of air) and because of the high toxicity of the neurotoxins produced by *C. botulinum*. *Clostridium botulinum* type E grows at temperatures >3.3°C (approximately 38°F). Since most home refrigerators are within the growth range of type E clostridia, caution must be the key word. There have been a number of studies on botulinum toxin production in various types of saltwater fish; however, very little can be found on freshwater fish. Theoretically, there should not be a great difference if fish are compared on the basis of composition (i.e. highly fatty vs. lean) and feeding habits. However, levels of spores of *Clostridium botulinum* in water does affect levels of such spores found in fish. For example, spore levels of clostridia in coastal waters off U.K. are less than 0.5%, but in coastal waters of Scandinavia, contamination of waters with clostridia can be found in excess of 50% of the

samplings. Occurrence of *C. botulinum* in the Great Lakes Region has been reported from 0 to 50%. In the U.K., incidence of *C. botulinum* in inland ponds ranges from 7 to 10%. We do not know the levels of *C. botulinum* in waters used for aquaculture in the Southeastern United States. I think this information is important and should be collected so that we can calculate the potential for occurrence of *C. botulinum* in our fresh aquaculture products.

The "OCCURRENCE" of *C. botulinum* is quite different from the "LEVELS" of clostridia occurring in fish. From the few studies reporting levels of *C. botulinum*, it appears that spore counts (if spores are present) are almost always less than 1000 per gram fish. Generally, they are below 50 spores/g fish. This means that it should take a long time for levels to build to high enough levels to detect measurable toxin production at 4°C.

Table 1 relates storage temperature, spoilage and production of *C. botulinum* toxin in various types of fish. A key factor to remember in evaluating this study is that if a fish is considered spoiled before toxin production is observed, this would be considered a relatively safe product. The longer between spoilage and toxin, the greater the safety margin. However, if toxin is detected before spoilage; this would be a very hazardous situation.

Several interesting points can be observed in this table. First, toxin production does vary depending on type of fish sampled. Only one of the 4°C samples had toxin production before spoilage and this was after 18 days. The more delicate fish such as flounder tended to spoil before toxin was produced. With the samples underlined in the table, people could have eaten the fish containing toxin since it was considered not spoiled. It is true that fish is cooked before eating and that botulinum toxin is destroyed by heating above 80°C for several minutes. However, it is quite possible that the fish might not reach that temperature during cooking.

The key factor which controls toxin production in fish is temperature. If temperature can be maintained below 3.3°C, the *C. botulinum* will not grow. Therefore, the safety of trout packaged under MAP will depend on the handling and temperature control during distribution. There are basically three ways that MAP can be incorporated into the distribution of aquacultured products. We can go the route of the red meat industry and transfer them in trucks where we expose them to a modified atmosphere but put them in a semipermeable film that allows oxygen transmission once the product is in the store. The second option is to use a "MASTERPACK" where we have a large package containing the MAP and small

packages inside with semi permeable film which will have the MAP until the large package is broken at the store. The third option is to actually make consumer packages which have the fish ready to take home in a MAP type package. This would give the consumer several days shelflife after taking the product home. The third option has distinct advantages. It also has inherent danger.

Consumers have a tendency to abuse food products rather indiscriminately. It is quite possible that a package could be accidently left on the counter overnight, placed in the refrigerator and opened several days later still smelling fresh, but containing deadly toxin. Some of the questions we need to answer with our research are how much shelflife extension is possible with trout and will the product be safe under a MAP film? Will the MAP affect appearance or cause undesirable odors? Will other pathogens such as *Salmonella* or *Listeria* grow in a MAP package of trout? The research which we are doing at the University of Tennessee on the SRAC grant is currently trying to answer these questions.

Table 1. EXTENSION OF SHELF LIFE OF FISH BY MAP (SPOILAGE VS. BOTULINUM TOXIN PRODUCTION)

STORAGE TEMPERATURE (°C)	TYPE OF FISH/ # SPORES (PER G) INOCULATED	TYPE OF MAP	SPOILAGE DETECTED (D)	TOXIN DETECTED (D)	REF
12	Salmon/10000	Vacuum	not detected	3	2
12	Salmon/10000	100% CO_2	not detected	6	2
12	Salmon/10000	70% CO_2/30% Air	not detected	6	2
12	Cod/50	Air	6	9	1
12	Cod/50	Nitrogen	13	6	1
12	Cod/50	100% CO_2	11	11	1
8	Flounder/50	100% CO_2	10	23	1
8	Cod/50	100% CO_2	23	19	1
8	Flounder/50	Air	5	>12	1
4.4	Flounder/1000	100% CO_2	18	>21	3
4	Salmon/100	Vacuum	42	>60	2
4	Salmon/100	CO_2/Air	24	>60	2
4	Cod/50	100 CO_2	53	18	1
4	Whiting/50	100% CO_2	15	27	1

References: (1) Post et al. (1985); (2) Garcia et al., (1987); and (3) Stier et al., (1981).

CATFISH QUALITY ASSURANCE PROGRAM

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What is quality assurance? Quality assurance for the aquaculture industry has been defined as "a proactive, industry-driven code of production practices, carefully designed to assure that producers supply a wholesome, safe product". "Proactive" and "Industry-driven" are key concepts. Quality assurance is a comprehensive system of production practices that are carefully put together to assure that producers are delivering a safe, wholesome, healthy product that consumers are satisfied with.

Why is quality assurance important? More importantly, why quality assurance for aquaculture? The answers can be found when we look around at other food animal industries and strive to learn some of the lessons that other industries have learned the hard way. We find that being proactive is extremely important. Most other animal industries have developed quality assurance programs in one form or another. Examples include pork, dairy, beef, veal and others. Most of these were reactive in nature. They were forced to develop quality assurance programs in reaction to problems that occurred (perceptual or real) with their consumer relationships. In some cases, consumer confidence levels were shaken by residue violations and other inadequacies in their products. What aquaculture would like to do is to be proactive, to be positioned to prevent problems before they have a chance to occur.

What will quality assurance do for aquaculturists? For the catfish industry, it will, for the first time, result in a single document, in a standard format, that presents all those things that catfish producers are already doing to assure quality of their product. As our Catfish quality assurance (CQA) program development team sat down and looked at what quality assurance might mean for the catfish industry we realized very quickly that the first thing needed was to compile into a single document all those steps that catfish producers already follow. We realized that quality assurance would not involve many new things above those practices already in place.

Secondly, quality assurance will identify critical considerations (similar to critical control points in HACCP) in catfish production systems. Critical consideration points include all those points in the production process where potential problems could occur. Producers should pay close attention to these critical considerations. The consumer-producer relationship -- the confidence that consumers have in the product -- is paramount. The driving force behind previous quality assurance programs in other animal industries is the consumer perception of safety of those products they have received from producers. The benefits of quality assurance, then, should be very obvious.

Consumer confidence in and support for catfish, for example is already high. The market for catfish continues to grow, and there are no safety concerns about catfish at either national or local levels. Catfish has not been burdened by the negative press that has plagued some other fish and seafood products. The catfish industry would like to maintain that image and be sure that its reputation does not regress; that it is continually enhanced. If this can be done, quality assurance will be deemed a success.

There is also a potential beneficial side-effect of quality assurance. It is likely that, in identifying and emphasizing critical consideration points, we might also inadvertently arrive at a set of "best management practices" for catfish or other species. Incorporation of such practices might provide a competitive edge for producers, making them more efficient while assuring product quality in the process.

Producers who participate in a QA program are informed. This is a vital point! Unfortunately, in aquaculture, the most informed group about food safety is the scientific community. The typical fish farmer has very little idea as to the meaning, or significance of quality assurance. But producers are the very group that needs most to know and to understand, since they are best positioned to ensure the safety of the product. As regulatory concerns increase, as consumer perceptions become more acutely sensitive, and as desires for food safety increase, producers inherit a greater responsibility to be accountable. The "informed" scientific community can meet and discuss these issues ad infinitum, but if producers do not understand the "why", "how" and "what" of quality assurance, then we have a real problem. Producers must become more informed and then become more actively involved in quality assurance.

Involving producers in an effective quality assurance program will increase their level of understanding and increase their ability to respond positively. This is an urgent matter! We are not dealing with an emergency in the sense that

consumer confidence of our product is shaken, at least not with catfish. We don't currently have any identified risks relative to violative residues, and consumer perception of catfish is very good. The situation is urgent, however, in that we want to be sure that these problems never occur; we need to be proactive, not reactive.

One need only look at the precedents set by other food animal industries and their associated experiences to see what can happen when consumer confidence fails. A scare, whether justified or unfounded, can cost our industry tremendously. An increased level of scrutiny at every level, coupled with the obviously important consumer relationship, make quality assurance an imperative for the catfish and aquaculture industries. Aquaculture has, for quite some time, escaped the mainstream consumer and regulatory scrutiny to which other food animal industries have been subjected. That is no longer the case. With the increasing value and prominence of aquaculture come also increased notoriety and public awareness. In early 1992, Consumer Reports featured an article on the safety of the seafood we eat. Fish, seafood and aquaculture are increasingly in the public limelight. We can no longer linger in the shadow of anonymity.

In early 1992, Catfish Farmers of America came to this very conclusion and approved official movement toward development and adoption of a quality assurance program for catfish. Questions to be answered included "what can we do?", "what exactly is quality assurance?", "how can a QA program be developed?", etc. This is the point where I first became acquainted with the concept of quality assurance. When approached by Hugh Warren, CFA Executive Vice-President, with these questions my response was an unequivocal "I don't know"! Quality assurance was as new to me as it was to most other aquaculturists.

However, we began to learn together about quality assurance. We gathered as much information as we could from other industries, and relied heavily upon our friends with the US Food and Drug Administration for insight and information. We already knew, for example, that in the processing sector of the catfish industry that quality assurance has long been a familiar concept. Voluntary inspection programs and a conscious commitment to product integrity have contributed significantly to the prestigious place that catfish occupies in todays food marketplace. We also readily recognized an obvious gap in the production-processing chain. Although processors carefully strive to maintain the quality of the fish that they receive and then market, they are, to a great extent, at the mercy of the producers who supply the fish. Processors cannot increase quality; they can only maintain the quality they are provided! Thus, the gap exists at the producer level.

We see a gap in the sense that producers have not been purposefully involved in making sure, thorough carefully conceived and practiced steps, that processors receive a product of the highest quality that they can pass along to the consumer. Producers must become more aware that if a processor receives contaminated fish there is probably not much that can be done to clean it up; the producer must supply quality to the processor so that the processor is in the best position to supply quality to the consumer. Thus, an important need right now is for catfish producers to extend a show of good faith to the industry, regulatory agencies, and to the consuming public to participate and devote their efforts to quality assurance.

Catfish Farmers of America, therefore, put together a team of extension specialists and related scientists from the four major catfish producing states. We tried to get a good cross-section of extension aquaculture specialists since extension is in the best position to serve as interface between academia and production. The key to the CQA, and the ultimate key to any subsequent QA program, is that is it truly producer-driven. The CQA is not something that a group of scientists or specialists dreamed up, developed, and then will extend to the industry. On the contrary, it is a program that is conceived, requested, driven, and facilitated by producers. Our development team has simply responded to the request and identified need. The program we have developed is a product to meet producer request and need.

We have developed a basic quality assurance program that can easily be slid into the "back pockets" of catfish producers. By that we mean that the CQA can be implemented with very little change in routine catfish production practices. The fact that catfish has risen to prominence, and enjoys a strong safety and quality record is no accident; catfish producers have long utilized safe production practices and procedures. The CQA really does little more than outline in a precise form the things that producers already do, but that we may have taken for granted. CQA puts these practices into a nice presentation format for everyone to see. We want others to know what catfish producers do to ensure that catfish is safe and wholesome.

One recommendation that CQA makes to producers is that they begin to keep detailed records of drug and chemical use. Some producers already keep such records, but others have not yet begun to do so. Record keeping is a wise management procedure, but it also will become increasingly important from a regulatory standpoint. Drugs that are used in catfish health management require observance of withdrawal times to prevent potential residues in the fish. Records are vital to calculating and observing appropriate drug withdrawal times. Fish

producers, like all other drug and pesticide users, will be required in the future to maintain drug, chemical and pesticide purchase, application and storage records. The adoption of record keeping procedures, before they are made mandatary by regulatory agencies, is another proactive move that illustrates good faith and good stewardship on the part of the catfish industry. Effective record-keeping procedures will also expedite producer participation in the INAD process for FDA drug approval considerations in the future.

We have identified several critical consideration points that are very similar to the HACCP critical control points that have been recently identified for catfish production. These were, however, developed mutually independent of each other. These critical considerations are really just common sense points in the production process where contamination could occur if the producer does not pay close attention to quality assurance procedures. It is at these critical consideration points that producers must pay particular attention to ensure that we don't encounter violative residues of drugs, pesticides or environmental pollutants.

A big question asked by many is "who participates"? Catfish quality assurance will be a totally voluntary program, as are most other commodity quality assurance programs. Obviously, we would like every catfish producer to participate. The fact that this program is producer-driven will hopefully encourage all producers to participate. A strong commitment on the part of most of the catfish producers will strengthen catfish quality assurance. Participation in catfish quality assurance simply will entail reviewing the quality assurance producer guide and returning an enrollment form to Catfish Farmers of America. Enrollment entails no additional obligations, but will ensure that the producer will be kept abreast of the status of drugs and pesticides used in catfish production. The dynamic situation with drug approvals for aquaculture requires constant attention to the latest information from FDA and other regulatory agencies. Participation in CQA will aid catfish producers in keeping up-to-date on these important issues.

Widespread participation in CQA will also provide anyone involved with the catfish industry another important capability. For the first time, we will be able to provide to potential critics substantive information regarding the real safety of farm raised catfish. During recent media coverage of fish and seafood safety concerns, we have often had a difficult time providing answers to media questions such as "is catfish safe to eat" and "how do you know that catfish is safe". With the arrival of a CQA document, and with the adoption of CQA by all catfish producers, we will now have the information and ammunition that we need to deal with, and refute if necessary, any negative press that catfish may receive. We can truly claim to be <u>proactive</u> and there will, hopefully, never be a need to be <u>reactive</u>. That, in a nutshell, is Catfish Quality Assurance.

QUALITY ASSURANCE INITIATIVES AND THE AQUACULTURE INDUSTRY: AN UPDATE

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Good morning. While reading the current issue of a glossy *Seafood* magazine, I was impressed by constant reference to safety. For example, and I'm quoting from advertisements:

> "we ensure quality of superior seafood through exacting standards"
>
> "only superior fish and shellfish can pass our rigorous seafood inspection and quality assurance program"
>
> "at Coldwater Seafood Corp., quality control isn't a figure of speech. It's a way of life."
>
> or, "products packed under federal inspection"

One of the magazine's feature articles focused on *What do consumers want? What do you think consumers want?* And then a featured columnist referenced THAT issue of *Consumer Reports* containing THAT article entitled "Is Our Fish Fit to Eat?" The answer was clear enough at the time - NO!

This past October, however, CR published an article called "Are You Eating Right?" And guess what a corps of nutrition experts recommended? That's right "eat fish at least twice a week." Realizing that the columnist writes for a seafood industry publication, he goes on to cite a study that tells us that consumers don't pay much attention to "seafood smears" anyway. He suggests we can relax a little.

This meeting and the signals I'm receiving from the people I work for suggests something to the contrary. Something more in line with the message sent by those advertisements I quoted from a few minutes ago. That is - the aquaculture industry isn't at all ready to relax a little! Not where our products, our future or our responsibility to the American consumer is concerned!

History is a wonderful teacher; it's a shame, however, that it tends to be savored most especially by historians. Bear with me while I relate a brief history of QA programs from traditional agri-business. There's a lesson here. A lesson that suggests we not relax.

For example, the National Broiler Council developed a Good Manufacturing Practices protocol four years ago. Their GMP provides guidelines for producers and increases public awareness of what that industry is doing to ensure a quality product. Approximately 95% of the producers are using the program to one degree or another. Note: their GMP was revised in September, 1990 - shortly after the "airing" of a *60 Minutes* segment on the poultry industry.

The National Milk Producer's Federation has a 10 point QAP. "Drug residues in milk can be prevented through proper drug use. Adherence to the program will reduce expenditures for animal health products, eliminate drug residues and increase consumer confidence," so states the Federation. The program is mandatory only for residue violations. A penalty system was initiated in January of 1992. Note: the program was developed in the fall of 1988 prior to media coverage.

The National Cattlemen's Association helps states develop their own programs, each designed to meet the needs of producers within a particular state. There are now 30 states with QA programs. Note: in the early '80s the beef industry became aware of its high profile, which included food safety issues. A task force was formed to study these concerns. The QAP approach came about as a result of the task force study. Approximately 65 - 70% of fed cattle are covered under a QAP.

The National Pork Producers Council has the oldest QA programs in the U.S. It's viewed as a way of protecting the market for the producer. It is consumer-oriented. It is funded at the national level with check-off funds and has state buy-ins. The 300,000 pork producers in this country are a diverse group. Approximately 15,000 producers are enrolled, representing 37 million pigs or 40% of annual production. Note: this program began in the 1980s in reaction to a 13% sulfa violation rate in the 1970s. And by the way, NPPC points to violative residues of less than 0.5% in 1990. And so - the other white meat!

The underlying reason for briefly describing these programs was to point out that each occurred as a result of food safety questions and/or resultant negative press. These industries reacted positively.

Our industry tends to operate in a reactive mode. That's understandable. We're young, we're few: the bureaucracy many. Our associations rely on volunteers for assistance. Our diverse leadership has only been engaged in serious dialogue for the past several years. It's reassuring that this industry is reacting positively on this matter. And doing so before it is forced to do so.

The U.S. Trout Farmers Association's Board of Directors recently approved development of a HACCP-based QA, complimenting that of the catfish industry. The program will be developed with participation of producers. Who knows their industry, its subtleties better? Several of the trout industry's larger producers/processors have QAs in place. But what about the vast majority of trout producers? USTFA believes it to be in their interest to offer a program to all who wish to participate voluntarily.

The program will likely be patterned after that of the pork industry; a ten critical control point program designed to assure quality. Such a program would assist trout producers in avoiding illegal drug residues, in improving management skills, while reducing production costs and increasing awareness of food safety concerns. Since good record-keeping is an integral part of such an approach, farmers will be in a position to collect INAD-related data, should they wish to participate in that exercise.

The program will be voluntary, as I've stated. It will be available to members. There will be a modest charge for participation. The association, with assistance from drug and feed manufacturers will pay an outside contractor to develop the materials. The association will "own" the program, as it were. Verifiers will visit participating farms at least annually. The association will be looking closely at funding sources required in future years to update such a program. The association fully anticipates working with Extension to assist in sensitizing and frankly selling producers on the merits of quality assurance programs. Experiences related again by our partners in agriculture suggest that this part of the picture cannot be ignored.

Briefly, I'd like to mention a complimentary QA initiative being fostered by the NAA in cooperation with the Northeastern RAC. This will be an introductory QA, again patterned after the pork industry. This will be a less-sophisticated program, a producer education program designed, again, to enhance quality. Consider it to be the "stepping stone" for the producer who may then

wish to participate in the more sophisticated programs being developed by the catfish and trout industries. The latter programs requiring verifiers, the introductory program requiring study and perhaps most importantly, commitment.

This particular program is being offered to provide an opportunity to farmers, who for a variety of reasons, may not wish to or be able to participate in a HACCP-based model. Currently, there are some 3400 farms in 23 states raising a variety of aquaculture products. A program such as this will ensure that all have an opportunity to participate.

In closing, sincere thanks for the opportunity to participate in this forum. And I'll relax when you do!

APPLICATION OF HACCP SYSTEM TO CATFISH PRODUCERS AND PROCESSORS

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The Food and Drug Administration and other federal and state food regulatory agencies are using HACCP as an effective way to help assure that only legally acceptable food products are available in the marketplace. The primary responsibility for the safety, quality, and other attributes of the food product, however, rests with the processor, distributor, or provider of that food, not the regulatory agencies. Therefore, it is needed to develop HACCP training programs for food industries. In our case, a HACCP training video has been developed for catfish producers and processors.

In order to present the HACCP information in an effective way, the training video consists of two parts in separate cassettes. Part I is introductory and titled, Overview of HACCP System. It runs for 15 minutes. Part II is titled, Application of HACCP System to Catfish Producers and Processors, and runs for 25 minutes. Because of the time limit, we are going to see Part II today. (Video text follows from here.)

Applying the HACCP food control system to the catfish industry involves catfish farming, processing conditions, handling and storage during wholesaling, and distribution for retail sale and consumption. In part 2 of "Overview of HACCP and its Application to the Catfish Industry," we will look at HACCP systems for catfish farming and processing.

As mentioned earlier, HACCP, or Hazard Analysis Critical Control Point, is a systematic approach to food safety control. It starts with the assessment of hazards and risks associated with growing and harvesting of raw materials and ingredients, processing, distribution, marketing, and the preparation and consumption of the food. Therefore, application of HACCP to the catfish industry should start at the beginning of the food chain, the catfish farm.

For each production facility or farm, the six steps to develop a HACCP plan should be followed.

1) Assemble the HACCP team. This team should be made up of managers, processing personnel, quality control and quality assurance personnel, outside consultants, and other advisors.

2) Describe the food and its distribution. For example, a catfish farm may write a description like, "The food, live catfish, is harvested from ponds and distributed by hauling trucks to processing facilities."

3) Identify the intended use and consumers of the food. "Live catfish are purchased by the processors where they are processed into a variety of value-added products for the consuming public."

4) Develop production or processing flow diagrams. A simple flow diagram for catfish production might look like this, noting several steps in the production of catfish, such as site selection, water supply, culture system, feed supply, production, harvesting, and delivery and transport.

5) Verify the flow diagram.

6) Apply the following seven HACCP principles.

A flow diagram is developed and verified. Now we are ready to apply the 7 HACCP principles. To review:

1) Conduct a hazard analysis

2) Identify critical control points

3) Set critical limits for each hazard at each critical control point

4) Devise a monitoring system to validate critical limits

5) Establish a corrective action plan for each critical limit

6) Verify your HACCP system in 3 ways

7) Keep records at all pertinent points

Let's take one step from the flow diagram and follow it through the 7 HACCP principles. In our example, we will look at water supply. Water sources for catfish growout areas may be wells, nearby rivers or streams, or surface supplies, each of which present different problems. Well water may contain heavy metals. Streams and surface water may contain herbicides and pesticides, or other potentially harmful chemicals that pose potential hazards to the animals as well as consumers. Thus a potential hazard for water supply is harmful chemical contaminants which can be controlled through your water source. Preventive measures for this hazard include reviewing geological and hydrographic survey data and available records on water quality, and controlling point and non-point source contaminated run-off. We now have completed a hazard analysis, which is principle #1 of the 7 HACCP Principles.

Principle 2 determines if this step is a critical control point, through the use of a decision tree. Remember - loss of control at a critical control point results in an unacceptable end product. Here is a decision tree for the water supply for a catfish pond. Let's apply Question 1 of the decision tree to water supply. "Could preventive measures exist for the identified hazard, chemical contaminants in water supply?" Yes, we have already discussed geological and hydrographic reviewing survey data and available records on water quality to control point and non-point source contaminated run-off.

If the answer is yes, proceed to Question 2. "Is the water supply specifically designed to eliminate or reduce the likely occurrence of a hazard to an acceptable level?" No, water supply is not designed specifically to eliminate or reduce the hazard.

Since the answer is no, we proceed to Question 3. "Could harmful chemical contaminants occur in excess of acceptable levels or could these increase to unacceptable levels?" Yes, water supply could cause the hazard to exceed acceptable levels.

Therefore, proceed to Question 4, which asks, "Will a subsequent step eliminate the chemical contamination or reduce the likely occurrence to an acceptable level?" No, therefore water supply is a critical control point.

From Principle 2, we proceed to Principle 3, establishment of critical limits. In the case of our example, harmful chemical contaminants in water supply, regulatory tolerances already exist for some pesticides and heavy metals. It is appropriate to establish critical limits that do not exceed regulatory tolerances.

Principle 4 requires establishment of a monitoring system. A monitoring system might consist of regularly checking the water supply source for content levels of metals, pesticides, herbicides, or other chemicals that pose a potential threat to the water supply.

Your corrective action, Principle 5, should define what you do when a problem occurs. For example, "If the water supply has levels of pesticides greater than regulatory tolerances, then sample the fish for pesticides in the edible flesh." Your corrective action would then detail your sampling plan, required analyses, alternate decisions for the use of the product, and the correction of the hazard in the water.

Principle 6 sets forth 3 verification activities for your HACCP plan. For this step, water supply, you would routinely verify that your critical limits meet regulatory tolerances, that your water supply still comes from the same source, and that analyses are properly documented and recorded.

Record keeping is the last principle. Retain records related to water supply, such as analyses, observed changes, verification activities, corrective actions, and disposition of product. Records must be signed by appropriate personnel and management.

This completes the seven HACCP Principles for one step, water supply. Many of the seven HACCP principles have already been applied to other steps in catfish farming. Let's take a quick look at these other steps.

First, **Site Selection.** Several factors should be considered in site selection. A study of the history of the previous use should be made. For example, it would not be appropriate to construct a catfish pond on a former landfill site. If a land use history is not available, then a minimal site survey should be conducted. Site selection is not considered critical if critical issues would be covered under the step, water supply. **Water supply**, which is step two, has been covered.

Three, the **Culture System.** Several types of culture systems are used in the growing of catfish. In addition to ponds, the culture systems include raceways and cages. Various types of equipment are used, equipment in a hatchery such as equipment for water filtration, water aeration, feed truck and feeding. Since the equipment itself is safe for the intended use, the major concern is the construction materials used and coatings that may be applied that could produce chemical contamination. Approved construction material and coatings should be used, construction of the equipment and facilities should be checked, and after installation, all equipment should receive regular and proper maintenance. This step is not critical.

Four, the **Feed Supply.** Feed and additives to the feed such as vitamins and antibiotics are major elements in finfish aquaculture. Additives in feed, as well as the feed itself, can be custom processed or "off-the-shelf." Depending on the process and process controls, the feed is subject to chemical and microbiological contaminations such as aflatoxin. Feed suppliers are presently regulated by law for labeling and proper addition if approved additives and antibiotics are used. This step should be rated as being critical.

Five, **Production.** Production includes selection of brood stocks, egg production and fertilization, hatching, fingerling rearing, and growout of adult fish. Practices in the industry vary. Each step in the production process has potential hazards that could affect the safety of the end product. Most important are chemicals that the fish may ingest throughout their life history that can accumulate in edible tissue through improper operation. These range from antibiotics to herbicides. Potential contamination from accidental oil spills or contamination outside the culture area could also create a potential hazard, such as human pathogen contamination of fish.

Six, **Harvest.** Techniques for harvesting adult fish depend on the type of growout facility. In most cases, the harvest process introduces no hazard to the product. Most problems are with monitoring when the fish should be harvested and controlling feed prior to harvest, which relates to the previous step, production. Harvesting is not a critical control point.

Seven, **Delivery and Transport.** After catfish are harvested, proper care should be taken during transportation. Chemicals or antibiotics are not used in transport. This step is not considered critical.

So the potential critical control points in catfish farming are water supply, feed supply, and production. A generic HACCP model for catfish farming that further describes these points is available. This model includes HACCP Principles 1, 2, 4, and 7. With the addition of the missing HACCP principles, your HACCP team can adapt this model to your individual facility. Models also have been developed for processing raw and breaded fish. Now that we've applied the six steps to creating a HACCP plan to catfish production, let's look at catfish processing.

Again, a HACCP team will be assembled and will describe the food and its distribution. While each facility's specific description will be different, the approach will be similar and should include product types processed at the facility and their distribution. The identification of the intended use and the consumers of value-added catfish products again will be similar among facilities. Such a statement might read, "Processed catfish products are intended to be fully cooked and consumed by the general public."

Next, a flow diagram is developed. Let's follow through with the raw fish flow diagram and the step, "Shipment." Shipping is the process of removing packaged product from frozen or chilled storage and loading onto transport. While there are multiple hazards with shipping, the hazard of decomposition will be addressed here. To prevent decomposition during shipping, adequate thermal protection, proper re-icing and container temperature, control of product loading, and loading only when the truck is at a proper temperature would be essential measures to take. This covers HACCP Principle 1.

For HACCP Principle 2, the critical control point determination, we will use the decision tree. Remember - loss of control at a critical control point results in an unacceptable health, wholesomeness, or economic fraud hazard at the product's end-use. Let's look at Question 1.

Question 1, "Could preventative measures exist for the identified hazard?" Yes, we have identified some preventive measures.

Since the answer is yes, we go to Question 2, "Is the step specifically designed to eliminate or reduce the likely occurrence of a hazard to an acceptable level?" No, shipment is not designed specifically to eliminate or reduce product decomposition.

Following the decision tree, Question 3 asks, "Could contamination with the identified hazard occur in excess of acceptable levels or could these increase to unacceptable levels?" Many catfish processors that have stringent preventive measures in place at this step would answer no, "This is not a critical control point."

Some, however, might answer yes and then proceed to Question 4, "Will a subsequent step eliminate identified hazards or reduce the likely occurrence to an acceptable level?" Yes, the distribution is a subsequent step. If a distributor receives an inferior product, in this case decomposed fish, he will reject it and return the product. Rejection by the distributor and subsequent recall of the product by the processor can disrupt a firm's operation and business. Recall of the product will reduce the frequency of decomposed catfish being shipped. Thus, "shipment" is not a critical control point. Since shipment is not a critical control point, Principles 3, 4, 5, 6, and 7 would not need to be done for this step.

Other steps in the processing of raw and breaded fish are critical, however. Let's look at the raw fish flow diagram again and briefly discuss each step.

Receiving. Live catfish are delivered to a processing plant and unloaded from a delivery truck into raceways. Hazards are unacceptable odor, off-flavors, and decomposed dead fish. This step is regarded as being critical.

Stunning. Catfish are laid on the conveyer belt. While the belt is moving, live catfish are stunned by electric shock. No hazards were identified for this step, and it is not a critical control point.

Heading and Gutting. Fish are headed and gutted. Gut contamination from bacteria and incomplete removal of viscera are the hazards. This step also is not critical.

Washing. Fish are washed with clean water. Hazards are contamination and microbial build-up. This step is not critical.

Sorting and Grading. The fish are sorted or graded depending on the weight of the fish. Contamination might occur, but the step is not considered critical.

Primary Processing. Fish are washed, skinned, filleted, chilled, candled, trimmed and boned. Hazards include bacterial build-up, time temperature abuse, contamination, and decomposition. Depending on your facility, at least one of these activities should be considered critical with critical limits, monitoring and corrective actions established.

Additives. Depending on the type of product, different types of additives are used for fillet or restructured products. Hazards are the use of microbiologically and chemically contaminated additives, the use of unapproved additives, and the abuse of approved additives such as phosphate. This step is regarded as a critical control point.

Grade and Sizing. Products are graded and then packed for fresh product or frozen product. Hazards include bacterial contamination and incorrect sizing. While not critical, if grades are marked on the labels, be sure to follow through when the final product is labeled.

Pack, Weigh, and Label. The products are packed, weighed and labeled. Examples of hazards at this step are short weights, incorrect labeling declaration such as size grading, extraneous material, and microbial contamination. This step is regarded as a critical control point.

Freezing. Individually quick frozen and blast frozen products have hazards such as incomplete freezing, dehydration, and contamination. This step is not a critical control point.

Glazing. Glazing the frozen product with water has such hazards as overglazing, which could lead to economic fraud, microbial contamination, and the use of unapproved additives or abuse of additives. This step is not critical.

Packout. Products are packed in cartons and stored for shipment. Some hazards at this step include product misidentification, underweight cartons, and extraneous material. Packout is not considered critical.

This flow diagram is general and your HACCP team must tailor it to your individual plant. Your facility might not have all of the steps listed here, or they might have more. In some facilities, some steps might be critical that are not critical in others. However, the HACCP team can make these determinations and apply all of the HACCP Principles to your critical control points.

Besides processing critical control points, the HACCP team must also include sanitation critical control points in the HACCP plan. Sanitation controls cross-cut throughout the plant, where processing controls are process step specific.

Examples of sanitation controls include such things as premises, building construction, lighting, ventilation, water supply, ice, disposal of waste, restrooms, construction and repair of equipment, cleaning and sanitizing procedures, chemicals, and personnel. These sanitation elements can be classified into minor, major, serious, or critical defects depending on their severity. Specific definitions for severity of defects are:

Minor Deficiency: not in accordance with their requirements. This is not major, serious, or critical.

Major Deficiency: inhibits general sanitation. Deterioration of product quality is not serious or critical.

Serious Deficiency: prevents proper plant sanitation. It may result in a tainted, decomposed or unwholesome product, but this is not considered critical.

Critical Deficiency: results in an unwholesome product. It presents health and safety threats. Sanitation critical control points most often involve:

- Ventilation systems that allow condensed water to collect over exposed product.
- Water supplies that are not accessible, subject to contamination, not clean, and not approved by an appropriate authority.
- Ice not made from clean water.
- Improper use of chemicals such as insecticides, rodenticides, unapproved chemicals and sanitizers.
- Personnel not taking precautions to prevent contamination of foods.

With the incorporation of process and sanitation critical control points in your HACCP plan, the plan is ready to be implemented. Remember, no plan is foolproof and expect to frequently verify and modify your plan, at least in the beginning.

In conclusion, HACCP systems must be designed by individual producers and tailored to their individual processing and distribution conditions. HACCP systems are designed and function in a manner consistent with the stated goal of preventing potentially hazardous products from reaching consumers. A HACCP system can be implemented by following the six steps to create a HACCP plan. Include your HACCP team.

The seven HACCP Principles are part of that six-step plan, including the definition of a critical control point and the Decision Tree. Training is essential in implementing your HACCP plan.

AQUACULTURE INDUSTRY ISSUES

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I'm just going to talk about catfish industry trends and touch on a few different things. Some of it may relate to food safety; some of it to what I will call economic safety - staying in business.

There it is right there - channel catfish. It's a durable fish that's been grown commercially in the United States for many years. I guess it began to be a little bit of an actual industry in the early 70s. Our major production states are Mississippi, Alabama, Arkansas and Louisiana.

Here are some catfish ponds in the Mississippi Delta. Of course as many of you know, the Mississippi Delta is the largest producing state. We have close to 100,000 acres of commercial ponds. A good part of that is devoted to food fish ponds. Generally speaking, it takes two pounds of feed to make a pound of fish and I'm sure that many of you know these things already. I am just going to touch on the background in the industry and how we got to where we are.

Catfish harvesting is now open year-round. We do have our higher levels of processing in the Lent Season which is coming up now. We have seen, though, processing level off over time. It used to be extremely low in the winter months, November and December, when everybody ate turkey and ham. Well, this November and December, we are probably around 33-35 million pounds each of those months so it's really coming around.

Here's a shot of some testing on processed fish. That looks like value-added products that are being tested for various reasons. Let me kind of mention something here a moment about food safety. The catfish industry would be nowhere today if it had not adhered to basic sound food safety/food quality techniques. Many of the plants have voluntary USDC inspection. The whole inspection picture seems to come and go but with what Congress is doing, we may have another inspection bill that will come up this year. In any case, the processors by and large give the fish as good a "going over" as they possibly can. Many of them have the USDC inspectors on board to come in on a regular basis. The FDA of course, comes in and does its own inspections from time to time so processors want to put out a quality product.

In thinking about Jin Kim's comments on the HACCP program a little while ago, Monday I was down in Wisner, Louisiana at the Cargill Fisheries Plant. Cargill has just been certified as the first seafood processing company in America under the new HACCP program under the National Marine Fisheries Service. Now that's not just a fresh catfish processing plant, that is the first seafood processing plant in the country, and they should be applauded for taking that big step. I think you are going to see perhaps more processors getting involved in that program.

Everybody likes to eat broiled catfish, and baked catfish, and microwaved catfish, and this-and-that, but fried catfish actually is "still the franchise" as some people say. The industry did a poll a few years ago where consumers were asked how they prefer their catfish, and fried was number one.

We processed 457 million pounds live weight in 1992. We have just grown tremendously in volume. Some years we didn't make any money at all - we lost money, but the volume has continued to increase. What will happen in the next 10 to 12 years remains to be seen. The consuming public is still turned on to catfish - the more they know about it, the more they understand it, and the more they are going to eat of it. Generally speaking, that 457 million pounds of live fish translates to about 232 million pounds of processed product.

Now one reason catfish achieved tremendous growth was because of a lot of marketing efforts by the Catfish Institute. It by no means is the only marketing effort that has gone on in the industry in the last several years, but they have probably done the biggest job and spent the most money. This is an ad that appeared in a number of magazines probably about three years ago. The Catfish Institute, as you may know, is a nonprofit entity set up by three feed mills in Mississippi, and they contribute $6 per ton for every ton of feed they sell to the Mississippi producers. This particular promotion does promote Mississippi catfish. Millions and millions of consumers all over the country in the last several years have seen this so this has helped educate people about farm-raised catfish.

Before I leave this slide, I will mention something about the Catfish Institute, and this is something that is almost "hot off the press." The February paper is not out yet. They have decided to make a formal appeal to feed mills and parts of the catfish industry outside of Mississippi to try to enlist them in the Institute. They want to drop the Mississippi designation and come out with a national generic program for farm-raised catfish. Of course, they have to get money, and they have to get contributions from the other feed mills. I wish them success because I believe we still have a long way to go in educating the public

about farm-raised catfish. You need good generic promotions at the same time the processors are doing their own brand of promotions. Here's something the Catfish Institute put together and I think that was on "Good Morning America" probably about three or four years ago.

Basically what this slide shows is growth or commercial acreage I think from July 1988 on up to July of 1992. You can see it happen there - late 80s, 90s - the tremendous growth in acreage. Everybody was jumping as catfish prices were good in '88, '89, and '90. But now it is starting to come down. The industry basically overproduced in '90, '91, and '92 and brought prices down. A lot of farmers could not "hack it" so some of them got out of the business. I just got the new quarterly USDA report on Monday - the quarterly survey of producers, and if I had another bar on that to represent January '93 it would show that the acreage has continued to come down. I think we had a high of 166,000 acres probably two and a half years ago. Now we are at 155,000 acres - so we are losing some acres - we're having something of a shake-out you might say.

Low cost. I am going to switch gears now and talk a couple of moments about how we got here and move into what's coming down the road. I will add one more thing about how we got here, and this gets to the quality issue. Farm-raised catfish is the kind of a product that the American consumer likes because it's nutritious. It is moderately priced, you can do a lot with it, and it just fits the bill. The fish itself is why people buy it.

I think this industry is going into a real low cost period. We overproduced, brought prices down, some people are exiting the industry. These farmers are going to have to get lean and mean, and cut costs where they can. Each processor is going to have to get lean and mean, and I can see this happening now. The processors, especially the bigger ones, are moving toward new ways of processing fish or at least as much as they can to lower that cost in the plant and the farmers are doing the same thing.

There's a lot of ground that we still have not covered in low cost production at the farm level. We have to get the price of raising a fish down. We have to get a fish that can perhaps grow faster, and we have to get our feed costs down just wherever we can to save a penny here or there.

Harvesting is one area certainly where we can save money. You know, getting the fish to the consumer is not an easy job. Catfish, unlike a lot of other particular animal industries, can't be seen except during feeding or when you harvest them. Whereas with other animals, you can. So it's always a difficult process to get exactly what the consumer wants in terms of size.

Now, there are some things going on in the industry right now that are focused on harvesting, sorting, grading procedures because you can save money at both ends of it - processing and farming. If you got all kinds of different sized fish at the plant, you are going to have to pay someone to sort them out manually, and it's very inefficient. The big fish do eat more than their share in the pond. This is a problem that is just now getting some attention.

That is a basic plant scene there. I put that in just because processing efficiency is becoming a real buzz word in the industry. I think the attitude is coming over to where poultry has been for many years, and that is keep the product moving. Once it stops someone is going to have to come back and move those boxes of fish. So try to take a lot of the manual labor out of it and move toward automation.

More intensive farming. That's definitely going to happen. It is already happening in many places. Get the most you can out of each acre; of course, that creates a lot more production problems. You are going to be feeding more in the pond, and just all kinds of problems shape up when you increase your stocking rate from 3,000 fish per acre on up to 15,000 fish per acre. So it is just going to be an intensive "hands-on" program.

That's a shot at the Stuttgart Fish and Wildlife Service Lab there. They do a lot of good work. They are trying to do research on a number of projects and farm-raised catfish to help the producer. We have a lot of great research programs going on. You have people here at Auburn University. You have the Fish and Wildlife Service's expanded facility in Marion, Alabama. You have places in Mississippi and Louisiana, so there is an awful lot of work going on there.

Greater awareness of catfish. I showed you a few moments ago how awareness helped us to get to where we are today. We have a long way to go though. I feel like there is a new climate for a farm-raised catfish. Catfish right now still enjoys a great positive image in most places; places where it doesn't is because they don't understand it. Processors are doing better work in their marketing efforts and there are just a lot of good positive things going on right now.

Here are some ads that we shot out of a recent issue of *Seafood Leader* showing new products. That particular magazine goes to seafood buyers all over the country. That's Southern Pride here in Alabama - same magazine. Here is one out of Mississippi - *America's Catch, Gourmet Catfish*, here's one for *Delta Pride*. On *Delta Pride*, they recently came out with a gumbo. I don't know if anyone has seen it in the supermarkets, but it is sold for retail and food service.

Delta Pride also recently launched a series of co-merchandising efforts whereby they identify themselves with famous nationally known other brands. In December they had a promotion with Lee & Perrins for a holiday catfish dip. Here's a new one they just did with Martha White cornbread mix that goes in tandem with the gumbo promotion, so it works very nicely.

I'll stop here. Catfish is truly a national product. It is a product that enjoys a good reputation but one we have to continue to work on; food safety/food quality - that's number one, and as we develop conferences like this, I think we are all going to continue to do good work with catfish. Maybe next year we'll do 500 million pounds and before long we'll do a billion pounds. I hope so anyway. Catfish are here to stay.

AQUACULTURE PRODUCTS SAFETY FORUM

MICROBIAL WORKING GROUP REPORT

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INTRODUCTION:

The break-out session was a brainstorming discussion with a group (representing 7 Universities, FDA, USDA-ARS, Alabama Fish Farming Center) to identify issues and concerns relative to the microbial aspects of aquacultured products safety:

I. Present status/microbes with which we are concerned

II. Future concerns of the industry relative to product safety (from microbial standpoint)

III. Researchable goals during the next few years

I. PRESENT STATUS:

The initial discussion centered around how best to address the many aspects of aquacultured product food safety, such as:

- From "farm to fork," or just selected aspects (production, processing, marketing, etc.)
- Raw vs. cooked, ready-to-eat products
- All species vs. individual species

The consensus of the group was to limit discussion to processing operations (i.e., we don't have control on what happens in the production phase)

There is not much of a problem with raw products in the U.S.; there is very little consumed raw; most is frozen which kills organisms

Aquacultured products have a good safety record so far. Why?

- Rapid spoilage rate of fish . . . before pathogens are produced (i.e., short shelf-life)

- Many buyers (of products) have microbial market specificaions

- In general, products are cooked before being eaten

- Processing practices help eliminate some of the problems (i.e., skinning, washing, etc.)

- Marketable forms of product:

  - Greatest percentage is frozen which kills organisms

  - Fresh products used quickly (and not a large percentage of raw product marketed)

- Industry structure (i.e., larger processing plants designed to reduce contamination)

Many potential spoilage/pathogenic organisms are "naturally-occurring" in production waters, and may come into the processing plant along with the fish:

1. *Vibrio*
2. *Salmonella*
3. *Listeria*
4. *Aeromonas*
5. *Camplyobacter*
6. *Mycobacterium*
7. *Clostridium*

There was some concern that "resistant" bacteria (pathogens) may show up due to the use of therapeutants.

Comments limited to catfish, trout, and crawfish for this discussion

II. Concerns Relative to Product Safety

General concerns with regard to regulatory rates of FDA, NMFS, and USDA

- Regulatory clarification of raw vs. cooked, ready-to-eat products (especially crawfish)
- Clarification of regulatory posture relative to *Listeria* and *Salmonella*
- Regulations relative to water availability, discharge, and treatment (such as chlorination, bromination, ozonation, iodination)

Special concerns for certain segment of population who may be more susceptible to microbes:

- Expectant mothers
- Very young and/or very old persons
- Those whose immune systems may be compromised

Imported products and how they fit into the picture, i.e.,

- Microbiological quality
- Inspections
- Special restrictions

Most of raw-consumed products are shell-fish (i.e., oysters)

- Better management/monitoring of production areas
- Can we develop new methods of preparation?

Concerns about evolving processing technologies and how they will address the reduction of pathogens and spoilage bacteria

III. Research Goals

Development of better processing technologies, such as:

- Smoking
- Pasteurization
- MAP, CAP
- Irraditation (UV, gamma ray, etc.)
- Additives, chemical tests
- Advanced and emerging packaging materials
- Vacuum packaging may be a problem; there is a need for more microbial work with this packaging method

Validation and verification of Hazard Analysis Critical Control Points (HACCP) methodology in processing settings

- Development of specialized HACCP methodologies for each species

- Determination of the effects of evolving processing technologies on the critical control points and microbes of concern, particularly with increased automation

New product development and quality control

For aquacultured products to be "safe," what are the minimum tolerance levels for microorganisms?

Consumer education

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AQUACULTURE PRODUCTS SAFETY FORUM

RESIDUES WORKING GROUP REPORT

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The Southern Regional Aquaculture Center (SRAC) Aquaculture Food Safety-Residues Project was discussed by each objective.

Objective 1

Survey and review data bases for pesticide, metal, and pharmaceutical residues and develop a database for chemical contamination in farm-raised channel catfish, crawfish and rainbow trout.

Explanation - Agencies to be surveyed include FDA, EPA, USFWS, state agencies and universities, industry and other suitable sources. Mississippi State University (MSU) has established a database for residues in food products and animal feeds. Survey information would be submitted to the MSU Center. Data will be collected and reviewed followed by recommendations for additional analyses.

Comments - Concern was expressed about the various institutions and the quality of existing residue data. Does the data differentiate between wild and aquaculture produced species? It is perceived that existing residue data is not adequate.

Objective 2

1. Develop guidelines and protocols for a residue monitoring program at a processing facility.

2. Coordinate these guidelines with existing quality control programs in a processing facility.

3. Establish protocols for sampling, sample analysis and interpretation of data.

Comments - The Food and Drug Administration is considering the need for a training workshop concerning analytical methods and protocols.

Objective 3

Develop educational materials for producers and processors concerning the safe use of chemicals in or around production and processing systems.

Explanation - The development of these materials will depend upon information developed in the other objectives. Printed and visual materials will be developed based on the needs of the industry. The Project Steering Committee will prioritize these funds at the end of the first project year.

Comments - Other groups and agencies are developing educational materials and programs related to quality assurance. These SRAC materials will be designed around a quality assurance program.

Objective 4

Adapt, develop and disseminate a chemical application record-keeping system for aquaculture producers. A recording form and user-friendly computer software will be developed. The purpose of this system would be to help limit residue problems and potential liability.

A record-keeping form and computer software will be developed that will have the flexibility to be used by catfish, crawfish and trout producers.

Comments - In the development of a Quality Assurance Program, record keeping will be an important tool for the producers.

Objective 5

To determine the fate of residues from the farm through the processing plant to a product which would be prepared by the consumer. The fate of pharmaceutical and pesticide residues in channel catfish will be determined in a series of experiments conducted by several participating institutions. In addition, analytical methods for selected pharmaceutical compounds will be developed and evaluated for aquacultural products. These methods will be developed from established procedures which have not yet been adapted for catfish products.

Objective 6

Conduct additional sampling of channel catfish and other aquaculture products to improve the data base. Because of the related costs, additional funds may be needed from industry and/or federal sources.

Other Comments and Issues

- The Residues Working Group reached a consensus that this project will support industry Quality Assurance initiatives.

- If this project identifies any problems in an individual operation or industry-wide, it is our responsibility to inform the individual(s) involved and work with them to solve the problem.

- Selling the idea of a Quality Assurance Program to the farmers may be a problem because farmers may perceive that imports do not have to comply in areas of drug and chemical usage.

  It was recommended that FDA develop materials to educate producers of their ongoing activities to regulate and inspect imports.

- Concern was expressed about some aquaculture chemicals and drug advertising that implies their legal use and availability to the farmer.

- Concern was also expressed about chemicals, pesticides and drugs used in farm and recreational ponds. Any management recommendations would have to comply with FDA and/or EPA regulations.

  Note: Low priority enforcement chemicals could be used on game fish species if applied according to FDA regulations.

- It was pointed out that the INAD process may over commit region's research facilities and divert them from other research projects. It was suggested we may want to try to coordinate INAD projects in the region through the new INAD Coordinator at Michigan University and through SERA-IEG-9.

- It was recognized there is a need for the SRAC Residues Project to communicate with FARAD. Their objectives are different but complement SRAC project objectives.

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AQUACULTURE PRODUCTS SAFETY FORUM: EVALUATION

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The Aquaculture Products Safety Forum was attended by 45 people from 11 states. Each attendee received an evaluation form in their registration packet (example appended at the end of this paper). Eighteen evaluation forms (40 percent of the number distributed) were completed and returned.

The evaluation solicited attendees' ratings of 10 items. A standard 5-point Hedonic scale was employed, where:

1 = Poor
2 = Fair
3 = Average
4 = Good
5 = Very Good

Subsequent discussions of ratings are based on a sample size of 18 (with the exception of two items pertaining to lodging and travel accomodations). Ratings are presented as means +/- standard deviations.

The overall format of the Aquaculture Products Safety Forum received a very favorable rating of 4.72 +/- .45. This indicates that the respondents liked the format, which was composed of two morning plenary sessions and two afternoon discussion group sessions. The attendees were also favorably impressed with the strength of the agenda (4.67 +/- .47) and the quality of the speakers (4.61 +/- .49). And, evaluation respondents indicated that the degree to which the Forum addressed the issue of aquaculture products safety merited a rating that was nearly median between "good" and "very good" (4.56 +/- .60).

Although conference facilities (meeting rooms, audio-visual aids, etc.) received a rating of 4.55 +/- .83, the rather high standard deviation resulted from a diversity of opinions about the facilities. The most common complaint was that the lecture room for the plenary sessions was too cramped. The eleven attendees who were lodged at the Auburn University Hotel and Conference Center felt the hotel rooms merited a rating of 4.54 +/- .50. And food service at the Conference Center, including the reception, luncheons, and breaks, received a rating of 4.39 +/- .83. (The large standard deviation of .83 can be attributed to a divergence of opinions about the food that was served, when it was served, and the method of preparation.)

Although the Forum was held on the campus of Auburn University, which is 110 miles from the Atlanta Airport, Forum location nonetheless received a rating of 4.44 +/- .68. However, the three evaluation respondents who flew into Atlanta only rated availability of ground transportation as "good" (4.00 +/- .82).

The effectiveness of the breakout sessions received the lowest rating (3.83 +/- .69) of the ten items included in the evaluation. While some participants felt that the efforts of the breakout groups were right on target, others thought they were slow to start or difficult to get focused. It is not surprising that the output from the breakout groups was not unanimously applauded, bearing in mind that: (1) many participants had not previously functioned in a discussion group setting; (2) the working group sessions were composed of 32 individuals from industry, academia, and regulatory agencies; and, (3) the intent of the working group sessions was to develop a consensus of opinion.

To summarize the results of the Forum evaluation, with the exception of the item discussed immediately preceeding, all aspects of the Aquaculture Products Safety Forum received ratings that ranged between "good" and "very good". It is hoped that these evaluation results will be of value to the planners of similar future efforts.

AQUACULTURE PRODUCTS SAFETY FORUM

EVALUATION

PLEASE RATE THE FOLLOWING ON A SCALE OF 1 TO 5 WHERE:

1 = POOR
2 = FAIR
3 = AVERAGE
4 = GOOD
5 = VERY GOOD

1. STRENGTH OF AGENDA ____
2. QUALITY OF SPEAKERS ____
3. EFFECTIVENESS OF BREAKOUT SESSIONS ____
4. OVERALL FORMAT OF FORUM ____
5. CONFERENCE FACILITIES ____
6. HOTEL ROOM (FOR THOSE STAYING AT AUH&CC) ____
7. FOOD SERVICE (RECEPTION, LUNCHEONS, BREAKS) ____
8. LOCATION OF FORUM ____
9. AVAILABILITY OF GROUND TRANSPORTATION (FOR THOSE WHO FLEW INTO ATLANTA) ____
10. DEGREE TO WHICH FORUM ADDRESSED THE ISSUE OF AQUACULTURE PRODUCTS SAFETY ____

PLEASE COMPLETE THIS EVALUATION FORM AND LEAVE IT AT THE SPEAKERS' PODIUM. PLEASE DO NOT SIGN THIS EVALUATION FORM.

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