SEAFOOD SAFETY

ARING

 ORE THE

SUBCOMMITTEE ON FISHERIES MANAGEMENT

OF THE

COMMITTEE ON MERCHANT MARINE AND FISHERIES HOUSE OF REPRESENTATIVES

ONE HUNDRED THIRD CONGRESS

FIRST SESSION

ON

SEAFOOD SAFETY AND H.R. 1412

A BILL TO ESTABLISH A NATIONAL SHELLFISH SAFETY PROGRAM

JUNE 23, 1993

Serial No. 103-34

Printed for the use of the Committee on Merchant Marine and Fisheries

U.S. GOVERNMENT PRINTING OFFICE

71-898 ⇆ WASHINGTON : 1993

For sale by the U.S. Government Printing Office
Superintendent of Documents, Congressional Sales Office, Washington, DC 20402
ISBN 0-16-041479-2

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SEAFOOD SAFETY

WEDNESDAY, JUNE 23, 1993

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON FISHERIES MANAGEMENT,
COMMITTEE ON MERCHANT MARINE AND FISHERIES,
Washington, DC.

The Subcommittee met, pursuant to call, at 2:00 p.m., in room 1334, Longworth House Office Building, Hon. Thomas J. Manton [chairman of the Subcommittee] presiding.

Present: Representatives Manton, Hughes, Unsoeld, Taylor, Hamburg, Cantwell, Coble, and Hochbrueckner.

Staff Present: Jim Mathews, Staff Director; Linda Livingston, Assistant to Staff Director; Ann C. Vogt, Assistant to Chief Counsel; Greg Lambert, Counsel; Suzanne J. Waldron, Press Secretary; Jean Flemma, Jill Brady, Bill Wright, and Ed Lee, Professional Staff; Cynthia Wilkinson, Minority Chief Counsel; Rodney H. Moore, Jr. and Laurel Bryant, Minority Professional Staff; Shelley Cole, Joan Coyle, and Margherita Woods, Staff Assistants; Lori Rosa, Legislative Clerk, and Julie Roberts, Sea Grant Fellow.

Mr. MANTON. Ladies and gentlemen, we will start the business of the Committee.

OPENING STATEMENT OF HON. THOMAS J. MANTON, A U.S. REPRESENTATIVE FROM NEW YORK, AND CHAIRMAN, SUBCOMMITTEE ON FISHERIES AND MANAGEMENT

Mr. MANTON. Good afternoon and welcome. Today the Subcommittee takes up the issue of seafood safety and considers H.R. 1412, legislation introduced by Representative Unsoeld to establish a National Shellfish Safety Program. The safety of seafood is of great importance to me, both in my position as Chairman of this Subcommittee, and as a representative of the largest seafood consuming State in the Union, the beautiful State of New York.

Fish and shellfish are a healthy, nutritious part of our diet. Seafood is low in fat, sodium, and cholesterol, yet high in protein. Also, seafood is the best source of OMEGA 3 acids, which recent studies suggest reduce the risk of heart disease.

But as we ourselves are learning, no organism can continue to thrive or indeed survive in a polluted environment. The most effective action we can take to ensure the integrity and quality of the fish and shellfish harvested in U.S. waters is to ensure these waters are free of pollutants. Healthier waters mean healthier fish and shellfish. This Subcommittee, as well as the full Merchant Marine and Fisheries Committee, is dedicated to this task. However, our work does not end here.

We must strive to provide better controls in handling and processing seafood from catch to point of sale, and we must work to educate not only industry, but consumers themselves. Both the Food and Drug Administration and the National Marine Fisheries Service have sought to do this and they have made great strides. The joint effort of these two agencies in developing the voluntary Hazard Analysis Critical Control Point Program or HACCP is a step in the right direction, with government and industry working together in a proactive rather than reactive manner. Now, it is our job to evaluate their work and set our sights on the future.

I thank the witnesses in advance for the testimony and the insight they will provide on this very serious issue. I particularly wish to thank my good friend and colleague, the Chairman of the House Energy and Commerce Committee, John Dingell, for being with us today. Chairman Dingell has been a driving force behind Congress' efforts to ensure a healthy and safe supply of seafood. I look forward to working with him in the days ahead to address this important issue.

I now turn to the absent distinguished ranking member, the Honorable Don Young for an opening statement, and perhaps we will have an opportunity to hear from him in person later, but for the moment without objection we will insert his statement for the record, and we will do the same for the Honorable Jack Fields. The gentlewoman from Washington.

[The opening statements of Congressmen Young and Fields follow:]

STATEMENT OF HON. DON YOUNG, A U.S. REPRESENTATIVE FROM ALASKA

Mr. Chairman, I see that the issue of seafood safety has once again come before us. It will be interesting to see what has changed since the last time the House addressed this topic.

We all would like to be assured that the food we eat does not make us sick. Having safe seafood benefits the consumers, processors, and fishermen. The question we face is how to reduce the risk of illness without destroying the fishing industry.

While it is hoped that a mandatory seafood safety program might reduce the risk of unsafe food products, success cannot be guaranteed. According to the National Academy of Sciences, "most health risks associated with seafood safety originate in the environment and should be dealt with by control of harvest or at the point of capture. Inspection at the processing level is important to maintain safety of seafoods, but there is little evidence that increased inspection activities at this level would effectively reduce the incidence of seafood-borne disease." A mandatory seafood inspection program may not eliminate all of the concerns related to seafood safety. Furthermore, an extensive program that furnishes little additional protection at great cost needs to be carefully examined—especially during these times of budgetary constraints.

If we can ultimately provide a safer product for the consumer and reduce the incidence of seafood-related illnesses, an expanded program may be extremely important. However, if we are simply adding another layer of red tape for the producers at increased prices for the consumers, then we may be better off leaving things alone.

Mr. Chairman, I look forward to hearing from the witnesses and to working with you on this issue.

STATEMENT OF HON. JACK FIELDS, A U.S. REPRESENTATIVE FROM TEXAS, AND RANKING MINORITY MEMBER, COMMITTEE ON MERCHANT MARINE AND FISHERIES

Mr. Chairman, during the past several sessions, this Committee has examined various pieces of legislation addressing seafood safety.

This issue remains a hot topic of debate because the seafood industry does not have a mandatory system of grading and inspection of its products, comparable to that of beef and poultry.

In the past, Congress has been unable to resolve the controversies over whether seafood should be inspected, how it should be examined, who should do it, and who will pay for the inspection.

While the Food and Drug Administration (FDA) and the National Marine Fisheries Service (NMFS) does provide, for a fee, inspection services on a voluntary basis, there are some who believe this system is inadequate.

Nevertheless, it is important to remember that the National Academy of Sciences (NAS) has stated that "most seafoods available to the U.S. public are wholesome and unlikely to cause illness in the consumer." NAS went on to state that, "the major risk of acute disease is associated with the consumption of raw shellfish, particularly bivalve molluscs."

The purpose of this hearing is not to create another public scare over the health risks of seafood. It is, however, to provide this Committee with some idea of what the FDA is planning for the future, and how the activities of NMFS will complement that system.

Our seafood industry does not need another magazine article castigating seafood retailers. What it does need is support from the agencies and the consumer groups to educate the public on how to handle seafood at every point from the sea to the dinner table. This educational process must include the most important aspect for the consumer, how to properly cook seafood, in order to destroy parasites and bacterial containments before consumption.

I look forward to hearing the testimony on this important issue. The witnesses will assist this Subcommittee in assessing the problem and developing a fair and reasonable strategy to address these matters.

Thank you, Mr. Chairman.

Mrs. UNSOELD. Mr. Chairman, out of deference to the time constraints on the very distinguished and busy Chairman from Energy and Commerce, I would yield to him to speak first and then I would give my opening remarks after, if that would be convenient for both of you.

Mr. MANTON. The Chair thanks the gentlewoman and the Chair recognizes our good friend and colleague, John Dingell, Chairman of the Energy and Commerce Committee for a statement. Welcome.

STATEMENT OF HON. JOHN D. DINGELL, A U.S. REPRESENTATIVE FROM MICHIGAN

Mr. DINGELL. Mr. Chairman, first, thank you for your hospitality and thank you for the privilege of appearing here before you. I commend you and the distinguished gentlewoman from Washington State for your interest in this very important matter of fish inspection. I also want to commend our dear friend, Mr. Studds, the Chairman of this Committee, for his longstanding interest and commitment in that matter.

Just as an aside, I have spent many happy years of my life in this room, first when it was the Committee room of the Committee on Energy and Commerce, then known as the Committee on Interstate and Foreign Commerce, and we had many interesting sessions here, as I am sure you might understand. More lately I had the privilege of serving here when this was the committee room of the Committee on Merchant Marine and Fisheries when I was a member of this Committee and the Chairman of the Subcommittee on Fisheries and Wildlife Conservation which did, as you very well know, some outstanding work, both in the area of fisheries, wildlife, the environment and a number of other matters of concern to

both you and the distinguished gentlewoman from Washington State, Mrs. Unsoeld.

Our two committees have worked together successfully in the past on the question of fish inspection, and I am satisfied with the continued efforts by yourself, Mr. Chairman, Mrs. Unsoeld, and the very able Chairman of this Committee, Mr. Studds. We will continue to do so. The work of Representative Unsoeld and her knowledge on this issue has been extremely helpful. Her legislation has been referred jointly to the two committees, and it is one which I intend to see to it will move in an expeditious and proper fashion.

The bill deals with a critical component of a comprehensive Seafood Safety Program, shellfish safety. Mrs. Unsoeld is indeed to be commended for her efforts and her commitment to this matter, and we shall seek to address her concerns in our discussions about this matter.

Two of your witnesses today, Mr. Chairman, appearing on behalf of the Centers for Disease Control and Prevention and the Food and Drug Administration will talk in detail about some of the programs under the Public Health Service Act. The Centers for Disease Control and Prevention, CDC, maintains surveillance of seafood illness so consumers derive better information about illness related to seafood. And we do, indeed, need better CDC surveillance so that we can understand more clearly the role of seafood in causing illness, the sources of problems, and ways to correct these problems and therefore prevent illness. Improved CDC, State, and local disease surveillance will, indeed, contribute greatly to more effective evaluation of the Seafood Safety Program and indeed to all of our food safety programs, and, again, I reiterate my pledge of support for your efforts in these matters and in improvement in CDC programs.

The Food and Drug Administration operates a Seafood Safety Program which includes standards setting, mandatory inspection, and sampling and enforcement. Congress has held oversight hearings about the program for very good reason. We were concerned about seafood safety. We have seen to it that the program has received increased fundings over the last several years, so that it can be more effective as the industry changes and as consumer preferences change. We need to continue to be vigilant so that the program has the necessary authority, resources, and funds that it requires to be effective.

I will say this: Our Subcommittee on Oversight has run a number of hearings and investigations and inquiries into the question of the overall matter of safety of seafood, shellfish, and similar issues. We find that resources are inadequate, the basic statutes are not strong enough, and that consumers are not receiving the protection they require because of that inadequacy overall. Happily, some increases in funding have occurred and the situation is now better. More needs to be done and the legislation before us will significantly contribute to that end.

Consumers are concerned about seafood, and they properly should be. We continue to hear press reports about illness related to eating fish or shellfish. Just within these past few weeks we have been warned again about the risk associated with eating raw oysters. This worries consumers who wonder whether they are vul-

nerable to seafood-related illness and cannot be certain about the safety of the seafood they wish to purchase in a market or restaurant. It worries the seafood industry because every time there is a report of illness they face a potential loss of business and significant economic hardship.

Several years ago Congress took some definitive actions to try to address this problem. The result was an increase in funding of about 60 percent for the FDA seafood program. This was good and it was proper, but it did not alone solve our problem. We still hear that the government has not done enough, and that is true. Consumers still ask why the government seems only to be reactive, and that is a good question. We are being told, and I agree, that the government needs to promote safety and prevent harm. We have considered omnibus legislation. Many in the consumer community and in the business community support such a legislative approach.

While we have done this before, and I am ready, willing and able to do so again, the program that we bring forward legislatively must be, in fact, strong, workable, comprehensive. I am pleased that while the Congress has continued to grapple with the issue, NOAA in consultation with FDA has developed a voluntary inspection and labeling program based on the Hazardous Analysis Critical Control Point, or HACCP, approach. This program will go a long way toward assuring consumers because of the NOAA seal on the product which will indicate the high quality required by the NOAA program. However, a voluntary program can only be a partial solution if we want tough mandatory standards that all products must meet. That is what consumers want for seafood and that is what I believe this Committee also wants.

I was, therefore, pleased when FDA Commissioner Kessler announced in March that FDA would soon propose regulations to establish a mandatory HACCP-based seafood inspection program. According to Dr. Kessler, that program will be designed to be preventive and to assure safety virtually from water to table. I am told that regulations to implement this preventive program will soon be proposed. They will reflect the knowledge gained by FDA and NOAA in pilot studies the two agencies conducted in developing the NOAA voluntary HACCP program. These rules will be grounded in the HACCP approach. I am anxious to review the proposal of FDA, and I think, like this Committee, we share two goals.

First, to see to it that the elements of FDA's proposal are consistent with the goals of our committees. Our two committees have worked well together, as you very well know, regarding assuring the safety of seafood and the development of strong, measurable, and enforceable standards and a regular evaluation and inspection program to assess the effect of the standards and the extent to which they are being met.

Second, we need to make certain that FDA has the wherewithal to implement a strong and effective program. We will look at FDA's proposal with an eye toward ensuring that current law provides sufficient authority for FDA to carry out the program effectively from inspection through to enforcement. Further, I believe that we need to look at the proposal to assess whether FDA currently has the resources it needs to implement the program. I would observe that our Committee's ongoing scrutiny, as you are

very well aware, Mr. Chairman, of FDA indicates that it is a fine agency, but that it lacks the resources which it needs to deal with all the many responsibilities which it has in inspecting and regulating about 25 percent of the United States' Gross National Product.

In any event, one of the things we will have to do is see to it that as the proposal goes forward, we assure that it has not only the strength that it needs to be properly enforced, but also the resources, both the money and the people that are required to carry out the proper responsibilities that the law imposes. It is critical that FDA's proposal be published soon so that all of us—the Congress, the industry, and consumers—will have a chance to evaluate and respond. The sooner it is done, the sooner we will have in place a stronger, better, and more effective seafood safety program. The sooner the better.

Mr. Chairman, our committees, this great Committee on Merchant Marine and Fisheries and the Committee on Energy and Commerce, have worked together over the years on this matter, and I believe that we can again work profitably. I have instructed our staff to work closely with the very able staff of the Committee on Merchant Marine and Fisheries, and I want you to know that I look forward to working with you, the Committee, Chairman Studds, you, Mrs. Unsoeld, and the members of this Committee to accomplish an important goal: The assurance that seafood, shellfish, and similar resources are fully safe from the time that they are caught until the time they have reached the plate of the consumer.

This is an important hearing, Mr. Chairman. I thank you for your invitation. The issue is, as I have said, an important one, and I believe that our two committees working together as we have in the past can bring forward a good resolution, both legislative and regulatory, to address a significant problem. I am hopeful that the administration will have learned from the misfortunes of a prior administration which did not have the wisdom to work with us as they indeed should have about the joys and the virtues and the happiness and success of working with our two committees as we work on this legislation. Thank you, Mr. Chairman.

[The statement of Mr. Dingell can be found at the end of the hearing.]

Mr. MANTON. Thank you, Chairman Dingell. It is indeed an honor and a privilege to have you here today. As you indicated, you spent many of your early working days in Congress as a member of the Merchant Marine and Fisheries Committee. I think much of the legislation that the full Committee is associated with, was your work product. So it is indeed a great coincidence that we will be able to work together to see to it that the very important issue of seafood safety for all of our consumers is timely met. I look forward to working with you, Mr. Chairman.

Mr. DINGELL. Well, our two committees have many shared interests, shared members, great friendships, and I have the memory, as you have observed, Mr. Chairman, of very happy associations in this Committee. I want to say that when I watched to see what is happening on the Floor, I always note that this Committee is doing a good job of protecting the legislation which we enacted in the old

days. I suspect that between us we will have the chance not only to work on this matter but perhaps to assist our good friend, Mr. Hamilton, as he goes about his business of recommending the reorganization of the House and seeing to it that even that document achieves the required level of perfection.

Mr. MANTON. Again, I thank the Chairman and I recognize the gentlewoman from Washington.

Mrs. UNSOELD. Thank you very much, Mr. Chairman, and thank you very much, Mr. Chairman (Dingell). Obviously, it was appropriate that I allowed you to speak first and hopefully between us we will indeed impress upon the administration the importance of working with our two committees.

Mr. DINGELL. We did a great job, if you will recall, in the last Congress. We assisted the leadership of this body. We assisted our good friends on the Agriculture Committee. We assisted our good friends downtown in the administration. We assisted some of the consumer groups who were slightly errant on one occasion, and we even assisted the Majority Leader in the Senate to achieve the right conscience and a proper conclusion to a legislative problem.

STATEMENT OF HON. JOLENE UNSOELD, A U.S. REPRESENTATIVE FROM WASHINGTON

Mrs. UNSOELD. With such a Chairman at your side you hardly need anyone else.

Mr. Chairman, if one is to believe recent media reports, millions of Americans sitting down for seafood tonight are going to dine on an appetizer of nervousness and a main course of fear. Consumer Reports, CBS Evening News, Time Magazine and most recently even The Washington Post have all questioned the effectiveness of the current Federal regulatory system for shellfish. The fuel that feeds these fires is real.

Toxics, such as vibrio, red tides and domoic acid, and economic fraud in the seafood trade pose significant health risks, health risks Congress attempted to address during the last Congress when our Committee, together with the distinguished leadership of the Energy and Commerce Committee, drafted comprehensive seafood safety legislation. The centerpiece of that proposal, which was approved by this Committee and the House, was the establishment of a National Shellfish Safety Program.

Widespread support and justification was evident in testimony to this Committee by the Interstate Shellfish Sanitation Conference: "While the present cooperative shellfish program has been outstanding in evaluating State programs and making progressive recommendations, it is not structured to address imminent health concerns associated with seafood products. This additional legislation is needed to give the designated Federal agency more authority to adequately regulate the safety of seafood."

The unfortunate demise of this comprehensive legislation, Mr. Chairman, prompted me to initiate discussions with the industry and FDA focusing more narrowly on the issues of shellfish safety and the concept of a National Shellfish Safety Program. The result of this effort, H.R. 1412, the Shellfish Safety Act. This bill is based upon the previous efforts of our committees and incorporates many

of the principle findings by the National Academy of Sciences on shellfish safety.

In simple terms, it requires FDA to issue minimum standards and procedures for State shellfish programs, and mandates that importing countries meet equivalent standards. Mr. Chairman, as I talk to representatives of this industry, I am impressed by their commitment to producing quality products. The region of the country that I represent leads the Nation in oyster production and enjoys a reputation for producing safe, high quality shellfish products. These individuals support enactment of the Shellfish Safety Act because they recognize that by addressing consumer safety they are not only ensuring the future of their industry, but they are ensuring that shellfish are kept on the dinner plate where they belong and off the front pages. Thank you, Mr. Chairman.

Mr. MANTON. I thank the gentlewoman. Unless there are other members that have questions of the distinguished Chairman, Mr. Dingell, we will excuse him, knowing that he has lots of other duties to involve himself with.

Mr. DINGELL. Thank you, Mr. Chairman. Thank you, members of the Committee.

Mr. MANTON. Thank you, Mr. Dingell.

Mr. Taylor, you are recognized for purposes of an opening statement.

Mr. MANTON. At this point, we would like to combine both panels two and three because I think we are liable to get some Floor action coming up within the next hour, so if we could have—suppose we can fit everybody up there, our next panel which will consist of Ms. Nancy Foster, Acting Assistant Administrator for Fisheries; Mr. Thomas Billy, Director, Office of Seafood, Food and Drug Administration; Mr. Bill Taylor, President, Pacific Coast Oyster Growers; Dr. Paul Blake, Acting Chief of the Foodborne and Diarrheal Diseases Branch, National Center for Infectious Diseases; Mr. Jim Salmon, First Vice President, National Fisheries Institute and Senior Vice President of Purchasing for Red Lobster Restaurants, and, finally, Mr. Bill Morgan, President, Shellfish Institute of North America.

If you would kindly come to the witness table. As you do that, I want to express my disappointment and concern over the fact that Dr. Kessler, the Chairman of the Food and Drug Administration, has chosen not to testify today. While I understand his representative, Mr. Billy, is the Director of FDA's Office of Seafood and well versed in the issues, I believe the Subcommittee should be hearing directly from the Commissioner.

Quite frankly, one of the reasons we are holding today's hearing is because Dr. Kessler has brought renewed attention to this issue through his recent public statements and articles. He says that there is a problem and a need to develop a national program, and I regret he is unable to directly brief the Subcommittee with jurisdiction over this issue. While Dr. Kessler and the FDA may believe they have the authority to develop this program through regulations, there are many in the Congress, including members of this Subcommittee, who believe legislation will be needed to implement a new Seafood Safety Program. And, with that said for the record, we will hear from our next witness, Ms. Nancy Foster.

STATEMENT OF NANCY FOSTER, ACTING ASSISTANT ADMINISTRATOR FOR FISHERIES, NATIONAL MARINE FISHERIES SERVICE, NOAA, U.S. DEPARTMENT OF COMMERCE

Dr. FOSTER. Thank you, Mr. Chairman and members of the Subcommittee. My name is Nancy Foster, and I am the Acting Assistant Administrator for Fisheries in NOAA. I am pleased to be here this afternoon to give you NOAA's views on seafood safety and to tell you a little bit about the programs that we have in this area. I am sure everyone is aware that there is continuing pressure both on Congress and on the Federal regulatory agencies to improve the current system of seafood inspection and seafood safety programs.

Those folks who are our critics will say that the current programs aren't as effective as they could be in addressing hazards associated with seafood consumption. However, I think it is important to note that NOAA is in agreement with the conclusions of the National Academy of Sciences report on seafood safety, when they said that most seafood available to the U.S. public is wholesome and unlikely to cause illness.

The National Academy of Sciences study also endorsed incorporating HACCP principles into any system that we use to control safety risks. We think this is important because we believe that HACCP offers industry and the government a seafood protection program that is based on sound and modern technology, and a program that can supply consumers with safe, wholesome, and properly-labeled fishery products that they have a right to expect both from their government and from the industry.

We find that one of the strong selling points of the HACCP-based system is that it allows the industry to use the knowledge and experience that it has acquired to help design and to implement a system for controlling risks. We in NOAA are in the business of seafood safety because of our legislative mandates for the conservation, management, and wise use of living marine resources, and for a requirement to provide assistance to the seafood industry. We believe that these mandates encompass a concern that seafood provided by the industry that we regulate can be safely used for human consumption.

We fulfill our responsibilities through an inspection program, a research program, technology transfer, and finally through fishery management efforts. We get our authority from several laws not the least of which is the Magnuson Fishery Conservation and Management Act of 1976. Now, within our Seafood Quality and Safety Program, we carry out, as you heard before, a voluntary fee-for-service seafood inspection program, but in addition to this we also carry out our product quality and safety research program aimed at both environmentally and process-induced hazards.

In fiscal year 1993 our research program was funded at just over $14 million, and I think it is significant that this $14 million funding level is included in the President's 1994 budget request. In addition to the $14 million the seafood industry in 1992 paid $12 million, which is the fees that they paid us to cover the costs of our direct inspection services. I would also note that as a part of our voluntary inspection system we began in 1992 to implement a HACCP-based program. We now have completed arrangements

with five facilities and are looking at another 15. In carrying out our seafood inspection and safety programs, we coordinate extensively with our colleagues at FDA. We do this both informally and formally.

One of the mechanisms we use for formal coordination is memoranda of understanding, and we have MOUs for research, for inspection, and in the area of molluscan shellfish. In addition, we have significant interactions with EPA, and we deal a lot with State, public health, and fisheries agencies and with universities that conduct research on seafood safety.

Mr. Chairman, this concludes my testimony, and, again, I thank you for the opportunity to be here and will try to answer any questions you might have.

[The statement of Dr. Foster can be found at the end of the hearing.]

Mr. MANTON. Thank you very much. The next witness is Mr. Thomas Billy.

STATEMENT OF THOMAS BILLY, DIRECTOR, OFFICE OF SEAFOOD, FDA

Mr. BILLY. Yes, thank you, Mr. Chairman and members of the Subcommittee. I request that my entire testimony be entered into the record. I am Thomas Billy, Director of the Food and Drug Administration's Office of Seafood. I am pleased to be here today to describe the current legal and regulatory regime for seafood safety and to update the Congress on our activities. However, before I get into my prepared remarks, I would like to personally acknowledge the past role and support of the Merchant Marine and Fisheries Committee and its Chairman, Mr. Studds. We look forward to a continued cooperative relationship, including this new Subcommittee on Fisheries Management.

Ensuring the safety of seafood presents special challenges to both the industry that produces it and to the FDA and the other Federal and State agencies charged with protecting the public health. Seafood is a disparate array of products encompassing hundreds of edible species that have little in common other than their aquatic origin. Collectively seafood has perhaps the most diverse and complex microbiology of any food commodity. The range of habitats for edible species is also extremely diverse.

These habitats have a bearing on the types of microorganisms, toxins, parasites, chemicals, and other potential hazards that fish and shellfish may be exposed to. Yet another complicating factor in ensuring the safety of seafood is the fact that no other flesh food is imported in the quantity, the variety or from as many countries as seafood. Regarding the safety of seafood, there are conclusions that we believe can be drawn with confidence because they reflect general scientific consensus. The National Academy of Sciences conducted an extensive study of seafood safety and concluded in its 1991 report that "most sea foods available to the U.S. public are wholesome and unlikely to cause illness in the consumer." We agree.

As with most foods, illnesses do occur, but they are not frequent and for the most part they are not severe. Concerns also have been

voiced about chemical contamination of seafood. We know that fish can absorb chemicals from the environment, so the question is a valid one. FDA has more than doubled our sampling program for chemicals in the past few years. We seldom detect chemical contaminants at levels of concern in commercial species. There are no available illness data that link commercially supplied seafood with chronic health effects from chemicals.

Regarding FDA's regulatory efforts, we operate a $40.5 million annual program for seafood. This sum reflects an increase of over 60 percent from the $25 million provided by Congress in fiscal year 1990. The essential elements of our mandatory program are surveillance inspections of domestic seafood processors and related commercial entities, sampling and analyzing fish for toxins, chemicals, and other potential hazards, targeted examination of imported seafood shipments, negotiation of international agreements, research, Federal-State cooperative programs, and public education.

In addition to our mandatory surveillance program, the National Marine Fisheries Service operates a voluntary fee-for-service program which Nancy just described. The two agencies have worked well together over the years on seafood issues, and we are proud of our relationship with the National Marine Fisheries Service. States also conduct inspections for seafood processors, so the overall frequency of inspection, combining Federal and State is much higher. The State of Alaska, for example, which accounts for half the domestic seafood tonnage has a substantial inspection program. We consider the States to be a critical and integral component of a seafood safety net.

As my testimony has already described, there are a variety of environmental and processing hazards to which seafood can be exposed from water to table. It is imperative that those who handle and process seafood commercially understand the hazards and keep them from occurring through a system of routine preventive controls. Hazard analysis critical control points or HACCP is a system of preventative controls that are established and maintained by a processor for the purpose of keeping hazards from occurring.

Two years ago Commissioner Kessler requested that the agency study the feasibility of requiring industry-operated HACCP systems for seafood. Coupled with our routine mandatory surveillance inspections by FDA that, among other things, would review the adequacy of those inspections or HACCP systems. Such a step would reflect a logical extension and evolution of longstanding policy and program. It would also be responsive to the strong support for the adoption of a mandatory HACCP-based inspection system for seafood shown by consumers, the Congress, and broad segments of the seafood industry. Based on the results of that study, Commissioner Kessler announced last March that FDA is developing mandatory HACCP requirements for the seafood industry as part of its inspection program.

Those requirements will establish HACCP preventative controls that take into accounts the unique characteristics of seafood products. FDA believes that a HACCP approach would strengthen its programs to ensure that seafood is safe and prepared under sanitary conditions. We also are exploring the application of HACCP to imports. FDA is contemplating requiring that both importers and

their foreign processors operate on the basis of HACCP controls. The harmonization of international approaches to regulating seafood safety through HACCP offers the dual benefit of aiding the U.S. industry to compete in the global economy and to assure international cooperation on hazard intervention strategies applied to all sea foods.

Mr. Chairman, that completes my formal testimony. Time does not allow me to go into our activities related with the States, some of our cooperative programs, research and consumer education. However, I would be happy to answer any questions you might have.

[The statement of Mr. Billy can be found at the end of the hearing.]

Mr. MANTON. Thank you, Mr. Billy. We have inserted your full testimony in the record, and I am sure that there will be some questions from the members that will elicit some of the answers that you might not have—or some of the subjects you might not have touched.

Our next witness, Dr. Paul Blake, Acting Chief of the Foodborne and Diarrheal Diseases Branch, National Center for Infectious Diseases.

STATEMENT OF PAUL BLAKE, DIRECTOR, ENTERIC DISEASES BRANCH, NATIONAL CENTER FOR INFECTIOUS DISEASES

Dr. BLAKE. Thank you. I am Dr. Paul Blake, Acting Chief of the Foodborne and Diarrheal Diseases Branch of the National Center for Infectious Diseases, Centers for Disease Control and Prevention. I am pleased to respond to the Subcommittee's invitation to discuss seafood-borne disease surveillance and CDC's role in preventing foodborne disease and characterizing foodborne hazards.

Foodborne disease is an ever changing public health challenge and can be called an emerging infectious disease. Recently the Institute of Medicine issued a report called "Emerging Infections," which identifies factors such as changes in human behavior, technologic advances, and microbial adaptation that lead to emergence of microbial threats. Each of these factors has affected the safety of our food supply.

I will provide the executive summary of the Institute of Medicine report for your consideration for inclusion in the record.

Epidemiologic data are necessary in order to design focused risk-management strategies for seafood-associated diseases. CDC's activities in identifying and characterizing foodborne hazards fall into five categories. First is the foodborne disease outbreak surveillance system; second, investigations of outbreaks; third, studies of specific foodborne diseases; fourth, laboratory-based surveillance of specific foodborne microorganisms, such as salmonella; and fifth, laboratory studies of foodborne microorganisms that may be submitted by the States and acquired through investigation.

The foodborne disease outbreak surveillance system, the first of these, collects and analyzes data on outbreaks provided to us by State health departments. Although the system has been useful, it has many limitations which are often not considered when talking about the data. First, the reported outbreaks represent only a

small fraction of the actual number of outbreaks that occur, so we cannot measure the precise size of the problem of foodborne disease. Secondly, we cannot compare the frequency of foodborne disease outbreaks in one area with another area because the investigative ability of the State and local health departments vary greatly. For example, the State of Washington reports a relatively large number of outbreaks of foodborne disease, but that does not mean that Washington has a lot more outbreaks than other States. Washington is just better at investigating the outbreaks. Third, the relative importance of the various foodborne pathogens and toxins is unclear because some outbreaks are more likely to be reported than others. Reported outbreaks are more likely to be large, interstate, restaurant-associated, involve serious illness or death, and have short incubation periods. These are the ones that get attention. Fourth, a final limitation of the surveillance system is that it only detects outbreaks, and most foodborne disease occurs as single sporadic cases.

In collaboration with the National Marine Fisheries Service and FDA, we have analyzed foodborne disease outbreaks reported between 1973 and 1991. Keeping in mind the many limitations of these data which I have just gone over, these are the overall results: During this period of 19 years there were 4,591 outbreaks of disease reported in which the causative food was known. These outbreaks affected 202,850 persons. Seafood accounted for 5 percent of the foodborne outbreak associated cases compared to 10 percent for poultry, 9 percent for beef, and 2 percent for eggs.

How can surveillance be improved to help control seafood-related and other foodborne diseases? First, we need to have nationwide rapid reporting and analysis of foodborne disease. The current system is very slow and usually runs several years behind. CDC has developed a computer-based data reporting and management system which permits public health laboratories to report electronically and is working with State public health lab directors in installing the system in all public health laboratories right now.

Second, simply making the existing surveillance system more complete and more rapid is not enough. We also need to have a sentinel surveillance system, with a few sentinel sites throughout the country where the epidemiologic and laboratory resources have been improved to allow intensive surveillance and investigation of foodborne disease. With such sites, we can more completely identify foodborne hazards, characterize their risk, help set foodborne disease prevention priorities, and evaluate the effectiveness of food safety programs and the impact of regulatory change.

To conclude, CDC collaborates with FDA, National Marine Fisheries Service, USDA, and State and local authorities in responding to food safety issues. Improving food safety and meeting emerging foodborne disease problems in the 21st Century will require changes in our surveillance program. Thank you for the opportunity to testify before the Committee. I will be happy to answer any questions you may have.

[The statement of Mr. Blake can be found at the end of the hearing.]

Mr. MANTON. Thank you, Dr. Blake.

Mr. MANTON. Our next witness will be Mr. Jim Salmon, First Vice President, National Fisheries Institute and Senior Vice President of Purchasing for Red Lobster.

STATEMENT OF JIM SALMON

Mr. SALMON. Thank you, Mr. Chairman. I am Jim Salmon, Senior Vice President of Purchasing for Red Lobster, a chain of over 600 seafood restaurants, and my company is a part of General Mills, Inc. Each year we provide over 120 million seafood meals to the American public. Our total sales last year exceeded $1.7 billion. It is obvious that a safe, wholesome supply of high quality seafood is essential to the success and future of our business and our 60,000 employees.

I am here also as the First Vice President of the National Fisheries Institute, commonly known as NFI. Red Lobster has been an active member of NFI for many years and has helped lead the association in its drive to improve the Nation's seafood regulatory inspection system. We appreciate the interest of this Subcommittee concerning seafood safety. You will find our interest mutual. The Nation's fisheries are tremendously important resources. This Subcommittee's responsibilities to oversee their management and harvest must include concern for fisheries population by consumers and the benefits of the fisheries throughout all regions of the country, not just the coastal production areas.

To illustrate this, Mr. Chairman, I would like to cite the most recent economic analysis on value of the fisheries. Seafood products are worth about $9 billion at the time of landing and importation. By the time value is added through processing, distribution of service, these products are worth more than $35 billion to consumers. This added value provides for hundreds of thousands of jobs, fuels the economy, and represents the huge contribution of seafood to the Nation's nutritional needs and quality of life. This topic is indeed important and we urge the Subcommittee's continued interest.

As we heard earlier, it appears that we are on the verge of a whole new chapter in the evolution of the Nation's food protection system. The plans by the Food and Drug Administration to publish a new regulation proposal requiring seafood processors to institute a system of preventative controls in their operations is a watershed event. We anticipate this program will serve as a model for a similar action in the entire food industry in the future.

Hazard analysis and critical control point principles, commonly called HACCP, are not new to Red Lobster. We actually began incorporating this concept in our internal inspection system in 1979. My written statement details the extensive quality assurance program employed by Red Lobster. We regularly visit every processing plant supplying us no matter where it is located in the world. Our specifications include organoleptic and microbiological standards. We have four regional seafood inspection laboratories and a national microbiological laboratory. We currently utilize the services of the U.S. Department of Commerce to provide a check on our inspectors to ensure uniformity to our specifications.

Each member of the management in our restaurants is a member of our quality assurance team. When you go to a Red Lobster, the person with the thermometer in his or her pocket is probably the manager. Temperature control is a critical part of seafood quality and is built into a HACCP system. Since its founding in 1968 Red Lobster has made safety and quality a part of its operating credo. We believe it is in the best interests of our company, our industry, and consumers if the entire industry employs a similar dedication to seafood safety. That is why we have urged the FDA to move forward with a HACCP proposal.

Mr. Chairman, there is no crisis in seafood safety to solve. There is, however, a need to move forward with new technology and regulatory procedures to give assurance to consumers that all reasonable steps are being taken to provide safe, wholesome seafood. Mr. Chairman, there have been many, many hearings on seafood safety and inspection in this Committee room and in others on both sides of the Capitol. There were hearings in the late 1960's, in the 1970's, still again in the 1980's and in the early 1990's. Despite all the interest there was never enough consensus to produce legislation mandating a specific seafood regulatory or inspection system.

Thousands of pages of testimony and dozens of bills were produced, but there was no legislation. In the industry, however, every new flurry of activity produced renewed self-examination and improvements. For example, the most recent legislative interest resulted in the development of HACCP models for every section of the industry. These manuals of HACCP models for every process from fresh fish to cooked shrimp plants are the guidelines for companies to be responsive to a HACCP regulatory program. These were developed by the National Fisheries Education and Research Foundation in concert with government and academic scientists. The legislative proposals of the last two sessions of Congress were based on use of a HACCP system. The industry supported that concept. Unfortunately the legislative process became embroiled in contention over jurisdiction and other agenda items extraneous to seafood safety, so there was not final action.

Now, it appears that FDA plans to make something new happen by initiating a bold new chapter in the evolution of seafood, regulation, and inspection. Let's not jeopardize this by reopening contentious debate in Congress. The industry wants to see the FDA proposal. We want a chance to comment on it and then put it into place. We can then determine if there is need for legislation to provide additional authorities or direction. Getting regulations on the books is only a first step. The industry wants to be sure enforcement is consistent and thorough enough to make sure all the industry adhere to the new requirements.

We believe FDA should consider establishing a force of expert personnel dedicated to the seafood program. There can be great advantage in forming a Federal-State compact like the Interstate Shellfish Sanitation Conference, or the ISSC to provide for ongoing cooperation among all concerned with the seafood safety in a HACCP regime.

In summary, Mr. Chairman, we commend the Subcommittee for its interest. We ask that nothing be done to impede or confuse the very positive steps planned by the FDA. Let a HACCP regulation

move forward and be put in place, then let's see if the needs of consumers and the industry are satisfied or if there is need for further legislation. Thank you for the opportunity to be here.

[The statement of Mr. Salmon can be found at the end of the hearing.]

Mr. MANTON. Thank you very much, Mr. Salmon.

Mr. MANTON. Our next witness Mr. Bill Taylor, President, Pacific Coast Oyster Growers.

STATEMENT OF BILL TAYLOR

Mr. BILL TAYLOR. Thank you. Mr. Chairman, members of the Subcommittee, my name is Bill Taylor. I am a shellfish farmer in Washington State and President of the Pacific Coast Oyster Growers Association. PCOG represents 120 member companies in Washington, California, Oregon, Alaska, and British Columbia involved in the farming of oysters, clams, and mussels. PCOG is the largest shellfish organization in the U.S.

Shellfish pose a tremendous regulatory challenge. They require a comprehensive inspection program unmatched in other foods. This fact was recognized as early as 1925 when the Surgeon General summoned State and local health officials to Washington, D.C. to develop a National Shellfish Sanitation Program.

Remarkably, the conclusions of that conference still serve as the foundation of today's inspection program. Because shellfish feed by filtering nutrients out of the water, the beds on which they grow must be inspected. The plants in which shellfish are prepared must be inspected, the products must conform to an established bacterial standard, the method of shipping must be inspected and finally, the responsibility for sanitary control of shellfish rests chiefly upon the individual States.

This year, the FDA issued a policy statement on the consumption of raw molluscan shellfish. In the statement, FDA endorsed the National Shellfish Sanitation Program as the best means of making molluscan shellfish as safe as possible.

In fact, the standards and procedures of the NSSP are the most comprehensive of all the regulatory programs for meat products. If you were to apply similarly stringent standards to beef production, for instance, you would have to establish bacterial standards for the soil in which the corn is grown that is eventually fed to the cattle.

But if the NSSP is so effective, why has so much of the seafood safety debate focused on shellfish? There are primarily two reasons, both of which are problems that the FDA acknowledges in its policy statement.

First is the illegal harvest of shellfish from closed waters referred to as bootlegging. In parts of the country where oystering is a wild harvest fishery, bootlegging is extremely difficult to control. In its policy statement FDA called bootlegging a practice that probably leads to most shellfish illnesses.

The second problem is that the current program is designed to protect against illnesses associated with pollution from human sewage, but perhaps the greatest health risks currently are from highly toxic, naturally occurring organisms unrelated to pollution,

such as paralytic shellfish poisoning or PSP, domoic acid and vibrio vulnificus.

For instance, PSP is prevalent on the West Coast during the summer months. Fortunately there are effective monitoring controls for PSP. Even though many growing areas on the West Coast are shut down completely during the summer, we recognize that the closures are in the best interest of the industry because they ensure the safety of our products.

The Gulf Coast States and FDA are faced with a similar problem in vibrio vulnificus, a warm water organism which can be highly toxic to certain high risk individuals. The difference is that no effective monitoring method or risk standard has been established for vulnificus. We are all aware of the unfortunate deaths that have been associated with vulnificus through the consumption of shellfish from the Gulf of Mexico. While these fatalities have had a disastrous effect on the shellfish industry in the Gulf States, the other shellfish-producing regions of the country have suffered as well from the publicity and subsequent erosion of consumer confidence in the safety of all shellfish.

Clearly vibrio vulnificus and other biotoxins pose the greatest health risks associated with shellfish at this point in time. Every effort must be made to find a responsible solution to the problems posed by vulnificus. The industry on all three coasts, not just the Gulf of Mexico, cannot survive continued fatalities associated with the consumption of oysters.

Before I conclude, I would like to thank Representative Jolene Unsoeld for introducing House bill 1412 establishing the National Shellfish Safety Program. It is an excellent, comprehensive bill that tackles head on the most pressing problems faced by the domestic shellfish industry, including: Protection and restoration of shellfish growing areas that have been impacted by pollution, requirements that foreign producers meet the same water quality, sanitation, and program requirements as the domestic industry; authorizing Federal support to State shellfish control agencies to help implement Federal guidelines; and extending FDA's enforcement authority to individual shellfish shippers.

PCOGA has submitted extensive written comments specific to H.R. 1412. We are wholly in support of the bill and urge the Subcommittee's support as well. Thank you. I would be open to any questions. Thank you.

[The statement of Mr. Taylor can be found at the end of the hearing.]

Mr. MANTON. Our last witness, Mr. Bill Morgan, President of the Shellfish Institute of North America.

STATEMENT OF BILL MORGAN

Mr. MORGAN. Mr. Chairman, members of the Committee, my name is Bill Morgan. I am the President of the Shellfish Institute of North America. I greatly appreciate the opportunity you have given me to testify in these hearings on House bill 1412, the Shellfish Safety Act of 1993.

I represent the oldest trade association in the United States. We also have the oldest inspection system in this country. Our Shell-

fish Sanitation Program has evolved over approximately the last 75 years to the present day National Shellfish Sanitation Program. In this extremely comprehensive program, FDA works cooperatively with the States and industry through the Interstate Shellfish Sanitation Conference. This inspection program has always been based on microbiological testing, not just on superficial sensory inspection. Not only are our shellfish products tested, but shellfish growing waters must meet strict microbiological standards to insure freedom from fecal contamination.

Our seafood industry, working with NFI and USDC, was one of the first to apply the HACCP concept for the control of foodborne hazards. Even USDA has acknowledged that their traditional continuous visual inspection system is not effective for invisible microorganisms. They are now looking to our program in developing an improved HACCP-based system to control potential microbiological hazards.

All of this is certainly ironic in view of the fact that certain consumer lobbying groups and regulatory agencies have used the media over the last six years to continuously propagate misleading or false information regarding the safety of domestic seafood and especially shellfish. They also relentlessly assert that our products are not properly inspected or that our current inspection is carried out by too many groups or agencies.

Our members will certainly concur with the latter, since we are, in fact, inspected by local and State regulatory agencies, FDA, EPA, and if we pay them, even USDC.

Those special interest consumer lobby groups and agencies who maintain that we are not sufficiently inspected and who continue to malign our products in the National press as unsafe have gained tremendous financial and political power. The press quotes them avidly without thought to researching the actual scientific facts and data. The FDA has gained a whole new division of seafood, and a greatly increased budget and bureaucracy. This has all been accomplished at the expense and near extinction of our very small but traditional shellfish industry that represents an important heritage in our coastal States.

If you consider that of 1,460 pounds of food consumed per person per year only 15.5 pounds represents fish products and less than one-tenth of a pound of this is shellfish, it is extremely hard to rationalize and justify the tremendous expense to the taxpayer and our industry for these numerous seafood hearings and proposed inspection systems. This is especially true when considering the actual scientific data and facts regarding seafood safety. The recently published National Academy of Science's seafood safety report clearly states that "most sea foods are wholesome and unlikely to cause illness in the consumer."

For all of these reasons and because House bill 1412 singles out only shellfish for additional regulations and expanded FDA authority, the majority of the shellfish industry is opposed to House bill 1412.

We have always supported a single HACCP-based inspection system for all sea foods, but cannot support additional regulations that solely target the overregulated shellfish industry.

House bill 1412 also gives authority to FDA to indiscriminately remove a single company from the interstate certified shellfish shipper's list. This type of legislation gives whistleblower power to competitors. FDA could target and close single companies that could not afford to defend themselves in court, even if an error had occurred. FDA already has the power to close a company for product adulteration or unsanitary conditions. However, once a company is removed from the certified shipper's list, it could take months to get through the red tape required to be reinstated. Most companies could not survive this financially.

My own company was inadvertently excluded from this list several years ago through a simple clerical error. We were unable to proceed with business for more than two months. We had no recourse for retribution.

I would like to make these final comments concerning business in general. Any business, particularly a highly perishable seafood business, cannot survive even temporary closures. Also, no company forced to sign a consent decree by FDA has been able to remain in business for even one year. Many members of our industry have already lost their heritage, their livelihood, and the future of their families and their employees' families over minor discrepancies that do not represent actual public health hazards. A prime example is the policy of zero tolerance for listeria monocytogenes, a microorganism commonly found in the environment, and which has never been documented as causing a single seafood-associated illness from domestic seafood.

Since the negative media campaign against seafood and shellfish began in 1987, our industry production has dropped more than 40 percent nationally, with a concurrent drop in price of 60 percent and overall losses of more than half of their businesses. Hundreds of processing plants have been forced to close, resulting in the loss of countless jobs.

President Clinton has committed to increase jobs in this country. Putting companies out of business for reasons which have no real or widespread public health significance puts people out of work. It is the small family businesses like ours which provide most of those desperately needed jobs.

The FDA and other agencies should not base their mission on expanding their power to more easily close American businesses, but should strive to work more closely with States and industry to help solve any existing or potential problems.

In view of the above facts and concerns, the shellfish Institute of North America cannot support House bill 1412. I thank you again for allowing me the opportunity to present some of my industry's views.

[The statement of Mr. Morgan can be found at the end of the hearing.]

Mr. MANTON. Thank you, Mr. Morgan. That concludes the testimony, and we will proceed with questions for our witnesses.

Ms. Foster, if I may pose this question, it is my understanding that currently NMFS has authority to close water only in emergency situations for 90 days. What mandates an emergency situation, what measures can be taken to indefinitely close certain waters to harvesting?

Ms. FOSTER. Well, under the Magnuson Act we can implement a 90-day emergency and then it can be extended for another 90 days. We do this under recommendations and in consultation with FDA; we do it when there is a recognized public health hazard. We are contemplating seeking an amendment to the Magnuson Act that would allow us to extend that emergency. I mean emergencies have a habit of not going away because your emergency rule expired, and we think that it makes more sense to have the emergency in effect until FDA indicates that the public safety hazard is gone.

Mr. MANTON. Mr. Billy, when do you foresee the seafood inspection rule being published in the **Federal Register**?

Mr. BILLY. I can share with you the current status. It is in the final policy clearance in the Commissioner's office. The proposed rule will then be forwarded to the department and then on to the Office of Management and Budget. We have had preliminary discussions with the department and are providing a briefing to the Secretary's office this coming Monday. I am not sure I can predict how quickly we will be able to get the proposed rule through that process, but the Commissioner is committed to moving the proposed rule as quickly as possible.

Mr. MANTON. After the inspection rule is published, does the FDA foresee the need for additional legislation granting the agency greater regulatory authority?

Mr. BILLY. We believe that we have adequate authority to publish this rule and implement a comprehensive mandatory HACCP-based seafood inspection program.

Mr. MANTON. Mr. Salmon, you and your company exercised great foresight in instituting your HACCP-based inspection program in 1979. What was the reasoning behind this, how has the program met, failed or exceeded your expectations?

Mr. SALMON. Actually our program started way before then. In 1972 we started our first buying department and we had put in our inspection labs at that point in time because of our concern about quality. It really starts with the philosophy of quality, value and service, which was our QVS, but we knew we had to have quality seafood to be more competitive, to stay competitive and to be one up. In so doing we started our labs at that time.

Our system has really been a HACCP system all along. I guess we just didn't know the name of it at that point in time.

Mr. MANTON. We like fancy names around here that you can't pronounce.

Mr. SALMON. Acronyms are great. We knew we had to have something in place. You can use the term "HACCP," but define those points along the line of where that food is going from source to plate and knowing where those critical control points are and putting something in place to check it, and that is what we did and so from that timeframe since 1972 up to the present we have been using a system that is very similar to a HACCP program.

Mr. MANTON. Thank you. I don't want to monopolize the time for questions. I will recognize the gentleman from North Carolina, Mr. Coble.

Mr. COBLE. Thank you, Mr. Chairman. I am sorry for my belated arrival. I have two other meetings going on. Good to have you all with us. Any of you can answer this, but perhaps Mr. Billy and Ms.

Foster might be the more appropriate ones. This is extending, Mr. Chairman, to some extent your question. It appears that each agency already has some type of seafood safety program. I would like to hear from either of you as to why your particular agency should be in charge of the mandatory Federal program, assuming one is approved, and how your agency currently distinguishes itself from the others that may be ongoing now.

Mr. BILLY. Maybe I could take the first shot at that. I don't think it is a matter of who should be in charge. I think that both the National Marine Fisheries Service and FDA complement each other in terms of our background and expertise and legal authorities to address this issue of seafood safety. I spent the first 27 years of my career working for the National Marine Fisheries Service. I am very familiar with their programs.

Now that I have joined FDA, it is clear to me that they are synergistic in terms of what we can bring to the table to address the issues of seafood safety, so I think that that is the approach or the idea that we should be thinking about is how do we work together to get this job done.

Dr. FOSTER. Yes, I agree completely. I think that the two programs absolutely complement each other. Before we get to the point of thinking about legislation, we should also consider whether or not some of the problems are simply that none of us are doing our jobs quite as well as we could and that we do have authority that we haven't exercised.

Mr. COBLE. Are the current programs presently being operated duplicative? To what extent is there any overlapping or duplicating result?

Mr. BILLY. I believe it is minimal at most, and perhaps nonexistent. We have, as Nancy mentioned in her testimony, a number of memorandum of understanding with—between the two agencies addressing coordinated research, coordinated inspection activities, coordinated involvement with the National Shellfish Sanitation Program, and coordinated enforcement, and through those mechanisms we work very closely together to carry out our respective responsibilities, so I think you will find that there is a lot of cooperation and not a lot of duplication.

Mr. COBLE. Do you want to add to that, Dr. Foster?

Dr. FOSTER. No, not really, just to agree again. I am sure that if you looked really closely you might find something, but I think it is minimal.

Mr. COBLE. Finally, Mr. Chairman, one more question, and I think the answer to this question will be in the negative, but I don't know with certainty without asking it. Is the United States Department of Agriculture involved in any way with what you all are doing as far as the safety program is concerned? As far as seafood goes?

Dr. FOSTER. We do use Department of Agriculture inspectors in our program through an agreement and consult with them whenever appropriate.

Mr. BILLY. The answer is, no, with respect to the Food and Drug Administration. With the exception that the USDA chairs the coordinating Committee on Aquaculture that is responsible for co-

ordination among the Federal agencies and promoting the development of aquaculture and the regulation of aqua culture practices.

Mr. COBLE. Thank you. I have no further questions, Mr. Chairman.

Mr. MANTON. The Chair will recognize the gentlewoman from Washington.

Mrs. UNSOELD. Thank you very much, Mr. Chairman. My purpose in putting this legislation together is to protect the industry by protecting the public's confidence in shellfish, and one of my principal goals is to establish a level regulatory playing field that is going to allow the domestic industry to compete with foreign imports.

Mr. Billy, do you agree that foreign products should have to comply with a regulatory program that requires equivalent standards of compliance?

Mr. BILLY. Yes, I do.

Mrs. UNSOELD. All right. How can foreign governments be required to meet those water quality monitoring and classification standards, and does FDA have the statutory authority? Two years ago when the issue came up you all said you didn't have the authority, and so I would like to explore that.

Mr. BILLY. OK. Our current approach to working with importers and foreign countries that ship molluscan shellfish to us is through seeking voluntary cooperative agreements with the countries. We have nine such agreements, six of which are active——

Mrs. UNSOELD. I am sorry, what—you have nine?

Mr. BILLY. Nine such agreements.

Mrs. UNSOELD. Are you referring to MOUs?

Mr. BILLY. MOUs, that is right. These are voluntary. We seek them with countries that ship products to us. We are not satisfied with that approach, and so as we have considered the application of HACCP to the seafood area. We believe that relevant to your first question that the same kinds of requirements that are applied to the domestic industry, including the molluscan shellfish industry should also be applied to imported molluscan shellfish products.

Mrs. UNSOELD. Currently those MOUs, as you indicate, are voluntary. You don't have them with all countries?

Mr. BILLY. That is correct.

Mrs. UNSOELD. And when you do have them, the ones I have seen, the one I have in front of me says that—it only requires that the government with whom you have the MOU can ensure that that country's program can do certain things, not that they do it, so how would you contemplate through regulatory means to actually have enforcement with some teeth in it to protect our American shellfish industry from shellfish coming in that have come from bad water?

Mr. BILLY. You have to step back and look at the principles of HACCP. Under a HACCP-type system a responsible business is required to identify all of the potential hazards and then more importantly identify the controls that are in place to address those hazards. In the case of molluscan shellfish, this would apply not only to what happens during the processing period but also the waters from which those shellfish were harvested, so in a HACCP-type system the importer, and through the importer the foreign proces-

sor would be looked on to provide information and records that would demonstrate that the products that they were importing come from certified waters consistent with the standards that are in place in the United States.

Mrs. UNSOELD. But the foreign country would not have that responsibility.

Mr. BILLY. Well, the foreign country could be the means by which that certification process occurs, and we would be, as we are now, seeking on a voluntary basis agreements with countries that are prepared to operate water quality monitoring and certification systems equivalent to those in the United States.

Mrs. UNSOELD. Voluntary agreements would make me very uneasy when we are talking about enforcement of water quality in other nations, particularly when you may have within the administration points of view that are extremely unwilling to put trade restrictions or what appears to be trade restrictions on other countries. Don't you think that would make it less likely that you would put teeth in enforcement without a statutory provision?

Mr. BILLY. What we do now for those cooperative agreements is verify that, in fact, the countries are following the requirements as spelled out under the National Shellfish Sanitation Program. We verify that through periodic inspections of their programs in their countries.

At the outset before we will sign an agreement, we determine that, in fact, they have both the capacity and the program in place to handle the harvesting and processing of safe shellfish and then we periodically audit that program by visiting there and checking their system. We verify that their laboratories are still competent to do the necessary analysis, and we also monitor the products as they come into the United States.

Mrs. UNSOELD. How frequently is that done and what would be the means by which the United States would shut off the importation of that shellfish?

Mr. BILLY. Currently we monitor foreign country programs between—once every year to once every three years.

Mrs. UNSOELD. My time has run out, Mr. Chairman, and I will wait and come back to it after, but don't forget where we are, Mr. Billy. I will return to that.

Mr. MANTON. The Chair recognizes Mr. Hamburg from the State of California.

Mr. HAMBURG. Thank you, Mr. Chairman, just a couple of questions. These are actually for anybody that can shed some light. I would like to know first how extensive contamination of seafood is that is caused by toxics, heavy metals, PCBs, pesticides. Is that a problem that we should be very concerned about, and I would like to know what is being done to alleviate whatever problems we do have?

Mr. BILLY. I can take the first shot at that. We work cooperatively with the Environmental Protection Agency in monitoring chemical contamination of the marine environment. Based on the monitoring programs that are in place, what we find basically is where extensive chemical contamination from PCBs or other types of contaminants tend to be localized and associated with certain types of industries that manufacture those compounds or use them in some

capacity in their operation. EPA, through their water program, because of this has identified several hundred sites around the country. They are primarily in freshwater and lakes and rivers or in the near shore area, and closely monitors the contaminants in those areas.

In addition, EPA works with the States to issue advisories, and there are approximately 1,200 advisories that are issued annually to potential consumers of the fish or shellfish. I must add that based on a recent report from EPA, it was determined that essentially all of the hazard associated with this is limited to recreational fishers, that there are no commercial fishing operations in these areas. We do not see, based on our monitoring, any significant level of chemical contamination out in the open ocean environment.

Mr. BILLY. Occasionally you can detect a very limited or very small amounts of certain contaminants, but it is not common and it is not an area of significant concern to us.

Mr. HAMBURG. Anyone else?

Mr. BILL TAYLOR. I would say that it is not a chemical or a—toxic contamination is not a problem with the domestic industry for the most part. Our regulations are good, tight on a lot of the chemicals, and the harvest does not occur—for commercial harvest, at least, does not occur in those areas.

I think one of our major concerns is that those countries that import into the U.S. do not have MOUs. We do not really know. There is minimal amount of inspection as the product comes into the U.S. but we have some major concerns about what is coming into the country from other countries that do not have programs that are equivalent to ours.

Mr. HAMBURG. In this background memo that was handed out to the Committee it stated that recreational subsistence harvest of fish present the second highest risk category to consumers.

I was wondering if anyone could comment on specific problems. Do they exist mostly in urban areas that have high pollution, these ones you mentioned, or do they also exist on some of the—you know, when I think of recreational subsistence fisheries, I think of the Native American fisheries of the Pacific Northwest.

Are we having problems in rural areas in addition to in these polluted urban waters?

Dr. FOSTER. I can't speak directly to that. NOAA does have a status and trends program where we monitor environmental conditions around the country, not the actual organism or animal itself, but what we find is that the pollution is concentrated in various hot spots around the country, such as Puget Sound, and off Miami.

So fish taken from these areas are the ones more likely, I think, to cause a problem.

Mr. HAMBURG. And in terms of what we are doing to try to minimize those risk and remove those risks, that mainly is in EPA's territory; is that right?

Mr. BILLY. In terms of monitoring the fish and shellfish out in the environment, I think that is correct, in addition to what NOAA does. However, we include a—we have an extensive contaminant monitoring program as part of our seafood program and we analyze over 2,000 samples annually taken from the marketplace, from all different sources for various types of chemical contaminants.

So it is an ongoing part of our program as well, looking at it from the consumer exposure point of view.

Mr. HAMBURG. But just for an example, if you had a pulp mill that had a certain amount of effluent going into a bay where there were oysters and clams and various fish being—various seafood being harvested, would you be monitoring that on a routine basis?

Mr. BILLY. Normally that is done by the State, and it is part of—if it involves——

Mr. HAMBURG. Because it is within the three miles?

Mr. BILLY. Yes, and if it is related to molluscan shellfish, it is in the requirements to the National Shellfish Sanitation Program.

So there is a system in place and it just depends on the area that you are concerned about.

Mr. HAMBURG. Thank you very much.

Mr. MANTON. The gentleman from Mississippi.

Mr. TAYLOR OF MISSISSIPPI. Thank you. If I am repeating anyone else's questions, please forgive me. First off is, some of the seafood producers in my area point to the demise of the oyster canning industry in particular and say that they were the victim of a double standard in that in their instance the oysters had to come from approved waters, be processed in an approved plant, and then the final product was judged as far as its content.

I point to an oyster that was grown in Korea in waters they said wouldn't pass and a plant they say wouldn't pass, but you never look at that. All you do is look at the can, and if the final product is OK, then everything is OK. They don't have to worry about step one and two.

How would you respond to that and how are we going to prevent something like that from happening again with this piece of legislation?

Mr. BILLY. Korea is one of the countries that we have a cooperative agreement with, and under the terms of that agreement, the Korean government monitors the waters from which molluscan shellfish are harvested or exported to the U.S.

Our concern is that the possibility exists that in some instances, particularly with countries where we do not have agreements, that they could, through the canning operation, mask the possibility of certain types of microbiological contamination.

For that reason, we are considering that problem. We have considered that problem and we have identified an approach under our HACCP proposal that will address that very specifically so that there is a level playing field for the domestic industry.

Mr. TAYLOR OF MISSISSIPPI. How would you address that?

Mr. BILLY. Like I said earlier, all hazards associated with any species will have to be considered and addressed by the processor and by the importer and in doing it that way and then verifying that, in fact, that is the case, we believe we will be focusing right in on—for molluscan shellfish, the waters from which they are harvested in assuring that the same types of water quality requirements are met in that instance as they are domestically.

Mr. TAYLOR OF MISSISSIPPI. I find a double standard in that in that I recently attended a meeting under the present shellfish laws where my home State is being considered for removal from the list, and that you are willing to take a Korean inspector at his word

that the tests were performed but you are not willing to take a Mississippi inspector at his word, and I would love for you to explain that.

Mr. BILLY. I believe that is not the case.

Mr. TAYLOR OF MISSISSIPPI. I would differ.

Mr. BILLY. We audit State programs and the foreign programs, and we use the same criteria as laid out in the National Shellfish Sanitation Program and require that molluscan shellfish that enter interstate commerce conform to the same set of requirements that are spelled out in the national program.

Mr. TAYLOR OF MISSISSIPPI. But that is my whole point. We are strictly dealing with a person's word here. Now, it is a heck of a lot easier for you to follow up on whether or not Mississippi is inspecting than Korea and we all know that areas that may be clean today after a heavy rainfall won't be suitable tomorrow.

It is pretty easy to see after a heavy rain whether people from Washington or Maryland or Mississippi or Louisiana are closing the reefs for the day and it is pretty easy to tell what day they were harvested since the tag says the day they were harvested and what route they came off of.

How do you go through all of these things when you are talking about a country halfway across the world, and is this really fair to our people?

Mr. BILLY. The way we approach that is, as part of the National Shellfish Sanitation Program, the responsible shellfish authority is required to keep records that show the opening and closing of the shellfish beds consistent with the criteria that are contained in the national program.

So when we go to Korea, which we do, and we audit their program——

Mr. TAYLOR OF MISSISSIPPI. Daily?

Mr. BILLY. Not daily, nor do we go to any State and audit their program daily, but when we audit the programs, we look and determine whether, in fact, we see the kind of pattern that is appropriate for monitoring the growing waters and proper closures when that is necessary because of extensive rainfall or any other type of problem.

Mr. TAYLOR OF MISSISSIPPI. Why not just a simple test to the finished product for all concerned?

And then number two, Mr. Chairman, is, you know, we have a situation throughout the country with rare exception to where most States have a limited waterfront and in almost every one of these States you end up having inland versus coastal fights in the State legislature as to the funding of these programs.

My State is an example. Alabama has two coastal counties. Louisiana has a minimum of coastal counties. It is pretty universal. If we are going to have this sort of thing, is the Federal Government willing to pay for the testing? Since I think you will find by and large that most States have more inland areas than coastal areas and the inland folks are going to say, heck with them, we don't want to pay for that.

Mr. BILLY. It would seem to me that since the resources we are talking about—molluscan shellfish occur by and large in the State waters, and bring a——

Mr. TAYLOR OF MISSISSIPPI. Sir, it would seem to you, but I can tell you I have observed in the State legislature, and I keep up with what they do and what is happening. In Mississippi, Alabama and Louisiana, it is not unique to those three States.

So my question to you is, is part of your proposal are you willing to have the Federal Government pick up the cost of inspecting here and pick up the cost of inspecting in those countries that you approve?

Mr. BILLY. We do cover our costs of inspecting both the States, auditing the State programs and auditing the foreign programs to assure that those that are either under cooperative agreements or under the National Shellfish Sanitation Program are following the requirements that are described therein.

Mr. TAYLOR OF MISSISSIPPI. You picked up the cost of auditing but not the day-to-day cost of the program.

Mr. BILLY. No. That is left to the given State or the foreign government that is associated with the product that is being produced.

Mr. TAYLOR OF MISSISSIPPI. Thank you, Mr. Chairman.

Mr. MANTON. The gentleman's time has expired. We will go to a second round.

I will recognize the gentlewoman from Washington.

Mrs. UNSOELD. Mr. Billy, as I think where we left off, we were having the once a year inspection that you might make overseas and in the meantime the responsibility for any monitoring that took place would lie with either the person importing it into the United States or the producer to monitor themselves.

Now, what I think is the merit of my program, my legislation, in trying to equalize what my colleague has been talking about, the double standard and the unjustification, is that I would require that each foreign country exporting to the U.S. enter into an MOU, but that MOU would require, one, that they manage their program, that the country manage the program under the standards and procedures at least equivalent to what would be required here; and, two, certified of the secretary those shippers located in the country that comply with the program; and, three, maintain and make a list of the available—of the harvest areas that were acceptable.

I feel that you would—without that kind of requirement, would not have the authority. Further, in this country, we monitor on almost a daily, sometimes hourly basis for some of these toxins.

A once a year inspection, Mr. Billy, how do you feel that you can do by regulation what would be adequate to give an equal playing field for our domestic producers compared to the foreign and still protect the public's confidence in shellfish?

Mr. BILLY. We believe that the 23 producing States that are part of the National Shellfish Sanitation Program, as well as the countries, the governments of the countries with which we have agreements, take a great deal of responsibility—their responsibility very seriously to follow the rules and the requirements of the National Shellfish Sanitation Program.

I think that is verified by the fact that, you know, shellfish can be consumed raw. With all the inherent risks that are associated with the consumption of any raw animal protein, I think we have a remarkable record over the last 75 years.

Mrs. UNSOELD. Our domestic producers do, I agree with you. I am going to cut you off. I am going to ask you one other question with a yes or no answer so other Members can have a chance.

Would the MOUs—will these MOUs you are going to enter into under the new regulations, will they specify that a foreign country *will* meet U.S. standards rather than *can* meet as is current, and will countries without MOUs be prohibited from importing into the U.S.?

You ought to be able to know what you are heading for.

Mr. BILLY. Yes. Our preference is to have them say——

Mrs. UNSOELD. And you would prohibit from importing into this country from those countries that don't?

Mr. BILLY. We would take action based on——

Mrs. UNSOELD. Yes or no.

Mr. BILLY. Yes, we would—we wouldn't prohibit but we would take action on shipments.

Mrs. UNSOELD. OK, that is enough.

Dr. Foster, my bill would put NMFS in the role of tracking water quality and shellfish growing areas in working to restore these critical shellfish habitats.

Do you think that is an appropriate role for NMFS?

Dr. FOSTER. Well, we are certainly very active in habitat conservation and in habitat restoration.

Mrs. UNSOELD. And I do not believe probably, Mr. Billy, that your regulations within FDA could extend to that degree.

Mr. BILLY. That is correct.

Mrs. UNSOELD. I will take you off the hook and focus on Mr. Morgan for a minute. You oppose additional regulation, but what would you do to restore public confidence? How do you propose to do that?

Mr. MORGAN. First of all, there are an awful lot of good points to this bill and my testimony properly did not take that effect.

The two main problems we had with the bill last year and this year were, first of all, that we felt—we feel like that all seafood should be involved with whatever safety regulations are applied to us.

That is the first thing, because we feel like we have been under the microscope too long.

Mrs. UNSOELD. May I respond to you on that because I deliberately chose only shellfish. I felt that what happens to fish is quite different and shellfish is such a specialized industry and so easily the public could be spooked that I felt that it needed a hand-tailored regulation that is worked out with the industry that has foremost in its own mind wanting to protect its reputation with the public.

So that was deliberate in order to try to tailor something to shellfish's needs.

Mr. MORGAN. Yes, I see that but we are trying desperately to get out of the limelight. They are still showing shows on Prime Time the night before last, of a show that was two years old with Ellen Hauss and Mr. Kilpatrick.

Mrs. UNSOELD. I know.

Mr. MORGAN. And we just really are not at the point where we have endorsed since 1985 a mandatory seafood inspection program. We don't care who does it.

We feel like our program is good enough so that we can eat food raw. Not anybody in an inspection field of food in this country can make that claim. So that is the first thing.

The second is the shippers list. The bill gives power to FDA to target a single company, and I don't see what that has to do with anything other than politics of the game, to be able to come in and target one company, I mean even companies in my field could try to target one company for one reason or another, for FDA to come in and use that——

Mrs. UNSOELD. That is something we can probably work on with you. But my time is expired again unfortunately.

Mr. MANTON. I don't think there are any more requests for time, so if you want to continue and exhaust your questions, please do.

Mrs. UNSOELD. Mr. Morgan, wouldn't the alternative—I mean, if you have got one producer and you have got some kind of contaminated water or some problem and you say it is—that we are focusing on only that one company, isn't the alternative to close down an entire State?

Mr. MORGAN. Well, I think that the industry in that particular State has a much better chance in effecting legislature with a large group rather than one company, if there is a problem in that State.

Whereas if a company had a problem with the State regulation, if that State regulation was not up to par with another State, then one company would not be able to do anything. They wouldn't have enough power to do anything.

So I think the system as it is now, and the gentleman from Mississippi I think may be able to help me on this a little bit because it has happened in Mississippi, if you had one industry out there, one industry member who was targeted by that State agency for a problem, it wasn't even his fault, then he would be closed down immediately and his industry would not come to the legislator to help him out because it is a competitor.

Mrs. UNSOELD. I think we can work on some protections, but, Mr. Morgan, would you support a mandatory seafood inspection of some kind?

Mr. MORGAN. Oh, yes. We have since 1985 since it was first deemed that we had a major problem. We still don't feel like we do, but we feel confident that we can work with any mandatory inspection program, particularly an HACCP based one, and whether it is FDA——

Mrs. UNSOELD. Would you not be anxious to ensure that foreign imports are going to meet similar standards to what you would be required to meet so that consumers who, when they put a shellfish on their plate and eat it, don't know whether it is coming as an import or is domestically grown, and how easily, if there were a problem, a Jack In The Box type situation, wouldn't you want to have to have the foreign countries behave as would our industry?

Mr. MORGAN. Yes. We are in 100 percent agreement with that phase of the bill. We have always felt like that the foreign companies know months ahead of time when FDA is coming. All they

have to do is check the plane records and they know long in advance when they are coming.

It is not that there are any internal leaks or anything. It is just that you know when they are flying on airlines, whatever, over there, that they know when they are coming.

So, yes, we are in 100 percent agreement with that part of the bill.

Mrs. UNSOELD. Mr. Taylor, you have been listening to all of this and I know you come from a long family line of working in this industry.

Are there any additional comments that you would like to make, particularly on water quality or any other aspect of this?

Mr. BILL TAYLOR. I would like to say, I guess, that mandatory inspection, HACCP based type of inspection is something that the industry probably welcomes.

We need to try to get out of the limelight, like what Bill says, and what you said in your opening statement, get off the front pages and get on the table. We have lost sales and we have lost public credibility, and because people think we are a voluntary program, and I think what we need—we really don't have a voluntary program.

As anybody in the industry realizes, we have—we have mandatory regulations in our States, and what this bill does, and I think would probably help us out, is realize that FDA would actually have the superior authority, and I think that that would be beneficial to take and take away some of this credibility problem that we are running into with the public.

Mrs. UNSOELD. I thank you and I thank you very, very much, Mr. Chairman, for the hearing and for your patience and attention.

Mr. MANTON. In that case, all time has expired and we will declare this meeting to be at an end.

I thank all the witnesses for being with us. There is a vote on the Floor.

[Whereupon, at 3:45 p.m., the Subcommittee was adjourned and the following was submitted for the record:]

I

103D CONGRESS
1ST SESSION

H. R. 1412

To establish a National Shellfish Safety Program.

IN THE HOUSE OF REPRESENTATIVES

MARCH 18, 1993

Mrs. UNSOELD introduced the following bill; which was referred jointly to the Committees on Merchant Marine and Fisheries and Energy and Commerce

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A BILL

To establish a National Shellfish Safety Program.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Shellfish Safety Act of 1993".

SEC. 2. PURPOSES.

The purposes of this Act are to—

(1) protect against the hazards to human health associated with the consumption of shellfish; and

(2) ensure the public confidence in the wholesomeness and labeling of shellfish products consumed in the United States.

SEC. 3. NATIONAL SHELLFISH SAFETY PROGRAM.

(a) ESTABLISHMENT.—Not later than 9 months after the date of the enactment of this Act, the Secretary, in consultation with the Secretary of Commerce, other appropriate Federal agencies and the Conference shall establish a National Shellfish Safety Program to carry out the purposes of this Act.

(b) GUIDELINES.—The National Shellfish Safety Program established under subsection (a) shall include the issuance of guidelines for—

(1) shellfish growers, shellfish harvesters, shellfish shippers, and their vessels;

(2) water quality of shellfish growing and harvesting areas;

(3) monitoring the movement of domestic and imported shellfish in interstate commerce;

(4) monitoring and controlling biotoxins and other naturally occurring pathogens and bacterial, viral, and chemical contaminants in shellfish; and

(5) such other matters as are necessary to carry out the purposes of this Act.

(c) EXISTING GUIDELINES.—The Program shall be consistent with guidelines adopted by the Conference pursuant to the Memorandum of Understanding between the Conference and the Food and Drug Administration, dated March 14, 1984.

(d) REVIEW AND REVISION.—The Secretary, in consultation with the Conference, shall periodically review and revise the Program to ensure that the program continues to carry out the purposes of this Act.

SEC. 4. DOMESTIC SHELLFISH SAFETY.

(a) STATE SHELLFISH SAFETY PROGRAMS.—Each shellfish producing State shall submit to the Secretary, within 6 months after the establishment of the Program and annually thereafter—

(1) a proposed State shellfish safety program to—

(A) manage its shellfish safety program consistent with the Program;

(B) monitor and classify shellfish growing and harvest areas in the State consistent with the Program;

(C) establish procedures for the closure and reopening of shellfish growing and harvest areas in the State that do not meet the standards of the Program;

(D) certify those shellfish shippers in the State that comply with the requirements of the Program; and

(E) provide adequate monitoring and enforcement to ensure that standards and procedures established under the Program are met.

(b) CERTIFIED SHELLFISH SHIPPERS LIST.—Each State shall submit to the Secretary each month, a list of those shellfish shippers that are certified by the State as meeting the requirements of the Program.

(c) CLASSIFIED WATERS LIST.—Each shellfish producing State shall submit to the Secretary each month, a list of those shellfish harvesting and growing waters that are classified by the State as meeting the requirements of the Program.

SEC. 5. IMPORTED SHELLFISH SAFETY.

(a) MEMORANDUM OF UNDERSTANDING.—After the date of the establishment of the Program, the Secretary may enter into a memorandum of understanding with any foreign country which the Secretary determines has a shellfish safety program that is at least equivalent to the Program.

(b) CONTENTS.—A memorandum of understanding entered into by the Secretary under this section shall—

(1) provide for such verification activities by the Secretary as the Secretary considers appropriate to determine that the shellfish safety program of the foreign country is at least equivalent to the Program; and

(2) require the foreign country to—

(A) manage its shellfish safety program under standards and procedures that are at least equivalent to the Program;

(B) certify to the Secretary those shellfish shippers located in the foreign country that comply with the Program; and

(C) maintain and make available to the Secretary a list of those shellfish harvesting and growing waters of the foreign country that are classified by the foreign country as meeting requirements at least equivalent to the Program.

SEC. 6. PUBLICATION OF LISTS.

The Secretary shall, within 60 days after the establishment of the Program—

(1) establish, maintain, publish, and distribute monthly a list of those shellfish shippers that are certified by a State or a foreign country as meeting the requirements of the Program; and

(2) establish, maintain, publish, and distribute monthly a list of those shellfish harvesting and growing waters that are classified by States and foreign countries as meeting the requirements of the Program.

SEC. 7. DELISTING OF CERTIFIED SHIPPERS.

After consultation with the appropriate State or foreign shellfish control agency and the Conference, the Secretary may remove a shellfish shipper from the list under section 6(1) if the Secretary determines that—

(1) the shipper is not in compliance with the standards and procedures established under the Program that are applicable to the shipper; and

(2) the State or foreign country which certified that shipper under section 4(b) or 5(b)(2)(A), respectively, has not taken appropriate action with respect to that noncompliance.

SEC. 8. CERTAIN SHELLFISH DEEMED UNFIT FOR HUMAN CONSUMPTION.

Shellfish is deemed to be adulterated for purposes of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) if—

(1) it is grown or harvested in a foreign country that has not entered into a memorandum of understanding with the Secretary in accordance with sec-

tion 5 within 6 months after the date of the enactment of the Program;

(2) it is grown or harvested in a State that does not have State shellfish safety program that is approved by the Secretary under section 4;

(3) it is harvested from waters that—

(A) have not been classified by a State or a foreign country as meeting the requirements of the Program; or

(B) are otherwise deemed by the Secretary to be unsuitable for harvesting; or

(4) it is shipped by a shellfish shipper not on the list published by the Secretary under section 6(1).

SEC. 9. ASSISTANCE FOR STATE SHELLFISH SAFETY PROGRAMS.

The Secretary may enter into cooperative agreements with States for developing, implementing, and maintaining State shellfish safety programs in accordance with the Program.

SEC. 10. RESTORATION OF SHELLFISH GROWING AND HARVEST WATERS.

(a) EVALUATION.—The Secretary of Commerce shall, in cooperation with the Administrator of the Environmental Protection Agency and the States—

(1) establish and maintain a list of those State shellfish growing and harvesting areas where shellfish harvesting is conditional or prohibited;

(2) determine the causes of those conditions and prohibitions; and

(3) evaluate the potential for removing those conditions and prohibitions.

(b) COOPERATIVE AGREEMENTS.—The Secretary of Commerce may enter into cooperative agreements with States for developing and implementing restoration programs for shellfish growing and harvesting areas listed under subsection (a)(1).

SEC. 11. DEFINITIONS.

For the purpose of this Act, the term—

(1) "Conference" means the Interstate Shellfish Sanitation Conference;

(2) "Program" means the National Shellfish Safety Program established under section 3;

(3) "Secretary" means the Secretary of Health and Human Services;

(4) "shellfish"—

(A) means any species of molluscan bivalves;

(B) includes oysters, clams, mussels, and scallops (except scallop abductor muscles); and

(C) includes any such species that is shucked, in the shell, fresh, frozen, canned, cooked, thermally processed, or breaded;

(5) "State" means any of the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Commonwealth of the Northern Mariana Islands, American Samoa, Guam, the Virgin Islands, and any other territory of possession of the United States; and

(6) "shellfish shipper" means any person that shucks, packs, repacks, ships, or processes (including cooking, canning, freezing, depurating, breading, thermal processing, or other handling) shellfish in interstate commerce.

○

Section-by-Section of the Shellfish Safety Act of 1993

Section 1 establishes this bill as the Shellfish Safety Act of 1993.

Section 2 establishes that the purpose of this Act is to protect public health and ensure public confidence in the wholesomeness of shellfish products consumed in the United States.

Section 3 directs the Secretary of Health and Human Services (Secretary), in consultation with the Secretary of Commerce, other federal agencies, and the Interstate Shellfish Sanitation Conference (ISSC), to establish the National Shellfish Safety Program (NSSP) to carry out the purposes of the Act.

The NSSP shall include guidelines for shellfish growers, harvesters, shippers, vessels, water quality, tracing domestic and imported products, and monitoring and control of biotoxins and naturally-occurring pathogens and bacterial, viral and chemical contaminants. These guidelines shall be consistent with the current ISSC guidelines and subject to periodic review by the Secretary, in consultation with the ISSC.

Section 4 requires each shellfish producing state to submit to the Secretary a state shellfish safety program. State programs shall ensure states (1) manage consistent with the NSSP, (2) classify and monitor harvest and growing waters, (3) establish procedures for the closure and reopening of growing waters, (4) certify shippers that comply with the NSSP, and (5) provide adequate monitoring and enforcement of NSSP standards and procedures.

The states will also be required to submit to the Secretary current lists of (1) shippers certified by the state as complying with the program and (2) growing and harvest waters classified by the state as open for harvest.

Section 5 requires each foreign country exporting to the U.S. to enter into a Memorandum of Understanding (MoU) with the Secretary. MoU's shall require foreign countries to (1) manage their program under standards and procedures at least equivalent to those of the NSSP, (2) certify to the Secretary those shippers located in the country that comply with the program, (3) maintain and make available a list of harvest and growing areas classified as open to harvest.

Section 6 requires the Secretary to publish monthly lists of certified shippers and open growing and harvest waters.

Section 7 allows the Secretary, after consultation with the state or foreign country, to remove a shipper or harvest area from the list required under section 6.

Section 8 deems shellfish adulterated if it is (1) grown or harvested in a foreign country without a current, active MoU, (2) grown or harvested in a state that does not have an approved program, (3) harvested from waters that have not been classified as open by a state or foreign country or that has been delisted, (4) shipped by a shipper not certified by a state or foreign country, or who has been delisted, or (5) otherwise deemed unsuitable for harvesting by the Secretary.

Section 9 authorizes the Secretary to enter into cooperative agreements with states for developing and implementing state shellfish safety programs.

Section 10 requires the Secretary of Commerce, in cooperation with the EPA and states, to establish and maintain a list of "harvest restricted" waters, determine the causes of those restriction, and evaluate the potential for removing the restrictions. This section also authorizes the Secretary of Commerce to enter into cooperative agreements with states to develop and implement restoration programs for harvest restricted areas.

Section 11 establishes definitions for "Conference," "Program," "Secretary," "shellfish," "State" and "shellfish shipper."

TESTIMONY OF THE HONORABLE

JOHN D. DINGELL BEFORE THE SUBCOMMITTEE

ON FISHERIES MANAGEMENT

June 23, 1993

Mr. Chairman and Members of the Subcommittee:

I am pleased to be here today to affirm my support for a strong seafood safety program, and my belief that the government has a significant responsibility to make certain that seafood is safe and to assure consumers that they can be confident of this fact. I commend you for your interest in this matter, and I commend Chairman Studds for his long-standing interest and commitment. We have worked together successfully in the past, and I look forward to continuing our productive efforts on this and other important issues.

I want to mention in particular the commitment of Representative Unsoeld to this issue, and acknowledge her legislation, which is referred jointly to our committees. This bill deals with one critical component of a comprehensive seafood safety program, shellfish safety. I commend Ms. Unsoeld for her efforts and commit to her that we shall address her concerns in our discussions about this matter.

My Committee has a strong interest in this matter for a number of reasons. Two of your witnesses here today, the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA), will talk in detail about some of those reasons. Under the Public Health Service Act, the Centers for Disease Control and

Prevention (CDC) maintains surveillance of foodborne illness. Consumers deserve better information about illness related to seafood, and we need better CDC surveillance so that we can understand more clearly the role of seafood in causing illness, the sources of problems, ways to correct those problems and therefore prevent illness. Improved CDC, state, and local disease surveillance will contribute greatly to more effective evaluation of the seafood safety program and, indeed, all our food safety programs. I pledge my support for improvements in these CDC programs.

The Food and Drug Administration (FDA) operates a seafood safety program which includes standards setting, mandatory inspection and sampling, and enforcement. Congress has held oversight hearings about that program

for good reason -- we were concerned about seafood safety. We have seen to it that the program has received increased funding over the last several years, so that it can be more effective as the industry changes and as consumer preferences change. We need to continue to be vigilant so that program has the authority and resources it needs to be effective.

Consumers are concerned about seafood. We continue to hear press reports about illness related to eating fish or shellfish. Just within these last few weeks, we've been warned again about the risk associated with eating raw oysters. This worries consumers, who wonder whether they are vulnerable to seafood-related illness and can not be certain about the safety of seafood they purchase in a market or a restaurant. It worries the

seafood industry, because every time there is a report of illness, they face a potential loss of business.

Several years ago, Congress took some definitive action to try to address this problem, and increased the funding nearly 60% for the FDA seafood program. This was good, and proper. But it did not solve our problem. We still hear that government has not done enough. Consumers still ask why the government seems to be only reactive. We are being told -- and I agree -- that the government needs to promote safety, and to prevent harm.

We have considered omnibus legislation. Many in the consumer community and in the business community

support such a legislative approach. We have done this before, and I am ready, willing, and able to do so again. We must have a strong, comprehensive seafood safety program.

I am therefore pleased that while Congress has continued to grapple with this issue, NOAA, in consultation with FDA, has developed a voluntary inspection and labeling program based on the Hazard Analysis Critical Control Point, or HACCP, approach. This program will go a long way toward assuring consumers, because the NOAA seal on a product will indicate the high quality required by the NOAA program.

However, a voluntary program can only be a partial solution if we want tough, mandatory standards that all

products must meet. That is what consumers want for seafood and that is what I want.

I was therefore extremely pleased when FDA Commissioner Kessler announced in March that FDA would soon propose regulations to establish a mandatory HACCP-based seafood inspection program. According to Dr. Kessler, that program will be designed to be preventive, and to ensure safety virtually from water to table.

I am told that regulations to implement this preventive program will soon be proposed. They will reflect the knowledge gained by FDA and NOAA in pilot studies the two agencies conducted in developing the NOAA

voluntary HACCP program. Those rules will be grounded in the HACCP approach.

I am anxious to review FDA's proposal. I have two goals in mind.

First, I want to determine whether the elements of FDA's proposal are consistent with the goals our Committees share regarding assuring safe seafood: strong, measurable, and enforceable standards and a regular evaluation and inspection program to assess the extent to which the standards are being met.

Second, we need to make certain that FDA has the wherewithal to implement a strong, effective program. We will look at FDA's proposal with an eye toward

ensuring that current law provides sufficient authority for FDA to carry out the program effectively, from inspection through to enforcement.

Further, we will look at the proposal to assess whether FDA currently has the resources it needs to implement the program. We will look at the potential for increasing resources, and the possibilities for cooperative working arrangements with other agencies -- such as NOAA -- that will enhance FDA's capabilities.

Finally, we will take a very close look at the proposal to be sure we understand how the FDA program can fit within the construct of whatever legislation we may develop. I want to be very clear. I believe the FDA program should go forward. Neither the proposal nor the

program itself should be held up waiting for the legislative process to play out.

It is critical that FDA's proposal be published soon, so that all of us -- Congress, the industry, and consumers -- will have a chance to evaluate it and respond to it. The sooner that is done, the sooner we will have in place a sounder, stronger, and more effective seafood safety program. The sooner, the better.

Mr. Chairman, I want to thank you again for the invitation to this hearing. This is an important issue, and I look forward to working with you and Chairman Studds on it.

TESTIMONY
OF
NANCY FOSTER
ACTING ASSISTANT ADMINISTRATOR FOR FISHERIES
NATIONAL OCEANIC AND ATMOSPHERIC ADMINISTRATION
U.S. DEPARTMENT OF COMMERCE

BEFORE THE

SUBCOMMITTEE ON FISHERIES MANAGEMENT
COMMITTEE ON MERCHANT MARINE AND FISHERIES
U.S. HOUSE OF REPRESENTATIVES

JUNE 23, 1993

Mr. Chairman and members of the Subcommittee:

I am Nancy Foster, Acting Assistant Administrator for Fisheries, National Oceanic and Atmospheric Administration (NOAA), U.S. Department of Commerce. I appreciate this opportunity to present NOAA's views on seafood safety and describe NOAA's programs that are directed towards helping assure the safety and quality of seafood.

There is continuing pressure on Congress and Federal regulatory agencies to improve current seafood safety programs. Critics believe that current programs are not as effective as they could be in addressing the hazards associated with seafood consumption. However, NOAA agrees with the conclusions reached by the National Academy of Sciences (NAS) in its 1991 report on seafood safety. In that report, NAS concluded that "[m]ost seafoods available to the U.S. public are wholesome and unlikely to cause illness in the consumer." NOAA also concurs with the report's conclusion that "...the health risks associated with

seafood -- although diverse -- are identifiable and, to a significant extent, controllable by innovative measures aimed at geographically restricted or species-specific problems." NAS noted that, for the most part, health risks cannot be identified solely by an organoleptic inspection system and endorsed the proper application of a Hazard Analysis Critical Control Point (HACCP) system to control seafood safety risks.

We believe that use of HACCP offers industry and government a food protection system based on sound modern technology that can supply consumers with the safe, wholesome, and properly labeled fishery products that they expect. HACCP offers the means for industry to use its knowledge and experience to help design and implement a system by which food safety, wholesomeness, and labeling risks can be controlled.

NOAA'S SEAFOOD QUALITY AND SAFETY PROGRAM

NOAA addresses seafood safety matters because of its legislative mandates for the conservation, management, and wise use of the Nation's living marine resources and for assistance to the seafood industry. These mandates encompass a concern that seafood provided by the industry can be safely used for human consumption. NOAA fulfills these responsibilities through its inspection, research, technology transfer, and fishery management efforts. NOAA's authority to address seafood quality and safety

concerns is contained in several different laws administered by various NOAA programs, including the Agricultural Marketing Act of 1946, the Fish and Wildlife Act of 1956, the Magnuson Fishery Conservation and Management Act of 1976, and the National Sea Grant College Program Act of 1966.

Within its Seafood Quality and Safety Program, the National Marine Fisheries Service (NMFS) of NOAA carries out NOAA's voluntary, fee-for-service, seafood inspection program, as well as a product quality and safety (PQ&S) research program on both environmentally and process induced hazards. In FY 1993, the PQ&S research program is funded at $14.2 million. This funding level is included in the President's FY 1994 budget request as well. In addition, the seafood industry pays fees to NOAA to cover the costs of direct inspection services ($12 million in 1992).

NOAA's seafood inspection program currently offers four services: (1) facility sanitation, product inspection, grading, and certification services furnished on a formal contract basis; (2) lot inspection services on an as-requested basis; (3) miscellaneous services, including plant sanitation surveys, laboratory analyses, consulting services, and label and product specification review; and (4) a HACCP-based inspection service. Participants in NOAA's inspection program are provided the opportunity to apply a Federal mark (including a U.S. Grade Mark)

on their product, and to receive certification that their facilities and products meet specific standards.

NOAA began offering its HACCP-based voluntary inspection service in 1992, in response to the NAS report and after a series of nationwide meetings with inspection participants on how best to implement HACCP. As of May 1993, five firms are using this service. There are 15 other firms presently in various stages of development of their HACCP plans.

During 1992 NOAA's inspection program covered approximately 995 million pounds of fishery products, including products in domestic commerce as well as products inspected and certified for export trade. NOAA's program accounted for about 22 percent of seafood products consumed domestically. An average of 240 plants participated in some manner in the program through April 1993. Facilities and product inspections were conducted by approximately 235 NOAA inspectors augmented by the services of cross licensed state and U.S. Department of Agriculture (USDA) inspectors. NOAA has cooperative agreements with 14 states and cross utilization agreements with five major inspection components of USDA.

NOAA conducts product safety and quality research in many of the areas covered by the NAS recommendations, including ways to address the impact on consumers and the fishing industry of

environmentally- and process-induced contamination of seafood. Research efforts are also directed to improving the overall quality of the U.S. seafood marketed domestically and internationally. PQ&S research activities are conducted in NMFS facilities located in Charleston, SC; Seattle, WA; Gloucester, MA; Pascagoula, MS, and in a number of state and regional Sea Grant programs. Sea Grant also conducts technology transfers in this area.

In carrying out its seafood safety programs, NOAA coordinates extensively with the Food and Drug Administration (FDA). Formal coordination includes separate memoranda of understanding for inspection, research, and molluscan shellfish. In addition, NOAA has significant interactions with the Environmental Protection Agency (EPA) and state public health and fisheries agencies and universities with respect to seafood safety matters.

I will briefly outline the areas of emphasis in NOAA's PQ&S research program and provide examples of our activities in each area.

1. Develop processing methods that limit process-induced and environmental safety hazards in seafood.

NOAA has undertaken research to develop processing methods that limit process-induced and environmental safety hazards in seafood. NOAA scientists have developed various control measures, such as processing techniques to eliminate the pathogenic bacterium Listeria monocytogenes in smoked fish products. Other research involves assessing the effectiveness of depuration, and developing alternative means to eliminate harmful microorganisms in shellfish. NOAA has worked closely with FDA, states, and the seafood industry to transfer process control information and technology.

2. Develop and improve techniques to detect marine biotoxins, microbial pathogens, and chemical contaminants.

In accordance with the NAS report's characterization of marine biotoxins, microbial pathogens, and chemical contaminants as the key areas of public health concern in seafood, NOAA's PQ&S research has focused on developing and improving detection techniques. The goal of the research is to provide effective diagnostic tools for both regulators and industry in providing assurance that seafood products are safe and wholesome for human consumption.

NOAA recently developed a national plan for marine biotoxins and harmful algae. Scientists and regulatory officials with

expertise in the subject met to evaluate U.S. research knowledge and capabilities, and to identify impediments to research progress and areas where funds should be directed for maximal benefit. NOAA leads the U.S. delegation to the Intergovernmental Oceanographic Commission's Intergovernmental Panel on Harmful Algal Blooms.

In response to outbreaks of marine biotoxins in the Northwest, NOAA cooperated with FDA and the states to prevent the harvest of toxin-contaminated fish and shellfish and to determine levels in products that do not represent a health hazard.

NOAA scientists have also developed several rapid microbial detection methods, as well as methods and standard reference materials to detect chemical contaminants in fish tissue.

3. Develop product standards and specifications for use by the seafood industry in domestic and international trade.

NOAA develops product standards and specifications for use by the seafood industry in domestic and international trade, establishes grade standards and specifications for the voluntary inspection program, and interacts with the U.S. Departments of Agriculture and Defense regarding specifications for seafood purchased under programs of those departments.

NOAA has participated in bilateral and multilateral fora regarding the effects of seafood standards, specifications, and inspection requirements on international trade. Activities have included the U.S./Canada Free Trade Agreement and semi-annual consultations with the European Community. NOAA heads the U.S. delegation to the Fish and Fishery Products Committee. NOAA representatives also serve as part of the U.S. delegation on several other committees of the Codex Alimentarius Commission -- the body responsible for establishing international food standards.

4. Provide scientific and technical support for inspection and risk management activities.

A variety of activities under the PQ&S program provide scientific and technical support for the voluntary inspection program. NOAA's HACCP-based service that was introduced last year requires each participating facility to employ at least one person trained in HACCP principles and certified by NMFS. In addition to training NOAA inspectors in HACCP principles, NMFS provides training for industry personnel on a fee basis, and has developed an examination to provide assurance that individuals have sufficient knowledge of HACCP principles to participate in the HACCP-based inspection service. The recognition and expansion of HACCP techniques domestically and internationally will continue to require extensive investment in training.

NOAA has also begun to implement a program of increased analytical testing to address product safety problems within its traditional inspection program as well as under the HACCP-based service.

5. Collect and analyze contaminant and consumption data for use by regulatory authorities and the seafood industry to address safety issues that impact on the utilization of fishery resources for human consumption.

Contaminant and consumption data are essential to assist regulatory authorities in assessing seafood safety risks and identifying appropriate strategies to manage risks. Uses include decisions to close areas to fishing activity and setting tolerances for contaminants in seafood.

NOAA is currently developing the Seafood Contaminants Risk Information System to acquire and evaluate available data from NOAA, other government agencies, and domestic and international scientific research on marine biotoxins, pathogenic microorganisms, and chemical contaminants. When this system is fully operational, data will be available to regulators and researchers for use in risk analysis activities, such as establishment of inspection criteria to accept or reject fishery products in commerce and selection of harvest options to minimize consumer exposure to contaminants.

Data on the hazards presented by contaminants, and the likelihood of their occurrence, must be combined with information on the extent of human exposure to the contaminants in order to assess the public health risk. Therefore, data on seafood consumption is needed. NOAA has addressed this by funding a study to develop seafood consumption models specifically for the purpose of gathering data for use in assessing seafood safety.

Mr. Chairman, this concludes my testimony. Thank you very much for the opportunity to appear before you today. I would be pleased to respond to any questions which either you or the members of the Subcommittee may have.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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STATEMENT BY

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FOOD AND DRUG ADMINISTRATION

PUBLIC HEALTH SERVICE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SUBCOMMITTEE ON FISHERIES MANAGEMENT

COMMITTEE ON MERCHANT MARINE AND FISHERIES

U.S. HOUSE OF REPRESENTATIVES

JUNE 23, 1993

TO BE RELEASED ONLY UPON DELIVERY

71-898 O - 93 - 3

Mr. Chairman and Members of the Subcommittee:

I am here today at the invitation of the Subcommittee to describe the current legal and regulatory regime for seafood safety and the adequacy of that regime for ensuring a reliable supply of safe seafood products to the American consumer. It has been a year since the last Congressional hearing on seafood safety. Consequently, this is an appropriate moment to update the Congress on our activities. I would like to offer some background first for the benefit of this subcommittee.

I. BACKGROUND

A. Seafood Presents Special Challenges

The Food and Drug Administration (FDA) is one of the primary Federal regulatory agencies responsible for food safety, including seafood safety, in the United States. FDA administers several acts including the Federal Food, Drug, and Cosmetic (FD&C) Act, which prohibits adulterated and misbranded food in interstate commerce. Although the FD&C Act does not distinguish seafood from other foods in this regard, we know from decades of experience that seafood has unique qualities that require specialized skills and knowledge for us to carry out our statutory responsibilities. For example, FDA has state-of-the-art research facilities dedicated solely to

seafood. We also have some of the world's leading experts in marine toxins and other specialties. Our organoleptic, or sensory, experts teach other nations how to examine seafood for signs of spoilage.

Ensuring the safety of seafood presents special challenges to both the industry that produces it and to FDA and other Federal and State agencies charged with protecting the public health. Seafood is a disparate array of products encompassing literally hundreds of edible species that have little in common other than an aquatic origin. Collectively, seafood has perhaps the most diverse and complex microbiology of any food commodity. The range of habitats for edible species is also extremely diverse. These habitats have a bearing on the types of microorganisms, toxins, parasites, chemicals, and other potential hazards that fish and shellfish may be exposed to that can affect human food safety.

Seafood is still predominately a wild-caught flesh food that must be harvested under frequently difficult conditions and at varying distances -- often quite significant -- from processing, transport, and retail facilities. These conditions, distances, and duration of fishing trips can tax any system of controls designed to assure safety and prevent spoilage.

This situation is further complicated by the hazards associated with the wide array of processes used in several thousand businesses, many of which are small or old. The seafood industry is characterized by small, fragmented operations that are sized in reference to anticipated benefits and to the significant, uncontrollable economic risks involved in that business. The seasonal nature of the industry can affect worker skills and practices relating to seafood safety, while older facilities and equipment can be more difficult to maintain for adequate sanitation, and proper processing and storage temperatures.

In addition, several hundred vessels are seagoing processing factories, many of which operate in remote waters. For regulators, ships that process at sea can be difficult and expensive to reach while they are operating, and individual inspectors face hazards such as ship-to-ship transfers on the high seas.

Seafood can come from a significant recreational harvest, some of which finds its way into commercial channels. Thus, recreational fishing can have a bearing on the safety of commercial seafood if it occurs in waters that are closed to fishing or if the catch is mishandled.

Yet another complicating factor in ensuring the safety of seafood is the fact that no other flesh food is imported in the quantity, variety, or from as many countries, as seafood. Nearly 60 percent of seafood consumed in this country is imported from approximately 135 countries. Several of these countries have advanced regulatory structures for seafood, but many others lack comparable structures for seafood sanitation and safety.

B. The Safety of Seafood: What We Know

There are many hazards that have the potential to affect safety. The question of how frequently these hazards occur and actually cause illness is not currently answerable with precision because foodborne illness is not always recognized or properly diagnosed; and because the system for generating and collecting reports on foodborne illness experiences significant underreporting.

Nonetheless, there are conclusions about the safety of seafood that we believe can be drawn with confidence because they reflect general scientific consensus. The National Academy of Sciences (NAS) conducted an extensive study of seafood safety and concluded in its 1991 report that, "Most seafoods available to the U.S. public are wholesome and unlikely to cause illness in the consumer." We agree. As with many foods, illnesses do

occur, but they are not frequent and, for the most part, they are not severe.

In arriving at its conclusion, the NAS took into account a number of factors, including the foodborne illness data reported by State and local health authorities to our sister agency, the Centers for Disease Control and Prevention (CDC). In the CDC system, seafood accounted for only 4.8 percent of reported cases of foodborne illness over the 15 year period 1973-1987. It should be recognized, however, that, as CDC has pointed out, comparisons of safety among different foods based solely on CDC outbreak data are not possible due to variations in the rates of reporting among different foods and other factors. Consequently, this percentage is not definitive with regard to relative safety and must be considered in terms of its consistency with other data.

While these data have limitations, they can be used to identify trends and emerging concerns about various diseases. In reviewing the CDC data, the NAS noted that the 23 percent increase in seafood consumption in the U.S. in the 10 year period ending in 1989 was not accompanied by a concomitant increase in reported seafood-borne illnesses. The NAS also noted that, despite the wide range of hazards that could cause illness, the data suggest that most seafood-related illnesses result from molluscan shellfish consumed raw or partially

cooked and from two natural toxins, ciguatoxin and scombrotoxin, which occur in certain species of finfish. Ciguatoxin can accumulate in certain warm water reef fish, and illnesses tend to be geographically localized. The most reliable preventive is to avoid fishing in reefs from which there have been toxic fish. Scombrotoxin can form when certain species are not properly cooled after capture. This mishandling hazard is completely preventable. We know that other seafood hazards do result in illnesses, but the available data indicate that illnesses from them are not common.

FDA conducted a risk assessment for seafood a few years ago in consultation with CDC. Using risk assessment methodology, including reasonable assumptions to fill in the gaps in the CDC data, we compared the risk of illness from seafood to that for other flesh foods. The risk assessment discerned that the notion promoted by some that seafood poses an orders-of-magnitude risk above that for other flesh foods is simply wrong.

It is worth pointing out that we must obtain more accurate and complete data on foodborne diseases in this country than we now possess if we are to avoid having to rely on questionable assumptions to fill in the gaps. New mechanisms to generate data will be necessary. "Sentinel surveillance" is one such mechanism that we have been pilot testing on a collaborative

basis with CDC. Dr. Paul Blake from the Centers for Disease Control and Prevention will describe sentinel surveillance in his testimony today.

Neither the CDC data nor the risk assessment take into account long-term risk from chemical contaminants, so I would like to address this aspect of seafood safety separately. There are simply no available illness data that link commercially supplied seafood with chronic health effects from chemicals. Nonetheless, we know that, like other sources of food, fish can absorb chemicals from the environment, so the question of risk posed by chemicals is a valid one. FDA surveillance programs include monitoring seafood for the presence of chemicals. We have more than doubled our sampling program for chemicals in the past few years.

We seldom detect chemical contaminants at levels of concern in commercial species. Most problems with chemical contaminants tend to be localized around known sources of pollution where commercial fishing is restricted.

The NAS similarly concluded that, except in some highly specific situations, mostly relating to fish originating outside of commercial channels, there is no evidence of an urgently critical situation as far as the general population is concerned. The NAS also pointed out that there are

uncertainties about the health effects of particular chemicals and about the extent of contamination. We generally agree with the NAS on these points. As I will discuss later in my testimony, we recently held a national conference on chemical contaminants in seafood to pool knowledge with State officials, scientists, the industry, consumers, and others on chemical contaminants in seafood. Statements made at this conference did not differ from the foregoing conclusions.

II. THE REGULATORY PROGRAM FOR SEAFOOD

A. Overview

FDA operates a $40.5 million annual program for seafood. This sum reflects an increase of over 60 percent from the $25 million provided by the Congress in fiscal year 1990. The essential elements of the seafood program are: (1) domestic inspections of seafood processors and related commercial entities; (2) sampling and analyzing fish and fish products for the presence of toxins, chemicals, and other potential hazards; (3) examination of imported seafood offered for entry into the United States; (4) negotiation of international agreements with countries that export to the United States; (5) research in support of the Agency's regulatory mission (for example, development of methods to detect pathogens, toxins, and chemical contaminants in fish); (6) Federal/State cooperative

programs, training, and technical support (for example, administration of the National Shellfish Sanitation Program, training State retail inspectors and shellfish plant sanitation inspectors, and training States on how to monitor shellfish beds for pollution); and (7) public education (for example, advising certain at-risk populations that they should not consume raw or only partially cooked molluscan shellfish). The Office of Seafood within FDA's Center for Food Safety and Applied Nutrition manages and establishes policy for this program.

I would like to elaborate on several of these program elements.

B. Domestic Inspection

FDA conducts mandatory surveillance inspections of seafood processors, packers, repackers, and warehouses. There are about 5,600 such entities in our seafood establishment inventory, 2,846 of which are processors. We regard about 1,000 of these processors to be "high risk" processors because of the products handled and processing methods used. For example cooked, ready-to-eat products require no cooking by the consumer, and thus must be pathogen free. FDA targets these firms for unannounced inspection at least once-a-year, and more often if problems are found. All other processors are targeted

for inspection at least every two years and, like high risk processors, more often if necessary.

In addition to our mandatory surveillance program, the National Marine Fisheries Service (NMFS) operates a voluntary fee-for-service inspection program for processors and others who wish to purchase it. Its program has traditionally been oriented toward product quality, providing grading and similar services, but also responds to safety problems consistent with a memorandum of understanding with FDA. The two agencies have worked well together over the years on seafood issues and we are proud of our relationship with NMFS.

States also conduct inspections of seafood processors, so the overall frequency of inspection -- combining Federal and State -- is much higher depending on the intensity of State activity. The State of Alaska, for example, which accounts for half of domestic seafood tonnage, has a substantial inspection program.

We are often asked whether our combined inspection frequency is adequate to ensure safety. The question is a valid one, and we and others have given it considerable thought over the years. The National Academy of Sciences, in its 1991 study of seafood safety, concluded that an increase in frequency would have no bearing on safety, but did advocate that inspections be

conducted on the basis of Hazard Analysis Critical Control Point, or "HACCP," principles.

C. Domestic Inspection: HACCP

HACCP is a system of preventive controls that are established and maintained by a processor for the purpose of keeping hazards from occurring. As my testimony has already described, there are a variety of environmental and processing hazards to which seafood can be exposed from water to table. It is imperative that those who handle and process seafood commercially understand the hazards and keep them from occurring through a system of routine preventive controls.

In essence, HACCP requires that processors have a written plan that (1) identifies the likely hazards that could affect their products; (2) identifies "critical control points" where a failure is likely to cause or permit the hazard to occur; (3) establishes "critical limits," or measurable operating parameters at each critical control point, such as cooking and refrigeration temperatures; and (4) establishes both monitoring procedures and recordkeeping procedures to systematically record the results of the monitoring.

FDA has consistently advocated HACCP controls for the seafood industry since the 1980's and, along with the National Oceanic

and Atmospheric Administration (NOAA), has devoted a considerable amount of attention and resources toward fostering that goal. Since the 1970's, FDA has operated the Nation's first formal, HACCP-based regulatory program, for low-acid canned foods, many of which are seafoods, and participated with NOAA in a joint, pilot HACCP program beginning in 1991. This pilot program involved working with seafood firms that volunteered to adopt HACCP-based controls and conducting inspections to determine how these firms were operating under HACCP.

Two years ago, Commissioner Kessler requested that the Agency study the feasibility of requiring industry-operated HACCP systems for seafood coupled with mandatory inspections by FDA that, among other things, would review the adequacy of those HACCP systems. Such a step could be a logical extension and evolution of our policy and program. It would also be responsive to the strong support for the adoption of a mandatory, HACCP-based inspection system for seafood shown by consumers, the Congress, and some sectors of the seafood industry itself. Based on the results of that study, Commissioner Kessler announced last March that FDA is developing mandatory HACCP requirements for the seafood industry as part of its inspection program.

The seafood industry -- indeed, the food industry as a whole -- must be primarily responsible for the safety and quality of the food that it produces. The regulator's primary role should be to verify that the industry is meeting this responsibility and to take remedial action when it is not.

D. Import Examination: Overview

Nearly 60 percent of the seafood consumed in the U.S. is imported. The number of U.S. Customs entries for seafood is approaching 200,000 annually. FDA is committed to ensuring that imported seafood products meet the same standards that are required of domestic products.

Our import inspection procedure is as follows: FDA reviews the entry documents received from Customs for all seafood entries. The Agency then decides whether to release, visually examine, or sample a given shipment. If FDA samples the product and it is found to be violative, the shipment is detained, and the importer has the choice of reconditioning the product (that is, bringing the article into compliance, if this can be done), destroying it, or reexporting it. If FDA approves the importer's proposed reconditioning procedure, the reconditioning may then proceed under FDA supervision. If the reconditioning is successful, FDA may release the goods; if

not, the goods must be reexported or destroyed, under U.S. Customs supervision.

When an imported product is found to be repeatedly violative, or if it has been found to be a serious health hazard, FDA may detain all future shipments of that product without sampling (a policy known as "automatic detention"), until the shipper, producer, or responsible government agency of the exporting country produces evidence to FDA's satisfaction that the shipments conform with the requirements of the FD&C Act.

In fiscal year 1992, FDA visually examined over 8,100 carefully targeted imported seafood entries or "lots," and tested approximately 7,300 lots for filth, microbiological or chemical contaminants, heavy metals, pesticides, and parasites. We also looked for false labeling that would result in economic fraud.

As with domestic products, we have been frequently asked whether we physically examine enough import entries. It has been pointed out that FDA physically examines less than 5 percent of all "lots" of seafood offered for import. This figure is generally accurate but is not the whole story. First, "lots" vary significantly in size and cannot be equated with poundage or any other unit of measurement. Also, the figure does not take into account the representative nature of the examinations, the targeting of specific lots based on

experience, FDA's automatic detention program for imports, or the fact that imports receiving further processing in the U.S. become subject to domestic inspection. Moreover, five countries with highly advanced regulatory programs for seafood -- Canada, Iceland, Norway, Australia and New Zealand -- provide over 30 percent of all imports. Nonetheless, it is true that most imported seafood is not physically sampled or examined by a Federal health official. Increasing the physical sampling and analysis of seafood to statistically significant levels would cost substantial additional public health resources.

E. Import Examination: MOUs and HACCP

FDA is pursuing two ways of increasing the scope of coverage for imports. The first involves the development of memoranda of understanding (MOUs) with countries that export seafood to the United States and have recognized inspection programs we can rely on. The purpose of a MOU would be to establish that the regulatory system of an exporting country and the regulatory system in the U.S. are equivalent in their ability to ensure safety. An MOU would provide for regular verification by both countries. Products from a MOU country would not require as much examination by FDA as those from other countries.

The second approach is HACCP. The HACCP feasibility study considered requiring that both importers and their foreign processors operate on the basis of HACCP controls. While many importers are conscientious about the safety and quality of the products they import, others have little understanding of the potential hazards. The occasional denial of entry of a violative lot may be regarded as simply a cost of doing business. The burden is on FDA to track down problems and require corrections. For the same reasons as provided for domestic inspections, this burden should shift.

We are convinced that a combination of international agreements and HACCP will provide much greater assurance that potential hazards are safely being controlled as a matter of design than the current system can ever provide. Also, the harmonization of international approaches to regulating seafood safety through HACCP has the dual benefit of aiding the U.S. industry to compete in a global economy and to assure international cooperation on hazard intervention strategies applied to all seafoods.

F. Seafood Exports

Starting July 1, 1993, and until December 31, 1994, the European Economic Community (EEC) will require that a "Health Certificate" accompany each shipment of fish and fish product

entering the EEC. These certificates show that the "central authority" of the source country attests that the product was made in a plant operating under a regulatory regime ("conditions") equivalent to that called for in EEC Directives. On January 1, 1995, the EEC intends to have a HACCP style program in place. After that time other countries will need to have equivalent manufacturing requirements in order to export to the EEC.

The industry has requested that FDA initiate a program to sign such export certificates. The Agency intends to do so.

G. Research

FDA has a vigorous research program for seafood in support of its regulatory mission. In a field as broad and complex as seafood safety, there will probably always be problems that require highly advanced research to solve. FDA research forms the basis for the Agency's understanding of the extent and severity of hazards, for risk assessment, and for risk management. Seafood research is carried out at the FDA's Northeast and Gulf Coast seafood laboratories, at our Seafood Products Research Center in Washington State, in FDA headquarters laboratories, and in several of the Agency's 19 field laboratories. FDA currently has about 100 ongoing research projects related to hazards posed by microbes,

chemical and drug residues, marine toxins, parasites, decomposition and new packaging technologies. Research on species identification and other areas that may result in economic fraud, and research into sanitation and filth contamination is also being conducted.

FDA coordinates its research as much as possible with ongoing research outside the agency. We work with academia, other government and private organizations. In particular, we maintain an active dialogue with researchers working at the National Marine Fisheries Service, and facilitate this exchange through a memorandum of understanding between the two agencies.

FDA also funds extramural research. Perhaps the most notable ongoing project is a study of the effects of methylmercury on the fish eating population of the Seychelles Islands. The results of that study will help the Agency determine whether its action level for methylmercury in fish is adequate to protect the public health.

H. Federal/State Activities

The Federal government cannot effectively regulate seafood without the existence and cooperation of strong State programs. FDA's HACCP initiative is not intended to -- nor could it possibly -- alter this reality. The several roles played by

the States in the regulation of seafood are crucial to the overall success of the collective Federal/State program. Together, we estimate that the total outlay by Federal, State, and local regulatory bodies for the regulation of seafood exceeds $100 million per year.

State roles include the operation of programs for the safety of molluscan shellfish, inspection of processors, and inspection of the hundreds of thousands of retail and food service establishments that are involved with seafood nationwide. FDA works with the States by providing funds (although unfortunately these have decreased recently), participating in Federal/State cooperative organizations such as the Interstate Shellfish Sanitation Conference and the Conference for Food Protection, and by providing technical support, training, and information.

I. Federal/State Activities: Molluscan Shellfish

One of the keystones of FDA's Federal/State program is the National Shellfish Sanitation Program (NSSP). The NSSP is a Federal/State/industry endeavor, involving 23 shellfish producing states and 9 foreign governments, that was established for the purpose of exercising sanitary control over all aspects of growing, harvesting, shucking, packing, and interstate transportation of molluscan shellfish. The

Interstate Shellfish Sanitation Conference (ISSC), an organization of Federal agencies, State officials, and the shellfish industry works with FDA to establish the uniform guidelines and procedures that are used by the shellfish control agencies of the States that belong to the NSSP. The NSSP and the ISSC operate together as a vital adjunct to the Federal seafood safety program.

The National Academy of Sciences has concluded that molluscan shellfish consumed raw or partially cooked probably cause the majority of illnesses associated with seafood in the United States. This is not surprising because flesh foods consumed raw are inherently more risky than flesh foods that are adequately cooked. In addition, molluscan shellfish are non-motile filter feeders that pump large quantities of water through their bodies and can absorb and concentrate many types of contaminants that may be in the water.

The majority of illnesses that are thought to occur from raw molluscan shellfish are mild gastrointestinal illnesses that are quickly resolved and are difficult to diagnose. More serious illnesses can occur but are uncommon. Such diseases as typhoid fever and infectious hepatitis are still commonly associated with raw molluscan shellfish in lesser developed countries but are largely controlled in the United States.

The key to ensuring that molluscan shellfish do not carry pollution-borne diseases is the proper classification and monitoring of shellfish growing waters. FDA is responsible for helping design and review the actions States take to classify their waters. States are required to take measures to ensure that illegal harvesting does not occur from closed waters and to certify that shippers operate in a sanitary manner. FDA publishes a monthly shippers list of all certified shippers in participating States. To comply with State food service codes, "receiving" States verify that shellfish come from certified shippers.

The program has its strengths and weaknesses. FDA's Office of Seafood recently identified several areas in which the States could improve their shellfish programs. This analysis was based on recommendations of the 1991 National Academy of Sciences report on seafood safety and a detailed analysis of the strengths and weaknesses of the procedures in the NSSP Manual of Operations. Areas identified in this analysis included uniform systems for tagging shellfish, effective prosecution of illegal shellfish harvesters, uniform criteria for evaluating patrols of growing areas, and consistent product handling and record retention requirements, as well as specific temperatures for the holding and transporting of these products. These efforts have resulted in the adoption of

beneficial changes by the ISSC, but some areas still require work.

FDA is also concerned that there are inconsistencies in funding and thus in implementation among the States that ought not to exist under the program. We recognize that in the current fiscal climate there are no ready solutions to this problem. Nonetheless, funding inconsistencies have the potential to affect safety and can have the effect of penalizing States that are devoting the most resources and doing the best jobs. This is a problem that remains to be solved.

J. Federal/State Activities: Training and Other Support

Although FDA has statutory authority over all seafood in interstate commerce, the Agency has traditionally exercised enforcement discretion with regard to retail establishments. The sheer number of these establishments would totally overwhelm any comprehensive Federal inspection system. FDA has traditionally provided training and other forms of technical assistance to States and local governments to inspect retail food establishments through the Agency's retail Federal/State cooperative program. The Agency also has working relationships with some retailers involving advice and information sharing.

A major part of our retail cooperative program has involved the development of model codes containing retail handling requirements for foods, some of which have been widely adopted by State and local governments. FDA is now consolidating those model codes into a single, updated food code for the retail sector. HACCP-type controls for seafood hazards at retail are included.

Such controls are needed. The National Academy of Sciences concluded in its 1991 study of seafood safety that the greatest microbiological risk associated with seafood other than raw molluscan shellfish appears to be mishandling at the retail and food service (post processing) levels. We commend Giant Food for its participation in the retail pilot HACCP program operated by FDA and NOAA last year. That pilot was aimed at determining the feasibility of adopting HACCP controls within the retail food sector.

K. Federal/State Activities: Chemical Contaminants

FDA currently has one tolerance, or binding legal limit, for a seafood contaminant. That tolerance is for polychlorinated biphenyls, or "PCB's." FDA also has "action levels" for contaminants in seafood that include methyl mercury, paralytic shellfish poison, histamine in canned tuna, and 13 pesticides. Action levels are not binding, however, and serve as guidance

only, to ourselves and to States, for deciding when seafood might be adulterated within the meaning of the FD&C act.

We are often asked why we have not issued more tolerances. The answer is complex, but in large measure, there are two reasons. First, as FDA has testified many times, the tolerance setting process is unwieldy and can take years to accomplish. Second, the knowledge required for a tolerance is not easily obtained. Unlike food additives, chemical contaminants do not have "sponsors" who submit data to the agency. The toxicity of many potential chemical contaminants is not well known. Finally consumption data, which are necessary to determine exposure levels, are expensive to obtain.

In addition, problems with contaminants tend to be regional. FDA has long debated the appropriateness of establishing national tolerances based on high exposure levels that occur in very localized areas.

FDA sponsored a chemical contaminant conference in May to address these types of issues. The participants, many of whom were State officials from across the country, shared information on chemical contaminants, exchanged views on priorities for data collection, discussed regional versus national solutions, and other matters. The conference represents the beginning of a long term process to develop a

Federal/State network for both collecting data and formulating strategy on chemical contaminants.

FDA is developing "guidance documents" to States on chemical contaminants. The first four to be developed relate to cadmium, nickel, arsenic, and chromium. Several others are under development. The purpose of these documents is to provide relevant scientific information on each contaminant so that States and localities can evaluate the public health significance of contamination of local and regional waters with those chemicals and determine for themselves when closures or public health advisories might be appropriate. We have chosen this approach for the time being in lieu of establishing a single, national tolerance for each contaminant that may or may not be appropriate or useful to deal with regional or local contamination issues. Local authorities can utilize the information in the guidance documents and combine it with local information on the level of contamination found locally and local consumption patterns to establish risk management approaches. FDA will monitor the success of this approach.

L. Education

One conclusion drawn by the NAS was that there is a lack of understanding of the nature of seafood hazards by the consuming public and that a vigorous information and education campaign

was needed, particularly for high-risk consumers of raw molluscan shellfish. We agree.

FDA has a longstanding education program that includes, among other things, the publication of a consumer oriented magazine, the development of videos, and the dissemination of information through the Agency's Office of Consumer Affairs, Office of Public Affairs, and public affairs specialists in all FDA districts across the nation. In addition, FDA's Center for Food Safety and Applied Nutrition opened a special "Seafood Hotline" (1-800-FDA- 4010) for consumers who have questions about hazards, purchasing, storing, handling, labeling, nutrition, economic fraud and other matters. The hotline is automated and accessible 24 hours a day with over 50 prerecorded messages. Callers who wish to speak with a specialist may do so between 12:00 - 4:00 pm, EST, Monday through Friday.

We received 14,000 calls in the first 8 months of operation. Questions about storage, freezing and refrigeration are the most common. Other questions involve general seafood safety, home preparation, and the condition of seafood recently purchased, among other things. Based on our experience so far, we believe that the Hotline is providing consumers with a very useful service.

We are also engaging in a special education campaign aimed at advising high-risk populations about the risk to them from consuming molluscan shellfish raw or partially cooked. Molluscan shellfish can carry within them certain naturally occurring marine bacteria of the genus Vibrio that can cause severe illness and even death if they enter the blood stream. In healthy individuals, Vibrio bacteria generally either cause no illness or cause gastroenteritis, which is rarely serious. Immuno-compromised individuals, on the other hand, can contract septicemia, or blood poisoning, from Vibrio bacteria. Approximately half of the immuno-compromised individuals who become septicemic from the most virulent of these bacteria, Vibrio vulnificus, do not survive. There have been about 12 to 26 reported cases of septicemia from Vibrio vulnificus annually, although the number will probably be slightly higher over the past year. One-third of these illnesses are usually from bacterial entry into the body from wounds. The reported fatalities have averaged between 5 and 12 annually although, again, the number for the past 12 months may be slightly higher. We estimate that there are about 9 million at-risk individuals who should not eat raw or undercooked molluscan shellfish.

FDA has published four brochures aimed at specific at-risk populations and has other ongoing educational efforts including distribution of information kits to so-called multiplier

organizations, articles in medical journals and community education programs initiated by our public affairs specialists. We have provided technical assistance and encouragement to the ISSC in its adoption of a point-of-purchase information message for at-risk individuals and are also monitoring the effect of mandatory labeling adopted by some States.

Mr. Chairman, that completes my formal testimony. I will be glad to answer any questions you may have.

STATEMENT OF
PAUL BLAKE, M.D.

CHIEF, FOODBORNE AND DIARRHEAL DISEASES BRANCH
DIVISION OF BACTERIAL AND MYCOTIC DISEASES
NATIONAL CENTER FOR INFECTIOUS DISEASES
CENTERS FOR DISEASE CONTROL AND PREVENTION
U. S. PUBLIC HEALTH SERVICE
BEFORE THE
SUBCOMMITTEE ON FISHERIES MANAGEMENT
COMMITTEE ON MERCHANT MARINE AND FISHERIES
U.S. HOUSE OF REPRESENTATIVES
JUNE 23, 1993

I am Dr. Paul Blake, Chief of the Foodborne and Diarrheal Diseases Branch of the Division of Bacterial and Mycotic Diseases, National Center for Infectious Diseases, Centers for Disease Control and Prevention (CDC). I am pleased to respond to the Subcommittee's invitation to discuss seafood-borne disease surveillance and CDC's role in preventing foodborne disease and characterizing foodborne hazards. As the Nation's Prevention Agency, CDC has knowledge, skills, and perspective that are critical to a comprehensive, science-based program for foodborne disease prevention.

Foodborne disease is a common and preventable public health problem. Over 80 million foodborne illnesses are estimated to occur each year in the United States.* Data suggest that foodborne disease is an ever-changing public health challenge--a problem of emerging infectious disease. The recent Institute of Medicine (IOM) report, Emerging Infections, identifies six factors that can lead to emerging microbial threats--changes in human demographics and behavior, technologic advances, economic development and land use, international travel and trade, microbial adaptation, and a breakdown of public health measures. Each of these factors has had an impact on the safety of our food supply. With your permission, I would like to submit a copy of the Executive Summary of the IOM report for the hearing record.

* Archer DL, Kvenberg JE. Incidence and cost of diarrheal disease in the United States. Journal of Food Protection 1985;48:887-94.

Like most other foods, finfish and shellfish have been recognized as potential sources of foodborne disease since ancient times. Seafood can become contaminated with disease-causing microorganisms and toxins while living in the natural aquatic environment, and from sewage and industrial pollution of harvest areas, as well as while being processed, distributed, or prepared. The greatest likelihood of illness is associated with shellfish eaten raw. The special nature of the seafood-associated diseases, and the special nature of the fishing industry, suggest that measures to reduce these diseases need to be tailored specifically to the diseases involved. Epidemiologic data on the nature of foodborne diseases are necessary to design these focused risk management strategies.

The tools CDC has developed to identify foodborne hazards and to characterize the risk to the public's health posed by those hazards are the Foodborne Disease Outbreak Surveillance System, intensive epidemiologic and laboratory investigations of foodborne disease outbreaks, surveys and studies of specific foodborne diseases, laboratory-based surveillance of specific foodborne microorganisms, and analysis of strains of foodborne microorganisms submitted to our reference diagnostic laboratories. I would like to focus most of today's discussion on CDC's Foodborne Disease Outbreak Surveillance System.

CDC has maintained a national foodborne disease outbreak surveillance system since 1967. The system consists primarily of

collection, collation, and analysis of data on reports of outbreaks provided to us by state health departments, and the dissemination of those data to appropriate individuals and organizations. In this system, an outbreak is defined as an incident in which 2 or more persons experience a similar illness after ingesting a common food that is epidemiologically implicated as the cause of the illness. A few exceptions exist; for example, one case of ciguatera or scombroid fish poisoning is considered an outbreak.

Data requested by CDC regarding each outbreak include: number of cases, persons hospitalized, and fatalities; clinical history of ill persons; incubation period and duration of illness; results of epidemiologic investigation, including the source of transmission by epidemiologic evidence; place of preparation of the contaminated item; place where eaten; manner in which the implicated food was marketed; factors, such as improper food handling, which were believed to have contributed to the outbreak; and pertinent laboratory data. Analysis of outbreak data has proved valuable in characterizing the risk of foodborne diseases and documenting the efficacy of regulatory controls developed in response to CDC recommendations.

The quantity and quality of the data on foodborne outbreaks, however, are limited, and these limitations must be recognized to avoid misinterpretation. The number of outbreaks of foodborne diseases reported by CDC's surveillance system represents only a small fraction of the total number that occur. The likelihood of an outbreak coming to the attention of health authorities varies considerably depending on consumer and physician awareness. For example, large outbreaks, interstate outbreaks, restaurant-associated outbreaks, and outbreaks involving serious illness, hospitalizations, or deaths are more likely to come to the attention of health authorities than are cases of mild illness following a family cookout.

A number of other factors also influence the completeness and representativeness of the data. The quality of the data depends upon the state or local health department's investigative and laboratory capabilities, capabilities that have been severely tested by scarce resources and high demands placed on the public health infrastructure during the past decade.

The likelihood that the findings will be reported to health officials varies from one locality to another. Thus, these data do not show the absolute incidence of foodborne diseases, and they should not be used to draw conclusions about the relative incidence of foodborne diseases caused by various pathogens. For example, foodborne diseases characterized by short incubation periods, such as those caused by chemicals or staphylococcal enterotoxin, are more likely to be recognized as common-source foodborne disease outbreaks than are those diseases with longer incubation periods, such as hepatitis A. Outbreaks involving less common or more difficult to culture pathogens, such as *Bacillus cereus*, *Escherichia coli*, *Vibrio parahaemolyticus*, *Yersinia enterocolitica*, or *Campylobacter jejuni*, are less likely to be confirmed because these organisms are often not considered in clinical, epidemiologic, and laboratory investigations. Pathogens that generally cause mild illness will be underrepresented in the data, while those causing serious illness, such as *Clostridium botulinum*, are more likely to be identified. Similarly, foods that are served to greater numbers of persons or restaurant- or commercial product-associated outbreaks have a higher likelihood of being detected and reported.

Because of these factors, the surveillance system is skewed toward more severe diseases, such as botulism and ciguatera, and diseases characterized by mild, rather nonspecific gastrointestinal symptoms are more often underreported. Finally,

diseases with a long incubation period, such as chronic heavy metal poisoning or cancer potentially associated with long-term consumption of fish from polluted water, would not be detected by CDC's National Foodborne Disease Outbreak Surveillance System.

Although our current Foodborne Outbreak Surveillance System is critical to our understanding of foodborne disease and its control, the information focuses only on outbreaks of diseases. However, most foodborne disease, including diseases associated with seafood, occurs as sporadic, or individual cases, rather than as part of recognized outbreaks. The characteristics of the sporadic cases can be very different. These differences have important implications for the control of illness in humans. For example, persons with liver disease who eat raw oysters can get a devastating, frequently fatal infection of *Vibrio vulnificus*, but no outbreaks caused by this bacterium have been reported. Data on such sporadic or individual cases, in addition to those from reported outbreaks, would be needed to fully characterize the risk associated with seafood products.

In 1989, in collaboration with the National Marine Fisheries Service, CDC analyzed data reported by the states on foodborne disease from 1973 through 1987. Recently, in collaboration with FDA, CDC analyzed foodborne disease outbreak data available for 1988-1991.

Keeping in mind the limitations of these data, we can examine the trends in foodborne diseases using this outbreak surveillance information for the period 1973 through 1991. During these 19 years, 4591 outbreaks of disease in which the causative food was known were reported to the CDC foodborne outbreak surveillance system. These outbreaks affected 202,850 persons. Seafood accounted for 20% of the outbreaks, compared with 8% for beef, 7% for poultry, and 1% for eggs. However, the number of cases of illness in these outbreaks is more important than the number of outbreaks themselves in determining the public health impact of diseases associated with a specific food vehicle. Because most outbreaks attributed to seafoods involved fewer persons than those due to other foods, seafood accounted for only 5% of all reported foodborne outbreak-associated cases, compared to 10% for poultry, 9% for beef, and 2% for eggs.

Despite our achievements in outbreak investigations, continuing hazards in our food supply tell us we must do better. We have identified activities that will lead to better control of foodborne disease. These activities include strengthened surveillance for emerging human pathogens, rapid and effective reaction to foodborne disease, and proactive foodborne disease prevention programs. I will discuss each of these in more detail.

Rapid and effective reaction to foodborne disease requires a nationwide system in which public health laboratories in all states identify potential foodborne pathogens, electronically transmit the information to CDC for cluster analysis and interpretation, and rapidly relay appropriate microbial isolates to CDC for molecular epidemiologic studies. CDC has developed a computer-based data management and reporting system (the Public Health Laboratory Information System) and is in the process of installing this system in all public health laboratories. We are also developing software modules for the foodborne pathogens of interest. CDC is expanding and improving pathogen subtyping systems which yield CDC important information regarding strain differences in foodborne pathogens. Such systems will help refine CDC's ability to identify case clusters and unusual events. Laboratory and human resource needs in state public health laboratories must also be addressed.

Proactive foodborne disease prevention programs for recognized hazards require quantitative risk assessment and

development of Hazard Analysis Critical Control Point plans for all foods and menu items. In the short term, effective prevention programs would include geographically and demographically representative sites for intensive surveillance and investigation of acute human illness due to currently recognized high-priority foodborne pathogens. Food microbiologic assessment coordinated with these efforts and foodborne disease outbreak investigations will generate data useful in the dose-response and exposure assessment phases of risk assessment. Collaborative investigations involving FDA, CDC, and state health departments on some foodborne infections, such as listeriosis, salmonellosis, campylobacteriosis, and Vibrio infections, have provided knowledge and experience with active surveillance programs.

In the longer term, to identify foodborne hazards more completely, characterize their risk, and help set foodborne disease prevention priorities, an expanded active surveillance program would be necessary to include additional infectious and noninfectious hazards, rapidly identify and characterize new and emerging foodborne hazards, and investigate chronic, as well as acute, adverse health effects. Long-term active surveillance and investigation could also be used to evaluate the effectiveness of food safety programs and the impact of regulatory change.

These activities would permit the comparison of seafood-related hazards with hazards associated with other foods. We could determine which types of seafood were associated with which pathogens by focusing attention on pathogens known or suspected to be transmitted by seafood, such as vibrios (e.g., *V. cholerae* 01 and non-01, and *V. parahaemolyticus*), *Plesiomonas shigelloides*, and some viruses (Norwalk agent, hepatitis A). Subsequently, by comparing seafood eaters who became ill with control seafood eaters who did not become ill, we should be able to learn about the factors which contributed to making the seafood a vehicle for disease, including source, handling between harvest and preparation, method of preparation, cross-contamination during preparation or storage after preparation, and such host factors as underlying diseases and lack of gastric acid.

We are already performing such studies on a limited scale. Several years ago, CDC and the Louisiana Department of Health and Hospitals conducted a study that successfully identified several factors in the preparation and storage of crabs which contributed to cholera. CDC, in collaboration with FDA and state health officials in Alabama, Florida, Louisiana, Mississippi, and Texas also conducts a special surveillance program for vibrios, organisms invariably linked to seafood or the marine environment. Although this reporting system is passive and probably detects only a small proportion of infections, it has provided important information on how to protect the public from infections with vibrios. CDC, FDA, and state health officials in Louisiana and Texas are also collaborating on an active surveillance project that will attempt to compare the relative importance of various foods in the transmission of foodborne infections with *Salmonella*, *Campylobacter*, and *Vibrio* in the Gulf Coast region. Such studies currently provide information on limited regions of the country and include a limited array of foods and foodborne pathogens.

Foodborne diseases continue to be a major and growing public health problem in the United States, producing millions of illnesses and thousands of deaths in this country every year. A 1991 report of the National Academy of Sciences that summarized data from CDC and other sources found that seafood available to consumers in the United States causes illness only infrequently, foodborne hazards continue to exist in all of our food commodities, including seafood. The authors concluded that continuing efforts are needed to improve our understanding of

foodborne diseases so we can be better equiped to prevent them. As we have observed with the re-emergence of tuberculosis and measles, adequate surveillance and other public health efforts are essential to prevent increased incidence of acute disease, increased numbers of persons with resulting chronic disease, and increased costs of disease control.

To conclude, CDC has an integral role to play, along with FDA, National Marine Fisheries Service, USDA, and state and local authorities, in the collaborative response to food safety issues. Improving food safety and meeting emerging foodborne disease problems in the 21st century will require a comprehensive surveillance program to: 1) rapidly determine populations at highest risk for foodborne infections and severe outcomes, 2) further document the important causes of foodborne disease and identify new foodborne disease threats as they develop, and 3) more completely determine which products, processes, and practices lead to foodborne infections. In addition to risk based regulatory programs of other agencies, effective educational programs for producers, processors, preparers, and consumers would be useful. Determining how foods become contaminated, developing rapid and accurate diagnostic tests for foodborne pathogens, and developing control strategies will minimize and prevent contamination of food by disease-producing microorganisms.

Thank you for the opportunity to testify before the Subcommittee. I will be happy to answer any questions you may have.

Mr. Chairman and members of the Subcommittee:

My name is Jim Salmon, and I am the Senior Vice President of Purchasing for Red Lobster, which is part of General Mills, Inc. I also am the First Vice President of The National Fisheries Institute, which is a trade association representing the United States fish and seafood industry.

My company and association thank you for this opportunity to testify on our company's commitment to quality seafood and our industry's views on the need to strengthen the federal inspection programs for fish and seafood products.

RED LOBSTER

Red Lobster operates nearly 600 full service restaurants, in 48 states, and employs over 60,000 people. We take pride in providing the highest quality seafood to our customers at reasonable prices. A typical Red Lobster restaurant, employs 100-125 people and generates nearly $3mm in sales each year.

Last year, Red Lobster purchased over 70 million pounds of seafood from hundreds of different suppliers in the United States and in over 30 foreign countries. Our total sales last year exceeded 1.7 Billion. We are the largest dinner house chain in the world.

RED LOBSTER COMMITMENT

In 1968 the tenets of Quality, Value and Service were established as the operating credo of Red Lobster. These tenets have been the cornerstone of our success. The founders of Red Lobster knew that quality, especially when applied to seafood safety, was essential in the long-term viability of a restaurant. A quality product by definition is a safe product as well as one which exudes the taste, texture and appearance of freshness and proper handling.

By adhering to our quality commitment, Red Lobster has always been a leader in the seafood industry in the establishment of strict quality standards and in the development of procedures to ensure a continuous supply of high quality, safe, and wholesome seafood. This commitment was reinforced by the formal establishment in 1971 of an in-house purchasing department with buyers traveling the world in search of quality seafood. Formal, strict specifications were established and have been maintained throughout our history.

In 1972 the Red Lobster Quality Control Department established Seafood Inspection Laboratories throughout our various warehouses and distribution centers nationwide. Our commitment was further demonstrated in 1976 with the establishment of a Microbiology Laboratory in Orlando that is certified by the State of Florida.

To achieve consistent seafood quality objectives, Red Lobster developed a rigid, formalized buying and quality control system. First, representatives from purchasing, quality control and restaurant operations establish strict specifications for each product purchased using a variety of standards including government specifications, such as those developed by the National Marine Fisheries Service. Included are workmanship, sizing, weights, packing, organoleptic criteria and microbiological standards. In many cases, Red Lobster specifications exceed industry standards.

Buyers who are certified through the Educational Foundation of the National Restaurant association (EFNRA) in applied foodservice sanitation, personal hygiene and food safety provide specifications to vendors throughout the world. Red Lobster buyers visit each vendor, domestic and foreign, to ensure product specifications and all sanitary conditions are met. In many cases, representatives from the quality control department will accompany buyers on these trips. Both purchasing and quality control personnel work closely with the vendor to ensure our quality standards. Red Lobster has in-country representatives in South America, Central America and Asia who ensure quality standards are met through frequent visits and detailed inspections.

Before Red Lobster establishes a purchasing program from a particular vendor, regardless of country of origin, the vendor must first meet all product specifications and the facility must comply with good manufacturing procedures of a food producing plant. Product samples must pass Red Lobster quality standards including microbiological testing. Only upon passing inspection will an initial order be placed.

When a domestic or foreign vendor ships product to one of the Red Lobster distribution centers it is subjected to a quality inspection. The shipment is put "on hold" while samples are taken and sent to a Seafood Inspection Laboratory for organoleptic inspection and samples to our Microbiological Laboratory in Orlando, Florida.

It is only after the product passes inspection that it is accepted by Red Lobster and released for distribution to the restaurants. No lots are released without passing all quality control check points. In many cases, when the shipment is from foreign sources, a Certificate of Health document accompanies the product.

The buyer's responsibility does not end with delivery of product to a port of entry or warehouse. They are responsible for their product from the boat to the plate. Checks are built into the system in the event a less-than-satisfactory product is discovered. Because of the lot inspection system, and the checks each lot must pass, a paper trail of each lots movement is established. Should that lot not meet specifications at any point throughout the system, it can be tracked and withdrawn. This system closes the loop from supplier to store. Red Lobster always know where product is, as well as its quality. (Note the attached brochure.)

Inspection continues once the product is released for distribution to the restaurants, Each member of management in the restaurant is also EFNRA certified and subjects the product to further inspection upon its arrival. In the restaurant, the employees receive training in food safety and act as another checkpoint when preparing the food.

Who better to evaluate good and bad seafood than an employee whose job it is to work with seafood each day - and who know excellent seafood from lesser quality seafood? Our Product Marking and Food Rotation system allows restaurant management to know exactly when a product was delivered, prepared and placed on-line for cooking.

Twice a day, at 11:00 a.m. and 4:00 p.m., management conducts formalized quality checks of the kitchen and all food product. The checks include all aspects of sanitation and food safety including temperatures, rotation, storage, and organoleptic checks.

As a further step in Red Lobster's commitment to quality, Quality Assurance Managers, all Registered Sanitarians, conduct unannounced, formal inspections of the restaurants. The Quality Assurance Managers also provide continuing education for management and staff in areas regarding food safety and sanitation. Because of this effort, Red Lobster restaurants across the country are used as examples by local health departments as how all restaurants should conduct their quality assurance programs.

From the outset, the philosophy of Red Lobster was to provide quality seafood to our guests. We have established long-term, mutually beneficial relationships with harvesters, fleets, and processors to allow them to do what they do best, and to allow us to do what we do best. We work hand-in-hand with a harvester, for example, in defining to them our standards and to work with them, if necessary, to achieve those high standards. When the product enters our distribution system, we take responsibility in ensuring that high quality is maintained throughout the distribution system - in our restaurants, in production, in cooking and, finally, in delivery to our guests. The lines of responsibility are clearly drawn and understood.

Therefore, we make our standards clear to our suppliers and work with them to achieve the stated quality objectives.

PRESENT FEDERAL AND STATE PROGRAMS

Red Lobster is regulated by a multitude of federal, state and local agencies. At the federal level, the Food and Drug Administration has jurisdiction over seafood and seafood plant inspections. United State Department of Agriculture inspects our beef and poultry products. The Department of Occupational Safety and Health Administration regulates matters of employee safety. The U.S. Customs Service also has jurisdiction of imported seafood in conjunction with FDA as well as jurisdiction over exported seafood.

State and local health departments also regulate food safety and sanitation. State Consumer Services regulate consumer fraud and product integrity. Federal and state agencies regulate fishing limits and quotas as well as opening and closing of shellfish beds.

Throughout our business, we deal with one or more of the above mentioned agencies - be it the at the border, distribution center, or restaurant.

As a restaurant company that is continually looking for ways to offer the highest quality seafood and one that is always listening to our guests, Red Lobster began discussions in 1985 with the United States Department of Commerce/National Marine Fisheries Service, to pursue a Voluntary Integrated Lot Inspection Program in an effort to offer government-approved seafood. This served two purposes. First, through the investigation process, we hoped to identify additional steps or procedures that might provide even greater quality in our seafood products. Second, we were becoming aware of increasing consumer demand for confidence in seafood quality. This program has been evolutionary step in our quality commitment by ensuring the Red Lobster program is second to none.

Red Lobster contracts with inspectors from the USDC's National Marine Fisheries Service to certify that the quality control checks and steps conducted by Red Lobster inspectors are proper and result in an accurate representation.

RED LOBSTER'S VIEWS ON FEDERAL INSPECTION

In 1979 Red Lobster was the first restaurant company in the United States to incorporate HACCP into our internal quality assurance inspection program. All Red Lobster Quality Assurance Managers use the HACCP principles when inspecting our restaurants. In addition, all store managers use in-house self-inspection cards based on HACCP principles. While the inspection covers a wide range of safety areas, the Quality Assurance Managers focus on critical areas of food safety which might lead to unsafe consequences. Temperatures, cross-contamination, proper storage, and personal hygiene are of particular emphasis.

In conjunction with the inspection aspect of their job, the Quality Assurance Managers provide continuing education and information to members of management and store staff. Manuals, posters, and video tapes are some of the training vehicles used. Hands-on time is spent with managers and store staff in not only providing the "rules", but providing the rationale for our standards.

HACCP has been a successful tool in monitoring our critical food safety points. We see no reason it cannot be successful for other operations.

As I mentioned earlier, I am testifying today on behalf of the National Fisheries Institute as well as my company. We have been an active member of the N.F.I. for many years and in the early 1980's we initiated the first step in the association's progressive stance towards improving the nation's seafood regulatory program.

At that time, concerns over inconsistent quality and fair dealing on the part of some in the industry prompted an industry education program. This in turn led to recognition that more effective regulation was needed.

Through NFI's instigation, Congress mandated the development of the model seafood surveillance plan which included the design of HACCP models for the many products produced by the industry.

All of the legislation which had been considered in the past several years was based on use of HACCP based regulation and inspection. NFI's position has been constant. It believes the nation would be well served by a comprehensive, constantly enforced seafood regulatory - inspection program.

NFI believes an improved mandatory program should be based the following principles:

- *The regulatory system should be based on the Hazard Analysis Critical Control Point (HACCP) principles endorsed by the National Academy of Sciences.*

- *A single federal agency should be responsible and accountable for regulating fish products and operations. Agency jurisdiction should be clearly defined to eliminate duplicate or conflicting authority or activities among agencies. Companies and products should not be subject to inspections for compliance by more than one agency.*

- *Delegation of inspection responsibilities to qualified states should be encouraged to avoid duplicate or conflicting programs.*

- *Tolerances and action levels for substances which may adulterate seafood should be based on definitions, criteria and practices which apply to all foods. Enforcement emphasis should be on surveillance testing and HACCP system correction.*

- *Enforcement and penalty procedures should provide due process and protect against disclosure of confidential business information. Harvesting and processing operations should be stopped only to avoid an immediate and serious adverse impact on human health.*

- *The system should apply to both domestic and imported product.*

- *Government costs should be covered in the same way as competitive food products.*

In the past two sessions of Congress the NFI has asked for legislation to put this type of program in place. While progress was made, no legislation resulted, as various factions used the legislative process as a platform for agenda items extraneous to seafood safety. Now FDA has indicated it plans to move forward with regulations which will require HACCP based preventive control systems throughout the industry. We commend this action as it's the heart of the various legislative proposals which had been considered in the past.

Since the FDA, which has regulatory authority over seafood, is initiating a bold new chapter in the evolution of the seafood inspections system, we believe it's critical to encourage the FDA to publish the regulations, put them in effect, and assess their efficacy before reopening the legislative process.

Congress has spent the last four years talking about seafood inspection. It had spent four years in the 70's talking about it and more years in the 60's. FDA's plans will actually make something happen. NFI does not want this positive action to be jeopardized by reopening contentious debate in Congress.

Instead, the NFI asks this subcommittee to give the FDA program a chance to work. Once the program is in place, it would be appropriate for the Subcommittee to initiate an oversight to see if the desired effect is being accomplished.

Looking ahead, the NFI does have concern over enforcement of the new HACCP regulations. Getting progressive regulations on the books is only the first step. Effectiveness will depend on consistency of enforcement. The action of the FDA represents a major step in the evolution of the food safety program in the United States by incorporating on going process monitoring into the system.

We urge the FDA to also reassess its enforcement apparatus to possibly institute a force dedicated to seafood. It's long been recognized that seafood is a unique food. Assessing its safety requires expertise. Assessment of HACCP procedures will require even more expertise. We would like the FDA to move towards a dedicated force of seafood experts to provide the best possible enforcement of the new program. The HACCP system will be effective only if all adhere to it.

We believe the state governments must be made a part of the new program as well. The Interstate Shellfish Sanitation Conference could well serve as a model for a joint federal-state cooperative effort.

In summary, the NFI is anxious to study and comment on FDA's proposal, the concept of which we fully support. It requests that attention be paid early on to developing a specialized enforcement capability. Finally, we ask Congress to reserve judgment on new legislation until after the new program is fully implemented.

Thank you again for the opportunity to participate in this hearing. I would be happy to respond to questions.

6/21/93/c:rlseafood/mkr

Pacific Coast Oyster Growers Association

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PHONE (206) 459-2828 FAX (206) 459-2829

TESTIMONY OF THE PACIFIC COAST OYSTER GROWERS ASSOCIATION

Before The

U.S. HOUSE OF REPRESENTATIVES

COMMITTEE ON MERCHANT MARINE AND FISHERIES

SUBCOMMITTEE ON FISHERIES MANAGEMENT

Presented by

WILLIAM J. TAYLOR

TAYLOR UNITED, INCORPORATED

JUNE 23, 1993

WASHINGTON D.C.

Mr. Chairman, Members of the SubCommittee:

My name is Bill Taylor. I am a shellfish farmer in Washington State and President of the Pacific Coast Oyster Growers Association. PCOGA represents 120 member companies in Washington, California, Oregon, Alaska, and British Columbia involved in the farming of oysters, clams and mussels. PCOGA is the largest shellfish association in the U.S.

Shellfish pose a tremendous regulatory challenge. They require a comprehensive inspection program unmatched in other foods. This fact was recognized as early as 1925 when the Surgeon General summoned state and local health officials to Washington D.C. to develop a national shellfish sanitation program.

Remarkably, the conclusions of that conference still serve as the foundation of today's inspection program:

- Because shellfish feed by filtering nutrients out of the water, the beds on which they grow must be inspected.
- The plants in which shellfish are prepared must be inspected.
- The products must conform to an established bacterial standard.
- The method of shipping must be inspected and finally,
- The responsibility for sanitary control of shellfish rests chiefly upon the individual states.

This year, the FDA issued a policy statement on the consumption of raw molluscan shellfish. In the statement, FDA endorsed the National Shellfish Sanitation Program (referred to as the NSSP) as "the best means of making molluscan shellfish as safe as possible".

In fact, the standards and procedures of the NSSP are the most comprehensive of all the regulatory programs for meat products. If you were to apply similarly stringent standards to beef production for instance, you would have to establish bacterial standards for the soil in which the corn is grown that is eventually fed to the cattle.

But if the NSSP is so effective, why has so much of the Seafood Safety debate focused on shellfish? There are primarily two reasons, both of which are problems that FDA acknowledges in its policy statement.

First is the illegal harvest of shellfish from closed waters, referred to as "bootlegging". In parts of the country where oystering is a "wild harvest" fishery, bootlegging is extremely difficult to control.

In its policy statement FDA called bootlegging "a practice that probably leads to most shellfish illnesses."

The second problem is that the current program is designed to protect against illnesses associated with pollution from human sewage. But perhaps the greatest health risks curently are from highly-toxic, naturally-occurring organisms, unrelated to pollution, such as Paralytic Shellfish Poisoning or PSP, Domoic Acid, and Vibrio Vulnificus.

For instance, PSP is prevalent on the West Coast during the summer months. Fortunately, there are effective monitoring controls for PSP. Even though many growing areas on the West Coast are shut down completely during the summer, we recognize that the closures are in the best interest of the industry because they insure the safety of our products.

The Gulf Coast states and FDA are faced with a similar problem in Vibrio Vulnificus, a warm-water organism which can be highly toxic to certain high risk individuals. The difference is that no effective monitoring method or risk standard has been established for Vulnificus. We are all aware of the unfortunate deaths that have been associated with Vulnificus through the consumption of shellfish from the Gulf of Mexico. While these fatalities have had a disastrous effect on the shellfish industry in the Gulf states, the other shellfish producing regions of the country have suffered as well from the publicity and subsequent erosion of consumer confidence in the safety of all shellfish.

Clearly, Vibrio Vulnificus, and other biotoxins pose the greatest health risks associated with shellfish at this point in time. Every effort must be made to find a responsible solution to the problems posed by Vulnificus. The industry on all three coasts, not just the Gulf of Mexico, cannot survive continued fatalities associated with the consumption of oysters.

Before I conclude, I would like to thank Representative Jolene Unsoeld for introducing House Bill 1412 establishing the National Shellfish Safety Program. It is an excellent, comprehensive bill that tackles head-on the most pressing problems faced by the domestic shellfish industry, including:

- protection and restoration of shellfish growing areas that have been impacted by pollution.
- requirements that foreign producers meet the same water quality, sanitation, and program requirements as the domestic industry;
- authorizing federal support to state shellfish control agencies to help implement federal guidelines; and
- extending FDA's enforcement authority to individual shellfish shippers.

PCOGA has submitted more extensive written comments specific to HR 1412. We are wholly in support of the bill, and urge the SubCommittee's support as well.

Thank You.

Shellfish
Institute of
North
America

A DIVISION OF
NATIONAL FISHERIES INSTITUTE

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STATEMENT OF

BILL MORGAN

PRESIDENT

SHELLFISH INSTITUTE OF NORTH AMERICA

TO

COMMITTEE ON MERCHANT MARINE AND FISHERIES

SUBCOMMITTEE ON FISHERIES MANAGEMENT

ON

SEAFOOD SAFETY LEGISLATION

JUNE 23, 1993

Shellfish
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Mr. Chairman, Members of the Committee:

My name is Bill Morgan. I am the President of the Shellfish Institute of North America (SINA). I greatly appreciate the opportunity you have given me to testify in these hearings on HB1412, "The Shellfish Safety Act of 1993".

I represent the oldest trade association in the United States. We also have the oldest inspection system in this country. Our Shellfish Sanitation Program has evolved over approximately the last 75 years to the present day National Shellfish Sanitation Program (NSSP). In this extremely comprehensive program, FDA works cooperatively with states and industry through the Interstate Shellfish Sanitation Conference (ISSC). This inspection program has always been based on microbiological testing, not just on superficial sensory inspection. Not only are our shellfish products tested, but shellfish growing waters must meet strict microbiological standards to insure freedom from fecal contamination.

Our seafood industry, working with NFI and USDC, was also one of the first to apply the HACCP (Hazard Analysis Critical Control Point) concept for the control of foodborne hazards. Even USDA has acknowledged that their traditional continuous visual inspection system is not effective for invisible microorganisms. They are now looking to our program in developing an improved HACCP-based system to control potential microbiological hazards.

All of this is certainly ironic in view of the fact that certain consumer lobbying groups and regulatory agencies have used the media over the last six years to continuously propagate misleading or false information regarding the safety of domestic seafood, and especially shellfish. They also relentlessly assert that our products are not properly inspected, or that our current inspection is carried out by too many groups or agencies. Our members will certainly concur with the latter, since we are, in fact, inspected by local and state regulatory agencies, FDA, EPA and even USDC, if we pay them.

Those special interest consumer lobby groups and agencies who maintain that we are not sufficiently inspected, and who continue to malign our products in the national press as unsafe, have gained tremendous financial and political power. The press quotes them avidly without thought to researching the actual scientific facts and data. The FDA has gained a whole new "Division of Seafood", and a greatly increased budget and beaurocracy. This has all been accomplished at the expense and near extinction of our very small, but traditional shellfish industry that represents an important heritage in our coastal states.

If you consider that of 1460 lbs. of food consumed per person per year, only 15.5 lbs. represents fish products and less than one tenth lbs. of this shellfish, it is extremely hard to rationalize and justify the tremendous expense to the taxpayer and our industry for these numerous seafood hearings and proposed inspection systems. This is especially true when considering the actual scientific data and facts regarding seafood safety. The recently published National Academy of Science's "Seafood Safety Report" clearly states that "Most seafoods are wholesome and unlikely to cause illness in the consumer".

For all of these reasons, and because HB1412 singles out only shellfish for additional regulations and expanded FDA authority, the majority of the shellfish industry is opposed to HB 1412.

We have always supported a single HACCP-based inspection system for all seafoods, but cannot support additional regulations that solely target the over-regulated shellfish industry.

HB 1412 also gives authority to FDA to indiscriminately remove a single company from the Interstate Certified Shellfish Shipper's List. This type of legislation gives whistleblower power to competitors. FDA could target and close single companies that could not afford to defend themselves in court, even if an error had occurred. FDA already has the power to close a company for product adulteration or unsanitary conditions. However, once a company is removed from the Certified Shipper's List, it could take months to get through the red tape required to be reinstated. Most companies could not survive this financially. My own company was inadvertantly excluded from this "List" several years ago through a simple clerical error. We were unable to proceed with business for more than 2 months. We had no recourse for retribution.

I would like to make these final comments concerning business in general. Any business, particularly a highly perishable seafood business, cannot survive even temporary closures. Also, no company forced to sign a "Consent Decree" by FDA has been able to remain in business for even one year. Many members of our industry have already lost their heritage, their livelihood, and the future of their families and their employee's families over minor discrepancies that do not represent actual public health hazards. A prime example is the policy of "0" tolerance for Listeria monocytogenes, a microorganism commonly found in the environment, and which has never been documented as causing a single seafood associated illness from domestic seafood.

Since the negative media campaign against seafood and shellfish began in 1987, our industry production has dropped more than 40% nationally. With a concurrent drop in price of 60% and overall losses of more than half of their businesses, hundreds of processing plants have been forced to close, resulting in the loss of countless jobs.

President Clinton has committed to increase jobs in this country. Putting companies out of business for reasons which have no real or widespread public health significance puts people out of work. It is the small family businesses like ours which provide most of those desperately needed jobs.

The FDA and other agencies should not base their mission on expanding their power to more easily close American businesses, but should strive to work more closely with states and industry to help solve any existing or potential problems.

In view of the above facts and concerns, the Shellfish Institute of North America cannot support HB1412.

I thank you again for allowing me the opportunity to present some of my industry's views.

The Seafood Industry is Being Regulated to Extinction

By Bill Morgan, W.F. Morgan & Sons,
President, Shellfish Institute of North America

In an in-depth review of the current state of the U.S. domestic fishing industry, one must conclude that there seems to have been an orchestrated effort among all of the federal agencies to regulate this small, but traditional and important industry to extinction. If that was not the original intention, it is most surely now the end result. To aid in this process, the media and consumer groups have continuously propagated misleading or false information regarding the safety of domestic seafood to the American public.

It is difficult to understand this type of attack when you consider that of the 1,460 pounds of food consumed per person each year, only 15.5 pounds are fish products. A few examples of the critical issues destroying the domestic fishing industry include dolphin-free tuna restrictions, turtle excluder devices for shrimpers, groundfish restrictions on New England fishermen, shark harvest restrictions, closing of large crab and oyster processing plants on the policy of "0 tolerance" for *Listeria*, an organism which can be commonly and widely found in the environment, and the extrapolation of a poultry epidemiological study in Seattle, WA to assess a 1 in 1,000 risk of illness from the consumption of raw molluscan shellfish throughout the country. Laws in Maryland and Virginia make it a criminal and civil offense to catch striped bass in the Chesapeake Bay. This has resulted in tremendous overpopulation of the species, which feed upon shad, herring, menhaden, trout, and other commercially important species. On the west coast, efforts to protect the sea lion have resulted in endangering commercially important fisheries including abalone and salmon.

I am afraid that NFI may have myopically regarded each of these attacks on the domestic fishery as an isolated problem for individual species. It is in fact pervading the entire industry, and the end result will surely be the elimination of the domestic fishing industry. The only survivor may be the foreign import industry which already represents 68% of the U.S. consumption. Our domestic trade industry will have no one to pay dues, our regulatory agencies will have no one to regulate, and unemployed fishermen, processors, packers and transporters will be on Welfare. This outlook seems bleak and pessimistic, but a recent telephone poll and personal visits indicate that it is unfortunately shared by members of the domestic fishing industry throughout the country. One optimistic voice on the west coast was from an importer of foreign seafood.

None of this is rational when you consider that the U.S. food supply is the safest in the world. The National Academy of Sciences "Seafood Safety Report" clearly stated up front that "most seafoods available to the U.S. public are wholesome and unlikely to cause illness in the consumer." They further concluded that those few problems that may exist were not at the processing level, but due to sewage pollution of the marine environment. The tremendous health benefits of seafoods have recently been made known to the public. Following the publicity of these benefits, the domestic seafood industry suddenly faced the deluge of regulatory and media attacks. The data however, clearly shows that reported illnesses associated with seafoods are very few compared with total food-borne illnesses, and there is little to no credible scientific data to support the conservation and management regulations.

Bob Brophy, NFI's Chairman of the Board, asks "Will we be allowed to harvest marine resources for the purpose of feeding people? We are consciously making a choice of feeding animals rather than people. Our ability to harvest is increasingly restricted by recreation and sports interest."

I recommend that industry representatives encourage NFI to create a "war chest" for possible litigation against agencies or groups when warranted. I further recommend communication with senators and congressman asking that they challenge actual scientific data generated by FDA, CDC, NMFS or other agencies involved in over-regulation of our industry based on questionable data.

Shellfish Institute of North America

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July 25, 1993

The Honorable Thomas Manton
331 Cannon House Office Building
Washington, D.C. 20515-3207

Dear Congressman Manton:

I would like to thank you again for your consideration of the seafood industry perspective of seafood safety.

In answer to your letter of July 5, 1993, you have five questions under Seafood Safety Hearing, and seven questions listed under Morgan heading. I shall list numerically as follows:

Questions for Seafood Safety Hearings

General:

(Q-1) How will the anticipated European Economic Community seafood standards affect the U.S. exporting seafood Industry? Will these standards have any effect on the domestic seafood industry?

(A-1) Irradiation is the only EEC standard other than the MOU's between the country and FDA which is unenforceable. As of July 1, 1993, European Economic Community seafood safety standards require U.S. exporters to obtain documentation from the FDA or USDC certifying that an export shipment was produced consistent with EEC requirements.

At the present time, the EEC is accepting certifications that a U.S. seafood company is complying with present U.S. requirements. Thus, EEC requirements have not been a major disruption to U.S. seafood exports. Future disruptions are possible, however, depending upon whether the EEC continues to accept U.S. certifications.

(Q-2) Do voluntary seafood safety efforts work?

(A-2) The NSSP has been in existence since 1925. The NSSP is the oldest food safety program and does have microbiological standards for shellfish growing waters and market guidelines for shellfish meats. Although it is considered "voluntary", it is essentially mandatory, since a state cannot ship shellfish in interstate commerce unless their program is in conformity with NSSP regulations and guidelines. The state program is evaluated by the FDA and must meet the criteria of the NSSP.

(Q-3) Are imported seafoods adequately inspected?

(A-3) No. All imported seafoods, including raw shellfish, should have to meet the same growing water, plant and market standards, guidelines and regulations as U.S. shellfish and other seafoods. 75% of shellfish related

illnesses in the last ten years occurred in 1982 and 1983, and involved mild Norwalk virus-like gastroenteritis from imported raw clams. This is a common human enteric illness with no associated mortality even in high risk individuals. (See USFDA New England Technical Services Unit 1992 report on molluscan shellfish illnesses, and the National Academy of Science "Seafood Safety Report"). However, the limitation of these illnesses, their mild nature, and the fact that they were mostly imported clams is never made clear to the public.

(Q-4) Should Federal seafood safety programs be consolidated into a single agency? Which agency and why?

(A-4) Why are only seafood safety programs singled out for inspection legislation and consolidation? The inspection of all foods should be within a single "Food Protection Agency". The expertise lies in several agencies. That expertise should be pooled into a single agency. This would eliminate needless bureaucracy, duplication of effort, red-tape and impossible expense to the industry and the tax payers. It would also be more efficient and logical.

(Q-5) Are discretionary State warnings to high-risk groups (e.g. those with liver diseases, gastrointestinal disorders, and AIDS) adequate to ensure safe consumption of seafood?

(A-5) Warnings incite fear in wholesale buyers. They simply eliminate business. What is needed is educational information for consumers. Consumer education works. Agencies should put more effort and budget into getting educational information to health care professionals and high risk consumers. The ISSC has already implemented an educational program concerning Vibrio-Vulnificus and other naturally-occurring marine bacteria for those individuals who have liver disorders and other immune dysfunctions. It is extremely important that the general public understand that marine vibrios are not a "contaminate"; they simply inhabit marine waters. V. Vulnificus poses no serious health hazard to normal healthy people. It is not an oyster problem; it is only a potentially serious problem in high risk individuals. I might add that since it is present in all marine waters, it cannot be removed from these waters or from raw seafoods. It can, however, easily be killed by cooking or irradiation.

Questions for Morgan

(Q-1) What do you forsee as the disadvantages of a cooperative system of state regulation of shellfish with federal oversight (as offered in H.R. 1412) instead of our present system of only state control.

(A-1) A cooperative system of state regulation of shellfish with federal oversight is exactly what we now have. No state has sole control over its shellfish program. It must meet all of the regulations of the NSSP and must pass inspection and approval by the FDA.

This new legislation effectively removes the cooperative system of state regulation with federal oversight that

we now have. It creates unnecessary additional federal override and adds another layer of bureaucracy. It makes it extremely easy for the federal government to step into a state and take over state authority. This always results in loss of more small businesses and jobs. Single companies could be targeted on a monthly basis. The paper work that would have to be generated by a state on a monthly basis would be enormous. The current NSSP has been very effective. It is essentially mandatory and it does not require legislation for additional federal power.

(Q-2) Are the rates of public health risks per pound of seafood consumed higher in the shellfish industry than say beef or poultry industries?

(A-2) There is no scientifically rational way to extrapolate risks per pound of seafood per consumer/year versus risks per pound of beef and poultry per consumer/year. Actual numbers of cases of seafood-related illnesses are very few compared with all food-borne illness, and as stated previously, 75% (about 2,000) of these cases reported in the last ten years were mild virus gastroenteritis from imported clams in 1982 and 1983 outbreaks. FDA, CDC, and the National Academy of Sciences has this information. See enclosure concerning CDC extrapolation of poultry study.

(Q-3) Who is behind what you perceive is a negative media campaign that started in 1987? What is their motive?

(A-3) The lobbying group, Public Voice, has gained tremendous national prestige and, no doubt, tremendous funding and power through continuous misrepresented attacks on domestic seafoods. Their Executive Director has now been appointed to a high level federal position with the USDA. The FDA has received an additional $40 million and a new Division of Seafood. They increased their power and funding at the expense of our industry. It would certainly be "a cruel irony" if there were no seafood businesses remaining for all of the new FDA Seafood Inspectors to inspect.

(Q-4) How should the public be protected from contaminated seafood, especially shellfish?

(A-4) Shellfish has the only valid inspection program now. This question carries negative load by adding "especially shellfish". The phrase "contaminated seafood" sounds frightening, but ridiculously non-specific. What specific contaminants are referred to here? Why use the term "especially shellfish"? The answer to the questions above clearly state that the main numbers of seafood illnesses were mild virus illnesses from imported clams. A more rigorous and equal program for imported raw shellfish would go a long way to protect the public and also the domestic industry.

(Q-5) How much of the 40% decline in the shellfish sales is due to reduced productivity vs. reduced demand?

(A-5) All 40% decline is due to reduced demand from negative press. Example, in 1988 shellfish were taken from menus of Red Lobster restaurants. My company was the supplier since 1968, with no illnesses.

(Q-6) Can you provide us with some examples of misleading or false information that you say is being used by consumer groups and the media regarding the seafood safety?

(A-6) See included in attachments, Dressel letter and Morris Potter poultry study.

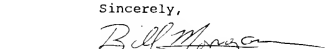
(Q-7) Can you elaborate on why you think striped bass are overpopulating the Chesapeake Bay and why you think sea lion protection efforts are endangering the Pacific salmon industry?

(A-7) Striped bass in the Chesapeake Bay have been protected by the interstate fishery management plan prepared by the Atlantic States Marine Fisheries Commission. Under the Striped Bass Act, the Secretary of Commerce must enforce this plan through statewide fishing moratoria without regard to the plan's impact upon other fisheries, or upon other marine species.

Sea lions are preying upon endangered populations of salmon and steelhead when they return to spawn in west coast rivers. All non-lethal efforts by local fishery management officials to deter this predition have failed. These mammals are protected under the Marine Mammal Protection Act and cannot be killed under federal law.

I hope these specifics will add insight to the decisions made by the committee. These decisions will have a great effect on our small industry. We can only hope your members are not only diligent but also fair. We ask you to help level the playing field in food safety.

Sincerely,



William C. Morgan, President
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Rt. 1, Box 241
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RESPONSES TO QUESTIONS SUBMITTED BY SUBCOMMITTEE FOLLOWING HEARING

JIM SALMON, SENIOR VICE PRESIDENT OF PURCHASING FOR RED LOBSTER

RED LOBSTER: QUESTIONS FOR SEAFOOD SAFETY HEARING

GENERAL:

1) How will the anticipated European Economic Community seafood standards affect the U.S. exporting seafood industry. Will these standards have any effect on the domestic seafood industry?

A. Our industry will have to get in gear to meet European seafood standards. The HACCP plan will help our industry get into compliance quicker. Both programs together can only make seafood products safer and a better quality. They compliment each other.

2) Do voluntary seafood safety efforts work?

A. They do work, but the problem is that not 100% of the companies feel they have to participate. Hence, inconsistency and potential problems. Mandatory inspection ensures participation, levels the playing field, and discourages fraud.

3) Are imported seafoods adequately inspected?

A. Yes. At this time, foreign packers are more closely monitored than domestic. By going to HACCP for both segments, this will be equitable to all and improve safety and quality.

4) Should Federal seafood safety programs be consolidated into a single agency? Which agency and why?

A. Yes. There are already too many interpretations of regulations and authority. One agency, one voice, will help ensure a consistent policy, and set one standard for all to follow. At this time, it looks like FDA has established itself in this leadership role.

5) Are discretionary State warnings to high-risk groups (e.g. those with liver diseases, gastrointestinal disorders, and AIDS) adequate to ensure safe consumption of seafood?

A. No. The key to seafood safety is education. A single Federal agency needs to ensure that these types of messages are reaching consumers through proper education.

FOR RED LOBSTER:

1) In your testimony, you suggested jurisdiction of seafood safety should be consolidated into one federal agency. Which agency would you suggest as a representative of Red Lobster and/or as a member of the National Fisheries Institute?

A. It looks like the lead agency should be FDA. It is the simplest solution to the inspection dilemma. NMFS's inspection branch could probably become a part of FDA, so there is no conflict of opinion on regulations and standards. FDA will need the manpower to institute HACCP.

ROLL CALL
THE NEWSPAPER OF CAPITOL HILL

Food & Drug, Alcohol & Tobacco

Roll Call Policy Briefing No. 56 • June 7, 1993

Photo by Maureen Keating

Yucky fish! Actually, these just-caught beauties at Maine Avenue are perfectly fresh, but the smell of seafood sometimes takes some getting used to, as Philip E.P. Jennings, age three, demonstrates. Food and Drug Administration Commissioner David Kessler wants to improve the safety and wholesomeness of the entire US food supply, and he says that "seafood's unique characteristics make...controls especially important." Most seafood health risks, he notes, come from the environment.

Top Policy Concern? It's Now Food Safety

By David Kessler

Recently, I read a survey conducted by the Institute of Food Technologists that asked various government watchers to list top federal policy concerns for 1993. The overwhelming choice was food labeling.

I would disagree with that assessment.

Certainly, food labeling has demanded considerable attention over the last several years. And while there is still work to be done to implement the rules, and an enormous educational task ahead of us to ensure that all Americans can take advantage of the new label, the policies are largely in place.

If I had been asked to respond to the survey, I would have named food safety as the number-one issue that will occupy federal policymakers over the next several years.

Those who closely observe the food scene would share one central observation: The way we produce food, distribute it, and consume it has changed in some very fundamental ways since the basic elements of today's food safety system were put into place.

If we are going to continue to ensure the safety and wholesomeness of the US food supply, we can't do our job the same way we were doing it 25 years ago — or even ten years ago. We need to recognize that the food industry has changed significantly, and that consumption patterns have, too.

Increasingly, the American consumer is relying on foods produced in high-tech, centralized processing facilities, shipped over long distances and packaged and stored in new ways. The consumption of prepared foods sold ready-to-eat at retail outlets is expanding rapidly. And more and more of the food that we eat originates overseas — more than one million import entries a year and growing.

Foodborne illness has always been a public health problem. But it appears to be on the rise. New pathogens have appeared.

There is more opportunity for food to be contaminated than in the past because food today is more extensively processed, handled at more steps between the farm or fishery and the table, and transported to and from more distant locations.

And contamination by pathogens is not the only problem. We still have to address the ongoing, unsolved problems associated with the increased use of industrial chemicals and the resulting environmental contaminants.

In the face of these changes in the production and consumption of food, consumers ask a very simple and legitimate question: Is the food supply safe?

And any time a problem arises, they also ask me: What are you doing to make it safe?

It's not that the public expects absolute assurances that food is perfectly safe. But they do expect that a system is in place to ensure that food is as safe as we can possibly make it — a system that is responsive to today's realities, today's risks, and today's consumer expectations.

The FDA Commissioner says the place to start is with a program of mandatory preventive controls for the seafood industry.

What are the elements of such a system?

Certainly, it is no longer enough to think of each processing plant in isolation, or each step in the production of food as a self-contained entity.

We must take the broad view: from farm or fishery to the dinner table; from the foreign processing plant to your local retail establishment. This calls for a shift in thinking.

Today we have a food safety system that is piecemeal. We examine a modest number of the food entries coming into this country, but only after they have arrived at our shores. And we have no authority to inspect foreign plants unless we are invited to do so.

We inspect domestic food processing facilities, but the tools we have give us only a snapshot of what is happening at the facility when our inspectors are present. It does not depict what went on before or what will go on after. And if we are in a plant only once every few years, we will never get the entire picture.

The history of food safety regulation is filled with government watchdogs chasing the horses after they've left the barn. The current system places too much of the burden on the taxpayer to find problems.

And the FDA's enforcement tools are so rudimentary that they make that burden overwhelming at times.

Continued on page 40

Dr. David Kessler is commissioner of the Food and Drug Administration.

Kessler: Safety Of Food Highest Priority

Continued from page 23

If there is an adulterated product being shipped, the FDA is not even entitled to the records that tell where that product has gone. I've faced that situation myself, and I can tell you that it becomes extremely difficult to provide consumers with the assurances they want.

Our current system of food safety regulation is reactive. What we need is a system that is built on preventing problems in the food supply, and one that gives regulatory agencies the tools to know that the system is working.

Industry needs to have in place basic quality assurance programs that prevent food safety problems. And the best of the quality assurance programs build on three decades of food industry experience with Hazard Analysis Critical Control Point methodology.

Such programs embody some very basic steps: Analyze the hazards; determine where in a processing operation a hazard is likely to occur; institute the controls needed to avoid the problem; monitor those controls; and maintain careful records.

Let me emphasize that no new knowledge, no new discoveries, are needed to meet the new food safety challenges. We can build on what some companies have been doing for years.

The time has come to institutionalize basic preventive controls to ensure the safety of the food supply. Companies need to develop and follow state-of-the-art quality assurance plans, and the government needs to be able to verify that the plans are being successfully carried out.

In some ways, it is a simple concept. But don't let the simplicity fool you. The program would represent a major shift in the way the food industry, regulatory authorities, and consumers approach the task of safeguarding the US food supply.

Foodborne illness has always been a public health problem. But it appears to be on the rise.

Such a preventive system could be applied to all segments of the food industry,' but I would like to focus on how it could be applied to one specific, important area, seafood.

Two years ago, the FDA quietly began an in-house study to determine the feasibility of mandatory preventive controls for the seafood industry, linked to inspections and based on the Hazard Analysis Critical Control Point (HACCP) concept.

That study is now virtually complete. It demonstrates that a mandatory HACCP system for seafood is feasible, and that it would offer a significant qualitative improvement over the current system. Moreover, the study indicates that we can implement such a program under our existing statutory authority.

While the general framework of a system of preventive controls can be applied across the board, we must also recognize that specific components of the food supply have unique elements.

Seafood's unique characteristics make the controls especially important.

As the National Academy of Sciences has pointed out, most health risks from seafood come from the environment. Seafood is still primarily a wild-caught product that involves more than 350 species from all over the world. Seafood is exposed to every hazard that can exist in the ocean, including marine bacteria, toxins, and human pollution. In addition, some seafood species can form their own toxins if strict temperature requirements are not adhered to from the moment the seafood is caught. Seafood is the most perishable of all flesh foods.

The seafood industry is highly decentralized and characterized by thousands of smaller, older businesses and facilities. There are literally hundreds of vessels that process seafood on the high seas. It is extremely difficult to reach these vessels while the processing occurs.

One-fifth of the seafood consumed in the United States is caught by recreational fishermen, and some of this finds its way into commercial channels. Recreational fishermen cannot be expected to understand or practice the safeguards we expect from commercial fishermen.

Seafood is consumed raw or partially cooked to an extent that is unknown for other flesh food. Finally, a majority of the seafood consumed in this country is imported — coming from more than 135 countries, some of which have advanced regulatory controls, but many of which do not.

While the 1991 National Academy of Sciences report concluded that seafood is basically a safe and wholesome product, the Academy noted problem areas and ways in which preventive controls can be strengthened.

Illnesses do occur from seafood — and most of them are preventable. More than 70 people became ill last summer from scombroid poisoning, a form of food poisoning caused by fish that has been left to decompose. In addition, we are finding natural toxins from the Pacific Northwest that we have not seen before. There is an unacceptable number of illnesses and deaths among high-risk individuals from Vibrio bacteria, which is transmitted by contaminated fish and can cause blood poisoning. And we have serious concerns about the high levels of decomposition we are seeing in some products.

Photo by Maureen Keaney

"Seafood is exposed to every hazard that can exist in the ocean, including marine bacteria, toxins, and human pollution," writes FDA Commissioner Kessler. The "Hazard Analysis Critical Control Point" concept is a feasible solution to the health risks involved in this "most perishable of all flesh foods." The illnesses that do occur from seafood, he stresses, are preventable.

No new knowledge, no new discoveries, are needed to meet the new food safety challenges. We can build on what some companies have been doing for years.

For all these reasons, it is imperative that producers understand the hazards and demonstrate this understanding by establishing preventive control systems that the industry, regulators, and consumers can readily verify.

Over the past two years, while working with the Department of Commerce, we have conducted HACCP pilot studies for domestic seafood processors. The participants generally agree that this transition was not easy; it required new ways of operating and thinking.

A new FDA survey of high-risk domestic seafood processors underscored this point.

The survey points out that the kind of preventive controls that would enhance consumer confidence in the final product are not always in place. For example, some companies had no controls to monitor the adequacy of their pasteurization process, the integrity of containers, or the appropriateness of storage temperatures.

The survey also documented that cleaning and sanitizing of processing equipment was not always undertaken at proper intervals.

The absence of these controls does not automatically translate into an unsafe product. The problem is that too many questions remain unanswered. Too much is left to chance. The likelihood of problems arising is greater, and it is more difficult to maintain consumer confidence. Consumers want to know that problems are being prevented before they can ever occur.

The burden of such a preventive system would fall to the industry. Such a system enables the regulator to take enforcement action if cooperatively developed quality assurance measures fail and processors' controls remain inadequate.

But while such a system would place additional responsibilities on the companies, I believe the industry is willing to meet that challenge and step up to the plate. The FDA is looking forward to working closely with Agriculture Secretary Mike Espy, who has already demonstrated a strong interest in consumer issues.

Establishing a preventive control system for seafood, using our current authority, will serve as the prototype for other industries.

Federal agencies overhauled the nation's food labeling system. Now, says Kessler, 'we need to turn our attention to the next great task.'

Everyone involved in the task of overhauling the nation's food labels deserves enormous credit for doing labeling right. Now we need to turn our attention to the next great task: a modern, comprehensive system to ensure the safety of the food supply.

Just How Safe Is That Seafood?

Says a Report: 'Most Seafood Products Are Wholesome and Unlikely to Cause Illness. Nevertheless, There Are Risks.'

By Sen. Ernest Hollings

Consumers are now receiving contradictory messages regarding seafood. We're told seafood is part of a healthy diet, that it is high in protein and vitamins and low in calories, relatively inexpensive, and may even lower the risk of heart disease.

And yet consumers have also been bombarded in recent months by a steady supply of disturbing reports that seafood is often contaminated, spoiled, or mislabeled. For instance, in a very detailed report last year, Consumer Reports concluded that "much fish is unfit to eat."

These contradictory messages are reflected in many consumer concern about the quality and safety of seafood and in the

Sen. Hollings's bill would establish a program to ensure that poor-quality seafood products are kept off the market.

relatively flat levels of consumer seafood consumption in recent years, as Americans struggle to decide whether seafood is a delicious part of a healthy diet or a dangerous product to be avoided at all costs.

So what are the facts? In 1991, the National Academy of Sciences (NAS) issued a comprehensive report which concluded that "most seafood products are wholesome and unlikely to cause illness in the consumer. Nevertheless, there are risks."

The principal risks identified by the NAS are illnesses caused by eating polluted raw shellfish and other seafood containing natural toxins and long-term health concerns stemming from contamination of seafood by mercury and other chemicals.

With this understanding of the problem, and at the request of both consumer organizations and the seafood industry, I have worked with other Members of Congress to develop legislation that would establish a cost-effective federal program to ensure that poor-quality seafood products are kept off the market.

In recent years, I have introduced two bills and held hearings in the Senate Commerce Committee on the elements of an effective seafood safety program. While we have reached a consensus on much of the program, a few outstanding issues remain to be resolved, including just what kind of program we should be looking to implement.

Traditional agriculture inspection programs simply will not work with seafood, in large part because of the unique nature of fish and the fishing industry. More than 200 species of fish are harvested in the wild and sold commercially in the United States. Billions of pounds of seafood are processed annually in remote locations and onboard fishing vessels, and almost two-thirds of the seafood consumed in the US is imported from more than 120 countries, each with varying degrees of seafood inspection and food safety expertise.

So in designing any seafood safety program, we must remember that what is effective in addressing potential food safety problems on a factory trawler in the Bering Sea may have little relevance for a catfish farm in southern Louisiana.

In addition, a significant amount of fresh seafood is recreationally caught and consumed locally without ever going to a processing plant, necessitating a strong and

Photo by Maureen Keating

Writes Senate Commerce Committee Chairman Hollings: "The consumer is the ultimate seafood inspector. By knowing how, when, and where to buy seafood and by understanding how to cook and store it, consumers can take steps to make sure that the product they eat is safe, wholesome, and will not lead to illness."

continuing effort to educate consumers. The consumer is the ultimate seafood inspector.

By knowing how, when, and where to buy seafood and by understanding how to cook and store it, consumers can take steps to make sure that the product they eat is safe, wholesome, and will not lead to illness.

How, then, can the federal government respond to consumer demand for an inspection and quality assurance program for seafood? And where do we begin?

First, we must look at just the federal government's existing expertise to work where it can do the most good. Currently, federal spending on seafood safety totals almost $70 million annually and is divided between two agencies, the Food and Drug

What is effective in addressing safety problems on a factory trawler in the Bering Sea may have little relevance for a catfish farm in southern Louisiana.

Administration (FDA) and the National Oceanic and Atmospheric Administration (NOAA). In addition, the states are estimated to spend an additional $20 million each year on seafood safety activities.

Currently, two national statutes provide authority for federal seafood inspection: the Federal Food, Drug, and Cosmetic Act gives the FDA the general responsibility for ensuring the safety of all foods destined for interstate commerce, and the Agricultural Marketing Act of 1946 allows NOAA to carry out voluntary seafood inspection and grading programs.

Recent increases in consumer and legis-

Sen. Ernest Hollings (D-SC) is chairman of the Senate Commerce, Science, and Transportation Committee and of its subcommittee on national ocean policy study.

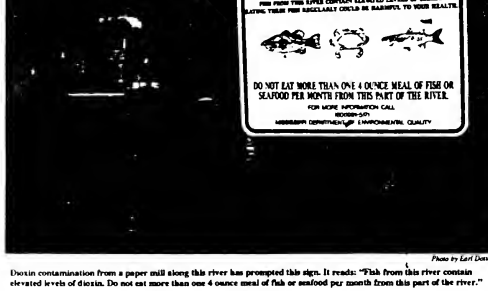


Photo by Earl Dotter

Dioxin contamination from a paper mill along this river has prompted this sign. It reads: "Fish from this river contain elevated levels of dioxin. Do not eat more than one 4 ounce meal of fish or seafood per month from this part of the river."

Hollings Bill Asks Seafood Safety Program

iative interest have sparked significant advances in the approach of the FDA and NOAA to seafood safety. The federal seafood safety budget has grown by about $10 million annually over the past four years, and the FDA has established an office of seafood safety.

In addition, both the FDA and NOAA are investing in the technology and techniques necessary to detect potential seafood problems. Meanwhile, NOAA and the Environmental Protection Agency (EPA) continue to work together to establish coastal monitoring programs to identify potential environmental problems and to warn recreational fisherman about them.

And the FDA recently announced plans to establish a mandatory, risk-based inspection program, greatly adding to its ability to discover potential problems.

Big while the government has made a substantial investment in seafood safety, the current national program is a patchwork of federal and state efforts and lacks the coordination necessary for a true, national seafood safety program.

Among the elements that should be included in a national seafood safety program (and were included in the legislation I proposed in the 102nd Congress):

- a comprehensive federal and state shellfish safety program based on the existing National Shellfish Sanitation Program;
- regulations for maximum allowable levels of chemical and biological contaminants in seafood;
- a national inspection system;
- enforcement of equal requirements for foreign and domestic producers through foreign program evaluations and inspection agreements with other nations;
- a monitoring program to identify the growing and harvesting locations in which contaminated fish are likely to be caught;
- financial assistance and delegation of inspection authority to states;
- public information and consumer education systems; and
- a comprehensive research plan to address seafood safety questions and improve monitoring programs.

A program for seafood safety is a realizable goal and one that can be achieved by strengthening existing programs, tightening federal and state laws, and applying the latest in technology and food safety science.

What we don't need to do in this area is re-invent the wheel by creating new, expensive, and largely redundant programs. There is not a national emergency in seafood quality. In large measure, the seafood available to the American consumer is safe and wholesome.

But a combined consumer/producer education program, close federal-state cooperation, and international agreements and enforcement will leave the consumer better protected and the seafood industry stronger.

Photo by Maureen Keating

Philip Jennings, age 3, cautiously eyes the offerings at the fish market on the Maine Avenue waterfront.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

AUG 3 1 1993

The Honorable Thomas J. Manton
Chairman, Subcommittee on Fisheries
Management
Committee on Merchant Marine and Fisheries
House of Representatives
Washington, D. C. 20515-6230

Dear Mr. Manton:

This is in response to your July 5, 1993, letter forwarding follow-up questions to the Subcommittee's hearing on seafood safety held June 23, 1993.

The responses to the questions are enclosed.

If we can be of any further assistance, please contact us.

Sincerely,

Jerold R. Mande
Acting Associate Commissioner
for Legislative Affairs

Enclosure

cc: The Honorable Don Young
Ranking Minority Member
House of Representatives
Washington, D.C. 20515-0201

Food and Drug Administration Response to Questions For The Record June 23, 1993 Hearing before the Subcommitte on Fisheries Management Committee on Merchant Marine and Fisheries

1. How will the anticipated European Economic Community seafood standards affect the U.S. exporting seafood industry? Will these standards have any effect on the domestic seafood industry?

European Community Council Directive 91/493 establishes conditions for fish and fishery products in the EC, either from domestic sources or imports. It requires that both member States and countries that export to member States take measures so that persons responsible for the production of fish and fishery products carry out safety checks based on identifying critical control points, establishing methods for monitoring these critical control points, and keeping written records with a view toward submitting them to a competent authority. These requirements describe, in effect, the system known as Hazard Analysis Critical Control Point, or "HACCP." It is reasonable to expect that the effect on that segment of the U.S. industry that exports to the EC will be the need to operate under a HACCP-based system that is verified by a regulatory authority in the United States acceptable to the EC. As FDA testified at the Subcommittee's hearing, HACCP regulations are being developed by FDA that will satisfy EC requirements.

2. Do voluntary seafood safety efforts work?

Under the Federal Food, Drug, and Cosmetic Act, it is illegal for anyone to introduce unsafe food into interstate commerce. A mandatory program that applies to everyone is the only realistic way to enforce this statute. A voluntary system alone would not work.

As you know, in addition to the mandatory requirements of the law enforced by FDA, NOAA operates a voluntary seafood inspection program under a memorandum of understanding with FDA. The NOAA program has traditionally focused on marketability factors, i.e., quality but, as discussed below, now looks at safety issues as well, and has recently switched in part to a HACCP-based approach that includes critical control points for safety. The NOAA program appears to work for those who volunteer to participate and adhere to the requirements.

3. Are imported seafoods adequately inspected?

As our testimony indicates, FDA reviews all U.S. Customs entries and selectively targets lots being offered for entry into the U.S. for physical examination and for laboratory analysis. FDA also places on automatic detention products that may be offered

for import that have a violative history or are found to be a serious health hazard. This status requires the importer to produce evidence that the shipment conforms to the requirements of U.S. law. Moreover, most States automatically reject molluscan shellfish imports unless they are from dealers certified under the safety criteria of the National Shellfish Sanitation Program, which FDA administers. These safeguards notwithstanding, FDA believes that the overall system can be improved through more memoranda of understanding with countries that trade with the U.S. and the application of HACCP principles to imports. FDA is pursuing both objectives.

4. Should Federal seafood safety programs be consolidated into a single Agency? Which Agency and why?

The safety of seafood in interstate commerce is the sole regulatory responsibility of the Food and Drug Administration. Consolidation in that sense is not necessary. NOAA's voluntary inspection program provides services toward the promotion of sales of U.S. products for those in the industry that wish to purchase NOAA's services. While it contributes to safety, it is not a regulatory program. Only recently has NOAA initiated adjustments to its program to directly address safety issues in products. Consequently, FDA believes that it is reasonable and appropriate for these two programs to be operated by different agencies so long as they are linked by memoranda of understanding and have good day-to-day working relationships, as is the case now. Other Agencies, such as the Environmental Protection Agency and the Fish and Wildlife Service, have programs that contribute to seafood safety, but these programs involve environmental and other issues beyond the normal scope of FDA's mission and are thus appropriately located where they are. The Department of Agriculture assists the expansion of the aquaculture industry through its promotional efforts.

5. Are discretionary State warnings to high-risk groups (e.g., those with liver diseases, gastrointestinal disorders, and AIDS) adequate to ensure safe consumption of seafood?

This question refers to the risk of infection from Vibrio bacteria in certain high-risk groups from the consumption of raw or undercooked molluscan shellfish. Certain individuals who are medically compromised risk serious illness and even death if they consume these foods, although the likelihood that they will become ill is not great.

Vibrio vulnificus is the most virulent of the Vibrio bacteria. Fatalities are primarily linked to this particular Vibrio. There have been anywhere from approximately 12 to 26 cases of illness from v. vulnificus reported annually in the United States, although the number appears to have gone up slightly in the past year or two. At least one-third of reported illnesses have

historically been from bacterial entry into the body in wounds. The fatalities reported annually have ranged from approximately 5 to 12; again, however, this number appears to have increased somewhat recently. FDA believes that these reported numbers should be doubled to compensate for underreporting. Illness from V. vulnificus is not on the list of reportable diseases in all States.

FDA has concluded that high-risk individuals should avoid molluscan shellfish that are not adequately cooked. FDA has engaged in an education campaign targeted toward these individuals. The Agency has also provided technical assistance to the Interstate Shellfish Sanitation Conference in the development of a discretionary point-of-purchase information message and has encouraged the use of such a message. Whether this message, or any such point-of-purchase message, can affect high-risk consumer behavior in a positive way is not yet known, but FDA believes that it is a reasonable approach. For the past few years FDA has also been considering the merits of a nationally mandated point-of-purchase message and is continuing to do so.

6. As of 1991, only 1,200 processors of the 4,000 processors (or 1/4th) nationwide had participated in the HACCP instructional workshops. How has the seafood industry responded to the voluntary HACCP program? Do you anticipate greater industry involvement even if the HACCP inspection plan is not mandated?

FDA defers to NOAA on the response to this question because it refers to the operation of voluntary programs only.

7. Are there overlaps and redundancies among the various Federal Agency programs dealing with seafood safety that could be consolidated?

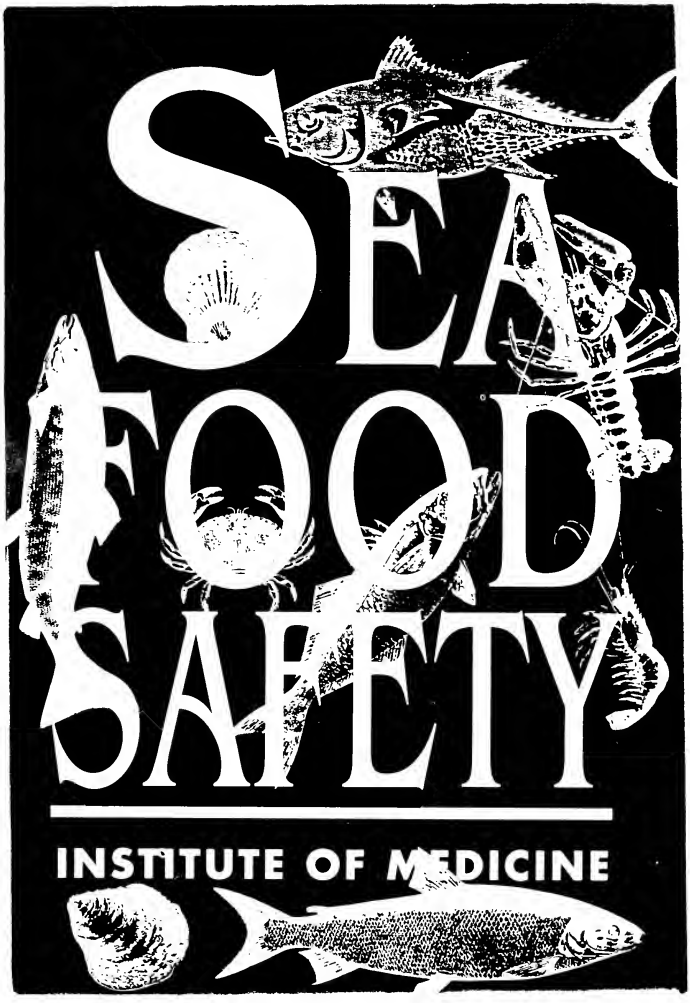
The appropriateness of such a consolidation is not clear. As stated earlier, for example, FDA's program is regulatory while NOAA's program is primarily service oriented. These complementary approaches both serve a useful purpose but should probably be operated by separate Agencies. It is true that FDA and NOAA both engage in safety-related research, but the Agencies work to avoid overlap and redundancy through a mechanism established by a memorandum of understanding between the Agencies.

8. When the seafood inspection rule is published, does FDA foresee the need for additional legislation granting the Agency greater regulatory authority; for example, the power to restrict fishing in certain waters?

The question of additional authority is, for the most part, unconnected to the proposed seafood inspection rule. FDA already

has a broad grant of authority under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, under which the Agency engages in inspections, import examinations, international agreements, sampling and analysis, education, research, Federal-State cooperation and assistance, and other functions. Additional authority is not essential to the operation of the program, although, as FDA has testified many times in the past, some very specific additional authority may be helpful. The larger question is whether additional authority can be justified solely for seafood or should be considered in the context of overall food safety.

One authority that you ask about that would apply solely to seafood is water closure authority. Such authority is theoretically desirable but implementation might prove to be extremely difficult. When a problem arises, such as the recent discovery in Pacific waters of toxins in species of fish and shellfish previously unknown to those species, it would be difficult at best to establish the geographical boundaries of a closure or to know whether to apply the closure to all fish of a particular species or to base the closure on size of fish or other factors. As a result, a water closure authority might raise expectations that could not practically be met. However, it is worthy of further consideration.


SEA
FOOD
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INSTITUTE OF MEDICINE

1

Executive Summary

OVERVIEW

Fish and shellfish are nutritious foods that constitute desirable components of a healthy diet. Most seafoods available to the U.S. public are wholesome and unlikely to cause illness in the consumer. Nevertheless, there are areas of risk. The major risk of acute disease is associated with the consumption of raw shellfish, particularly bivalve molluscs. For persons living in areas in which reef fish are consumed (Hawaii, Puerto Rico, the Virgin Islands), there is a risk of ciguatera; other natural toxins (paralytic shellfish poisoning, neurotoxic shellfish poisoning, etc.) have been associated with shellfish from endemic areas. Finally, there are less well-defined risks of acute and chronic disease related to environmental contamination of aquatic food animals. Dealing with such risks on a short-term basis requires improvements in the present system of regulatory control. In the long term, amelioration and eventual elimination of some hazards require strengthening and more effective application of control measures to prevent the disposal of human and industrial waste into offshore marine and fresh waters.

Because of the strong public interest in seafood safety and the declared intention at the congressional level to develop a new inspection system, a clear opportunity exists to introduce innovative methodologies for control that address directly the important health issues associated with seafood consumption.

This report reviews the nature and extent of public health risks associated with seafood, and examines the scope and adequacy of current seafood safety programs. The conclusions and recommendations arrived at are summarized in the following material:

- Most current health risks associated with seafood safety originate in the environment and should be dealt with by control of harvest or at the point of capture. With minor exceptions, risks cannot be identified by an organoleptic inspection system.
- Inspection at the processing level is important to maintain safety of seafoods, but there is little evidence that increased inspection activities at this level would effectively reduce the incidence of seafood-borne disease.
- With currently available data, it is possible to identify the source of much of the acute illness associated with seafood consumption, though the dimensions of the

carry microorganisms such as *Salmonella* or *Campylobacter*, which are commonly found in land animal carcasses and are the major causes of reported food-borne disease (though fish may acquire bacteria from contaminated water). Some ethnic practices in the preparation of fish for eating, place a small number of people at high risk from botulism, but this is not a significant hazard for most consumers of fish.

Thus, the health risks associated with seafood – although diverse – are identifiable and, to a significant extent, controllable by innovative measures aimed at geographically restricted or species-specific problems. Some risks, particularly those associated with environmental contamination, may be increasing; their elimination will require a major commitment on the part of both government and industry to change methods of waste disposal in our society. These and the more visible hazards mentioned can be greatly mitigated by a regulatory system specifically aimed at the causes, be they natural toxins, microorganisms, or contaminants. However, this will require something other than organoleptically based inspection systems, which may be useful for quality control and grading but are essentially worthless for detecting and controlling health risks.

NATURE AND EXTENT OF PUBLIC HEALTH RISKS

General

The principal source of data on the incidence of seafood-borne illness in the United States is the Centers for Disease Control (CDC). Its compilations are accumulated passively from state reports of food-borne outbreaks. An outbreak is an incident involving two or more sick individuals, except for botulism and certain chemical poisonings in which one sick individual constitutes an outbreak. A case is a single ill person. Unfortunately, not all states report each of the major types of seafood-borne disease, and within states there is considerable underreporting of incidents for a variety of reasons. Thus, CDC data may not be representative of actual disease occurrence and may omit altogether important seafood-originated disease outside the reporting format. The CDC information is useful when supplemented by other data on the occurrence of pathogens, an understanding of the patterns of seafood harvest and processing, a knowledge of the mechanisms of disease development, and – where available – independent epidemiological data. The CDC data cannot be used to estimate risks from chemical contamination, because no disease outbreaks have yet been reported from this cause.

Seafood-borne illness reported by CDC in the 10-year period 1978-1987 totaled 558 outbreaks involving 5,980 cases. However, fish and shellfish constitute only 10.5% of all outbreaks and 3.6% of all cases when food-borne illnesses from all foods are considered. The number of people made ill from beef (4%) and turkey (3.7%) exceeds the seafood total, whereas pork (2.7%) and chicken (2.6%) are slightly lower. If shellfish (2.3%) and fish (1.2%) are considered separately, the number of reported cases from each is lower than for any animal meat category. Nevertheless, when only muscle foods (e.g., red meat, fish, poultry) are consumed, seafood-borne illness represents 56% of all outbreaks and 21% of all cases when incidents of unknown etiology are included.

TABLE 1-1 Hazards and Risks of Seafood Consumption and Their Control Arranged According to Order of Importance

Hazardous Seafood [a]	Hazard [b]	Severity of Hazard [c]	Risk to Consumers [d]	Factors Enhancing Risk
Raw bivalve molluscs (oysters, clams, mussels)	(1) Viruses, enteric bacteria (2) *Vibrio* species	(1-2) Mostly mild gastroenteritis (2) Severe for susceptible hosts	High for consumers of raw molluscs	(1) Polluted growing waters (1-2) Temperature abuse (2) Host factors
Naturally toxic finfish	(1) Ciguatera	Moderately severe	(1) High in endemic areas	(1) Recreational fishing on reefs
	(2) Scombroid poisoning	Mild	(2) High for consumption of few species	(2) Temperature abuse after capture
Molluscs	(3) PSP, NSP, DSP, ASP	Mild to severe	(3) High if harvest is uncontrolled	(3) Recreational shellfish harvest
Chemically contaminated finfish and shellfish [a] (freshwater species, specific marine areas species)	Environmental chemicals such as mercury, lead, cadmium, PCBs, dioxin, pesticides	All levels mild to severe	High for subsistence recreational fishers in certain areas, pregnant women, and children	Subsistence and recreational fishing in areas of high contamination; species and fish portions eaten
Processed seafood	(1) *Clostridium perfringens* (2) *Salmonella* (3) *Shigella* (4) *Staphylococcus aureus* (5) *Vibrio parahemolyticus* (6) *HAV* (7) *Clostridium botulinum*	(1-5) Usually mild (7) Severe	Low when adequate cooking precedes consumption	Cross-contamination; temperature abuse; processor presentation errors

NOTE HACCP = Hazard Analysis Critical Control Point; PSP = paralytic shellfish poisoning; NSP = neurotoxic shellfish poisoning, DSP = diarrhetic shellfish poisoning; ASP = amnesic shellfish poisoning; PCBs polychlorinated biphenyls; HAV = hepatitis A virus.

[a] Fish or shellfish, the consumption of which can lead to disease.
[b] An organism, substance, or condition having the potential to cause disease.
[c] Severe: may cause disability, extended sequelae, and in some cases, death; moderate: may require medical

Factors Reducing Risk	Present Control Systems [e]	Deficiencies of Present System [f]	Proposed Corrective Measures
(1-2) Cooking (2) Rapid cooling (1-2) Irradiation	(1) Shellfish sanitation program (2) None	(1) Unreliable indicators (2) No indicators	(1) Identify reliable indicators (2) Rapid method for *Vibrio* identification; chilling molluscs; radiation (1-2) Warn consumers of dangers of eating raw seafood
—	(1) Voluntary harvest restriction	(1) No widely available test	(1) Regulate fisheries; develop reliable, rapid test(s)
(2) Good temperature control	(2) Rapid cooling; histamine testing	(2) Limited effectiveness of control	(2) Enforce temperature control through HACCP system
(3) Informed consumers	(3) State surveillance and harvest control	(3) Harvest closure not always effective	(3) Additional policing and stronger advisories
Decreased consumption (avoid during pregnancy); avoid high-risk areas and species; trim skin and fat	Local regulations and advisories; some federal tolerance and action levels	Action levels too few and too permissive; inadequate harvest management and control; noncancer effects poorly evaluated; poor contaminant data bases	Further reductions in discharges; harvest restriction by site and species; improve advisories and possibly label fish; improve risk assessment for cancer and noncancer effects
Adequate cooking; temperature control; proper processing and food service	Sanitation inspection; process control	Limited inspection; ineffective inspection methods; diverse processing	Inspection and control based on HACCP system; improved temperature control on shipboard and during distribution

intervention to avoid debilitating or life-threatening effect, rarely self-resolving; mild: symptoms are transitory, rarely lasting more than a few days, no sequelae, no threat to life, usually self-resolving

[d] Probability that a consumer will become ill from the hazard.

[e] Mechanisms to reduce or eliminate risk form hazard(s) by government, industry, or related individual action.

[f] Aspects of control systems that reduce their effectiveness.

[g] Presence of significant levels of undesirable chemicals (causing acute or chronic effects) in edible fish or shellfish tissue derived from natural environment of anthropogenic origin.

Natural seafood toxins – mainly ciguatera and scombroid poisoning and, to a lesser extent, paralytic shellfish poisoning – were responsible for 62.5% of all seafood-borne outbreaks of illness, but constituted only 28% of all reported cases. Shellfish-related incidents, although responsible for only 31% of the seafood illness outbreaks, involved 66% of all seafood-borne cases. Most of these (55%) were registered as of unknown etiology but are believed to be due mainly to Norwalk, Norwalk-like, or human enteric virus infections, with a smaller proportion caused by *Vibrio* bacteria. Fish-borne incidents due to causes other than natural toxins were only 9% of all outbreaks and 8% of all cases. They resulted mainly from bacteria, including common food-borne disease organisms, and from unknown etiology, suspected to be primarily enteric virus or recontaminant vibrios. Botulism is a specialized but significant component of fish-borne disease. Disease due to parasites was minimal (0.4% of outbreaks and 0.6% of cases reported from seafoods).

Shellfish-borne disease occurs mostly from molluscs consumed raw or lightly heated, which constitutes the largest consumer risk. Ciguatera is a highly regionalized and intense risk for inhabitants and visitors consuming certain reef-associated fish in Caribbean and tropical Pacific islands and in adjacent mainland areas. Scombroid poisoning is widely distributed geographically but is specifically associated with consumption of certain fish species, particularly tuna, mackerel, mahimahi (dolphin), and bluefish. Botulism is a hazard for native American groups in Alaska that eat traditional fermented seafoods. Other risks are typical of food-borne disease in general and result from errors in handling, storage, or processing procedures. These are no greater than for other foods of animal origin.

Intolerance to eating certain types of seafood is rare and more typically associated with certain individuals in risk categories predisposed by other health complications. Seafood allergies, distinguished as immunological reactions rather than the inability to digest, appear to be more prevalent, but they are difficult to diagnose and document. Specific allergens in seafood have thus far been only grossly characterized in few studies. Seafood intolerances and allergies can be due to food additives (e.g., sulfites) that cause symptoms and confuse diagnoses. Additional investigation of the biochemical and immunological characteristics of seafood allergies and their significance seems warranted. In light of this level of information on the cause and occurrence of this somewhat limited form of seafood-borne illness, regulatory response must depend on proper labeling to distinguish (1) species or seafood type, (2) ingredients in formulated and fabricated seafoods [e.g., fish base surimi (a washed mince of the separated muscle tissue from fish to which cryoprotectants are added) formed to resemble crab], and (3) ingredients used in preservation and processing (e.g., sulfites to retard shrimp melanosis).

Microorganisms and Parasites

Extent of Risk

Seafoods, like any food item, have the potential to cause disease from viral, bacterial, and parasitic microorganisms under certain circumstances. These agents are acquired from three sources: (1) mainly fecal pollution of the aquatic environment, (2) the natural aquatic environment, and (3) industry, retail, restaurant, or home processing

and preparation. With the exception of foods consumed raw, however, the reported incidences of seafood-related microbial diseases are low.

Available data from CDC and from the Northeast Technical Support Unit (NETSU) of the Food and Drug Administration (FDA) for 1978-1987, as well as literature reports, suggest that the greatest numbers of seafood-associated illnesses are from raw molluscan shellfish harvested in waters contaminated with raw or poorly treated human sewage. The majority of these illnesses have unknown etiologies clinically suggestive of Norwalk and Norwalk-like agents that cause human viral gastroenteritis. Although these are the most common seafood-associated illnesses, they tend to be relatively mild with no associated mortality.

Except for Guam, naturally occurring marine *Vibrio* species are responsible for fewer reported cases of infections involving the consumption of raw molluscan shellfish, but certain species such as *V. vulnificus* can be associated with high mortality (>50%) in persons who are immunocompromised or who have underlying liver disease.

The microbiological risk associated with seafood other than raw molluscan shellfish is much lower and appears to result from recontamination or cross-contamination of cooked with raw products, or to contamination during preparation followed by time/temperature abuse (e.g., holding at warm temperature long enough for microbial growth or toxin production to occur). This occurs mainly at the food service (postprocessing) level, which is common to all foods and not specific for seafood products.

Seafood-related parasitic infections are even less common than bacterial and viral infections, with anisakids and cestodes having the greatest public health significance in the United States. In general, parasitic infections are concentrated in certain ethnic groups that favor the consumption of raw or partially cooked seafoods.

Thorough cooking of seafood products would virtually eliminate all microbial and parasitic pathogens. Individuals who choose to eat raw seafood should be educated about the potential risks involved and how to avoid or mitigate them. In particular, immunocompromised individuals and those with defective liver function should be warned never to eat raw shellfish.

The greatest risks from the consumption of raw molluscan shellfish could be minimized by research to develop valid human enteric virus indicators for the proper classification of shellfish growing waters; by implementing and maintaining proper treatment and disposal of sewage to avoid human enteric pathogen contamination of harvest areas; by efforts to identify and limit the number of pathogenic *Vibrio* species in shellfish; by developing new diagnostic methods and improved processing technologies; and by applying risk-based regulatory and control measures for potential microbial pathogens in raw molluscan shellfish.

Other seafood-associated risks can be reduced by proper application of a Hazard Analysis Critical Control Point (HACCP) system. This cannot be achieved by the visual or organoleptic inspection currently used for meat and poultry. Seafood inspection should be directed toward identification of microbiological risks to consumers and the effectiveness of methods to reduce or eliminate such risks. Additional studies are necessary to determine levels of particular microorganisms that constitute a risk and that can be used as a basis for microbial guidelines. This requires appropriate epidemiological research. Inspection requirements should apply to imported as well as domestic products.

Principal Conclusions

- Most seafood-associated illness is reported from consumers of raw bivalve molluscs, and is due to unknown etiologies but is clinically suggestive of Norwalk-like viral gastroenteritis. The majority of incidents are due to consumption of shellfish from fecally polluted water. The disease is usually mild and self-resolving.
- Naturally occurring marine *Vibrio* species are responsible for fewer reported cases of infection from the consumption of raw molluscan shellfish, but species such as *V. vulnificus* can be associated with high mortality in persons who are immunocompromised or who have underlying liver disease.
- A lesser risk of microbial disease associated with other seafoods – resulting from recontamination or cross-contamination of cooked by raw product, or to contamination from other sources – is usually associated with time/temperature abuse. The etiologic agents most commonly involved, in order of reported frequency, are *V. parahaemolyticus*, hepatitis A, *Salmonella*, *Shigella*, *Clostridium perfringens*, and *C. botulinum* (mostly limited to Alaskan natives).
- Seafood-related parasitic infections are even less common than bacterial and viral infections, with anisakids and cestodes having the greatest public health significance in the United States. In general, parasitic infections have resulted from consumption of raw or partially cooked fresh- and saltwater fish of particular species (e.g., whitefish, salmon).

Principal Recommendations

- Consumers should be informed of the risks of eating raw seafoods, particularly molluscan shellfish. Individuals belonging to high-risk groups, such as cirrhotics, people with hemochromatosis, or immunosuppressed individuals, must not eat raw shellfish; this requires that health professionals be educated concerning hazards to high-risk individuals.
- Adequate and proper treatment and disposal of sewage must be implemented to avoid contamination of harvest areas by human enteric pathogens.
- Valid indicators for human pathogen contamination of growing waters must be developed. Seafood-borne infections by human enteric viruses in raw and improperly cooked molluscan shellfish could be decreased significantly by the development of valid growing water indicator(s) and of direct detection methodologies for enteric viruses.
- Effective enforcement to eliminate recreational commercial and illegal harvesting and sale of molluscan shellfish from contaminated growing areas should be developed and adequately funded.
- Means must be investigated and implemented to eliminate, or at least reduce, levels of potentially pathogenic *Vibrio* species in raw shellfish. This may necessitate restriction of harvest when water temperatures are high, rapid cool-down and continued chilling of products, and possibly irradiation of live shellstock and shucked products.
- Consideration should be given to monitoring *Vibrio* counts in molluscan shellfish during warm months.
- Because of the high risks associated with raw molluscan shellfish, the importation of live shellfish for raw consumption should not be permitted unless

standards for the microbial quality of harvest waters and of harvest processing in the exporting country are fully equivalent to those in the United States.

- Consumers should be advised to cook seafood sufficiently to destroy parasites and bacterial contaminants before consumption.
- Control systems for microbiological hazards must include inspection techniques, preferably HACCP based, that specifically test for the hazard itself or for some condition that enhances or reduces hazard. Valid microbiological guidelines, established with an appropriate epidemiologic data base, are needed for seafood products.
- Special attention should be addressed to ensure the safety of seafoods processed by newer techniques, such as *sous vide* and the use of controlled atmosphere packaging, that are potentially hazardous.
- New or improved methodologies [e.g., enzyme-linked immunoabsorbent assay (ELISA), gene probe, polymerase chain reaction] should be developed that provide for the rapid identification and quantification of indicators, seafood-associated pathogens, and microbial toxins in seafoods and harvest waters.

Natural Toxins

Extent of Risk

Incidents of illness due to naturally occurring seafood toxins reported to CDC in 1978-1987 were limited to ciguatera, scombroid fish poisoning, paralytic shellfish poisoning (PSP), and neurotoxic (brevetoxic) shellfish poisoning (NSP). Other intoxications, including puffer fish poisoning (PFP), were reported earlier; diarrhetic shellfish poisoning (DSP) and amnesic shellfish poisoning (ASP) are possible risks that should be anticipated. Naturally, toxic fish and shellfish are not distinguishable from nontoxic animals by sensory inspection, and the toxins are not destroyed by normal cooking or processing. Except for scombroid fish poisoning, natural intoxications are both highly regional and species associated, and toxins are present in the fish or shellfish at the time of capture. Scombroid poisoning is due to histamine produced by bacteria multiplying on fish that are mishandled after capture; illnesses are widely reported from different states.

Ciguatera is a sometimes severe disease caused by consuming certain species of fish from tropical waters usually associated with islands or reefs. The disease is most common (endemic) in the Caribbean and Pacific islands, with some outbreaks in southern Florida and sporadic cases in other states caused by imported fish or tourist travel to endemic areas. Ciguatera was responsible for about half of all reported outbreaks of seafood intoxication in 1978-1987. The treatment is largely supportive, but mortality is low. At present, no effective control systems are in place for the prevention of ciguatera because a test for toxic fish is not generally available. Warnings and advisories concerning the hazards of ciguatera and the risks of consuming particular species of fish from ciguatera areas are issued by various states. Active control is proposed based on regulation of fishing for dangerous species, supported by testing suspect fish at dockside or on board the fishing vessel to detect and reject ciguatoxic fish. Increased education of the consuming public, sports fishers, and health professionals on the hazards and symptoms of ciguatera is also recommended.

During the same period, scombroid poisoning reportedly caused a similar number of outbreaks as ciguatera but was much more widespread in occurrence. Tuna, mahimahi, and bluefish were implicated as the major cause of scombroid poisoning in the United States. The disease is generally mild and self-resolving, and symptoms can be ameliorated by antihistamine drugs. Because the histamine that causes scombroid poisoning is produced after the fish have been caught, as a consequence of improper temperature control, the disease can be prevented by rapidly cooling fish after capture to 10°C or lower (e.g., 0°C if kept for an extended period) and holding them at or below this temperature at all times before cooking and eating. A HACCP-based system would control this poisoning for commercially handled fish, but the education of subsistence and recreational fishers is also necessary.

Paralytic shellfish poisoning was a minor cause of seafood-borne illness in 1978-1987, with only two deaths reported. This is a remarkable record in view of the annual occurrence of toxic situations among shellfish on both the East and the West coasts of the United States, which indicates that current control measures applied by coastal states are highly effective. However, the increasing occurrence of toxic dinoflagellate blooms and changing eating practices (e.g., eating whole scallops) among some sectors of the consuming public require increased surveillance and the development of more rapid and simple tests for toxic shellfish.

Although none of the other natural seafood intoxications, except for a single outbreak of NSP, have been reported recently by U.S. consumers, the potential for their occurrence either from domestically produced seafoods or from imports is real. Increased vigilance concerning imported products based on a requirement for certified nontoxicity is recommended. Moreover, both state and federal laboratories should be prepared to test for these "other" toxins, and procedures to deal with outbreaks should be in place.

Principal Conclusions

- Natural toxin risks are highly regional or species associated.
- Natural toxins are present in the environment and are not affected by procedures during or after harvest. The one exception is scombroid shellfish poisoning, which is due to postharvest mishandling.
- Reliable, rapid tests for the natural toxins are either unavailable or not fully developed.
- Although PSP is well controlled by state inspection systems and industry controls are in place for scombroid poisoning, there are no regulations for the control of ciguatera.
- Recreational and subsistence fish eaters are at particular risk from natural toxins, and there is a lack of understanding by consumers of this risk.

Principal Recommendations

- Control for natural toxins in the food chain should be at, or prior to, harvest, either by closures or by testing at the point of harvest.

- Scombroid poisoning should be controlled primarily by rapid chilling on the vessel and by maintenance of refrigeration temperatures throughout distribution.
- Major emphasis should be placed on the development of rapid assays for each of the other natural toxins; without this, control is very difficult.
- Primary regulatory authority should be at the state level, with funding, quality control, and specialized assistance from a federal seafood safety program.
- Imported seafoods must be certified to be free of natural toxins through equivalency arrangements or more effective memoranda of understanding (MOUs) with exporters. An MOU refers to a formal agreement between a U.S. government agency (e.g., FDA) and another government agency (federal, state, local), or an informal agreement with a foreign government or other foreign institution.
- Educational programs on the dangers of natural seafood toxins must be developed for recreational and subsistence fishers, and health providers must be given information to improve the identification and treatment of illness due to seafood toxins.

Chemical Residues

Extent of Risk

Fish and shellfish accumulate chemicals from the environment in which they live, but the extent of accumulation depends on such factors as geographic location, species of fish, feeding patterns, solubility and lipophilicity of the chemicals, and their persistence in the environment. Moreover, whereas land animals used for human consumption are fed mostly food of plant origin, aquatic animals that contribute to the human diet are generally predators of other animals and, in some cases, predators of predators. Because of this, chemicals have an opportunity to become more concentrated through bioaccumulation.

The most difficult area for risk evaluation is the problem of chemical residues because the health effects suspected do not take the form of obvious, distinctive, and acute illnesses. The potential risks of concern (e.g., modest changes in the overall risk of cancer; subtle impairments of neurological development in fetuses and children) are generally quite difficult to measure directly in people exposed at levels that are common for U.S. consumers. Immunoincompetence may increase cancer risk. Inferences about the potential magnitude of these problems must be based on the levels of specific chemicals present, on observations of human populations and experimental animals exposed at relatively high doses, and on reasonable theories about the likely mechanisms of action of specific toxicants and the population distributions of sensitivity and human exposure. In nearly all cases the current state of knowledge on these subjects must be regarded as quite tentative. Additionally, the number and variety of chemical residues are substantial, although a small minority constitute the bulk of the risk that can be assessed quantitatively at this time.

Overall, several chemical contaminants in some species of aquatic organisms in particular locations have the potential to pose hazards to public health that are great enough to warrant additional efforts at control. Available information suggests that these risks, in the aggregate, are not generally of a magnitude comparable to the highest environmental health hazards characterized to date; nevertheless, their control would significantly improve public health. Some examples of risks that may be

significant include reproductive effects from polychlorinated biphenyls (PCBs) and methylmercury; carcinogenesis from selected congeners of PCBs, dioxins, and dibenzofurans (all of which appear to act primarily by binding to a single type of receptor); and, possibly, parkinsonism in the elderly from long-term mercury exposure. Several other metallic and pesticide residues also warrant attention.

Principal Conclusions

- A small proportion of seafood is contaminated with appreciable concentrations of potentially hazardous organic and inorganic chemicals from both natural and human sources. Some examples of the risks that may be significant include reproductive effects from PCBs and methylmercury, and carcinogenesis from selected PCB congeners, dioxins, and chlorinated hydrocarbon pesticides.
- Consumption of some types of contaminated seafood poses enough risk that efforts toward evaluation, education, and control of that risk must be improved.
- Present quantitative risk assessment procedures used by government agencies should be improved and extended to noncancer effects.
- Current contaminant monitoring and surveillance programs provide an inadequate representation of the presence of contaminants in edible portions of domestic and imported seafood, resulting in serious difficulties in assessing both risks and specific opportunities for control.
- Due to the unevenness of contamination among species and geographic sources, it is feasible to narrowly target control efforts and still achieve meaningful reductions in exposure.
- The data base for evaluating the safety of certain chemicals that find their way into seafood via aquaculture and processing is too weak to support a conclusion that these products are being effectively controlled.

Principal Recommendations

- Existing regulations to minimize chemical and biological contamination of the aquatic environment should be strengthened and enforced.
- Existing FDA and state regulations should be strengthened and enforced to reduce the human consumption of aquatic organisms with relatively high contaminant levels (e.g., certain species from the Great Lakes with high PCB levels, swordfish and other species with high methylmercury levels).
- Federal agencies should actively support research to determine actual risks from the consumption of contaminants associated with seafood and to develop specific approaches for decreasing these risks.
- Increased environmental monitoring should be initiated at the state level as part of an overall federal exposure management system.
- States should continue to be responsible for site closures, and for issuing health and contamination advisories tailored to the specific consumption habits, reproductive or other special risks, and information sources of specific groups of consumers.
- Public education on specific chemical contaminant hazards should be

expanded by government agencies and the health professions.

- For specific contaminants in particular species from high-risk domestic or foreign geographic areas, government agencies should consider the option of mandatory labeling.
- Additional study of potential chemical contamination risks associated with both domestic and imported aquaculture products is required. Because of different standards for drug or agricultural chemical use and water quality prevailing in other countries, imported aquaculture products should be effectively certified as meeting U.S. standards.

SCOPE AND ADEQUACY OF CURRENT SEAFOOD SAFETY PROGRAMS

Regulatory Guidelines, Monitoring, and Inspection

The current system of governance designed to protect the U.S. seafood consumer is composed of an intricate and complementary system of programs at the federal and state levels of government. Additional programs have been instituted in the private sector that offer a measure of industry self-regulation. At the federal level the principal responsibility for setting regulatory guidelines and for the surveillance and control of seafood safety is divided among the FDA, the Environmental Protection Agency (EPA), and the National Marine Fisheries Service (NMFS).

Within states, responsibility may lie with one or more of their health, environmental, fishery, or agricultural departments. States generally tend to adopt federal regulatory guidelines.

A primary role for the federal government is setting regulatory guidelines designed to promote inspection and enforcement activities both within and outside formal governmental programs. Existing regulatory guidelines can be divided into (1) those designed to reduce acute risk from microbial and natural toxin contaminants, and (2) those designed to reduce long-term or chronic risk due to chemical contamination. Guidelines for microorganisms and natural toxins are determined solely by the FDA and have been set primarily on an as-needed basis, that is, in response to a reported public health problem.

Properly collated and effectively presented guidelines could provide a strong basis for the production and supply of safe seafood. However, in several areas related to new processing techniques and other emerging problems, new guidelines seem both appropriate and necessary. Setting federal guidelines for residual chemical contaminants is a task shared by EPA and FDA. Their strategy has been to focus on a limited number of chemical contaminants and to set regulatory limits by means of "action levels." Results of various federal and state efforts to monitor contaminant loads in the nation's marine and freshwater environments suggest strongly that several chemicals require a more fundamental review and evaluation.

In terms of assessing and managing risks, the overall posture of relevant federal agencies, particularly FDA, appears to be almost totally reactive. In the committee's judgment, there has been less effort than would be desirable to discover and quantify hazards that are not yet on the public agenda, to evaluate options for reducing risks, and to implement policies that protect both the health of consumers and the stability of commercial markets.

One of the more important activities at both the federal and the state levels is environmental monitoring. Because the majority of seafood is from wild stocks, the quality of harvesting waters is of fundamental concern. The EPA and certain state governments [primarily by way of their involvement in the National Shellfish Sanitation Program (NSSP)] have instituted programs to establish the level of contaminants in seafood harvesting waters.

These efforts have led to important insights into general water quality but, for the most part, do not supply sufficient information on the question of seafood safety. Among other things, they lack (1) sufficient geographic scope, (2) a common methodological approach, and (3) sufficient focus on the edible portion of seafood in order to determine public health, as opposed to environmental health, impacts. This last point is an important one. Except for the monitoring of harvesting waters carried out as part of the NSSP, data evaluating contaminant levels in fish and shellfish do not consistently focus on the analysis of edible tissue. More often the focus is on whole fish or on liver and gallbladder analysis. These analyses, by their design, offer insufficient insight into contaminant levels in the edible portion of seafood products.

Inspection efforts by FDA and various state and local public health agencies are designed to ensure safety, but are insufficient to ensure in all cases that the regulatory guidelines defined by FDA and EPA are not being exceeded. The sampling strategies employed by these various agencies are designed to focus inspection and enforcement activities on areas in which the probability of a problem appears highest. Ongoing governmental efforts to develop new inspection programs, with a focus on the public health aspects of the raw product and the environment from which these products are derived, along with continued control of seafood production and processing, could provide measurable additional benefits in seafood safety.

Given many of the intrinsic attributes of seafood already discussed, it is clear that an approach recognizing the advantages of regional/local control and surveillance is essential. The question of seafood safety should continue to be one in which federal and state roles are viewed as a cooperative partnership. It is also apparent that seafood commerce is taking place within an increasingly interdependent international economy. Many of the major trading partners of the United States are developing or further refining formal regulatory programs for seafood safety. These efforts should be taken into account in designing a domestic program.

Principal Conclusions

- Federal (mostly FDA) guidelines for microbial and natural toxin contamination should be extended and updated. Those that exist have not been adequately conveyed to the fishing industry and to interested members of the public.
- Federal guidelines on chemical contaminants in seafoods are limited in scope and, in some cases, questionable as to the levels set. There is an apparent lack of coordination in the development and use of data on chemicals in the aquatic environment among FDA, EPA, the National Oceanic and Atmospheric Administration (NOAA), and the states. Better recognition is required of the importance of regional factors in the occurrence of toxic fish and shellfish and of the existence of high at-risk groups (e.g., pregnant women, children, recreational and subsistence fishers).

- The present federal monitoring and inspection system is too limited in frequency and direction to ensure enhanced safety of seafoods. The monitoring process depends too much on evaluation of the product, rather than on safety of raw materials, with the single notable exception of the NSSP. However, even NSSP is not providing adequate protection because molluscan shellfish appear to cause most seafood-borne disease.
- Recreational and subsistence fishing is largely ignored in health and safety monitoring at the federal level. Consumers of seafood from these sources can be at high risk from natural toxins and chemical pollutants in certain regions and in particular species of fish. The health risks include cancer and the subtle impairment of neurological development in fetuses and children.
- The present system of data collection on seafood-borne illness by CDC does not provide an adequate picture of the extent and causes of such disease.
- Seafood advisories warning of local or species-associated health risks are issued mostly by state authorities and vary greatly in both their content and their distribution. Nevertheless, these advisories serve a useful purpose.
- Because of the regional nature of much of the domestic fisheries problems, states seem the logical level at which to tackle seafood control problems. However, help and guidance from the federal level are required.
- State programs for monitoring, surveillance, and control of seafood safety are generally in place in coastal states that use federal guidelines and action levels where these are available. However, the quality and effectiveness of the programs vary greatly as a function of the financial and administrative support available to the responsible state units, and in accordance with the character of the resource. A greater emphasis should be placed on the development of formal arrangements with foreign producers to guarantee that imported seafood has been harvested and processed in noncontaminated environments.
- Present training and education of industry and regulatory personnel are too limited both in scope and in number. Insufficient attention is given to the education of physicians and other health professionals on seafood safety and the characteristics of seafood-borne disease. This is also true of the consuming public.
- The regulation of imported seafoods to ensure safety is largely based on end product inspection and testing, except where MOUs exist. This is ineffective because it involves a mainly reactive process.
- The regulation of imported seafood products is carried out largely without regard to other national or international programs. There is tremendous variance in both regulatory limits for contaminants and inspection protocols in various countries, which leads to excessive and cumbersome inspection strategies for the importing state, and may also lead to a general reduction in the number of countries engaged in international seafood trade in the future.

Principal Recommendations

- A more concise, comprehensive, and generally available single source for all FDA guidelines relating to seafood safety should be developed and updated on a regular basis. This information should be disseminated to industry and integrated into state regulatory processes through more routine and uniform training programs.

- The development of an interagency structure with a single focus on seafood safety could contribute significantly toward increasing communication within the federal regulatory system, but the responsibility for primary control should be with the state.
- Federal agencies should develop a set of monitoring and inspection practices focusing more strongly on environmental conditions and on contaminant levels in the edible portion of seafood at the point of capture.
- Strong consideration should be given to creating a marine recreational fishing license system that is linked to the distribution of information characterizing the level and scope of potential risk from eating recreationally caught fish. Strong consideration should also be given to the closure of recreational harvest areas deemed to pose a threat to human health.
- The CDC should develop an active and aggressive program, founded on community-based health surveys, to better determine the level and source of seafood-borne illness in the U.S. population.
- Consideration should be given to the development of agreements with foreign authorities and individual producers to ensure that imported products are treated in a manner consistent with and equivalent to domestic products.
- A more pronounced and consistently defined federal role in the risk characterizations leading to seafood health advisories should be developed. A more consistent and focused effort in determining and communicating public health risks from contaminated seafood should also be developed.
- As more countries require the equivalency of domestic and imported products, it is apparent that the time has come for the international community to begin a process that would minimize the differences existing among national regulatory guidelines and approaches.

OPTIONS FOR REDUCING PUBLIC HEALTH RISKS

Monitoring, Control, and Surveillance Measures

The current system involves (1) surveillance by federal and state agencies to identify seafood-borne disease (e.g., CDC and state health departments); (2) evaluation of risk and setting of guidelines and action levels mostly by federal agencies (e.g., EPA and FDA); (3) control of risk by inspection and testing of edible fish and shellfish (e.g., states, FDA, and NMFS); and (4) action to protect consumers by embargo, detention, seizure, or recall, and by issuance of warning advisories (e.g., states and FDA). This system needs revision and strengthening to develop a truly risk-based regulatory process.

The data base on which regulation depends is inadequate. The disease surveillance system of CDC suffers from inadequate resources and should be refocused to provide a more complete and balanced account of seafood-borne disease. More analytical data on contaminants are needed, which could be obtained by increasing FDA analyses and sponsoring broader integrated studies of marine and fresh waters by EPA and corresponding state agencies.

Inspection and testing should focus on actual problems (as in HACCP systems), and there should be increased efforts to develop rapid, reliable test methods for dangerous microorganisms, toxins, and contaminants. This will require a restructuring

of inspectional systems to accommodate newer methodologies and to train personnel in their application. Emphasis on purely sensory evaluation should be decreased.

Problems of interagency jurisdiction, unclear regulations, or poor cooperation among state and federal agencies should be addressed and rectified. This will require added resources.

Characteristics of Control Requirements

Control measures should be applied initially at the earliest stage of seafood production by monitoring of water quality and condition. Such measures would apply to the molluscan shellfish problem and to most natural toxins and chemical contaminants, and would permit the exclusion of potentially dangerous fish or shellfish from markets by fishing closures and use of advisories. Rapid and simple tests should be developed and used to screen potentially hazardous fish or shellfish at the point of harvest to reduce costs to the fishermen and to protect the consumer from toxins and dangerous contaminants. Postharvest control seems likely to be most readily achieved through an HACCP-based system focusing on cross-contamination, temperature control, and the effectiveness of handling and processing methods designed to inhibit or destroy microorganisms. This system must be based on safety considerations, not solely on quality.

The extent of chemical contamination of seafood species is both species and region dependent. A few chemicals such as mercury have strong species associations (e.g., swordfish). The concentrations of most organic chemicals tend to be less species associated and more dependent on geographic region. Within aquatic organisms, bioaccumulation may be organ specific or related to fat concentrations (e.g., methylmercury in muscle tissues and PCBs in fatty tissues).

Improvement of the total data base on chemical contamination of fish could enable regulatory agencies to target their efforts on particular species of fish in specifically defined areas and, thus, lead to considerable mitigation of individual and societal health risks with minimal economic effects. Improvement of the data base could also enable consumers, especially subsistence and sport fishers, to select the least toxic fish in their waters for consumption. Clearly, however, chemical contamination is ultimately a problem of environmental degradation due to waste dumping that can be solved only by the development of systems to reduce chemical disposal in fresh and marine waters and in the atmosphere. The improvement of environmental quality will mean safer fish.

The effectiveness of current fishing controls and consumer/fisher information programs in geographic areas with greater-than-average contamination problems is uncertain. Unfortunately, contaminated areas may be pocketed within broader fishing grounds, and the precise distribution of relatively high residue levels may be difficult to determine. In areas such as the Great Lakes, steps have been taken to prevent the commercial distribution of fish that have contaminants exceeding established tolerance or action levels. However, the adequacy of some regulatory levels is open to question in light of newly available information (see Chapter 6), and the degree of protection afforded the substantial population of consumers of sport caught fish by advisories based on those tolerance/action levels is even more doubtful.

Better control is needed of imported fish products, which represent over half of the fish and shellfish consumed in the United States. Seafood imports are coming from an increasing number of countries, some of which have poor internal control systems. A significant number of supplier countries are in tropical areas where some bacteria and toxin hazards are intrinsically high. Additionally, the United States is receiving increasing numbers of fish and crustaceans from foreign aquaculture operations (see Chapters 2 and 8). In view of the often regional and species-associated nature of seafood hazards, it would be appropriate to classify suppliers into risk categories for particular species or processed seafoods. Consideration should be given to extending the scope of MOU arrangements to cover all seafoods, and unfettered import of seafood products should be permitted only from countries with whom the United States has MOUs. Testing of imports for chemical residues should be carried out systematically according to a planned program designed to provide long-term estimates of the level of contamination in particular species or in the products of different supplier countries. In view of the very complex structure of international trade in fishery products, it is desirable that a better system be established to identify the country of origin of imported seafoods. This may require international agreements.

Legislative Considerations

Education and Information Measures

Programs should be established for training regulators and seafood industry personnel to be proficient in the regulatory programs under consideration. These programs should be well-coordinated across states, with more national guidance and increased consideration of the unique attributes of various geographic regions.

States should be required to produce advisories that can be used by both commercial and recreational personnel to learn about local public health risks and protective measures. In the development of advisories for reproductive effects, due weight must be given to the persistence of different toxicants in people. A useful federal function, besides producing advisories to meet national problems, would be development—with the states—of a standardized format for written and broadcast advisories so that there will be minimum confusion due to state and local differences.

Educational programs for safe preparation and service of seafoods in commercial and home settings must also be developed and delivered as a part of an integrated seafood safety program.

Recommendations for Improved Inspection Strategies

Inspection should continue to be based on shared responsibility between state and federal agencies. The general philosophy presented here involves the concept of a federal agency (or agencies) having responsibility for identifying and characterizing risks, establishing methodologies and acceptable or actionable levels of undesirable agents, and monitoring state inspection programs. In addition, the federal agency would continue to have primary responsibility for imported products and products in interstate shipment. The agency would establish well-equipped regional laboratories to conduct tests for the federal program and—where appropriate—for state agency

programs. States, with the financial support of federal sources, would carry out inspections and apply police powers to in-state fishing industry operations, by using methods and procedures that meet or exceed federal standards. Monitoring and certifying state programs to determine their eligibility for federal funding of such operations would be the responsibility of the federal agency. Results would include better use of state agencies and strengthening their role in inspection, rather than depending solely on a federal agency to perform nationwide inspection. The federal agency should have overall responsibility for coordinating the national program and carrying out those functions that states cannot or will not undertake, as well as ensuring the training of state personnel. Organoleptic inspection must be recognized as inadequate and of little value for seafood safety because it is unable to identify risks to humans.

Where new legislation is being considered in relation to the problems of seafood safety, the following important points should be considered: (1) the need to facilitate closure of harvesting areas on the basis of human health hazards, (2) the need for a strong state role in inspection that will require federal support, (3) the desirability of regulating vessels and dock facilities in relation to human health, (4) the collation of current regulations in easily available form, and (5) the need to train state and federal regulatory personnel.

POTENTIAL IMPACT OF PROPOSED OPTIONS

The proposed options outlined above will have the following impact on seafood and the consumer: (1) they will improve the general health of the public by focusing on the cause of disease, thus reducing the cases of seafood-borne diseases; (2) they will produce a quicker, more effective response when the public is subjected to unacceptable risks; (3) they will promote compliance through increased and improved communication among the involved agencies and industry, and through increased public knowledge; and (4) they will require the appropriation of funds to develop a comprehensive system incorporating the above recommendations.

DIRECTION FOR DATA COLLECTION AND FUTURE RESEARCH

Inasmuch as accurate risk identification is the first step in risk-based control programs, stronger epidemiologic data are needed to assess the extent of public health risk in terms of incidence, severity, vehicle, and setting. The two major viable data bases for seafood-borne illnesses from CDC and NETSU are too limited in scope and have discrepancies related to methods of surveillance and reporting that prevent consistent correlation of the outbreaks of some pathogens. In addition, more basic research is necessary to understand why and how certain pathogens or toxins cause illness. For example, there are bacterial pathogens, such as *Vibrio vulnificus*, or non-O1 *V. cholerae* that are commonly isolated from shellfish, that cause only a small number of clinical cases; we need to understand why only a minority of persons become ill after exposure to these organisms. Similarly, a better understanding is required of how natural toxins and chemicals are processed by fish, so that we can better predict when and where human illness will occur. Rapid, nondestructive, and

easy-to-perform tests for toxins, microorganisms, and chemicals [e.g., stick test for ciguatera, deoxyribonucleic acid (DNA) probes for specific viruses and bacteria, and instrumental chemical analysis] must be developed. The current programs for testing water and seafoods for potentially dangerous chemicals should be broadened to provide a satisfactory data base for regulation and control.

71-898 O - 93 (152)

ISBN 0-16-041479-2