INTRODUCTION

The history of the Aquaculture Products Safety Forum and this resultant Proceedings actually predated 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 Proceedings
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.
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 Aquicultural 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 officially 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 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 misused 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
SJT-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 country.

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