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Part I

THE SAFETY OF FOOD IMPORTS

HEARING

BEFORE THE

PERMANENT
SUBCOMMITTEE ON INVESTIGATIONS

OF THE

COMMITTEE ON
GOVERNMENTAL AFFAIRS
UNITED STATES SENATE

ONE HUNDRED FIFTH CONGRESS

SECOND SESSION

PART I

MAY 14, 1998

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THE SAFETY OF FOOD IMPORTS

THURSDAY, MAY 14, 1998

U.S. SENATE,
PERMANENT SUBCOMMITTEE ON INVESTIGATIONS,
OF THE COMMITTEE ON GOVERNMENTAL AFFAIRS,
Washington, DC.

The Subcommittee met, pursuant to notice, at 9:33 a.m., in room SD–342, Dirksen Senate Office Building, Hon. Susan Collins, Chairman of the Subcommittee, presiding.

Present: Senators Collins, Brownback, Domenici, Cochran, Glenn, Levin, Akaka, and Durbin.

Staff Present: Timothy J. Shea, Chief Counsel/Staff Director; Mary D. Robertson, Chief Clerk; Stephanie Smith, Investigator (Congressional Fellow); Don Mullinax, Chief Investigator; Kirk E. Walder, Investigator; Lindsey E. Ledwin, Staff Assistant; Pamela Marple, Minority Chief Counsel; Beth Stein, Counsel to the Minority; Brian Benczkowski (Senator Domenici), Butch Burke (Senator Stevens), Michael Loesch (Senator Cochran), Steve Abbott (Senator Collins); Felicia Knight (Senator Collins); Kevin Mattis (Senator Specter); Carolyn Farris (Senator Brownback); Linda Gustitus (Senator Levin); Nanci Langley (Senator Akaka); Marianne Upton (Senator Durbin); Antigone Popamianos (Senator Levin); Scott Brady (Senator Cleland); Pat Souders (Senator Durbin); Melissa Merz (Senator Durbin); Nick Castro (Senator Durbin); and Kevin Mulry (Senator Durbin).

OPENING STATEMENT OF SENATOR COLLINS

Senator COLLINS. Good morning. The Subcommittee will please come to order. Today, the Permanent Subcommittee on Investigations holds its first in a series of hearings on the safety of imported food. This hearing is part of an effort launched last June by the Subcommittee to ensure that our food supply remains one of the safest in the world.

Food safety is a serious and growing public health problem in America. The General Accounting Office has reported that as many as 81 million cases of foodborne illnesses and more than 9,000 related deaths occur in the United States each year. The medical treatment and lost productivity resulting from foodborne illnesses cost us billions of dollars each year.

The safety of our Nation's food supply is something that we take for granted. Whether we shop at a corner convenience store or a deluxe modern supermarket, we expect the quality of our food products to be consistently high. We fill our grocery carts, assuming that the food we bring home to our families is tasty, whole-

some, and, most of all, safe. We have come to expect year-round availability of the fruit and vegetables that we used to enjoy only in the summer months.

Today, we live in a global economy where national borders are more open and where trade barriers have fallen. Free trade has helped fuel our economic expansion. However, with free and open trade comes the responsibility to protect that part of the food supply imported into our country.

Much of our food safety efforts in the past have focused on American products. Ensuring food safety, however, can no longer be achieved by focusing solely on domestic production and distribution. Foods can be contaminated at any point throughout the food chain, from the farm to the table. But in the case of imported foods, we must be especially vigilant because part of that chain exists outside the United States.

Recent reports have raised serious questions about the safety of some imported fruit and vegetables. In 1997, for example, over 200 students and teachers in Michigan developed hepatitis after eating frozen strawberries imported from Mexico. The imported strawberries also caused at least 29 cases of hepatitis in my home State of Maine.

Moreover, in 1996 and 1997, over 2,000 people were infected with Cyclospora after eating tainted raspberries imported from Guatemala. This was one of the largest outbreaks of foodborne disease in recent years. Once again, this outbreak reached the State of Maine.

In response to these and other disturbing outbreaks, last summer, the Subcommittee undertook an extensive investigation of the systems and procedures used by Federal agencies to ensure that the imported food that reaches American consumers is safe. To assist the Subcommittee in its ongoing investigation, I requested the General Accounting Office to examine the efforts of Federal agencies to ensure the safety of food imports. During our hearing today, the Subcommittee will hear the findings from that GAO review, which represent a serious indictment of the standard practices used by the Federal Food and Drug Administration.

The Subcommittee's hearing will focus on the following important questions. First, how does the increasing volume of imported foods affect the safety of the U.S. food supply? Second, are resources efficiently deployed by the agencies charged with ensuring the safety of food imports? Third, are the agencies charged with protecting our food supply effectively conducting inspections at ports of entry? And fourth, are sufficient controls in place to prevent unsafe foods that are detected at our borders from entering U.S. commerce?

Our markets are increasingly filled with imported fruit and vegetables. Shipments of imported foods have more than doubled during the past 5 years. In 1996, the United States imported $7.2 billion worth of fruit and vegetables from at least 90 different countries, an increase in dollar terms of 48 percent from 1990.

In January of this year, a typical American grocery store displayed for sale fruit and vegetables not only from the United States, but also from 28 other countries, and this trend will continue. The Federal Food and Drug Administration has projected

that imports of fruit and vegetables will go up by another 33 percent between now and the year 2002. Yet, despite the increasing volume, the FDA inspections of imported fruit and vegetables have declined sharply. Those two trends are shown on the chart that is displayed.[1]

The National Cancer Institute is encouraging us to eat at least five servings a day of fruit and vegetables. As Federal officials encourage Americans to follow this excellent advice, the FDA and other Federal agencies responsible for food safety need to ensure that consumers can, indeed, have confidence in the safety of the food we eat. As more pathogenic organisms are showing up on fresh produce and as consumers become more aware of the serious consequences of foodborne illnesses, consumers are looking to the government to better protect our food supply.

The safety of food imports is literally a life and death issue for many Americans. The most vulnerable are the very young, the very old, and the very ill. As the vast majority of our food supply is safe, consumers obviously should not stop eating fruit and vegetables. However, the import inspection system must be improved so that consumers are protected from the risk of unsafe foods, particularly when contamination often is not detectable to the average consumer.

Finally, let me emphasize that this hearing is the Subcommittee's first step in shedding light on the weaknesses in the Nation's food import system. We will be holding three other hearings later this year. I want to make sure that our current programs are being effectively managed and that resources are focused on those imports posing the greatest risk. American consumers deserve no less than the safest possible food supply.

We will hear this morning from three witnesses. Dr. Mary Ellen Camire, Chair of the Department of Food Science and Human Nutrition of the University of Maine will discuss the seriousness of foodborne pathogens associated with imported foods.

We will then hear testimony from Robert Robertson, the Associate Director for Food and Agriculture Issues for the General Accounting Office. He will testify about the weaknesses in the current food import system discovered during GAO's recent examination.

Reggie Jang, a former FDA consumer safety inspector, will be our third witness this morning. He is awaiting sentencing on Federal bribery charges related to his FDA job. With almost 36 years of experience as an FDA inspector, Mr. Jang will discuss his firsthand knowledge of inspecting food imports.

We look forward to hearing from these witnesses this morning and to exploring ways to improve the food import system.

It is now my pleasure to recognize the Ranking Minority Member of the Subcommittee, the distinguished senior Senator from Ohio, John Glenn, for any statement that he may have.

OPENING STATEMENT OF SENATOR GLENN

Senator GLENN. Thank you, Madam Chairman, very much. I do welcome this hearing this morning. I want to thank you for your

[1] See Exhibit No. 1 that appears in the Appendix on page 64.

role in setting up this hearing to investigate this very important matter of food safety.

In the past 10 years, as you said, Americans have become much more healthy eaters. It all started off with our spouses giving us vitamins at the breakfast table and we hear over the radio, fruit, vegetables, grains, and beans, that is what you want to eat. You want to stay away from fat. That is bad. Do not plug up your arteries, and all this stuff. We are much more health conscious now than we were just a few years ago. There probably is not a person in this room that does not know what their approximate cholesterol count is. We are very much more tuned into health matters.

We now want to be healthy eaters, and so we are consuming more fresh fruit and vegetables than ever before. Unfortunately, the farmers in this country are not keeping up with all that. We get so much of our produce from California, Florida, and other States, but we cannot grow enough fresh fruit and vegetables to really keep up with all of our demand completely, especially during the winter months. So, as a result, we are importing more fresh foods from other countries than ever before.

We do insist that imported meat and poultry adhere to rigid U.S. safety standards, but there are no equivalent standards for other imported foods. In other words, we do not really know whether vegetables and fruit from other countries have been grown, harvested and packed in safe and sanitary conditions.

I am increasingly concerned with the speed with which new diseases are developing and showing up in our food supply. In my home State of Ohio, several hundred people have reportedly been seriously ill for weeks as a result of eating fruit contaminated with the parasite Cyclospora, and I think we will hear more about that later this morning.

Two years ago, I had never heard of Cyclospora. I did not know there was such a thing. I do not know how new it is or whether it has been around or whether it just immigrated into this country, but I had never even heard of Cyclospora, and yet, here it is and several hundred people are sick with it. There has never been an outbreak in the United States, as I understand it.

I want to emphasize that we do not want to scare people to death. The majority of our food in this country is safe and government agencies charged with overseeing food inspection work hard to keep it safe. But are we doing enough and are the standards enough, or what the inspectors have to work with in the ways of laws that really protect our people, are they adequate? That is what we have to address, also.

I want to thank our Chairwoman for bringing this issue to the forefront. I hope we can enact legislation to ensure that all food, not just most of it, but all food eaten by American consumers, whether imported or domestic, has to come up and meet the same rigorous standards. There cannot be dual standards, one that is less for imported food and higher for what we have in this country.

I look forward to hearing from the witnesses today about ways we can work to ensure the safety of our food. Thank you very much.

Senator COLLINS. Thank you, Senator Glenn.

Senator Durbin has also been a leader in this issue and I would call upon him now for any opening statement that he might have.

OPENING STATEMENT OF SENATOR DURBIN

Senator DURBIN. Thanks, Senator Collins, and thank you for having this hearing. Food safety is an issue that I got interested in about 10 years ago when I was serving in the House of Representatives on the Agriculture Appropriations Subcommittee, which was responsible for the USDA and the Food and Drug Administration.

I think one of the most educational trips that I have ever taken as a member of Congress was when I spent a day in Nogales, Arizona, at the border and watched the actual inspection process. I watched a sample being taken by an FDA employee and then I followed that sample into the Los Angeles laboratory. It arrived the next day. I learned more about the process of how it works by just being there firsthand than I could have ever possibly learned in the course of a hearing.

There were some real eye-openers 10 years ago, and I am anxious to find out from the FDA how many of them have changed. The man who took the sample in Nogales, Arizona, was a retired individual who came to work on a bicycle. This was a part-time job. He knew everybody, including the truckers as they came through, and he took the sample. He put it, as he was supposed to, appropriately, in the brown paper bags and then took it off to be shipped by bus to Los Angeles. Congress had cut the money for shipments of the samples by airplane. We decided we could not afford that any longer.

Well, the problem, of course, is obvious. By the time the sample reached Los Angeles, the food had already reached the market somewhere, and if there was something wrong with it, the best the FDA could do was hope that they would catch it the next time around. That is the system that was in place then and I am anxious to find out if it has changed much.

Incidentally, that FDA laboratory in Los Angeles was a mess. The ceilings were falling down. There was inadequate equipment. I left there really concerned about it. I think there have been substantial improvements since then in new headquarters and in new equipment, which are certainly long overdue. The condition of labs, I think, is part of this, as well.

There is no doubt that there has been a dramatic increase in the import of fruit and vegetables in this country. Walk into any produce section of any grocery store in America and look at what you see and compare that to what you might have seen 20 years ago. Our appetites are so diverse now. We want to try everything, and the produce department tries to offer everything. We do not grow everything in America, so they bring it in from countries all around the world.

But the interesting thing is, as the imports of fruit and vegetables have increased dramatically, creating a lot of health challenges, we have not met our obligation on Capitol Hill to provide the Food and Drug Administration with the resources to keep up with this flood of imports of fruit and vegetables. I think that this hearing is going to pinpoint that and really show that not only does

the FDA have the responsibility to inspect, but Congress has a responsibility to provide the resources so that FDA can inspect.

As I look at some of the statistics that we have here before us, it is troubling to see all of this outbreak of illness that is related to fruit and vegetables. I know that there are other food products that are equally dangerous. I want to emphasize, as the Chairman has, that we are blessed with the safest food supply in the world, but we can do a lot better. Let me suggest a couple of areas where we can do better.

First, this recent GAO report recommends the formation of a single food inspection agency for the United States of America. This radical idea was proposed in 1994 by Vice President Gore, and I have introduced legislation, the Safe Food Act, S. 1465, to replace the fragmented Federal food safety system with a single, consolidated, independent agency with responsibility for all Federal food inspection.

Currently, there are 12 different Federal agencies and 35 different laws governing food safety and inspection functions. With so many bureaucrats in the kitchen, it is no wonder that breakdowns occur. Overlapping jurisdiction, Federal agencies without accountability, and resources that are wasted are just inexcusable. A single independent agency that will focus our policy and improve the enforcement of food safety inspection is really overdue.

Let me give you an example. Typical was this case that was cited by the Chairman of the outbreak of hepatitis A attributed to strawberries suspected of being of Mexican origin. Now, which Federal agency was going to take a look at these strawberries? Well, strawberries are regulated by the Food and Drug Administration, except in this case, because these strawberries were headed for the school lunch program, the U.S. Department of Agriculture also had jurisdiction. Dueling agencies, is that a good idea? I do not think it is. I think it is a waste of resources and something we can certainly do something about.

Consider eggs. An egg in the shell is under the jurisdiction of the Department of Agriculture. A broken egg falls within the jurisdiction of the Food and Drug Administration. A pepperoni pizza, Department of Agriculture. Cheese pizza, the Food and Drug Administration. Go figure. This is how the laws are written in America and they do not make sense. It is time for us to change them.

Let me also say that the limitations on the Food and Drug Administration need to be examined. The Food Safety Inspection Service of USDA has the authority to require exporters of meat and poultry to the U.S. to have systems equivalent to ours. The Food and Drug Administration does not have this authority. It allows food imports from almost any country and takes on the burden of ensuring the safety of imported foods only as they arrive in the United States.

In 1997, about 2.7 million imported shipments of food were received in the United States. The FDA inspected 1.7 percent of those shipments. In 1997, administration initiatives on food safety proposed the FDA be given equivalency authority, like the Department of Agriculture. Senator Mikulski introduced S. 1707, which would achieve this, and I think it is a good thing for us to do that.

As we see more and more imports, we have to ask whether the system is on overload. According to GAO, in 1997, the number of import entries per USDA inspector was approximately 1,645. Contrast this with the Food and Drug Administration. The average number of annual food shipments per FDA inspector was approximately 10,555. Is it any wonder that they are missing things? I think, frankly, that we have got to give them the resources and the legal authority and then hold them accountable for exercising that authority properly.

I am glad the administration has stepped forward in enacting HACCP, a new standard which, frankly, will bring food inspection in the United States into the 20th and 21st century. I think this is something that has to be done with the cooperation of both political parties and all agencies of the Federal Government.

The legislation I have introduced to consolidate agencies is not about more regulation, it is about effective regulation, lower costs, and clearer goals. To mangle a metaphor, let us step up to the plate together and make sure it is safe to eat what is on it. Thanks.

Senator COLLINS. Thank you, Senator Durbin. Senator Levin.

OPENING STATEMENT OF SENATOR LEVIN

Senator LEVIN. Thank you, Senator, Collins, for your leadership, for calling this hearing to discuss a very, very critical issue, which is the safety of imported foods and also the GAO's findings on the adequacy of our Federal Government food inspection efforts. I commend the GAO for its thorough and its well-reasoned report and look forward to their testimony.

Ensuring the safety of this Nation's public food supply, whether domestic or imported, must be a top priority for our government. In February, I introduced the Safe Food Plan Act to emphasize food safety in the Department of Agriculture and to create a food safety rapid response team within the agency to react timely to food safety crises. Some important features of that bill, including the establishment of the FEMA-like crisis management teams to respond to foodborne illness outbreaks, are incorporated in the Senate bill that we just passed, S. 1150, the Agricultural Research Extension and Education Reform Act of 1998.

Based on the studies that I have seen, including this GAO report, our laws have big gaps, the remedies that are in the existing laws are woefully weak, and our enforcement is understaffed, given the huge increase in imported food. We have to reevaluate our inspection schemes for imported foods in light of the statistics which Senator Durbin and others have given showing the huge growth of agricultural imports to the United States.

CRS estimates that over 33 million Americans get sick each year from cases of foodborne illness, with over 9,000 deaths resulting from those same cases of foodborne illness. The case of Lindsey Donneth in Michigan comes to mind. She attends school in Marshall, Michigan. Her mother, Sue Donneth, testified before this Committee in February, relating the incident in which her daughter, as well as hundreds of other Michigan school children and teachers, contracted hepatitis A from tainted strawberries that were imported from Mexico. They were part of a strawberry shortcake that was part of a school lunch program. While Federal law

prohibits the use of imported foods in the school lunch program, those strawberries somehow or other made it into the program.

Lindsey Donneth experienced a horrific reaction to the contaminated strawberries. She was hospitalized and she continues to have significant heath-related problems as a result of the incident.

In addition to the suffering and the other unquantifiable costs that are caused to victims, our Attorney General, Frank Kelly, has estimated that this single incident of tainted strawberries in our school lunch program cost my home State almost $1 million. That is the quantifiable cost, not the suffering and the pain and the loss, just the dollar cost to our State. Calhoun County's costs to combat this outbreak alone were $150,000.

So we have major problems here with our food, our food supply, and particularly our imported food, and I look forward, Madam Chairman, to these hearings and again commend you for the initiative which you and so many other Members of this Committee, our Ranking Member, Senator Glenn, and Senator Durbin and others have taken in this area.

Senator COLLINS. Thank you, Senator Levin. I know this is of great personal concern to you, given the outbreak in your home State.

Prior to this hearing, as Chair, I sent letters to 21 consumer and industry groups inviting them to provide written statements on the safety of food imports. As of today's hearing, not all of the statements have been received. The hearing record will, therefore, be left open for 10 days so that all statements can be printed in the record, and also, without objection and for the convenience of Members, all exhibits previously made available to the Subcommittee, including the charts that we will use today, will be made part of the hearing record.[1]

In front of us today is an assortment of imported fruit that the staff purchased last night at a Virginia supermarket.[2] Just to give you some idea in case the labels are not clear, we have fruit from Mexico, Guatemala, Dominican Republic, Ecuador, Belize, Costa Rica, South Africa, Chile, New Zealand, Turkey, and Thailand. I think that is very typical of what one finds in the marketplace nowadays.

Our first witness this morning is Dr. Mary Ellen Camire. Dr. Camire is the Chair of the Department of Food Science and Human Nutrition at the University of Maine and a recognized expert on food safety. She has testified previously before a House Committee as an expert witness on food safety.

She earned her A.B. degree from Harvard Radcliffe, a master's degree from the University of Massachusetts, and her Ph.D. from Texas Woman's University. She is the author of more than 20 scientific papers and four book chapters on food safety and we are delighted to have her here with us today.

Pursuant to Rule 6, all witnesses who testify before the Subcommittee are required to be sworn in. It is not that we do not believe you will tell the truth, it is part of our procedures. So I will ask at this time that you rise and raise your right hand.

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[1] Exhibits 1 through 19 appear in the Appendix beginning on page 64.
[2] See Exhibit No. 2 that appears in the Appendix on page 65.

Do you swear that the testimony you are about to give the Subcommittee is the truth, the whole truth, and nothing but the truth, so help you, God?

Ms. CAMIRE. I do.

Senator COLLINS. Thank you.

Unfortunately, Dr. Camire has been stricken with laryngitis, so we will do the best that we can, and if you need more water at any point, please just motion the clerk. Senator Glenn asked whether it is a result of a foodborne illness from imported food. [Laughter.]

Please proceed, and bring the microphone as close to you as possible and speak right into it. Thank you.

TESTIMONY OF MARY ELLEN CAMIRE,[1] ASSOCIATE PROFESSOR AND CHAIR, DEPARTMENT OF FOOD SCIENCE AND HUMAN NUTRITION, UNIVERSITY OF MAINE

Ms. CAMIRE. Thank you. First of all, I would like to thank Senator Collins for inviting me to speak today and for bringing this important issue to the forefront.

My name is Mary Ellen Camire and I am Chair of the Department of Food Science and Human Nutrition at the University of Maine. I think food safety is a concern for many Americans today. I would like to give you an overview of the problem of the safety of foods brought into our country, first looking at some of the more serious pathogenic disease-causing microorganisms that have been found in foods and then addressing some things that could be done to address these issues.

Most of the pathogenic microorganisms that are found in foods are really spread by contact with feces. It is not a very appealing thought, but contact with feces is pretty much the only way you can contract a foodborne illness. Human feces are the highest risk because human diseases are more easily passed, but animal feces also contain a number of pathogenic microorganisms that can also cause human disease.

When we import foods from less developed countries, they may have untreated sewage. This contaminates the drinking water and it also contaminates the water used to irrigate fields and wash produce in processing areas. When tourists are advised not to drink the water, we do not stop and think that they are using this same water to wash the foods that are then shipped to our stores.

We also have a problem with sewage that is discharged into the ocean in these countries, that oysters and clams and mussels, shellfish, filter seawater, and in filtering the seawater, they concentrate these microorganisms in them, and when you go to eat them, they are just full of the bacteria and viruses.

The problems with sanitary conditions in farm fields have been a major hazard. One of the ways to reduce this risk is hand washing by farm employees. This is not particularly easy to do. Portable toilets may be available to workers, they may not be, but since farm workers are paid by the piece, they do not necessarily want to take the time to go to the portable toilets and use the sanitation facilities there. They may or may not have hand washing. They lose time, and time is money, so they tend to just go right there.

[1] The prepared statement of Ms. Camire appears in the Appendix on page 47.

Contamination from animal feces is a major problem, that farms create huge piles of manure that they will eventually use for fertilizer. When it rains or there are floods, the manure will spread out over the farms and contaminate the produce.

You also have a problem with cats and farm animals and even wild animals walking through the fields and spreading. We have found deer and wild birds' feces contain many of the microorganisms that give us illnesses.

The first microorganism I would like to discuss is Cyclospora. Previously, this microorganism had only been associated with drinking water. In fact, we only really heard about it in the 1980's, so Senator Glenn was correct. We did not know about this microorganism until the 1980's. No one heard of it. Previously, it was only found in remote areas in the drinking water. If you went hiking, you may contract it.

Guatemalan raspberries were associated with the 1996 outbreak that made almost 1,500 people ill in 20 States. Cyclospora produces a very violent form of diarrhea, with fever, cramps, vomiting, and other unpleasant symptoms that occur within a week of ingestion. Although it can be treated to some extent with antibiotics, it is not a bacteria, it is a parasite. There is a possibility for fatal dehydration to occur in very young children and very elderly patients.

There is not a simple test for this parasite. You can screen patients and examine their feces for this microorganism, but you cannot test food for this microorganism. There is not an easy way. If a worker has this disease, there is no easy way to test them other than collecting a fecal sample, and we are not really sure right now of the effects of processing, such as freezing and canning and blanching on Cyclospora. We do not know if the microorganism survives the freezing process.

Another microorganism that has been associated with imported foods is hepatitis A. FDA has classified hepatitis A as a serious food hazard. It can survive in the environment or on food surfaces for many weeks, is resistant to drying and heating, and these are two of the methods we use to preserve foods.

Hepatitis A is also spread through feces. Contaminated water as well as food transmit the virus to the small intestine, and then it goes from there to the liver, and then it goes into the blood stream. You only need 10 to 100 particles to produce an infection.

What happens with shellfish is that they will filter this in the ocean. Sewage is discharged in the ocean. It is easier to collect the shellfish close to shore, where the sewage is discharged, and they concentrate the virus. They are harvested, they are shipped to market, and they are full of the virus.

Strawberries and salad greens have also been identified as sources of contamination, and these require a fair amount of handling. The strawberries must be hand picked and then they are put in the boxes. So every time someone touches a berry, there is a potential of contaminating that berry with hepatitis A.

Salad greens also must be hand collected and then washed, and there is a big trend now with the baby greens and the more exotic greens, and those require, again, more hand contact, which increases the risk of contamination. Mechanically harvested crops,

where you have a machine shaking the product onto a basket, poses a much lower risk.

Hepatitis A is like other viruses, such as chicken pox, in that once you have been exposed to it, you get an immune response and that gives you immunity against repeated infection. In these other countries, it is a common childhood illness. In Mexico, inspectors went from the Centers for Disease Control. Farm workers in the suspected farms were not sick. Yes, they had hepatitis in their system, but they were not obviously sick because they had had it as young children and developed immunity. They did not get sick from it again.

It is fairly mild in children. Just remember, chicken pox is always worse when you have it as an adult. It is the same thing with these other viral illnesses. It is just milder for children, that virtually all children in less developed countries can be exposed to this and they develop immunity.

In 1997, over 150 people in Michigan became ill from eating these frozen strawberries which were processed in California. They were distributed in six States, but other States, including Maine, received these berries. In California, the children were immunized as a precaution. The company paid for the immunizations. They needed to have two immunizations and there was a cost of approximately $100 per student for the immunization.

There are several forms of hepatitis, but another form that may be a problem in the near future is hepatitis E. This is an emerging disease in Asia, in Africa, and Mexico. This is also spread through the fecal contamination of water and I anticipate that this could be another foodborne illness in the near future, and this is one for which we have no immunization available.

A bacterial form of food poisoning that we will see is salmonella. I think more people are aware of salmonella poisoning. This is a traditional church picnic type of food poisoning. The typical symptoms include vomiting, nausea, diarrhea. It is sort of acute. You get it within a few days or maybe a few hours of eating the food. The bacteria also can go into the blood stream and cause severe infections, particularly in the elderly and in individuals who already have another disease.

There are several species of salmonella. Salmonella enteritidis is one that we are seeing more and more associated with eggs and poultry. This causes a severe infection, but we also see one that causes what we used to call in the old days typhoid fever, and that is salmonella typhi. This has a fatality rate of 10 percent. So 10 percent of the people who contact this disease will die from it. For most salmonella species, it is only 1 percent.

People are familiar with salmonella, but I do not think they realize the potential for fatalities. The elderly are very susceptible to fatalities for any of these salmonella infections. People in nursing homes and hospital patients are particularly at risk because they may already have other illnesses which have weakened their immune systems and they cannot fight back.

Two large outbreaks of salmonella were traced back to cantaloupes imported from Mexico in 1989, in 1991, and there were several deaths associated with those outbreaks.

One of the particularly insidious things that occurs with salmonella infections is chronic conditions. My youngest brother contracted salmonella when we were children, and I can tell you, it is not a pleasant thing to do. If you do not die or have chronic symptoms, you have severe diarrhea and you almost wish you were dying at some point.

Many people, within a few weeks after the initial bout of the nausea and diarrhea is over, start developing a form of arthritis that sets in. Many bacterial infections will cause autoimmune disorders to develop, and for salmonella, we have traced this back to arthritis pain.

The final species I would like to discuss is E. coli, and particularly E. coli 0157:H7. E. coli is found in our intestines and there are very different strains that have developed in recent years. Two of these strains were associated with imported foods, but E. coli 0157 we are familiar with the Jack in the Box poisonings. This has been traced back to juices and sprouts and a variety of other food products. It has not yet been detected in imported foods, but American foods shipped to other countries have been identified as a source of this problem, so it goes both ways. American foods have also been fingerprinted as being a source of contamination.

I notice that my red light is on.

Senator COLLINS. If you have a few more comments you want to make, go right ahead.

Ms. CAMIRE. OK. I just have a couple more comments.

Senator COLLINS. OK.

Ms. CAMIRE. I believe that preventative measures at the farm level are the best precaution, that inspections are not effective because you cannot test every single shipment. In many of these pathogens, we have no effective way of measuring them in foods. So, therefore, inspection will not tell you anything. To go back to the farm, make sure that the farm, the processors are employing safe practices by the use of HACCP and other practices. It is, I think, the best protection to the American public.

In summation, I think without any further intervention, the outlook for foodborne illnesses from imported as well as domestic foods is not very good. New pathogens will continue to develop. Using science to plan screening programs to improve safety was efficient in terms of cost and manpower. We must remember that imported foods are not the only problem.

The American public has changed. Americans are more susceptible to foodborne illnesses. There are more individuals with HIV, who have been treated for cancer, had transplants, and more elderly people alive today. We must do more to educate them on how to protect themselves against foodborne illness.

As a resident of a State that has a very short growing season and relies heavily on imported food, I think it is time that we ensure the safety of imported produce, in particular. Thank you.

Senator COLLINS. Thank you very much, Dr. Camire. You have certainly succeeded in spoiling our appetites for the rest of the day. None of us will touch any fruit or vegetables. [Laughter.]

In all seriousness, I really appreciate your coming forward and helping us to understand the pathogens involved and just how serious this issue is.

We are going to have 10-minute rounds of questions now, so we will have the lights on for the Senators, as well.

As I mentioned earlier, my staff went to a local grocery store and was able to gather some imported fruit that you see before you on the table. Now, you are a trained scientist. You are an expert on food safety. Can you just by looking at this fruit, as you would in a grocery store, identify which ones are tainted or possibly contaminated or pose a risk?

Ms. CAMIRE. No. I could not tell you, just looking at them. No one could.

Senator COLLINS. So it is not realistic to expect the consumer to solve this problem. There is no way that the average consumer could tell whether or not these fruit are contaminated if you, a scientist and an expert could not, is that correct?

Ms. CAMIRE. Right. [Nodding head up and down.]

Senator COLLINS. Are there pathogens that could remain on this fruit or vegetables even if the consumer rinsed it and properly prepared the fruit or vegetable?

Ms. CAMIRE. There have been some studies. This is an area, in fact, that there has been very little research, but the research that has been done shows that simply rinsing, which is what most people would do, will not remove all bacteria.

And then you have a problem. You have got cut melons. If I was going to point out something that might be a risk, it would be those cut melons, because you cannot scrub them. If you have a whole watermelon, you can scrub the outside pretty well. That is what is going to be contaminated. But once somebody cuts it, you do not know how well they have washed the outside of that before they have cut the melon.

Senator COLLINS. So even if a consumer carefully rinses the vegetables and fruit that the consumer buys, while it is a good step to take, it is no guarantee that is going to make the vegetable or fruit safe?

Ms. CAMIRE. Correct.

Senator COLLINS. As we have mentioned earlier, the volume of imported fruit and vegetables has soared in the past 5 years and it is expected to increase even more in the future. Are there any unique risks that are posed by imports that we should be concerned about?

Ms. CAMIRE. I think, in particular, any of the crops that are hand picked, such as the berries and the leafy greens pose a particular risk.

Senator COLLINS. Is there also an issue here because of the sanitation methods in lesser developed or developing nations, that they may not be equivalent to what we are used to in the United States? You mentioned some of the hand picking and sanitation process and your belief that you really need to cure this problem at the farm.

Ms. CAMIRE. Yes. I think what I have seen from the cases in Mexico and Guatemala is that once the farmers realized what was going on, they were able to institute practices that made the food safer. But not all the farmers are aware of this. So if we do a top-down approach and ask the governments of each country to make sure that the farmers understand the practices and follow through

on them and provide adequate sanitation on their farms, I think that is a big first step in securing food safety from imported foods.

Senator COLLINS. Another problem posed by food imports is that American consumers may not possess the natural immunity to certain microbes that are common in developing countries. Is that an issue, and do you foresee that certain viruses or bacteria or parasites would pose particular problems to the American consumer because we have not tended to be exposed to them prior to the import of these fruit and vegetables?

Ms. CAMIRE. Yes. There are certain ones, like hepatitis, that you can develop immunity to certain viruses and some kinds of bacteria. But the parasites, like Cyclospora, Cryptosporidium, and Giardia, we are not sure yet. So it is possible once someone is exposed, they can develop immunity, but most Americans have not been exposed to it, other than these imported foods, unless they have traveled extensively. So as we import from more and more exotic locations, the possibility that Americans will be exposed to more exotic diseases is more likely.

Senator COLLINS. You mentioned in your testimony quite explicitly that some of the symptoms associated with foodborne illnesses are very serious. A lot of us tend to think of foodborne illnesses as being a temporary bout, perhaps, of nausea or diarrhea, but something that goes away. But are there some chronic illnesses that have been associated with foodborne pathogens?

Ms. CAMIRE. Yes, there are. There are a number of bacteria that have been associated with chronic health problems. Yersinia, shigella, salmonella, Campylobacter, and E. coli can lead to arthritis. Yersinia and giardia can cause a form of autoimmune thyroid disease. E. coli 0157:H7, streptococcus, and shigella can lead to permanent kidney damage. Toxoplasma, which many people associate with having cats and pregnancy, will cause birth defects, but can be also transmitted by food. And worm parasites, which is something no one really likes to think about, can cause permanent neurological damage. The worms, you eat them and they migrate to your brain. Actually, in some countries, that is the major form or cause of mental problems.

Senator COLLINS. You have mentioned also that the people in the United States who are going to be most vulnerable are the very young, people with compromised immune systems, such as someone who has gone through chemotherapy or an AIDS patient, and also the elderly. Are there any particular precautions that those vulnerable populations could take?

Ms. CAMIRE. I think it would be helpful for them to be warned to be sure to wash the food thoroughly, to cook it if at all possible, because cooking will reduce the risk for most of these pathogens. But encouraging people to eat healthy foods, fresh fruit and vegetables and fresh salads, and there is not too much you can do to a fresh salad to really reduce the risk other than rinsing it. So that is not help. But to let their caregivers know, perhaps, to substitute canned fruit instead of fresh fruit would reduce the risk.

Senator COLLINS. One final question for you. As we are increasing our reliance on imported fruit and vegetables, as a scientist, do you predict that we are going to see more outbreaks of foodborne illnesses?

Ms. CAMIRE. I do. I think we will be seeing more different types of species coming into our food supply.

Senator COLLINS. Thank you. Senator Glenn.

Senator GLENN. Thank you, Madam Chairman. I have a couple of questions and then I will turn the rest of my time over to Senator Durbin. I know he has a long list of questions.

I want to know how people can protect themselves against this. If you eat fruit or vegetables, let us say there is nothing contaminated on the outside, but let us say the fruit or vegetable grew in a contaminated soil. Just nature protects us, does it not?

Ms. CAMIRE. Yes.

Senator GLENN. The interior of that, the moisture inside, will be OK. In other words, if I have an orange that was grown in contaminated soil and I peel it and I do not get some of the contamination on with my hands, that fruit inside is OK even though it was grown in contaminated soil, right?

Ms. CAMIRE. Correct.

Senator GLENN. Well, then, things that we eat in their entirety, though, with the shell or whatever on it, like lettuce, or the exterior of it that we eat, can you protect yourself to some extent by putting this not only in water but a tiny amount of Clorox or something like that in to wash it? Can we do that with cantaloupes and melons and all sorts of things to kill whatever is on the outside? Just for people that may be watching this or possibly somebody who might even read the hearing transcript someday, what do they do? What is the ratio that they can use?

Ms. CAMIRE. I have not done it lately, but I believe it is about a tablespoon in two gallons of Clorox. It is not a lot. One of the concerns, however, chlorine is very effective in killing microorganisms, but there has been a lot of concern that the chlorine will also produce carcinogenic compounds, so it is sort of a no-win situation. But at this point, I would say that the risk of the microbes is worse than the risk from the carcinogenic compounds.

Senator GLENN. But could people use that and then wash the chlorine off in fresh tap water? How long do you have to leave it in to kill these little bugs?

Ms. CAMIRE. Oh, at least 10 minutes.

Senator GLENN. Ten minutes?

Ms. CAMIRE. Commercial enterprises in this country do that for the fresh salads.

Senator GLENN. Wash them well in about a tablespoon or two of chlorine per two gallons of water, about what you would fill up a sink with, I guess, put a couple tablespoons of Clorox in and wash them or let them sit in there for 10 minutes or so and then wash them off with tap water——

Ms. CAMIRE. Plus it may not taste as good.

Senator GLENN [continuing]. Because I do not think you want to drink chlorine. Would that be something people could use to protect themselves?

Ms. CAMIRE. Yes, and I think more and more people are, and to use a scrub brush will do a lot, because you have to physically remove them. But even a mild detergent, because a detergent makes it slippery and the bacteria cannot stick as well.

Senator GLENN. Is there anything besides Clorox or something like that? Is there any other thing as good in this regard?

Ms. CAMIRE. No. We have not found anything yet. Now, natural preservatives, salad dressings and fruit and jams will stay is because bacteria do not survive well in acid conditions. Unfortunately, the bacteria are mutating and they are becoming resistant to acid, becoming resistant to salt, they are becoming resistant to many of the anti-microbial compounds we put in to preserve foods. So we are running out of options.

Senator GLENN. I think my wife, Annie, is going to have to get a new bottle of Clorox because we are going to start using that at home, I think. [Laughter.]

I have just one other question. How does inspection of domestic products differ from inspection of imported products? Is there a major difference in the way they are inspected, or is it that we just do not do enough of them? Are they basically the same inspection?

Ms. CAMIRE. I am not really an expert on the inspection process, but I believe they are very similar. But the problem is, you cannot see these things on the food.

Senator GLENN. Are there any other things we can do at home? The fruit on display this morning looks great. I wanted to get a spoon and dig into this a little while ago and I looked over here——

Senator COLLINS. We would be glad to give them to you.

Senator GLENN. I do not think I will. We may want FDA to check them out first before we do that. That would have been a neat deal, too, to have FDA see which ones are contaminated here.

Is there anything else we can do at home besides just scrubbing or Clorox or things that protect us at home, because we are not going to stop eating these things.

Ms. CAMIRE. I think to make sure that you are keeping it cold, because cold will slow down the growth of most of these microorganisms and that will help it, not to go to the farm stand and buy it and then keep it in the car while you do your other errands, because that allows them to grow even faster.

Senator GLENN. Thank you. I yield the rest of my time to Senator Durbin.

Senator DURBIN. I yield to Senator Levin.

Senator LEVIN. Thank you both. I have a bill coming up on the floor that I have to manage. Thank you.

The Food and Drug Administration, as I understand it, does not have authority for these kinds of fruit and vegetables coming from countries to say they cannot come into the United States unless those countries have equivalent protections to the United States. Our Agriculture Department does have that authority relative to meats, but the FDA does not have that authority relative to fruit and vegetables.

Now, we have a whole list of countries here on the Chairman's list[1] and my question is this. Is there any reason why we, as a Congress, should not give to FDA the same authority to stop products from coming in, vegetables and fruit, which come from countries that do not have equivalent protections to ours that our Agri-

[1] See Exhibit No. 2 that appears in the Appendix on page 65.

culture Department has relative to meat coming in? Should we not do that?

Ms. CAMIRE. We should give them that authority. Obviously, we have not had any outbreaks of foodborne illness recently traced back to imported meats or poultry.

Senator GLENN. So is it working with meats and we ought to do the same thing with other imported food products?

Ms. CAMIRE. It is working with those products.

Senator GLENN. I think so. Thank you very much, and thank you, Madam Chairman.

Senator COLLINS. I am going to turn to——

Senator DOMENICI. That is fine. I was here late. Go ahead.

Senator COLLINS. Senator Durbin.

Senator DURBIN. Thank you very much.

Dr. Camire, you have given us a lot of food for thought. [Laughter.]

So we should scrub our watermelons, run our salads through a bleach process, and put the cantaloupes in the washer? I understand that we have to take it seriously, it is a serious subject, but it is quite a departure from what people ordinarily do in their homes and kitchens, and I take it that since this is your field, that this is a practice that you recommend?

Ms. CAMIRE. Yes. When I was in school, we never even considered these as being a problem. It was not a problem. You worried about meat, dairy products and eggs being sources of foodborne illness, not fruit and vegetables. So we are going to have to reeducate consumers on how to protect themselves. But I think a more effective thing is to make sure that we are getting safer food into the system.

Senator DURBIN. You have discussed a lot of—and forgive me, I am a liberal arts major, so hang with me for a minute here—you have discussed a lot of bacteriological-related illness, and there are other elements that are part of this. For instance, when I visited with the Food and Drug Administration, one of the things that they were looking for was the improper application of agricultural chemicals, the drift of pesticides and insecticides and other things from perhaps an apple orchard to strawberries or watermelons and the like, and that presents a whole different range of challenges, does it not?

Ms. CAMIRE. Yes, it does.

Senator DURBIN. Let me try to put this in a context, though. Let me give you a hypothetical. Let us assume for a minute that we took anything from this table, the grapes or whatever it happened to be, and brought it to you in your laboratory and said, is there anything wrong with this? Tell me, just in summary, how long would it take you to establish and come back to me and say, there is nothing wrong with it. We have tested it. We have tried everything we can think of that might be a danger to you as a consumer. How long would it take you to go through the procedures to reach that conclusion?

Ms. CAMIRE. First of all, we could not guarantee complete safety, but to look for specific pathogens in pesticides would take at least a week.

Senator DURBIN. So a week, but——

Ms. CAMIRE. By then, it would be spoiled.

Senator DURBIN. By then, it would be spoiled, but we would have to give you a clue going in. We would have to say, we suspect that there is something on these grapes that may be related to one of the things you mentioned, whatever it happened to be, and then you have a clue, and then, in the course of a week, you will be able to test it and report back to us as to whether or not it might pose a danger or not, is that correct?

Ms. CAMIRE. That is correct, and there is also no test available for many of the foodborne pathogens yet.

Senator DURBIN. So you need a clue, there are no tests available for some of the problems, and it would take you a week to do it if we had given you that clue. Now, what if you do not have a clue? What if you were an FDA lab and we have just handed you these grapes and said, are these safe to sell in America? How long would it take you to consider all the possibilities that might be dangerous to American consumers?

Ms. CAMIRE. In reality, it might take several weeks, because with the bacterial testing, you sort of grow the bacteria and then try to spread out and see what is in there, and some of these things just do not grow very well in the conditions that we have traditionally used for microbiology.

Senator DURBIN. So when we are dealing with perishable food and we want to be completely safe, the honest answer is, you cannot be completely safe.

Ms. CAMIRE. Correct.

Senator DURBIN. The second question I have to ask you is, what kind of equipment is necessary for you to go through this testing process? Again, forgive me for not remembering it, but when I went to Los Angeles to the FDA lab, after they have broken down the sample and ran it through this chemical test, they had a range of different chemicals they were looking for to see if chemicals had been improperly applied, and there was some sort of spectrograph, does that sound right?

Ms. CAMIRE. Yes.

Senator DURBIN. I cannot believe I remembered that. There was a spectrograph, and they would look for this range of chemicals to see. Now, give me an idea of the equipment necessary in a laboratory to test for the different illnesses and problems which you have told us about.

Ms. CAMIRE. For the microorganisms, it is not really sophisticated equipment. It is more traditional incubators and heaters, more supplies more than anything else. But then you also have to take steps to make sure that the staff do not get contaminated and you have to have special hoods that will keep the bacteria from blowing back. It is more protecting the staff than anything else.

But I would like to make a point. My concern right now, because we do a lot of pesticide testing in my department, pesticides, we are really not sure how dangerous they are. They may kill you in 20 years. Some of these illnesses will kill you in 2 days.

Senator DURBIN. Could you give me some kind of an estimate of what a well-equipped laboratory might cost today to be prepared to test fruit and vegetables and other food products that are coming in so that you could say with some reasonable scientific certainty

that products are safe for consumers? What are we talking about, a range, if you will? I am not going to hold you to an exact figure.

Ms. CAMIRE. I would say easily a half million dollars to a million dollars.

Senator DURBIN. And, of course, a lot of personnel who would also be involved.

Ms. CAMIRE. Yes.

Senator DURBIN. How many people would work in a lab like that usually?

Ms. CAMIRE. I would say at least a dozen, and the problem is, we are not training scientists fast enough to meet the demand.

Senator DURBIN. The reason I raise that question in that context is to give some indication of the challenge that has been placed before us as a Nation and whether we can meet it. I think from your testimony there is a serious question as to whether we can meet this challenge. If Americans want to continue to eat a variety of fruit and vegetables, many of them exotic and not indigenous to the United States—and, I might add parenthetically, we cannot assume everything grown in the United States is safe, but certainly those imported have raised a lot of concern—then you have kind of put it in a very important context for us.

There is a limit to what science can tell us. There is a limit to the period of time that science can give us the information and it be of any value while the fruit and vegetable is perishing. It is an expensive investment in terms of equipment and people for us to do this, and we are taking it beyond the context of a bunch of grapes that I have just handed you and putting it in the context of literally millions of shipments of imported fruit and vegetables coming into the United States.

I asked the staff to come up with some information about how Congress has been funding the activities here for food safety at the Food and Drug Administration. There is a line missing from the graph over there that would be interesting,[1] and that is the Congress' funding of inspectors for food safety during the same period of time. We have seen a dramatic increase in imports. We have seen a dramatic decline in inspections. We would also see that during this same period of time, the number of people that Congress has paid for to do this job has basically been flat-lined, that we have not seen any type of increase in personnel. I probably would see the same thing holds true when it comes to equipment in these laboratories.

So if we are serious about this and if we really want to give the consumers some kind of assurance, then we are going to have to make an investment to make that happen in terms of well-trained people, and in terms of equipment. I do not know if we are prepared to do that in the context of a balanced budget and tax breaks and whatever else we decide to spend our money on. I am not sure we are prepared to do that.

But I thank you for your testimony. It has been very valuable.

Senator GLENN. If you would just yield for one question.

Senator DURBIN. I would be happy to yield.

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[1] See Exhibit No. 1 that appears in the Appendix on page 64.

Senator GLENN. I have just one question. You mentioned the pesticides. Will the chlorine rinse neutralize those pesticides, because they can have a bad impact on their own. That would be a very much more complex chemical reaction, I guess, with the pesticides.

Ms. CAMIRE. No. In fact, if anything, it would probably be the chlorine would make the pesticides worse.

Senator GLENN. The what? Would you say that again?

Ms. CAMIRE. The chlorine would make the pesticides worse, if anything. But no, there is not too much we can do about neutralizing pesticides on the foods.

Senator GLENN. Do you want me to tell Annie to cancel that buy on the chlorine? [Laughter.]

You gave me a solution, then took it away.

Ms. CAMIRE. In the trade-off, those fruit and vegetables contain many phytochemicals that prevent cancer. So the chemicals in the foods themselves may protect against the pesticides, but there is nothing in the food to protect against pathogens.

Senator GLENN. Thank you.

Senator DURBIN. Thank you.

Madam Chairman, one last thing I would like to point out for the record, I asked for a history of the FTEs, the full time equivalent employees, at the Food and Drug Administration in the Food Safety Resources Section based on the amount of money appropriated by Congress. In 1993, there were 2,636. If you put it on this chart,[1] you can get an idea. During the period of time when the FTEs decreased from 2,636 in 1993 to 2,154 in 1997, food imports basically doubled. That is an 18 percent decline in the people doing the inspecting while the imports doubled. So if we are going to meet this obligation, it is going to be a substantial one, and I am glad that the Chairman of the Budget Committee is here to hear that. [Laughter.]

Senator COLLINS. Senator Domenici, that is your cue.

Senator DOMENICI. Yes. I wanted to come this morning to congratulate you, Madam Chairperson, for taking up this issue last June. Before anybody else was involved, you saw a problem, and I think before you are finished, something very constructive will come of this. My understanding is you started being concerned when we had the problem with Mexican strawberries, is that not correct?

Senator COLLINS. That is correct.

Senator DOMENICI. That was May or June of last year. I commend you for that.

For me, it is just a welcome reprieve to come down here and be party to a hearing like this. Where I have been the last few days, I wish on no one. [Laughter.]

Senator DOMENICI [continuing]. Trying to negotiate an ISTEA bill with the House with 3,000 special projects that they want. Excuse me. I did not know the TVs were on here.

Senator DURBIN. Now you are in trouble. [Laughter.]

Senator DOMENICI. Well, I have told them that, too, that I did not think that was a very good way to do business, but I might not win on that.

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[1] See Exhibit No. 1 that appears in the Appendix on page 64.

Let me ask, what makes a particular food product a high risk food?

Ms. CAMIRE. One that is handled a lot, like berries, that is hand picked. One that you cannot rinse very well, like a raspberry is very soft, so you could not scrub it, whereas an orange, you could scrub very well. And shellfish are a particular problem. I would not say the fin fish and crabs and things were quite as big a problem as the shellfish in terms of seafood. But certain crops, things that are low to the ground, it is easier for them to be contaminated with feces than bananas up in a tree.

Senator DOMENICI. I think you testified earlier that the country of origin labeling is not a food safety issue, in your opinion.

Ms. CAMIRE. No. I believe it is more of a consumer information. Many people want to buy American and not everybody realizes that we cannot produce those crops year around. We think California can do everything for us. But I do not think that necessarily there has been any indication to show that any of these outbreaks have been traced back, that every farm in that country has had that disease on its produce. It has been with respect to a few farms in each country. Therefore, knowing which country it is from, there may be farms that are following very good practices, but they get penalized as well as the bad farmers.

Senator DOMENICI. Thank you very much. I have no further questions.

Might I say to you, Dr. Camire, I am very pleased to hear you testify today and to note that you have chosen the profession you have chosen. We have an academic system in America that produces marvels in terms of what it excites people to do, and clearly, we need more people like you. I mean, you are off in your laboratory system, but you are able to share some very important information from time to time with your national policy makers. I am sure you do a lot of other good research and I commend you for that.

Ms. CAMIRE. Thank you very much.

Senator COLLINS. Thank you very much, Senator Domenici. We appreciate your tearing yourself away from ISTEA negotiations to join us. Feel free to stay as long as you can.

Senator DOMENICI. Thank you. Thank you.

Senator COLLINS. Senator Akaka, welcome.

OPENING STATEMENT OF SENATOR AKAKA

Senator AKAKA. Thank you very much, Madam Chairman. I want to congratulate you and commend you for having this hearing, because it is so important to the health and welfare of the people of our country. I also want to commend your staff for providing such good material for us. I know, too, that this will result in some changes that will help the people of our country.

Dr. Camire, I am sorry I did not hear all of your statement, but I was interested very much in this subject. I know Senator Durbin would be, too, because he has been to Hawaii, where we grow papayas, mangos, and pineapples, as well. Over the years, the latter years, Hawaii has not been able to compete because of the costs of labor, but we always feel that our quality is good. We are part of the United States, so we come under all the laws and policies that

dictates how you should treat fruit and vegetables. So whatever comes from Hawaii, I guess I would say, would be safe.

We have always been concerned about how foreign countries produce their fruit and vegetables and how they send it in to us. One concern that I have, and I think you mentioned it, was when it does come from a foreign country and we think it has been treated with pesticides, how do we or the people who handle food handle this? Do they just put it on a plate and send it to you to eat, or do they treat it somehow? Do they use chlorine? And who does this? Do the restaurants, the hotels, use a system of cleaning it up before it is served?

Ms. CAMIRE. It varies tremendously. Some of the importers will do some cleaning. Some of the processors will do some cleaning. But none is mandated, so it could come directly from the field in another country, directly to the grocery store and directly home to your kitchen table without any further treatment.

Senator AKAKA. I see. If they did treat it, one of the treatments is to use chlorine, is that correct?

Ms. CAMIRE. Yes.

Senator AKAKA. Do the restaurants, do you know, use chlorine to wash or clean vegetables?

Ms. CAMIRE. Some do, more and more. There is a concern about the taste, but they do use it. I think, unfortunately, a lot of people rely on tap water having enough chlorine and it does not have enough. But it is done to some extent in restaurants, though I do not think they do that industry-wide as a practice.

Senator AKAKA. If they do use chlorine, would there be any risk to the diners if they use chlorine to clean vegetables that are used in salads?

Ms. CAMIRE. There is a concern in California and in Europe that chlorine does produce compounds that are carcinogenic. But, as I say, I am looking at immediate risk versus a long-term possible risk, and in terms of the scientific-based risk assessment, I think it is more important to kill the microorganisms. I choose my poison.

Senator AKAKA. We are very, very concerned about this and that is why I commend the Chairlady here for having this hearing. It may be necessary that we should have policies or regulations that would require that vegetables or fruit that come from foreign sources can be cleaned before they are placed on the plate for diners. Thank you very much.

Senator COLLINS. Thank you very much, Senator.

Thank you very much, Doctor. We really appreciate you sharing your expertise with us today. Especially given your laryngitis, we very much appreciate your willingness to strain your voice in order to educate not only us but the American public.

I would now like to call forward our second witness this morning. He is Robert E. Robertson, who is the Associate Director of Food and Agriculture Issues at the U.S. General Accounting Office. Accompanying Mr. Robertson is Keith Oleson, who is also from the U.S. General Accounting Office.

Mr. Robertson has been examining the issue of food safety for at least 10 years. Today, he will present the results of the GAO's study on the adequacy of Federal efforts to ensure the safety of food imports.

I want to begin by complimenting Mr. Robertson and your staff for your excellent report. It was extremely well researched and we appreciate the amount of work that you have done in this area.

As I have explained, pursuant to Rule 6, all the Subcommittee witnesses do need to be sworn in, so I would ask that you stand and raise your right hand.

Do you swear that the testimony you are about to give to the Subcommittee is the truth, the whole truth, and nothing but the truth, so help you, God?

Mr. ROBERTSON. I do.

Mr. OLESON. I do.

Senator COLLINS. Thank you. You may proceed, Mr. Robertson.

TESTIMONY OF ROBERT E. ROBERTSON,[1] ASSOCIATE DIRECTOR, FOOD AND AGRICULTURE ISSUES, U.S. GENERAL ACCOUNTING OFFICE; ACCOMPANIED BY KEITH OLSON, SAN FRANCISCO REGIONAL OFFICE, U.S. GENERAL ACCOUNTING OFFICE

Mr. ROBERTSON. Thank you, Madam Chair, Senator Durbin, and Senator Akaka. I am happy to be here this morning to talk about our work on imported food safety.

I will just reintroduce Keith Oleson. He is with our San Francisco Regional Office. He has been involved with food safety issues for years and he is intimately involved with the work that we have just completed. Senator Durbin, like you, he has accompanied inspectors and knows of what he speaks.

I will go ahead and summarize my statement and ask that the full statement be put in the record.

Senator COLLINS. It will be put in the record. Thank you.

Mr. ROBERTSON. Madam Chair, because imported foods play an increasingly significant role in the Nation's food supply, it comes as no surprise that the safety of the food consumed in the United States is in part dependent upon the safety of these imported foods. My comments this morning will highlight findings from our recent report,[2] which concludes that our system for keeping unsafe imported food from entering the United States has a number of weaknesses which we think can and should be addressed.

Let me begin by noting that there are two Federal agencies that are primarily responsible for the safety of imported foods. USDA's Food Safety and Inspection Service, which I will be referring to from this point on as FSIS, is responsible for the safety of meat, poultry, and some egg products, and the Food and Drug Administration is responsible for all other foods. These two agencies coordinate their efforts with the Customs Service and Centers for Disease Control.

Our recently completed review of FSIS' and FDA's efforts to ensure the safety of imported food highlighted weaknesses in three basic areas. First, FDA lacks the authority to require that countries exporting foods into the United States have food safety systems that are equivalent to ours. This is an authority that FSIS has and uses to share the burden of ensuring safe foods with ex-

[1] The prepared statement of Mr. Robertson appears in the Appendix on page 54.
[2] See Exhibit No. 3 that appears in the Appendix on page 66.

porting countries. Without such authority, FDA relies almost exclusively on its port-of-entry inspections to identify unsafe foods and stop them from entering our food supply. As was pointed out earlier, inspections in 1997 accounted for less than 2 percent of the shipments coming into the country.

The second area of weakness that we identified involves ineffective targeting of port-of-entry inspections. More specifically, we found that FSIS and FDA could make more effective and efficient use of port-of-entry inspection resources by better targeting shipments for inspections that posed the highest food safety risk.

To truly appreciate why it is so important that FDA and FSIS deploy their inspection resources with great care, you only need to look at the statistics on the number of shipments arriving at U.S. ports. Last year, for example, FDA was responsible for determining which of 2.7 million shipments should be inspected, while FSIS was responsible for making similar decisions on about 118,000 shipments.

We found that both agencies could improve decisions on which shipments to inspect by better using available health risk information. For example, to help its inspectors make informed decisions, FDA has databases containing information on, among other things, imported foods that have histories of safety violations and the results of FDA laboratory tests conducted on inspected foods. Unfortunately, these systems are not well integrated and they are awkward to use. As a result, inspectors often do not use the information and instead rely on their own memory and their personal judgment.

In addition to making better use of existing health risk data, FDA could further improve its inspection targeting by improving its guidance to inspectors concerning which shipments to select for inspection and by taking enforcement action when importers are found to inaccurately describe the contents of their shipment.

The third and final area of weakness that we found related to the lack of control that FDA and Customs have over goods arriving at U.S. ports. Weaknesses in these controls in some cases allows unsafe products to enter the Nation's food supply. Under current procedures, importers are allowed to retain control over shipments before they are released. If importers move shipments into domestic commerce without an FDA release, and what I mean here is before FDA inspects them or when FDA laboratory tests reveal that the products do not meet U.S. standards, FDA has no effective means of requiring importers to return the shipments for inspection, destruction, or reexport.

For example, in Operation Bad Apple, which took place in San Francisco last year, Customs officials identified 23 weaknesses in the controls over imported shipments. In this investigation, Customs found that about 40 percent of imported foods determined to violate U.S. standards were never redelivered to Customs for destruction or export. Additionally, for about half of those that were redelivered, other products were substituted for the original product. Now, what this means is about 70 percent of the products that were ordered returned because they were unsafe are presumably in commerce.

We also found other weaknesses in the controls over imported shipments beyond those identified in Operation Bad Apple. For example, when FDA requires an importer to provide evidence that a suspect shipment is safe, the agency allows the importer to select the laboratory that picks the samples and conducts the tests. This has raised concerns over whether or not some importers are able to falsify test results in order to obtain FDA's approval to release foods into commerce.

Finally, FDA's and Custom's principal deterrent for ensuring that importers comply with U.S. requirements, and that is the collection of damages from violators, is uneven and uncertain. For example, in 1997, Customs in Miami assessed damages for only about 25 percent of the identified cases involving improper distribution of food products.

Madam Chair, that is, in a nutshell, a summary of our past work. If I am given a couple more minutes, I can run through the two charts that we have here to give you a flavor of the scrutiny that shipments coming into the United States receive.[1]

Senator COLLINS. That would be helpful. Please proceed.

Mr. ROBERTSON. Let us start with FDA, because that is a little more complicated. Starting at the top of the chart, you will see that there is about, as was mentioned earlier, 2.7 million entries in 1997 that arrived at U.S. ports.[2]

If you go down to the next level, you see that about 56 percent of these 2.7 million entries were automatically released by a Customs Service computer after that computer basically analyzed information on these shipments.

If you move down to the next level, you will see that an additional 42 percent of these entries were released after an on-screen review by an FDA inspector.

Senator COLLINS. If I could just interrupt you to clarify, so 56 percent were just automatically released without a visual inspection or without any kind of review at all?

Mr. ROBERTSON. There was basically a review by the Customs Service computer on information pertaining to that shipment, but there was no visual review.

Senator COLLINS. And that contrasts to what you are going to tell us with FSIS, where there is a visual review of every shipment.

Mr. ROBERTSON. Yes.

Senator COLLINS. Please proceed.

Mr. ROBERTSON. Actually, this is a good time to pause, because even after the on-screen review by the FDA inspector, what we are talking about is a total of, if my math is correct, 98 percent of the entries have been released without visually inspecting them by anybody. These are all released through computer reviews, through document review, that type of thing.

So now we are down to the final 2 percent on the very bottom of the chart, 1.7 percent basically were physically inspected or had some type of laboratory analysis performed on them by FDA, and you will notice there is another block on the bottom that talks about entries detained automatically because of prior violations.

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[1] See Exhibits No. 4a. and 4b. that appears in the Appendix on pages 130 and 131.
[2] See Exhibit No. 4a. that appears in the Appendix on page 130.

This 0.3 percent also had some laboratory analysis performed, but it was not performed by FDA. It was performed by private laboratories that were selected by the importers.

So that is a quick overview of what takes place in the FDA inspection system.

If we move to the USDA or FSIS system, it is a little simpler to run through.[1] As I said earlier, in 1997, they had roughly 118,000 food entries coming across the border, and remember that all of these entries came from countries whose food safety systems were certified as equivalent to ours.

Now, the thing to remember here, as you pointed out earlier, is 100 percent of these entries at least were visually inspected by USDA inspectors for transportation damage, labeling problems, that type of thing.

After that initial examination, basically, the information on those entries is run through a USDA computer, which automatically selects which shipments need to be sampled, and as the chart shows, about 80 percent of the shipments are released and 20 percent are analyzed either by lab or have some further inspection by a USDA inspector.

The bottom line is of the total 118,000 or so shipments that came in in 1987, about 5 percent were rejected. So again, that is just a quick summary of the two processes and the differences in the two processes.

With that, we will be happy to answer questions.

Senator COLLINS. Thank you very much, Mr. Robertson. Again, I want to commend GAO for its excellent work in this area.

It seems to me that you have identified two issues for us to think about. The first is whether the FDA needs an expansion of its legal authority in order to have the same sort of equivalency system that helps protect us in the case of imported meat, poultry, and egg products, that the FSIS has. But the second issue is whether the FDA, to a greater extent, but both agencies are targeting their resources effectively and making the most effective use of what they have now. Is that correct?

Mr. ROBERTSON. That is correct.

Senator COLLINS. In your review, did you find a problem with the FDA not focusing its resources on those imports that posed the greatest health risks?

Mr. ROBERTSON. Yes. I mean, we found problems, frankly, with the way that both FDA and USDA distributed their inspection resources at the ports of entry. From an FDA perspective, the problems we found were that FDA did not give its inspectors adequate guidance to help them select which shipments they should be inspecting and which shipments they should not be inspecting.

We also found that the tools that were available to inspectors to help guide their decisions on what shipments to inspect left a lot to be desired. What I am talking about here is that these inspectors rely in part on several information systems to help them make their selections and these information systems were not well integrated. As a result, they were difficult to use by the inspectors, and some inspectors, as I said earlier, did not use them.

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[1] See Exhibit No. 4b. that appears in the Appendix on page 131.

The third area of problems that we found in regard to the way FDA was doing business at the port-of-entry inspections had to do with their inability or their problems with assuring the accuracy of information that importers submitted on shipments that were coming through the border. Now, the reason that this is important that this information be accurate is that it is the information that USDA relies on to choose the shipments to inspect.

So from an FDA perspective, those were the key problems we found in regard to the way they were allocating their resources.

Senator COLLINS. I am very alarmed by the results of Operation Bad Apple, where in this select case, some 70 percent of the shipments that had been pulled by the FDA as being suspect nonetheless made its way to the American marketplace. Is that an accurate description of what happened?

Mr. ROBERTSON. Yes, that is accurate.

Senator COLLINS. How can that happen? Walk us through what are the weaknesses that would allow tainted imported food products, that have been targeted by FDA—this is a case where they have actually caught it, despite the low inspection rate, despite the clearing that is done automatically—and yet 70 percent of the shipment found its way to the American marketplace anyway. How can that happen? What are the weaknesses in the current system that allow that?

Mr. ROBERTSON. Under the current system, basically, importers of FDA-regulated goods retain control over their shipments as the shipments come in and go through the border crossings. They are supposed to——

Senator COLLINS. And if I could just interrupt, that is in contrast to what FSIS does, is that correct, where in the case of the Department of Agriculture, if there is a suspect shipment, the Department of Agriculture takes custody of it.

Mr. ROBERTSON. Right.

Senator COLLINS. But in FDA's case, the importer retains custody?

Mr. ROBERTSON. Yes. Maybe the easiest way to approach this is just to talk about the two or three biggest differences between the way USDA operates its system and the way that FDA operates its system.

As you correctly pointed out, when a shipment comes in for USDA inspection, those shipments are held in a USDA-registered warehouse until they are released to go across the border. From the FDA perspective, basically, as I said earlier, importers retain control over those shipments.

A second difference in the controls between the two agencies' systems has to do with the fact that FDA performs all of its laboratory analysis, whereas, as I mentioned earlier, under certain circumstances—did I say FDA? I meant USDA performs all of its own laboratory analysis, whereas under certain circumstances, FDA allows importers to choose the laboratories where its samples are going to be analyzed.

And a third fundamental difference between the two operations has to do with the control that they have over the goods; has to do with what happens when goods basically do not meet standards. In USDA's case, the goods are stamped "Refused Entry," with the

hope that they will never be confused with any other products. FDA does not do this.

Senator COLLINS. Why does not the FDA stamp the shipment "Rejected," the way that the Department of Agriculture does? It seems like such a simple step that could be taken to ensure that rejected shipments do not get re-exported.

Mr. ROBERTSON. What they have told us is that they do not have the authority to do that.

Senator COLLINS. The FDA is arguing that it does not have the authority to actually stamp a shipment "Rejected"? I do not know whether you are an attorney or not——

Mr. ROBERTSON. I am not an attorney.

Senator COLLINS. Does that not seem unlikely to you? Is that not a normal regulatory power that an agency would have?

Mr. ROBERTSON. All I can do is tell you the explanation that they gave us, which was they do not have authority to do that.

Senator COLLINS. We will explore that with the FDA.

So, essentially, what you are telling us is that if a shipment has been targeted by the FDA because there is reason to believe that it may be tainted, the importer controls the shipment, selects the sample for the laboratory analysis, selects the lab that is going to perform the analysis, and the FDA is relying completely on the integrity of the importer?

Mr. ROBERTSON. The only modification I would make to that is to make sure that when we are talking about selecting samples, selecting the lab, that we are talking about those goods that were automatically detained.

Senator COLLINS. Correct.

Mr. ROBERTSON. Yes.

Senator COLLINS. Does that not invite problems by an unscrupulous importer?

Mr. ROBERTSON. It does not protect you against problems that could be caused by that type of an importer.

Senator COLLINS. It would also be possible for the importer to mis-enter into the data system what the product is and, thus, avoid detection that way, is that correct?

Mr. ROBERTSON. That is possible.

Senator COLLINS. Is this system pretty easy, then, for an unethical importer who has tainted product to avoid detection altogether?

Mr. ROBERTSON. Let me put it this way. We went to about six locations and we found evidence of weaknesses in these controls at most of those locations. So the short answer to your question is, it is relatively easy.

Senator COLLINS. I would like to turn to a chart that was in your report on page 47.[1] It listed some of the major outbreaks that we have experienced in recent years. I was interested to note that the outbreaks that are listed are associated with fruit and vegetables or seafood that is under the jurisdiction of the FDA. Does that suggest to us, and the other findings in your report, that the Department of Agriculture's system does provide more protection to consumers than the FDA's process?

[1] See Exhibit No. 3 that appears in the Appendix on page 66.

Mr. ROBERTSON. I would suggest this, that from our perspective, USDA has a better approach to ensuring safety because it does rely in part on assuring that countries that are exporting foods into the United States have systems that are equivalent to ours, whereas FDA does not have that same assurance. So from that perspective, I think that the design of USDA's system is stronger than that of the FDA's system.

Senator COLLINS. I want to turn to the issue, again, of the non-health-related risks of some of these foods that have been targeted for inspection. Your report was critical of both agencies for targeting its inspections based on non-health-related risks. Could you expand on the kinds of risks? Are you talking about, for example, missing labels as opposed to tainted foods?

Mr. ROBERTSON. Sure. We are talking about missing labels, we are talking about incorrect weights, we are talking about mislabeled, that type of thing, more along the lines of economic-type considerations than health considerations.

Senator COLLINS. I believe that we do need to provide more authority to the FDA, that we probably need to provide more resources, but do we not also need to expect the FDA and the Department of Agriculture to do a better job of targeting the resources that they have now if we are going to truly protect the American consumer?

Mr. ROBERTSON. Yes. That is what a good part of the focus of our work is, that you can make better use of your existing resources and deploy them more effectively along the borders.

Senator COLLINS. Senator Durbin.

Senator DURBIN. Thank you very much.

Thank you, Mr. Robertson. Let me just say the two charts that you presented here with FSIS and FDA,[1] I think, make the case for the legislation I am pushing. It is time to put this all under one roof, one set of rules, eliminate the bureaucracy and the overlap, try to make certain that the American consumers know that whatever the food product is, it is going to be subject to a standard of inspection that is the best that we can do at the moment, and I think you made that point in your testimony.

But I want to walk through with you for a minute, so that I can understand and the record is clear, the difference between the FSIS, the Food Safety Inspection Service of the Department of Agriculture, and the Food and Drug Administration. The Food Safety Inspection Service, I think your report says, focuses, maybe not exclusively, but primarily on meat and poultry imports, is that correct?

Mr. ROBERTSON. Correct.

Senator DURBIN. And most of those meat and poultry imports coming into the United States are probably frozen or processed, is that correct?

Mr. ROBERTSON. Senator, you get frozen, processed, and fresh meat.

Senator DURBIN. There is some fresh? Do you know what percentage——

Mr. ROBERTSON. Very little poultry.

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[1] See Exhibits No. 4a. and 4b. that appear in the Appendix on pages 130 and 131.

Senator DURBIN. Do you know what the percentage of fresh would be?

Mr. ROBERTSON. We could provide that for the record.

Senator DURBIN. But in the FSIS or Department of Agriculture approach to it, they really have three steps, as I understand it. One step is to have a certificate from the company that is exporting into the United States that they are adhering to certain standards in terms of processing, preparation, and inspection, step No. 1.

Mr. ROBERTSON. Right.

Senator DURBIN. Step No. 2 is that we actually send employees from the Department of Agriculture out to take a look at these plants overseas that are processing the meat and poultry and make sure that the exporting companies are not lying to us.

Step No. 3 is FSIS will take samples of food coming in to find out whether it is safe. So there is a 3-step process here.

In contrast, the FDA just does the last step. As the food presents itself at the border, we do an inspection.

Now, the suggestion here on equivalency is to give to the FDA the same authority as FSIS. Let me walk through for a moment, if I can. Your GAO report said that the FSIS in a given year, and I think it was 1997, was able to visit 30 out of the 37 exporting countries to the United States. I am not sure what that is, but let us say 80 percent. They visited 80 percent of the countries which had plants processing meat and poultry and are sending it to the United States with these certificates. Now, do you know how many employees FSIS uses to meet their responsibility?

Mr. ROBERTSON. I think last year, they were about 84 staff years.

Senator DURBIN. Eighty-four staffers for all of the things that I have mentioned, reviewing certificates, inspecting overseas, and then doing the actual processing and inspecting here in the United States?

Mr. ROBERTSON. Yes.

Mr. OLESON. Senator, they use 12 staff years to do the overseas work and the rest go to the port-of-entry inspection operations.

Senator DURBIN. OK. Now, the Food and Drug Administration for its import food inspection employees, I believe, somewhere in the neighborhood of——

Mr. ROBERTSON. Total of 463 last year.

Senator DURBIN. I thought I had read on page 25 of your report the figure 257 staff years.

Mr. ROBERTSON. It is 257 inspectors and there are 463 total. Those include laboratory analysts, that type of thing. So it is 257 inspectors.

Senator DURBIN. Contrasting the volume of imports between FSIS responsibility and FDA responsibility suggests that FDA has about 25 times the number of imports to deal with as the Department of Agriculture, is that correct?

Mr. ROBERTSON. Correct.

Senator DURBIN. So that would lead us to conclude, what, in terms of just looking at staff years? If they need 80 people in FSIS to do 4 percent of the work that they would do in the Food and Drug Administration, how many more employees would we need in the Food and Drug Administration to do the same things that the FSIS is doing today?

Mr. ROBERTSON. I cannot give you an estimate on that right now. But for the exact reasons that you have cited—because of the huge volume of shipments that FDA is responsible for assuring the safety of—it makes a lot of sense to me that, rather than try to catch unsafe food with whatever number of resources you have at the border, that you go back to the countries to make sure that their systems——

Senator DURBIN. I want to get to that next.

Mr. ROBERTSON. Oh, OK.

Senator DURBIN. I am just trying to stick with the basic premise here, and if the premise is FSIS with 80 employees does 4 percent of the work that the Food and Drug Administration should be doing, then it suggests to me we need 2,000 employees in the Food and Drug Administration, assuming the FSIS is efficient, to do the same thing that the Department of Agriculture is doing with their responsibility. It is 25 times the number of shipments, just roughly.

Mr. ROBERTSON. OK, roughly.

Senator DURBIN. Now, let me add another factor. You say we have 400 and how many?

Mr. ROBERTSON. Total of 463.

Senator DURBIN. So we are talking about quadrupling the number of inspectors in the Food and Drug Administration to meet this responsibility that the FSIS has if we are doing equivalency, 1-for-1. Maybe it will turn out we do not need that many, but in the order of magnitude, that is a starting point, quadrupling the number of inspectors in the Food and Drug Administration.

Secondly, is there not a qualitative difference in your inspection responsibility if you are going to a processing plant for meat and poultry as opposed to going to the Nation of Guatemala and looking at all of the fields where they plant crops?

Mr. ROBERTSON. I am not sure if I am following you, but the purposes of the inspections would be totally different. In going to Guatemala, what you would be doing if you were under an equivalency system is looking at the system there. You would be looking to see that it has the basic components that are necessary to assure that, in essence, the food coming out of there is at the same level of safety as what is coming out of the United States. So you are looking at the big components of the system. Do they have inspectors? Do they have a set of laws? What do the laws say? Can they enforce the laws?

Senator DURBIN. In the FSIS, they go a step beyond that, do they not? They actually visit the plants.

Mr. ROBERTSON. Yes. They do some plant sampling.

Senator DURBIN. So when Dr. Camire comes before us and says the origin of a lot of the contamination for fruit and vegetables is very, very basic as to what very poor people who are picking these vegetables are doing about their own hygiene and the fields they work in——

Mr. OLESON. Senator, let me clarify one thing. When FSIS goes over to a foreign country and visits a plant, they are going to the processing or slaughter plant, not to the barns.

Senator DURBIN. Understood.

Mr. OLESON. Also, they are going to basically verify that the country's system is working. They are not going into that plant to

try to determine if it is sanitary and all that. They are doing that, but it is to ensure that the system works, not the individual——

Senator DURBIN. But they are also looking at the sanitary conditions.

Mr. OLESON. Yes, they are.

Senator DURBIN. If they saw the system and all the papers were in place and took a look at this plant and it was filthy——

Mr. OLESON. That is correct.

Senator DURBIN [continuing]. They are going to do a visual inspection. I am just trying to really compare, make sure we have an accurate comparison between the responsibility of the Department of Agriculture here and the responsibility we are suggesting for the Food and Drug Administration. I am saying, on the one hand, we are talking about a dramatic increase in the number of employees in this agency if we are going to give them equivalency and ask them to use the same standards.

Secondly, I think it is a little different challenge, a discrete number of processing plants as opposed to a system of agriculture in a foreign country. How many countries do we import fruit and vegetables from?

Mr. ROBERTSON. We are talking in the neighborhood of, what, 200 or so.

Mr. OLESON. I think there are 188 countries in the world. FDA's records show something like 266 different countries since they started their automated system—or 244, excuse me. That number probably has some changes in names of countries and may be counting some territories, but it is a lot of countries.

Senator DURBIN. So let us say 200 as a rough figure, and FSIS looks at 37 and they manage to visit 80 percent of them. Now the Food and Drug Administration has the responsibility under our suggestion here of looking at 200 countries and trying to make sure they have enough people to visit them and, at least, at a minimum, make sure that the standards they purport to hold to are actually being followed.

Let me speak for a moment about the FDA process, and you are going to have to update me here because I am going to tell you what I saw a few years back and you tell me how it has changed. I know it has changed in one respect.

When the shipment of tomatoes comes to the border, the FDA inspector at Nogales, Arizona, would walk onto that loading dock and would take a sample from different parts of the truck and put it in a brown paper bag, mark it as to the shipper, and send it off to the FDA lab. Is that about what you saw when you visited, something like that?

Mr. OLESON. Yes, Senator. They do not use brown paper bags anymore. They put them in ice packs generally to retain the freshness and things of that nature. And then they fly them to the lab instead of busing them.

Senator DURBIN. They fly them to the lab. While they are in the process, they punch into the computer the name of the shipper and the grower that they are inspecting at that spot. If nothing comes up to suggest that there has been a violation in terms of what they have sent into the United States, the shipment heads for the grocery store. The tomatoes are on their way to Joel Domenic's in Chi-

cago and Safeways all over the United States while the sample is on its way to the laboratory. In most instances, by the time they are finished in the laboratory, reaching their conclusion, the product is already on the shelf and may have already been sold.

Mr. OLESON. They have changed the speed in which they turn their lab samples around now. They try to get them back in 24 hours. Under the conditional release which we are talking about, the importer is responsible for retaining control of that shipment until he gets a release from FDA.

Senator DURBIN. But are all shippers under a conditional release requirement?

Mr. OLESON. The way it works is that, basically, we do not have bonded warehouses for FDA-type products, in a sense, so they go to the importer's warehouse. Some of the importers continue shipping products on if they are perishable to the destination, but they are supposed to be able to bring the products back if FDA finds they are violative.

Senator DURBIN. And in 70 percent of the cases, they do not get it back.

Mr. OLESON. That is part of our problem.

Senator DURBIN. Now, let us assume that they find a violation. It used to be that if they found a violation and the shipment was already gone, the next time that particular grower and shipper came through, they came up on the computer and then a different standard was used. They were held until the inspection was completed. Is that still the case?

Mr. OLESON. When they have a history of violations, they put them on what they call automatic detention, or detained without physical inspection is the correct term now. That means that the importer still retains control of the shipment, but he has to provide some evidence that that shipment is clean or beats the U.S. standards. That is where they go and select a private laboratory and the private laboratory pulls the samples and does the test and provides the information to FDA.

Senator COLLINS. Senator Durbin, your time has expired from this round, but we will do another round.

Senator DURBIN. OK. Thank you.

Senator COLLINS. Mr. Robertson or Mr. Oleson, I want to follow up on a point that Senator Durbin made. Even if we quadrupled the number of FDA inspectors that we have, if FDA continued to rely on port-of-entry inspections, if FDA continued to allow importers to retain custody of suspect shipments, if FDA still allowed the importer to select the samples and the lab that was going to do the work, if FDA continued to focus on shipments for reasons unrelated to health risks, even if we increased the number of inspectors by a factor of 4, do you believe that we would solve the problem and that we would have a safer food supply coming into this country?

Mr. ROBERTSON. Well, again, that is why we are saying in regard to FDA is the most effective use of any number of resources that you wind up with is to make sure that the countries that are exporting the products have systems, have safety systems that are equivalent to ours. I do not care what level of resources that you have. The idea is to develop a system that basically tries to assure that the food is safe as it is coming into the United States as op-

posed to trying to catch it with inspectors once it reaches the border of the United States.

Mr. OLESON. If I may add to that, Senator——

Senator COLLINS. Yes, Mr. Oleson?

Mr. OLESON. Port-of-entry inspections or end product inspections have been widely discredited as being effective means to ensure that something meets the standards it is supposed to meet.

Senator COLLINS. That was going to be my very next question. In your report, you used that phrase, that port-of-entry inspections have been widely discredited. Could you give us some history on that? Is it just GAO——

Mr. ROBERTSON. No.

Senator COLLINS [continuing]. Or have other groups been critical? Has not one of FDA's own advisory groups discredited its system years ago?

Mr. ROBERTSON. In fact, the United Nations Food and Agriculture Organization has been critical of it and the advisory group that you spoke of just a minute ago in 1991 basically called that approach an anachronism. So it not just us that is saying, this is the way you should approach the design of the inspection system.

Senator COLLINS. Mr. Oleson, do you want to add anything to that, based on your work?

Mr. OLESON. I think he captured it fine there, Senator.

Senator COLLINS. I want to go back to the issue of focusing the resources on shipments that are not related to health reasons or health risks. It is my understanding, if I am remembering your report correctly, that you found that in fiscal year 1996, about 86 percent of the refused shipments by the Department of Agriculture inspectors were not related to health risks, is that correct?

Mr. ROBERTSON. Yes, that is correct.

Senator COLLINS. Most American consumers would believe that the inspection resources would be targeted towards health risks, but you found that 86 percent of the Department of Agriculture's refusal of shipments were not health related.

Mr. ROBERTSON. Right.

Senator COLLINS. Is there a comparable figure for FDA?

Mr. ROBERTSON. I do not think FDA has figures on the refusal, is that correct?

Mr. OLESON. FDA has the information for the laboratory tests they perform, which is actually about 0.6 of 1 percent of all entries are actually sent to an FDA lab for testing. There is about a 17 percent violation rate from those tests, but they do not necessarily end up in a refusal. They could be appealed or something may happen to allow them to continue entry. In addition, the 1.3 percent, that is the difference between the 1.7 percent and the 0.6 percent, the 1.3 percent that are physically inspected by an FDA inspector, they do not have the refusal rate on that, so we do not know what their rejection rate is.

Senator COLLINS. Is that not troubling, as well, that we do not have the data?

Mr. OLESON. Yes, it is.

Senator COLLINS. GAO's review found another weakness that we have not touched on yet and that is the system for penalizing importers who do not obey the law. It is my understanding that you

took a look at the Customs Service's operations in Miami and found—well, why do you not tell me what you found when you looked at that. Mr. Oleson?

Mr. OLESON. For the Miami district, where we were able to capture the information, Customs, in effect, for those improper distributions of refused entries, they assessed penalties on only 25 percent of those cases. And then when they actually collected damages, it resulted in about 2 percent of what they assessed.

An example would be, and this is one of the extremes, but we have many of them, is for an incidence of swordfish which was distributed. The initial assessment was for $100,000, but the penalty that actually came out that was collected was $100. We have another case of snow peas. The assessment was $16,000. The collection was $200. They go on and on like that.

Senator COLLINS. So the assessment in the first case that you gave us was actually $100,000 and the actual fine that was paid was only $100?

Mr. OLESON. That is correct.

Senator COLLINS. Why is this happening? That does not strike me as a very good deterrent if we are cutting fines and penalties to that extent.

Mr. ROBERTSON. We have already gone on record as saying that there have been problems in the deterrent value of the penalties in the past, and this is something, by the way, that, as you know, we are going to be exploring further over the next few months.

Senator COLLINS. Does this not encourage the unethical importer to treat these fines as just a cost of doing business?

Mr. ROBERTSON. Well, it would certainly say to him or her that I am not going to be penalized very much if I go ahead and do not carry out my responsibilities.

Senator COLLINS. I see that Senator Cochran and Senator Brownback have joined us. We welcome you and I am going to, instead of using the rest of my time now, turn to both of you for questions, and then we will go back to Senator Durbin, and then I may have a few concluding questions, as well. Senator Cochran.

OPENING STATEMENT OF SENATOR COCHRAN

Senator COCHRAN. Thank you, Madam Chairman. I came to congratulate you and the staff and the GAO for helping us understand what is going on in this food inspection area. We all have other responsibilities here in the Senate that coincide with this situation. I know in my case, being on the Agriculture Committee and also on the Appropriations Committee, we have undertaken to conduct oversight reviews of these programs, whether we are talking about the Food Safety and Inspection Service at the Department of Agriculture or the Food and Drug Administration's work under the obligations it has under the law.

But what has come through to me during all of these experiences is that we have a hard time getting all the facts with just one hearing every year. For example, in the Appropriations Committee, usually because of all the other programs that we have to look at, and in the Agriculture Committee, when we undertake a review from time to time, we have limited resources. But Chairman Collins has undertaken to mobilize the resources of this Subcommittee

with the staff and with GAO's assistance to really dig into this in a way that has never been done before, and I think that is going to be very revealing and helpful to us as we try to make decisions about how much money to allocate to various inspection activities and programs.

We have a sharing of responsibilities among agencies right now, and sometimes it is confusing, who is responsible for what. Things tend to fall through the cracks under the current way things are organized, and I think your report points that out. We need to have tighter controls of management over what is being done, with follow-ups to be sure people pay their fines, for example, which we just heard about, and there are many other areas.

In seafood inspection, you mentioned the swordfish. We have been trying to get seafood inspection laws reformed for a long time now and we just never can quite get a consensus of support here in Congress because of the various pressures from people who are not for it for one reason or another.

But I think these hearings can serve a purpose there, too, and that is to help convince other Members of Congress that we need some reforms in these areas. We do not need just more money pumped into the things that are being done in a slipshod way, where they are and where there are shortcomings in the system. We do not just need to add more fuel to that fire. We need to put out the fire and we need to make some important reforms and you are helping us to figure out how we can do that and how we can do that in an effective way to help protect the consuming public. I think we are going to be better off for these hearings and I appreciate very much your conducting them and leading us.

Senator COLLINS. Thank you very much, Senator. Senator Brownback.

OPENING STATEMENT OF SENATOR BROWNBACK

Senator BROWNBACK. Thank you very much, Madam Chairman, and thank you for holding the hearing. I think this is a very important topic and I appreciate you really leaning in and looking and getting a focus on this. I appreciate the witnesses and the report that has been done.

I come with some background on this topic and have had some great concern about it. I was Agriculture Secretary in Kansas for 6 years. I worked in the trade field, worked on the NAFTA treaty with the U.S. Trade Representative's Office. One of the things that was always raised to us was that as you expand your agricultural trade, as you lower those barriers, particularly as you lower what was always called the non-tariff barriers, the sanitary, phytosanitary issues, that is good for our exporters but there is always a reciprocity that goes with it, which is that then they can import into this country and a number of our producers are always questioning the production systems that were used in other nations to produce these products and were they under the same EPA regulations, inspection regimes as what ours are.

I missed a good portion of this hearing, but did you find substantial differences in inspection regimes in these countries coming into ours?

Mr. ROBERTSON. The scope of our work this past time around did not include looking at other countries' inspection systems.

Senator BROWNBACK. Would you advise us to go further and look at that, as well?

Mr. ROBERTSON. Well, one of our recommendations, basically, is that from an FDA perspective, that FDA be given authority to require that countries that are exporting food to us have systems that are equivalent to ours, food safety systems that are equivalent to ours.

Senator BROWNBACK. That is already required under a lot of the trade negotiated treaties, so if it is not in place, we already have footing to pursue something of that nature. I think we have to keep much more on top of this. It has been a legitimate issue raised for some period of time and we need to do something about that.

One thing I would like to ask you about, in your report, you state that there is up to 9,100 deaths occurring each year because of foodborne illnesses.

Mr. ROBERTSON. That is estimated, yes.

Senator BROWNBACK. Estimated? That seems extraordinarily high. Could you explain the methodology you used to obtain that number?

Mr. ROBERTSON. Basically, it is not our methodology. That comes out of some work we did a couple of years ago, and basically, in that work, what we did is reviewed a number of studies that tried to get a handle on the impact of foodborne illnesses. What that study did is basically identified the research that had been done and presented the research in our report. So that 9,100 figure was from some of the research that we uncovered doing work for that report. It was not our estimate.

Senator BROWNBACK. So that is for all food-associated foodborne illnesses——

Mr. ROBERTSON. Right.

Senator BROWNBACK [continuing]. Whether they come from imported products—I mean, you cannot really comment on the methodology of that?

Mr. ROBERTSON. No. We do talk about where the figures came from in that report. We will just leave a copy of the report with you.

Senator BROWNBACK. OK. I appreciate that, and Madam Chairman, I appreciate your hearings. I do think we owe it, obviously, to the consumers to have a safe food supply. I think we also owe it to producers that they be competing against equivalent-based systems in other countries and that we need to look at that aggressively, as well. While this study did not cover that area, they are supposed to be equivalent-based systems.

It is supposed to be on environmental and on food safety inspection systems and I hope we can pursue and push that, that as we push these fines being implemented at the level that they are supposed to be, we also push the inspection system to go in-country to make sure that these nations that are producing products for our people are doing it under the same basis that our producers have to go under, and thanks for holding the hearing.

Senator COLLINS. Thank you, Senator. Both you and Senator Cochran have a great deal of expertise in the agricultural field and

I know that your participation is going to be really helpful to us as we go forward in this area. Senator Durbin.

Senator DURBIN. Thanks, Madam Chairman. I have one last area of questioning. I will try to make it as brief as I can, and it is about the laboratory involvement here, which is an important part of your conclusion.

If I remember correctly, under the FDA inspection standard, once a shipment came in, a sample was taken and sent to the FDA lab. If the results came back and indicated that there was something wrong with that shipment, the companies were then put on notice that the next shipment that came in would be under surveillance, which meant that such shipment had to be held until another sample could be tested at an FDA lab. It could not be sent into commerce. And finally, if there was a second violation, the shipment would be detained, and detained until the shipper/grower had submitted evidence that a test had been taken on that shipment and that it had no problem.

So there was an increasing magnitude of inspection and detention based on whether we had bad actors and violators. Is that still basically the regime that is followed?

Mr. OLESON. I believe so, Senator. I am not sure about the second surveillance test, if that is still required there, where they notify them that they will be on surveillance. We would have to check that.

Senator DURBIN. OK. Now, your observations about laboratories, I think, relate to detentions only. Assuming private laboratories are chosen by growers and shippers because they have got a history of problems, and someone in that laboratory or someone associated with the shipper picks the sample off the truck, your concern, and obviously a legitimate concern, is that it is a little too cozy there.

Mr. ROBERTSON. Yes, sir.

Senator DURBIN. There is no independent third party involved in this process.

Mr. ROBERTSON. Correct.

Senator DURBIN. OK. Is there any other evidence of private laboratories being brought into this system, other than that case of detention by the FDA where they have got a bad actor?

Mr. ROBERTSON. Actually, I think FDA is moving towards using them in other areas, too. Can you elaborate on that a little bit?

Mr. OLESON. Yes, Senator. They are moving toward using private laboratories for their normal processes. Seafood is the most recent example they are trying to move toward, recognizing their own labs are getting overburdened, so they are trying to shift some of the work back to private ones.

Senator DURBIN. When I visited FDA's inspection laboratory for seafood in the Boston area, it was a very limited operation. You would be surprised. The one thing that I recall about that particular visit is that many times, seafood will tell you when it is bad. [Laughter.]

Mr. OLESON. That is one of the tests they use.

Senator DURBIN. The inspector told me to take a whiff of one of those which he called a neck-snapper, not a red snapper but a neck-snapper, and once I took a whiff, I understood what he said.

But that is clearly an area, poultry and fish are areas of real serious concern in terms of foodborne illnesses.

Madam Chairman, thank you very much.

Senator COLLINS. Thank you very much, Senator Durbin.

Mr. Robertson, I only have a few more questions, but I do want to point out an issue that troubles me, and that is that these problems in our system for food safety have been exacerbated by the increase in imports, but they have existed for a very long time. I looked back at a December 1977 report by the Governmental Affairs Committee. It is over 20 years ago and it was part of a 6-volume series on various aspects of Federal regulation.

One volume was on our food safety system, and the Committee concluded in part that, "Divided responsibility between the Department of Agriculture and the Federal Food and Drug Administration for food regulation has created a regulatory program which is often duplicative, sometimes contradictory, undeniably costly, and unduly complex." Have we made any progress in 21 years?

Mr. ROBERTSON. Well, I am sorry to say, but the situation really has not changed a whole lot, and I am sorry that Senator Durbin is not here because earlier he did just a fantastic job in describing the problems with the current piecemeal approach that we are taking to food safety.

Senator COLLINS. I will play his role right now. I have two cans of soup. One is a vegetable soup, one is a vegetable beef soup. They are produced in the same factory. Can you tell me who inspects the vegetable soup, Mr. Oleson, and who is responsible for inspecting the vegetable beef soup?

Mr. OLESON. Let us start with the vegetable beef soup. It seems it has beef in it, and under the rules, that comes under FSIS's regulatory authority. FSIS will inspect that plant every day each and every operating shift. So if they operate two shifts and an overtime, they will be in there three times in the same day. For that plant, depending on the size of those plants, they have permanent inspectors in those plants.

To take the other one, the vegetable soup, since there is no meat or poultry in that, that is under FDA's regulatory authority and they will, then, inspect that plant—they do not have a mandatory inspection requirement, but they will visit that plant maybe once a year or something like that.

Senator COLLINS. Are we misallocating our resources?

Mr. OLESON. Absolutely.

Senator BROWNBACK. I think it just tells you to eat more beef. [Laughter.]

Senator COLLINS. Spoken like a Senator from Kansas.

Senator BROWNBACK. It is good for you.

Mr. OLESON. To add one more part to that, the real problem with that is not so much what is the food that is in it, it is the processing that they undergo, and low-acid canned foods are a high-risk processing operation and we want to ensure it is done right because of botulism. So it is the process that makes a difference in that case.

Senator COLLINS. The other area that you hit upon in your report that we have talked about at length today is the issue of giving FDA what is known as equivalency authority, which the Depart-

ment of Agriculture already has. This means that FDA would essentially certify the food safety system of a country before we would get imported foods from it, is that correct, essentially?

Mr. ROBERTSON. That is essentially correct.

Senator COLLINS. Now, the President has proposed equivalency authority for the FDA, but we seem to be getting conflicting signals about whether the FDA wants to have this authority. Could you explain to the Committee the reaction that you got in your discussions with FDA on the issue of mandatory versus discretionary, concerns about impact on trade?

Mr. ROBERTSON. Sure. FDA, in responding to our recommendation that basically would require equivalency for other countries' food safety systems, basically said that you cannot do that in a mandatory fashion because it is going to disrupt trade. We think that it should be done on a discretionary basis.

Senator COLLINS. We, meaning FDA?

Mr. ROBERTSON. Exactly. Our response to that is that we are not talking about banning all imports until a country has a system equivalent to ours. What we are talking about is phasing in this equivalency requirement over what could be a relatively long period of time. But our point still is, again, I keep going back to the statistics that say there are 2.7 million entries arriving at U.S. ports each year and you cannot hope to assure the safety of those entries with just port-of-entry inspections. You have got to go back to the source. You have got to go back to the other countries to make sure that their systems are equivalent to ours.

Senator COLLINS. So if we do not change the system and we continue to have this flood of imports, do you believe that we are going to be posing an ever-greater risk to the American consumer?

Mr. ROBERTSON. Yes. I think the system needs to be strengthened and we have presented a couple of ways that it can be strengthened so that those risks are decreased.

Senator COLLINS. Thank you very much. We very much appreciate your assistance in this area.

I would now like to call our final witness for the day. His name is Reggie Jang. Mr. Jang is awaiting sentencing after pleading guilty in California on Federal charges of accepting bribes from a company seeking to bypass inspections of imported food products. He is currently cooperating with Federal law enforcement officials against other individuals indicted in California.

Pursuant to the Subcommittee's agreement with law enforcement officials which has led to the testimony we are going to hear today, Mr. Jang will testify only about his knowledge of the FDA's import inspection system and will not provide any specific testimony about current Federal criminal investigations in which he is a witness or a defendant.

Mr. Jang retired in August of 1997 after serving almost 36 years as a consumer safety inspector at the Federal Food and Drug Administration and he will testify today about his firsthand experiences with regard to the food import inspection system.

Mr. Jang, I would ask that you now stand and raise your right hand. As I have explained to the other witnesses, all witnesses are required to be sworn in.

Do you swear that the testimony you are about to give to the Subcommittee will be the truth, the whole truth, and nothing but the truth, so help you, God?

Mr. JANG. Yes.

Senator COLLINS. Thank you. Please proceed.

TESTIMONY OF REGGIE JANG, FORMER FOOD AND DRUG ADMINISTRATION CONSUMER SAFETY INSPECTOR

Mr. JANG. Madam Chairman and Members of the Subcommittee, thank you for allowing me to testify today with regard to the adequacy of the Nation's food import inspection program.

As you mentioned, I retired in August 1997, after serving almost 36 years as a consumer safety inspector at the Food and Drug Administration. As you stated, Madam Chairman, I recently pleaded guilty to a felony in Federal court in San Francisco in an ongoing investigation and I am scheduled to be sentenced this fall. Consistent with the Subcommittee's subpoena, I cannot discuss any details of the ongoing investigation or my case.

Today, I would like to focus my remarks on some of the weaknesses in the current food import system. I do so not out of any sense of resentment or revenge but out of my concern for our Nation's food supply. I also testify out of my respect and concern for the FDA, as well as my desire to atone for any past misdeeds.

Port-of-entry inspections are ineffective. Port-of-entry inspections are ineffective because many importers or brokers acting on the behalf of importers participate in port shopping and clear shipments through ports of entry where FDA inspectors release specific types of food products without examination. For example, some unscrupulous food importers bring food products from Southeast Asia through ports of entry where FDA inspectors rarely see such products and are unfamiliar or unaware that these products are on the automatic detention or alert list.

Unscrupulous importers also have a tendency to port shop and use, in some cases, two to four different aliases to hide their identity. All these importers have to do is to use the Social Security number and the name of a relative to import as another company.

Importers know through word of mouth and by sharing of information with other importers which ports of entry are easier to bring in their food products. It is not unusual for West Coast importers to clear their shipments on the East Coast and send by rail the products across the country, while still making a reasonable profit. On the West Coast, importers have brought food products in at the Port of Los Angeles and transported the products up the coast to San Francisco for a cost of only $300. This small cost makes it very tempting to port shop.

The FDA's newly implemented paperless system, referred to as the OASIS system, also makes it easier to bring in unsafe foods. Importers know that if a shipment contains products with a history of no problems or violations, the FDA will release the item electronically with no questions asked.

One technique used by unscrupulous importers is to stack questionable food products in the back of a container and place the good products in the front. It is very likely that an FDA inspector would release this entire shipment with no questions asked. Another tech-

nique is to commingle questionable food products in a container with other types of merchandise, such as furniture.

Based on my experience, I believe it would be very beneficial for the FDA to target more inspections of importers' warehouses and perform more surveillance of retail outlets to determine the sources of the questionable food products they have in storage and on their shelves.

We know there is and will continue to be a shortage of consumer safety inspectors. Therefore, it is important that the FDA, in coordination with other Federal enforcement agencies, continues to make effective use of blitzes. Blitzes are short-term, very intensive surveillance efforts of a specific food product or a specific port of entry. Let me emphasize that blitzes are effective only if all FDA districts do them, or else it will invite port shopping.

The FDA is not deploying its inspectors effectively. Each FDA district office has its own ideas on how to best utilize its inspectors for collecting samples and conducting examinations of imported food products. Sometimes management is inflexible to new ideas, even though the ideas may be common sense. For example, some inspectors have to spend more than half their productive time traveling to and from locations to collect samples or conduct examinations of imported foods. It may take 30 minutes to collect a sample, but it may take from 2 to 3 hours of travel time.

One possible solution would be to place FDA inspectors closer to the proximity of their workload. FDA inspectors could share office space with a Customs office which is already located at the port of entry. FDA import operations are all computerized and assignments could be transmitted electronically from the district office to the inspector.

Proper deployment of inspection resources may not be the only problem. The techniques on how to examine suspect food products must be updated. The cheaters are now smarter and more innovative in hiding questionable products from the FDA. The demand and the potential revenue of up to four times the original purchase price makes more importers willing to take the risk. Penalties and fines now set at three times the invoice value should be increased to three times the expected selling price.

Annual work plans are inadequate. For FDA district offices to fulfill their annual work plan is often very difficult. The number of samples to be collected, as required in the work plan, are nonachievable because the plans often are not based on current or accurate data and field offices are not allowed to provide input.

The district offices try to accomplish what is dictated by FDA headquarters, but the requirements are often too high. The FDA district does not take into account port shopping, importers moving to other geographic areas, importers going out of business, demand decline of selected products, importers shipping directly to buyers, the availability of inspectors to collect samples, and the capability of the laboratory to handle samples.

Regional and district management place tremendous pressure on food import inspectors to accomplish the unrealistic goals in the work plan. There always has been a concern by management of losing staffing in the districts and regions if the workplan numbers are not met. Inspectors try their best to collect the samples and

conduct the examinations, but the trade-off is strictly one-sided. There is insufficient coverage given to the areas of greater risk, such as suspect importers or food product that may contain potential health risks.

With regard to health risks, FDA inspectors are not provided sufficient and timely information on known health risks associated with imported food. It would be a tremendous benefit to inspectors when they are at an importer's warehouse to know that certain products have been discovered to pose a greater health risk than others, or possibly that recent laboratory results have shown a particular product to be contaminated.

The import operations branch is the focal point of alerting all field offices to any health risk problem. An alert notice should be issued by them. In most cases, when an inspection by a field office discovers a problem food product, that information is generally circulated only to the other inspectors in the district and often not circulated nationally.

Current import procedures allow fraud and abuse. It is very easy for an importer to substitute food products from a good shipment to a rejected one. Most FDA field offices allow movement of imported food shipments to the importer's own warehouse before sampling. If the FDA rejects a shipment, that shipment will remain at the importer's warehouse for either private laboratory sampling, FDA audit sampling, or re-exportation, but that food is still in the importer's control.

Importers have been known to sell portions of a rejected food shipment and replace the products sold with products they have scheduled to arrive in another shipment. When an unscrupulous importer has a shipment rejected by the FDA and must re-export it out of the United States, the importer substitutes food from a good shipment to increase the chances it will pass inspection when the importer tries to re-enter that shipment.

In addition, when a private laboratory selects a food sample for analysis, there is no assurance that the importer shows the analyst the rejected product. The unscrupulous importer may show the lab analyst a good product stored next to the rejected product.

The FDA should have procedures to monitor and track importers who substitute food products. After one substitution violation, future rejected shipments should be placed in a bonded warehouse controlled by the Customs Service at the importer's expense.

Some importers also ignore FDA's recall of food products for destruction or re-export and distribute the products to American consumers. The reason is very simple—money. Importers can ignore the FDA's recall notices, pay the fine, and still make a reasonable profit.

That concludes my testimony, and I will try to answer any questions that you may have. Thank you.

Senator COLLINS. Thank you, Mr. Jang.

Mr. Jang, you discussed in your testimony that some importers use port shopping in order to ship questionable food products into the U.S. economy. Based on your experience, how common is port shopping? Is this a widespread problem or is it just an isolated example that you told us about?

Mr. JANG. Port shopping is getting to be a widespread problem, a wide area problem. Personally, I know of at least several ports of entry that they are port shopping, bringing in rejected products back into the country. The communication of importers who port shop is very good from importer to importer. They know which port of entry is easier to bring in their product without sampling, especially their problem products.

Senator COLLINS. So an unscrupulous importer who has a questionable product knows which ports are easier to ship the product into than others? Some have tougher inspections than others?

Mr. JANG. Yes.

Senator COLLINS. So this can have a real impact on our food safety, is that correct?

Mr. JANG. Yes.

Senator COLLINS. The General Accounting Office discussed Operation Bad Apple, where government investigators found that in 70 percent of a particular case, the unsafe products were released into the American marketplace. The investigators found that importers often used product substitution. For example, they substituted a good product for the laboratory tests that the FDA required for the tainted product. Can you explain to us how importers can get away with that, how they could substitute good products for bad?

Mr. JANG. In past years, cartons that came in, say, about 10 years ago were specifically marked and identified to a specific invoice and packing list. You can specifically identify that shipment with those paper documents. It would have on the carton itself the location of the importer, the carton number, like you have canned pineapple number 1 to 100, canned mushrooms 101 to 200. Some would have the production code and the name of the vessel.

Now, because Customs has relaxed their labeling requirements, the labeling on cartons is now identical from shipment to shipment. You cannot specifically identify one shipment from another shipment.

Senator COLLINS. So the shipping label is not going to prevent product substitution, the substituting of good products for bad, is that what you are telling us?

Mr. JANG. Yes.

Senator COLLINS. I have one final question for you before I turn it over to Senator Durbin. What has been your experience in using the current system of fines and penalties to deter the illegal distribution of imported foods?

Mr. JANG. This is a slap on the wrist. There is no deterrent to prevent importers from selling rejected merchandise. The fines are mitigated downward. It is, like you mentioned, it is a cost of doing business.

Senator COLLINS. Thank you, Mr. Jang. Senator Durbin.

Senator DURBIN. Thank you, Madam Chairman.

Mr. Jang, I am interested in the personal contact which an FDA inspector has with a party interested in a shipment that is being inspected. What is the usual contact? Is there a person there with the shipment when the FDA inspector does the actual inspection?

Mr. JANG. Generally, when an inspector goes to an importer's warehouse to examine the shipment, there will be someone there to show the inspector the shipment or where it is located. It could

be the importer himself or it could be a laborer to point out where the shipment is located.

Sometimes, the importer would stack the shipment in such a way in the warehouse that it would be difficult for the FDA inspector to reach or sample the product. You might stack it four stacks high and then the FDA inspector would be unable to obtain the sample. So the importer at that time might offer to assist the FDA inspector by going through it and collecting a sample. That is where product substitution might take place.

Senator DURBIN. Now, you talked a lot about fraud and abuse in the current system, and what I am trying to establish is your experience. Is this fraud and abuse well known within the FDA to be associated with specific importers?

Mr. JANG. It essentially is a problem that we have identified, that we have caught, or that Customs have caught, that have substituted.

Senator DURBIN. What I am trying to establish is whether or not the people working within the FDA, in your experience, would say, listen, when you go over to that importer's warehouse, be careful because we know in the past they have been guilty of practices which raised many questions. Is that the case?

Mr. JANG. Yes. We have a listing of problem importers. When we do issue assignment, we would forewarn the inspectors that this is a problem importer. Mostly, in the case of a problem importer, we would do an intensive type of examination along with U.S. Customs in a Customs-controlled warehouse where we have it there so there will be no manipulation by the importer.

Senator DURBIN. Because there is always a danger of manipulation.

Mr. JANG. Right.

Senator DURBIN. The importer's employee may not want you to see the shipment, may stack it too high or keep some part that is objectionable way from you. That is the problem that you might run into.

Mr. JANG. Yes, or substitution.

Senator DURBIN. Can you associate these importers with any specific countries of origin? Is there any country of origin for the shipment that is a perennial problem in terms of the shipments coming into the United States and the importers trying to circumvent the law?

Mr. JANG. On the West Coast, we deal mostly with Southeast Asia or Asian countries. There, we find a high degree of problem with many of the shipments.

Senator DURBIN. From any particular countries?

Mr. JANG. I would say in most of the countries, not any particular country. We do find a high rate from China, from Thailand, from the Philippines, and from Hong Kong.

Senator DURBIN. As I understand it, the GAO report says that the Food and Drug Administration does not have the authority to fine importers who distribute adulterated food shipments or fail to retain shipments for inspection. The Food and Drug Administration relies on a bond agreement between Customs and the importer for those shipments valued at more than $1,250 as a way to achieve compliance.

I assume that goes back to your point, that these importers know that they have very little to lose by trying to cheat when it comes to inspection.

Mr. JANG. Yes. Even though the importer paid a fine for not retaining the shipment for FDA inspection or a rejected shipment is disposed of before they are supposed to re-export it or destroy it, they still make a reasonable profit from that. You can make from two to four times the original invoice value of the merchandise.

Senator DURBIN. Your recommendation about tripling the fine based on the value of goods rather than the invoice price is one that GAO also follows, and I think, Madam Chairman, it is one thing that we ought to seriously consider as part of these hearings, that we give additional authority to the Food and Drug Administration so that those who try to defy the system really have a penalty that might catch their attention.

Mr. Jang, thank you for your testimony.

Mr. JANG. You are welcome.

Senator COLLINS. Thank you very much, Senator Durbin.

That concludes our hearing for today. As I mentioned in my opening statement, this hearing is the first in a series of four hearings that the Subcommittee will be holding to examine the issue of the safety of our Nation's food import system. We will be announcing a schedule for those hearings shortly.

The second hearing will focus on a case study involving tainted raspberries that were imported from Guatemala. We will trace how those raspberries got through the current system.

The third hearing will look at fraud and abuse in the system, an issue that Senator Durbin and I have discussed this morning.

The final hearing will focus on the remedies to this problem. We will hear from all the Federal agencies that are involved and we will discuss proposals for reform that have been put forth not only by the GAO but by Senator Durbin, Senator Coverdell, Senator Brownback, Senator Mikulski, and Senator Cochran and others who are interested in this area. We hope that these hearings will lay a foundation for real reforms that will help ensure that the safety of our imported foods do not compromise the health of the American public.

I want to thank Senator Durbin for his participation today and I want to thank the staff for its hard work. I particularly want to thank Dr. Stephanie Smith of my staff. She is a food scientist who is on loan to us who has brought a whole new degree of expertise to the Subcommittee's deliberations.

Finally, let me say that our plan had been to donate to a food kitchen the fruit that we bought, but based on what I have learned today, I am going to ask the staff to consult very closely with Dr. Camire before we do that, to make sure that we are not sending unsafe food to an unsuspecting food kitchen.

Thank you very much. The hearing is adjourned.

[Whereupon, at 12:05 p.m., the Subcommittee was adjourned.]

A P P E N D I X

Testimony
of
DR. MARY ELLEN CAMIRE
Associate Professor and Chair
Department of Food Science & Human Nutrition
University of Maine
to the
Senate Permanent Subcommittee on Investigations

May 14, 1998

I thank Senator Susan Collins for the opportunity to speak today on the safety of imported foods. My name is Mary Ellen Camire and I am an associate professor and chair of the Department of Food Science and Human Nutrition at the University of Maine, Orono, ME.

Food safety is a concern today for many Americans. I would like to present an overview of the problem of insuring the safety of foods brought into our country, beginning with a look at some of the serious pathogenic, or disease-causing, microorganisms that have been found in imported foods.

Food Pathogens

The majority of pathogenic microorganisms, including bacteria, viruses, and flagellates, are spread through contact with feces. Human feces present the greatest risk, but farm animals, pets, and wild animals also shed microbes in their feces that can infect humans. Untreated sewage contaminates drinking water in less-developed nations. While tourists are advised to "not drink the water" while in such countries, this contaminated water is used to wash foods, some of which is destined for export to the U.S.

Sewage discharged into the ocean is no less hazardous. Oysters, clams and mussels feed by filtering sea water. Everything in the water becomes concentrated in the shellfish, including bacteria from feces. Therefore raw shellfish pose a great risk to consumers.

Unsanitary conditions in farm fields has also proven to be a major hazard. Even when portable toilets are available to workers, as opposed to some farms with open latrines or no facilities at all, hand-washing stations are often absent. Sanitizing hands by washing or through the use of chemical sanitizers will greatly limit the spread of such diseases.

Contamination from animal feces is widespread. Runoff from farm manure piles contaminates streams, and improperly-composted manure literally sows disease upon crops for which it used as fertilizer. Farm animals and pets wander through plots on smaller farms, and wild

animals may free range in some areas. Additional sites of contamination include processing plants where hand-washing is not enforced.

Cyclospora cayetanensis

This pathogen had previously been associated with contaminated drinking water, but foodborne cyclosporiasis is on the rise. Guatemalan raspberries were associated with a 1996 outbreak that made 1,465 persons ill in 20 states, the District of Columbia, and two Canadian provinces. *Cyclospora* produces a violent form of diarrhea with accompanying fever, cramping, vomiting, and other discomforting symptoms within a week of ingestion. Although the disease can be treated with antibiotics, fatal dehydration is possible in the very young and very old.

At the FDA's request, the Guatemalan government and the raspberry industry voluntarily suspended exports to the U.S. It was not clear how the berries became contaminated. One theory suggests that contaminated wild birds spoil the berries as they fly overhead. Extensive research by the CDC and other groups traced the suspect berries to approximately five farms in Guatemala. Farms have implemented Hazard Analysis of Critical Control Points programs and improved sanitation on farms, but a second outbreak occurred in 1997. There is no simple test for detection of this parasite. Infected workers cannot be screened easily, nor can contaminated fruits be separated from wholesome products. The effects of common food processing methods such as blanching and freezing on *Cyclospora* are now being studied, but it is not yet known how low a freezer temperature is necessary, or how long foods must be held in frozen storage.

Hepatitis A

The FDA has classified hepatitis A as a Severe Hazard. This virus can survive in the environment for weeks and is resistant to heat and drying, two methods commonly used to kill bacteria. Like the food pathogens previously mentioned, hepatitis A virus is spread through feces. Contaminated water and food transmit the virus to the small intestine, and from there it is carried to the liver through the blood stream. The infectious dose is only 10-100 particles. Shellfish filter the virus from sewage-contaminated seawater, and so oysters and clams pose a risk. Strawberries and salad greens have also been identified as sources of the virus, since these crops require a fair amount of handling by farm workers. Mechanically-harvested crops pose a much lower risk to the public.

Since the incubation period varies from 15-50 days after infection, it is very difficult to trace back to the source of the contamination. Often the suspected food is gone, so there are no samples available for testing. Viruses are shed into the bile duct, which transports them to the intestine, where they are excreted in feces. A person can be shedding these viruses before any symptoms are apparent. As infected liver cells are destroyed by the immune system, fever, nausea, anorexia and jaundice develop. Fortunately, only 0.4% of cases in the U.S. are fatal, and most fatalities occur among elderly victims. However, permanent liver damage is a possibility, and most victims are debilitated for several or even months, causing loss of income. The estimated cost per case for

hepatitis A is $5,000. With over 30,000 documented cases in our country annually, this disease represents a considerable economic as well as safety problem.

Like other viruses, such as the one that causes chickenpox, hepatitis A elicits an immune response that confers protection against re-infection. A vaccine against hepatitis A is available. As with chickenpox, the disease is much milder in children; adults face more serious symptoms and longer recovery period. In developing nations, where sanitation is poor, virtually all children are exposed to the virus.

This situation became critical in 1997, when over 150 persons in Michigan became ill after eating frozen strawberries imported from Mexico and processed in California. A secondary issue was the fact that imported produce was sold for the USDA school lunch program, which requires that only American foods be used. The contaminated berries were distributed in Michigan, Arizona, California, Georgia, Iowa, Tennessee, and Maine. Twenty-nine cases of hepatitis A were reported in Maine. In California, thousands of schoolchildren were immunized - at a cost of about $100 per student- against hepatitis A as a precaution.

Using sophisticated analytical techniques, the CDC was able to identify the particular strain of hepatitis A from the U.S. outbreaks as one endemic to Baja California. The San Diego fruit processor's records indicated that the contaminated berries came from four farms in the Baja region of Mexico. Mexican authorities were skeptical of U.S. investigators' concerns, since hepatitis A is a common childhood illness there with few consequences. However, most Americans lack immunity to this virus, so exposure is serious, especially for elderly adults. Inspection of the suspect farms revealed modern production facilities, with one key flaw: open latrines for workers without any hand-washing equipment. Workers relieved themselves, then went right back to using their bare hands to twist the caps off the strawberries. Not an appetizing idea. Although some farms are improving sanitary facilities for workers, their produce continues to be shipped to our tables.

In our country, portable toilets and hand-washing stations are required, but of course, not all workers use them. It may be easier to immunize all children against this disease than to improve sanitary conditions in other nations, but we are still faced with a very real threat to our elderly and other immunocompromised adults.

Another hepatitis strain, E, is an emerging disease in Asia, Africa, and Mexico. Since these two diseases are spread by fecal contamination of water, hepatitis E contamination of foods may be possible as well. There is no immunization available for hepatitis E.

***Salmonella* species**

Several species of Salmonella cause human illness. The typical symptoms include acute nausea, vomiting and diarrhea. These bacteria can also enter the bloodstream, causing severe infections in the elderly and other weakened individuals. *Salmonella enteriditis* is most often associated with consumption of contaminated raw eggs in this country. *S. typhi* causes typhoid fever, with a fatality rate of 10%, compared to 1% for most *Salmonella* species. Fatality rates are

higher for all species in the elderly population. Older nursing home and hospital patients are especially at risk, since other diseases have already weakened their immune system. Two large outbreaks of salmonellosis caused by contaminated Mexican cantaloupes occurred in 1989 and 1991, with several deaths. Chronic arthritic pain may develop within a few weeks of the acute symptoms, and other autoimmune-type disorders may be related to previous infection with *Salmonella*. There is some evidence that certain species are developing resistance to common antibiotics.

Escherichia coli 0157:H7

E.coli is a bacterial species that normally inhabits our large intestine. However, new dangerous strains have evolved in recent years. Two of these strains were associated with outbreaks of foodborne illness due to imported foods. Another potential hazard is *E. coli* 0157:H7, which is most often associated with meat, as in the infamous Jack in the Box case a few years ago. Unpasteurized juices and cider and sprouts have also been identified as sources of *E. coli* 0157:H7. This variety produces a potent toxin that kills cells in the lining of the intestines.

As few as 10 bacteria can serve as an infectious dose. Victims experience severe cramping and diarrhea at first (1-2 days), followed by bloody diarrhea in 2-12 days as the intestinal tissue is destroyed in most cases. This discharge has earned the name hemorrhagic colitis. Less severe cases may not be diagnosed. Young children and some immunocompromised adults (HIV patients, persons receiving chemotherapy or other immune system -suppressing treatments) can develop hemolytic uremic syndrome (HUS). This potentially fatal (3-5% mortality rate) form of kidney failure can develop in up to 15% of all *E. coli* 0157:H7 patients. Permanent kidney function loss may result, necessitating dialysis or kidney transplants. Older adults may develop another syndrome, thrombotic thrombocytopenic purpura (TTP), that affects the nervous system with strokes and seizures, but the kidneys are less affected than with HUS.

Although no U.S. outbreaks have yet been traced back to imported foods, the potential for such an outbreak is high. A large outbreak in 1996 in Japan prompted authorities there to consider banning U.S. beef, but later locally-grown radish sprouts were found to be the culprits. South Korea reported that *E. coli* was detected in frozen American beef. However, the original seeds were imported from the U.S. Pathogens know no national boundaries; a problem in one country will soon be a problem elsewhere. We must take care to insure a rational, scientific approach to screening imported foods rather than reacting to xenophobia.

Chemical Contaminants

A related problem with imported foods is the presence of pesticides and veterinary drug residues. Pesticides increased crop yields; antibiotics enhance weight gain for farm and aquaculture animals. Although Codex Alimentarius has set maximum pesticide levels for many foods, individual farms may choose to use higher levels. Such contamination is not simple nor inexpensive to detect.

Dr. Rodney Bushway in my Department maintains a database of common pesticides for wild blueberries. Blueberry processors in Maine accept fruit from Canadian growers. Some pesticides are approved for use on blueberries in Canada, but are not permitted in the U.S. Fruit contaminated with these chemicals must be diverted back to Canada or destroyed. Exports of Maine wild blueberries depends on the wholesome natural image of the fruit. Detection of an unapproved pesticide on berries could ruin foreign and domestic markets.

Adequacy of Domestic and International Food Standards, Codes of Practice, and Other Guidelines Pertaining to Imported Foods

Preventative measures at the farm level are the best protection for U.S. consumers. U.S. and international codes are probably sufficient, but action is needed to enforce such codes. Other governments should be responsible for the actions of farmers and food processors within their jurisdiction. Noncompliant organizations should be penalized.

The World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) states that each WTO member must accept as equivalent a food regulatory system of another country if it provides an equal level of health protection as is provided to its own consumers. This policy does not dilute our own food safety efforts, rather it permits a streamlined process for our inspectors to work with those in nations that hold equally high standards. In fact, in some cases our standards may not be the highest in the world. I believe that U.S. participation in this process will maintain safety of imports from those countries with good practices, while allowing FDA to focus on problem nations and products. It is conceivable that another country may have excellent operations for seafood, but abysmal sanitation for fresh fruits. Flexibility will be critical for the success of this program. Already the U.S. has a similar type of understanding with New Zealand.

Importance of a Science-based and Risk-based Inspection System

Although all food pathogens are enteric, fecal contamination is usually not visible, and certainly the microorganisms are not visible to the naked eye. Pathogens do not produce off-odors or visual defects and thus casual inspection will fail to detect contamination. Current inspection procedures do not test all, or even most, shipments, thus it is likely that contaminated food will enter the country.

I do believe that extensive microbiological and chemical testing of all imported foods is unnecessary and far too expensive to consider. However, high-risk foods (Table 1) should be tested thoroughly. For example, all peanut shipments destined to become peanut butter are tested for aflatoxin, a chemical produced by mold that leads to liver cancer. Rather than looking for a "needle in a haystack" FDA and other agencies should focus on high-risk foods.

Certain types of food are likely sources of contamination with *Salmonella* species. Such foods are sampled 2-4 times as much as are foods with lower risks for carrying these pathogens. A major problem for all parties is the lack of rapid, accurate testing methods for many food pathogens.

IDEXX Laboratories in Westrook Maine has developed a rapid method for Salmonella -- only 22 hours instead of several days. For most people, this amount of time hardly seem rapid.

Fresh fruits, vegetables and seafood are highly perishable, and on occasion these foods have spoiled before laboratory results could be confirmed. We are not alone in this problem, as no nation has access to rapid methods for the newly emerging pathogens. IDEXX has branches eight nations, all of whom are our trade partners and who also have high public health standards Furthermore, I believe that the producer or importer should bear the cost of safety testing, rather than the U.S. government.

Low-risk foods	**High-risk foods**
mechanically-harvested produce	hand-picked produce
bananas	peeled or cut fresh produce
root crops	sprouts
grains	filter-feeding shellfish
high acid canned foods	low acid canned foods

Merits of Various Initiatives
Trace-back mechanisms

It is imperative that FDA and CDC staff be able to locate the original source of contamination. Many companies already track individual shipments from each farm as part of their quality assurance programs. This practice should be expanded, if not mandated. This policy will allow FDA to punish the culprits without penalizing farmers and processors who employ good hygiene in their operations. However, farm cooperatives could have difficulty complying with this practice, since many farmers "pool" crops for sale.

Nation of origin labeling

From a safety perspective, I believe that it is not necessary to label the country of origin for produce. Many Americans do want to buy American products whenever possible, so I feel that labeling has merit. A label bearing the name of the country does not tell the consumer anything about the conditions under which the food was produced. In any nation there are farms that follow good agricultural practices, and there are other farmers and processors that should be put out of business for their shoddy conditions. Many retail chains already display the nation of origin, and other stores exhibit cartons marked with the country of origin. Frozen orange juice manufacturers also indicate that their products may be a blend of U.S. and Brazilian juices. If the U.S. continues to pursue food safety Memorandums of Understanding (MOUs) with other nations, then I think that

knowledge of those countries would be beneficial for safety-conscious consumers. Requiring the other nation to demonstrate the safety of all export producers within its borders should imply that any sample from that country is relatively safe.

This is a subject that would greatly benefit from improved consumer education. It is obvious to me that any fresh berries sold in the winter must be imported, but the average shopper may be unaware that the seasons in the Southern Hemisphere are opposite our own. Since much imported produce is sold when local crops are out of season, I think that these products play an important role in providing nutrients and variety to the winter diet.

Hazard analysis of critical control points (HACCP)

This program came into being during the 1960's to provide safe food for astronauts. The U.S. has a role in training other nations to use this program since we have been running HACCP longer than anyone else. HACCP alerts staff on a farm or in a company to the risks in that organization, and ensures that an action plan is ready for enforcement. The U.S. could provide other nations with a crop-specific HACCP outline. We are already training personnel abroad. The National Marine Fisheries Service and FDA send scientists to other countries in order to train seafood processors how to set HACCP in their own plants.

Indonesia sent one of its Directorate of Fisheries employees to the University of Maine to learn more about food safety. He worked with me on a project to track New England seafood as it was shipped around the country. He implemented new programs upon his return to Indonesia, and he has been sent back for advanced training in seafood inspection and HACCP. These programs resulted in increased acceptance of Indonesian products exported to the U.S. This success prompted Indonesia to examine the safety of foods that it imports.

Recently new guidelines to developed to improve the safety of those foods. Some critics of HACCP have labeled it as a barrier to trade, but I feel that it is a scientifically-proven process that insures food safety. Our leadership in developing and implementing HACCP has improved food safety internationally. The FDA is considering accepting food from countries that have not yet implemented HACCP but have demonstrated an understanding of the safety hazards to which their foods are liable and the ability to identify and apply controls that prevent or reduce the possibility of such hazards occurring in those foods.

Summary

Without intervention, the outlook for food-borne illnesses from imported as well as domestic foods is grim. New pathogens will emerge to daunt public health personnel. Using science to plan screening programs will improve safety while being efficient in terms of cost and manpower. A key point to remember is that imported foods are not the only problem--Americans have changed. More immunocompromised (HIV-infected, cancer and transplant patients, elderly) individuals are alive and active in society than ever before. We must act to protect all Americans from preventable illnesses. As a resident of a rural state that relies heavily on imported foods, I feel that this is the time for corrective action to occur.

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United States General Accounting Office

GAO

Testimony

Before the Permanent Subcommittee on Investigations, Committee on Governmental Affairs, U.S. Senate

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FOOD SAFETY

Federal Efforts to Ensure Imported Food Safety Are Inconsistent and Unreliable

Statement of Robert E. Robertson, Associate Director,
Food and Agriculture Issues,
Resources, Community, and Economic
Development Division

GAO/T-RCED-98-191

Madam Chairman and Members of the Permanent Subcommittee:

Thank you for the opportunity to discuss our work on federal efforts to ensure the safety of imported foods. As the American public consumes more and more foods from other countries, the challenge of ensuring the safety of these foods is growing. Recent outbreaks of foodborne illnesses demonstrate that imported foods have introduced new risks or have increased the incidence of illnesses. As imports increase, it is imperative that federal agencies have the most effective systems in place, and make the best use of their limited resources, to ensure that imported foods are safe to eat. The primary responsibility for ensuring the safety of imported foods is split between two federal agencies: the Department of Health and Human Services' Food and Drug Administration (FDA) and the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS). FSIS and FDA work closely with the U.S. Customs Service (Customs) in the Department of the Treasury and the Centers for Disease Control and Prevention (CDC) in the Department of Health and Human Services in carrying out their responsibilities.

Today, I will discuss findings from our recent report in which we pointed out how limitations in FDA's authority and approach for regulating imported foods adversely affect its ability to ensure food safety, how FDA's and FSIS' procedures for selecting shipments to review result in the ineffective targeting of inspection resources, and how weaknesses in FDA's and Customs' controls allow unscrupulous importers to market unsafe products.[1]

In summary, we found the following:

- The Food and Drug Administration lacks the legal authority to require that countries exporting foods to the United States have food safety systems equivalent to ours--an authority that the Food Safety and Inspection Service has and uses to share the burden of ensuring safe foods with the exporting countries. Without such authority, the Food and Drug Administration must rely primarily on its port-of-entry inspections, which covered less than 2 percent of shipments in 1997, to detect and bar unsafe foods. Such an approach has been widely discredited as an effective protective measure.

- Both the Food and Drug Administration and the Food Safety and Inspection Service could make better use of their inspection resources by using available health risk information to target shipments for inspection that pose the highest food safety risk. Additionally, the Food and Drug

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[1]Food Safety: Federal Efforts to Ensure the Safety of Imported Foods Are Inconsistent and Unreliable (GAO/RCED-98-103, Apr. 30, 1998).

Administration could further improve the use of resources by clarifying its communications to inspectors about which shipments to select and by taking enforcement action when importers are found to inaccurately describe the contents of shipments. With such improvements, the Food and Drug Administration could better ensure that it is using its scarce resources to identify the foods posing greater risks.

-- The Food and Drug Administration's procedures for ensuring that unsafe imported foods do not reach U.S. consumers are vulnerable to abuse by unscrupulous importers. Under current procedures, the Food and Drug Administration generally allows importers to retain control over shipments until the agency grants their release. If importers move shipments into domestic commerce without a Food and Drug Administration release--that is, before the Food and Drug Administration inspects them or when a Food and Drug Administration laboratory test reveals the products do not meet U.S. standards--the Food and Drug Administration has no effective means of compelling importers to return the shipments for inspection, destruction, or reexport. In addition, when the Food and Drug Administration requires an importer to provide evidence that a suspect shipment is safe, the agency allows the importer to select the laboratory that picks the samples to be tested and that conducts the tests. Finally, the Food and Drug Administration's and Customs' principal deterrent for ensuring that importers comply with U.S. requirements--the collection of damages from violators--is uneven and uncertain.

BACKGROUND

Foodborne illnesses in the United States are widespread and costly. While the magnitude of the problem is uncertain, we reported in May 1996 that studies have estimated up to 81 million cases of foodborne illnesses and as many as 9,100 deaths occur each year.[2] Recent estimates suggest that the number of illnesses may be even higher. While there is a wide range of estimates, according to the U.S. Department of Agriculture, the cost of these illnesses and deaths, measured in medical treatment and productivity losses, have been estimated to range from $7 billion to $37 billion a year.

A significant amount of the food we consume is imported, and the percentage is growing. For example, between 1980 and 1995, the imported share of all fresh fruit consumed by the American public rose from about 24 percent to about 33 percent,

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[2]Food Safety: Information on Foodborne Illnesses (GAO/RCED-96-96, May 8, 1996).

FDA estimates that the volume of imported fruits and vegetables will grow by 33 percent between now and 2002. The sheer volume of these imports, along with the difficulty in ensuring that they are safe, adds to the risk of foodborne illnesses and makes it essential that steps to ensure their safety are effective.

Some of these imported foods pose especially significant risks of foodborne illness. They can introduce pathogens previously uncommon in the United States, such as new strains of Salmonella and the Cyclospora parasite. In 1996 and 1997, outbreaks of foodborne illness linked with the Cyclospora parasite in raspberries from Guatemala affected nearly 2,500 people in the United States and Canada, causing prolonged gastrointestinal distress and other painful symptoms. In addition, imported foods may contain pathogens, such as hepatitis A, that cannot be easily detected by examination or even laboratory analysis.

FSIS has jurisdiction over meat, poultry, and some egg products, while FDA regulates all other foods. FSIS and FDA work closely with Customs and CDC. Customs refers imported foods to FSIS or FDA for their review before releasing the shipment into U.S. commerce. CDC monitors the incidence of foodborne illness, works with state and local health departments to investigate outbreaks of illness, and collaborates with FSIS, FDA, and others to conduct research on foodborne diseases.

As we have reported numerous times, the U.S. food safety system is characterized by a fragmented organizational structure with numerous agencies implementing a hodgepodge of inconsistent regulations and laws. This lack of a uniform, risk-based approach has adversely affected our nation's ability to protect itself from a host of domestic food safety problems. That same fragmented structure and inconsistent regulatory approach is being used to ensure the safety of imported foods as well.

LACK OF EQUIVALENCY AUTHORITY DIMINISHES FDA'S ABILITY TO PROTECT U.S. CONSUMERS

To ensure the safety of meat and poultry imports, FSIS has a statutory mandate to require that each country wishing to export meat and poultry products to the United States demonstrate that it has an equivalent food safety system. As of January 1998, FSIS had certified the eligibility of 37 countries for exporting meat and poultry to the United States. FSIS has used equivalency authority to shift most of the responsibility for food safety to the exporting country, which performs the primary inspection of products before they reach the United States. This approach allows FSIS to leverage its resources by focusing its reviews on verifying the efficacy

of exporting countries' systems rather than by relying primarily on ineffective, resource-intensive port inspections to ensure the safety of imported foods.

In contrast, FDA, although it is expected to ensure that imported fruits and vegetables and other foods meet U.S. standards, does not have a similar equivalency authority and therefore cannot require that countries exporting food products to the United States have safety systems in place that are equivalent to ours.[3] As a result, FDA must rely primarily on selecting and testing import samples at ports of entry to ensure that foods are safe. Such an approach has been widely discredited by the United Nations Food and Agriculture Organization, an FDA Advisory Committee, and our own analyses as ineffective because individual product samples tested at the ports of entry may not represent the health risks of all shipments from that exporter. To exacerbate matters, FDA has been unable to keep pace with increasing imports, and its inspection coverage has fallen from an estimated 8 percent of import shipments in fiscal year 1992 to an estimated 1.7 percent in fiscal year 1997.

Given the ineffectiveness of port-of-entry inspections, FDA cannot realistically ensure that unsafe foods are kept out of U.S. commerce. Even if FDA could inspect more shipments at ports of entry than it currently does, such an approach would still provide little assurance that imported foods are picked, processed, and packed under sanitary conditions because inspectors have no assurance that the exporting country has an effective food safety system. An equivalency requirement would allow FDA to share the burden of ensuring safety with the exporting country and allow it to make better use of limited resources. FDA agrees it needs such authority but believes the authority should be discretionary, so that equivalency could be applied when FDA believes it is most appropriate, thus limiting disruptions in trade. In our April 1998 report we recommended that equivalency should be mandatory for all imported foods, but the requirement could be phased in, so that it would not disrupt trade. Such mandatory authority would (1) impel FDA to take a proactive approach to preventing food safety problems, instead of requiring equivalency in countries after problems become apparent and (2) enable FDA to leverage its staff resources by sharing responsibility for food safety with exporting countries.

AGENCIES COULD MORE EFFECTIVELY TARGET RESOURCES TO INSPECT UNSAFE FOODS

FSIS and FDA use computer systems to review information on each import shipment and to help identify the import shipments requiring inspector action.

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[3]In 1997, an administration initiative on food safety proposed equivalency authority for FDA.

However, neither agency's system takes maximum advantage of available data to target those imported foods posing the greater health risks. Each agency has opportunities to use its resources more effectively.

FSIS relies primarily on the violation history of previous shipments from the exporting firm to target entries for inspections or laboratory tests, but the violation history may not always indicate the shipments more likely to pose health threats. For example, many violations, such as incorrect shipping labels, may not directly affect consumer safety. In 1996, about 86 percent of FSIS' refused shipments, excluding those refused entry for transportation damage, were not directly related to health risks such as excessive residues, microbiological contamination, unsound condition, or defects caused by disease. Nevertheless, these violations triggered a series of inspections on subsequent shipments of the same product from the same exporting firm until at least 10 consecutive shipments were found to be in compliance. When limited resources are targeted in this fashion, fewer resources are available for products posing greater health risks.

FSIS could further improve its automated screening system if it developed information on patterns of violations, which would allow it to determine whether Salmonella contamination, for example, was a recurrent problem in a particular country or an exported product and increase its inspection frequencies for such shipments. FSIS possesses raw data on those problems but has not designed its computer system to use these data to identify patterns of violations, such as firms or countries with repeated problems, that are directly related to food safety. According to FSIS, the agency will consider modifying its automated screening system to identify patterns on violations when it redesigns the system this year.

FDA's system for selecting imports for examination relies heavily on inspectors' judgment. To help its inspectors make informed judgments, FDA provides a number of tools, such as annual work plans, compliance programs, and databases containing historical or other pertinent information to inspectors. However, these tools are often confusing, inconsistent, or not readily available to FDA inspectors and hence provide guidance of little practical value.

Specifically, FDA's annual work plans set the number of activities, such as the number of inspections and tests each FDA district is to conduct for the 10 specific food programs that cover imports. Each day, the inspectors attempt to select shipments on the basis of the work plan's targets. According to FDA, its compliance programs, not the work plans, contain specific guidance on inspection requirements. However, we found that FDA inspectors rely on the numerical inspection targets set forth in the annual work plan for guidance. These targets are sometimes inconsistent with the direction given in the compliance programs. Such inconsistency in guidance

for inspectors serves only to distract and confuse them as they attempt to carry out their duties on a daily basis.

Moreover, FDA's computer system for screening imported food shipments is not programmed to help inspectors effectively use laboratory test results, violation histories, and other information on shipments to identify those shipments posing the greatest food safety risks. With respect to laboratory tests, FDA has not integrated its laboratory database with its automated import screening system; thus, inspectors do not have the results of prior laboratory tests available when making decisions on which imported products to inspect.

Furthermore, FDA inspectors do not have ready access to some useful data on previous violations by foreign plants in the automated import screening system when making their decisions on which products to inspect. For example, FDA has databases with information on prior violations by foreign plants or countries and information on registrations of foreign firms producing certain canned foods, but the automated import screening system cannot review the databases, and the process for having the inspectors do so can be cumbersome and time-consuming. To obtain these data, inspectors must close their automated import screening system and open the other databases. We observed this process and found that it took 3 to 10 minutes each time the inspector wanted to switch from one database to another. Given that inspectors may have to process as many as 200 shipments per day, not all inspectors bother changing databases to look for this information.

Instead, inspectors told us, they often rely on their memory of the information in the database or notes. Because inspectors have these difficulties in obtaining needed data on health-related risks and are under time pressure, they decide which samples to select on the basis of incomplete information. As a result, inspectors may rely on individual biases. For example, one inspector told us he believed one country did not have sanitary facilities and therefore assumed that all food products imported from that country were contaminated with filth. This inspector routinely selected samples of food from that country for filth tests, although the laboratory staff told us that such tests were lower priority than tests for microbiological contamination and therefore were frequently not conducted. As a result, the resources used to select these samples were not effectively used. According to FDA officials, the agency received funds to enhance the screening system in fiscal year 1998 and will begin integrating the databases (the Laboratory Management System, the Import Alert Retrieval System, and the Low-Acid Canned Food database) with the automated import screening system this year.

Finally, the information identifying the contents of imported food shipments is, in most cases, entered directly into an automated import processing system by

importers, some of whom have an incentive to misrepresent their goods in the interest of avoiding inspectors' scrutiny. Importers who have demonstrated competency with the electronic system, known as paperless filers, are allowed to enter shipping information into the system without providing actual shipping documents to FDA. To ensure accuracy, FDA retrospectively verifies a sample of the importer-provided information and, according to its guidelines, may withdraw paperless filing privileges from filers with error rates of 10 percent or higher. However, FDA records show that no corrective actions to withdraw paperless filing privileges have been taken for even the most error-prone paperless filers. According to a January 1998 FDA survey, over 300 paperless filers, nearly 15 percent of those audited, had error rates of 10 percent or greater, but paperless privileges were not withdrawn from any of these filers. As a result, importers aware of FDA's inaction could evade FDA's inspections by incorrectly describing the contents of a shipment. Such intentional circumvention was demonstrated in 1993, when an importer was found guilty on 138 counts, mostly related to misrepresenting the source of seafood in an attempt to avoid FDA's automatic detention.

WEAKNESSES IN IMPORT CONTROLS ALLOW THE ENTRY OF UNSAFE PRODUCTS

In addition to the problems associated with FDA's system for selecting food shipments for inspection, several weaknesses in its controls over imported products enable some importers or their representatives to sell unsafe foods in the United States. Because of these weaknesses, some importers are able to (1) falsify laboratory test results on suspect foods to obtain FDA's approval to release them into commerce, (2) sell potentially unsafe imported foods before FDA can inspect them, and (3) sell imported foods even when FDA has found a violation and prohibited entry. In addition to the absence of controls, violations are seldom punished effectively. In this environment, FDA has little assurance that contaminated products are kept off U.S. grocery shelves.

With respect to falsifying laboratory test results, FDA's system for automatically detaining suspicious products pending testing to confirm their safety may be easily subverted, because FDA does not maintain control over the testing process--importers are allowed to choose the laboratory that selects and tests the samples. In fiscal year 1997, FDA detained nearly 8,000 import shipments automatically because it had identified violations in previous shipments of related products. Most of these shipments, according to FDA, were released after importers presented their private laboratory test results showing that the shipments met U.S. standards. However, Customs and FDA officials are concerned over the reliability of private laboratories chosen by importers and hence the reliability of their test results. According to Customs inspectors, some importers, to ensure their products appear to

meet U.S. requirements, share shipments that have already been tested and proven to be in compliance--a practice referred to as "banking." FDA says it lacks the explicit authority to place restrictions on which laboratories importers can use to test products. Thus, FDA cannot control the selection of the samples tested nor insist on objective testing.

FDA does not maintain control over products before releasing them into U.S. commerce, enabling importers to sell products before inspection or even after FDA has found a violation. Importers of FDA-regulated foods generally retain possession of import shipments until FDA releases them and must make the shipments available for FDA's inspection if requested. At the ports we visited, imported shipments under FDA's jurisdiction often entered U.S. commerce before being delivered to FDA for inspection or were not properly disposed of when refused entry. In Operation Bad Apple, which took place in San Francisco in 1997, Customs officials identified 23 weaknesses in controls over FDA-regulated foods. Importers' practices to circumvent FDA's controls included (1) ignoring FDA's requests that shipments in violation be redelivered to Customs for disposition and (2) substituting cargo so that FDA inspectors would not see contaminated foods. In this investigation, Customs found that about 40 percent of the imported foods determined to violate U.S. standards were never redelivered to Customs for destruction or export, as required, and presumably entered domestic commerce. Moreover, when shipments were redelivered to Customs for destruction or export, Customs officials said other products had been substituted in about 50 percent of the shipments before redelivery. The results of this investigation are consistent with the findings in our 1992 report on pesticides,[4] which found that 60 percent of the perishable foods and 38 percent of the nonperishable foods that FDA found to be adulterated with illegal pesticides were released into U.S. markets, or not returned to Customs for destruction or reexport as required. Customs and FDA officials recognize that this problem is occurring at other ports.

In addition, there are few consequences for importers found to violate safety standards. Lacking the authority to fine importers who distribute adulterated food shipments or who fail to retain shipments for inspection, FDA relies on a bond agreement between Customs and the importer for most shipments as a way to achieve compliance. The bond amount is based on the importer's declared value of the imported shipment, and damages (i.e., penalties) may be assessed against violators at up to 3 times the value of the bond. But such penalties are ineffective because Customs often does not collect full damages from importers that fail to

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[4]Pesticides: Adulterated Imported Foods Are Reaching U.S. Grocery Shelves (GAO/RCED-92-205, Sept. 24, 1992).

comply with FDA's requirements. For example, in fiscal year 1997, Customs in Miami assessed and collected damages for about only 25 percent of the identified cases involving the improper distribution of food products. Customs and FDA attributed the low figure to (1) laxity in communicating information about refused shipments between the agencies, (2) unclear guidance for Customs officials' handling of the shipments, (3) a malfunction in the Customs computer system for storing case files, and (4) a halt in collections pending the resolution of a court case involving the collection of damages. Even when the damages were assessed, Customs only collected about 2 percent of the original assessment. In one case, Customs collected damages of $100 from one importer for not returning a shipment with a declared value of $100,000. According to Customs officials, any reduction in damages must be in accordance with Customs guidelines, and both Customs and FDA must agree to reduce the damages.

- - - -

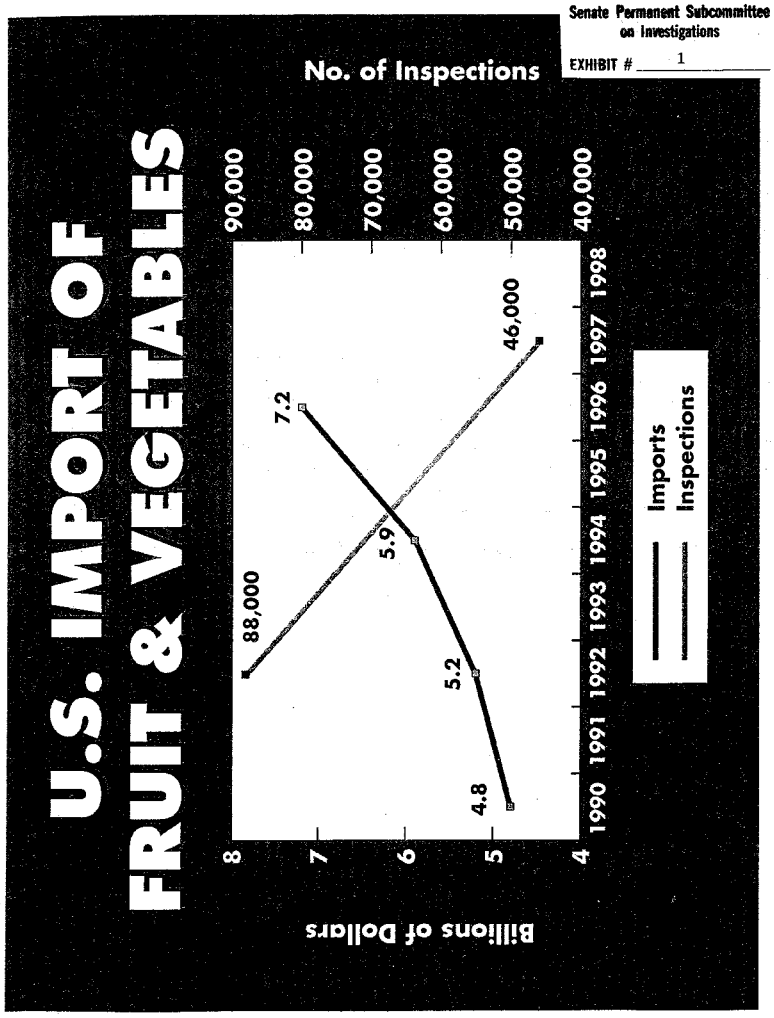
In conclusion, Madam Chairman, we believe that it is vitally important that the nation's efforts to ensure the safety of imported foods be improved. As the portion of the U.S. food supply from imported sources continues to grow, it is clear that the safety of the U.S. food supply cannot be ensured unless food imports are safe. However, our system for keeping unsafe imported foods from entering the food supply has a number of weaknesses. These weaknesses can and should be addressed. We have made a number of recommendations to this end in our recent report, and we hope to develop additional recommendations as part of our ongoing work for you.

That concludes our prepared statement. We would be happy to respond to any questions you or members of the subcommittee may have.

(150650)

Senate Permanent Subcommittee on Investigations

EXHIBIT # 1



Senate Permanent Subcommittee
on Investigations

EXHIBIT # 2

IMPORTED FRUIT AND VEGETABLES

The imported fruit and vegetables on display in the hearing room were purchased yesterday at a Virginia supermarket. They include the following:

MEXICO	Watermelon Papaya Mangos
GUATEMALA	Mangos Honey Dew
DOMINICAN REPUBLIC	Cantaloupes Tamarindo
EQUADOR	Bananas Plantains
BELIZE	Papaya
COSTA RICA	Pineapples Tamarindo
SOUTH AFRICA	Pears
CHILE	Grapes
NEW ZEALAND	Kiwi
TURKEY	Apricots
THAILAND	Papaya

United States General Accounting Office

GAO

Report to the Chairman, Permanent Subcommittee on Investigations, Committee on Governmental Affairs, U.S. Senate

Senate Permanent Subcommittee on Investigations
EXHIBIT # 3

April 1998

FOOD SAFETY

Federal Efforts to Ensure the Safety of Imported Foods Are Inconsistent and Unreliable

GAO/RCED-98-103

GAO United States
General Accounting Office
Washington, D.C. 20548

Resources, Community, and
Economic Development Division

B-279329

April 30, 1998

The Honorable Susan M. Collins
Chairman, Permanent Subcommittee
on Investigations
Committee on Governmental Affairs
United States Senate

Dear Madam Chairman:

This report responds to your request that we evaluate the federal government's efforts to ensure the safety of imported foods. The report contains recommendations to the Congress and to the Secretaries of Agriculture and of Health and Human Services that are designed to enhance the federal government's authority to review the safety of food imports, improve the effectiveness and efficiency of systems and staff to screen imports, and strengthen internal controls.

As agreed with your office, unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days from the date of this letter. At that time, we will send copies to interested parties and make copies available to others upon request.

Please call me at (202) 512-5138 if you or your staff have any questions about this report. Major contributors to the report are listed in appendix VI.

Sincerely yours,

Robert A. Robinson
Director, Food and
Agriculture Issues

Executive Summary

Purpose

Each year, millions of Americans become ill after eating tainted foods, and thousands die. Ensuring the safety of domestically produced foods is a daunting task, but the challenge of ensuring the safety of the entire food supply is even more difficult as Americans consume more foods imported from other countries. The primary responsibility for ensuring the safety of imported foods is split between two federal agencies—the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) and the Department of Health and Human Service's Food and Drug Administration (FDA).

Concerned about the safety of imported foods, the Chairman of the Permanent Subcommittee on Investigations, Senate Committee on Governmental Affairs, asked GAO to review the efforts of federal programs to ensure the safety of food imports. Specifically, this report discusses (1) the differences in the agencies' authorities and approaches for ensuring the safety of imported foods and (2) the agencies' efforts to target their resources on foods posing risks. In addition, the report discusses weaknesses in the controls over imported foods.

Background

Foodborne illnesses in the United States are widespread and costly. The magnitude of the problem is uncertain, however, because these illnesses are underreported and health officials often cannot determine their source. As GAO reported in May 1996,[1] up to 81 million cases of foodborne illnesses and as many as 9,100 deaths from these illnesses occur each year. According to the U.S. Department of Agriculture's Economic Research Service, the costs for medical treatment and productivity losses associated with these illnesses and deaths range from $6.6 billion to $37.1 billion. Recent outbreaks of foodborne illness demonstrate that imported foods have introduced new risks or increased the incidence of familiar illnesses. The increased consumption of imported foods in the United States further heightens the risk of illness.

FSIS has jurisdiction over meat, poultry, and some egg products, while FDA regulates all other foods. FSIS and FDA work closely with the Customs Service (Customs) and the Centers for Disease Control and Prevention (CDC). Customs refers imported foods to FSIS or FDA for their review before releasing the shipment into U.S. commerce. CDC monitors the incidence of foodborne illness; works with state and local health departments to investigate outbreaks of illness; and collaborates with FSIS, FDA, and others to conduct research on foodborne diseases.

[1] Food Safety: Information on Foodborne Illnesses (GAO/RCED-96-96, May 8, 1996).

Results in Brief

Federal agencies cannot ensure that the growing volume of imported foods is safe for consumers. Although the Food Safety and Inspection Service and the Food and Drug Administration require imported foods to meet the same standards as domestic foods, their approaches to enforcing these requirements differ. By law, the Food Safety and Inspection Service places the principal burden for safety on the exporting countries by allowing imports only from those countries with food safety systems it deems to be equivalent to the U.S. system. The Food and Drug Administration, lacking such legal authority, allows food imports from almost any country and takes on the burden of ensuring the safety of imported foods as they arrive at U.S. ports of entry. Relying on port-of-entry inspections to detect and prevent unsafe foods is ineffective, given that (1) this approach does not ensure that foods are produced under adequately controlled conditions, (2) the Food and Drug Administration currently inspects less than 2 percent of all foreign shipments, and (3) inspection will not detect some organisms, such as Cyclospora, for which visual inspections and laboratory tests are inadequate.

The Food Safety and Inspection Service and the Food and Drug Administration are not deploying their inspection resources to maximum advantage. The Food Safety and Inspection Service focuses its inspection and testing resources on shipments from exporting firms with a history of violations, such as contamination, processing defects, and incorrect or missing shipping labels. However, many of the violations, such as the incorrect or missing shipping labels, may bear little relationship to food safety. Using available data on health-related risks from shipments that do not meet U.S. standards could help the Food Safety and Inspection Service focus more closely on the imports posing the greater risks. The Food and Drug Administration's annual work plan does not set achievable targets for inspection activities; as a result, inspectors do not have clear guidance for conducting inspections. For example, in fiscal year 1997, the Food and Drug Administration conducted only half of its planned inspections of imported foods. Furthermore, the Food and Drug Administration does not make health risk data readily available to guide inspectors' selections. In addition, when making decisions on which shipments to inspect, the Food and Drug Administration relies on importers' descriptions of shipments' contents, which are often incorrect. As a result, the agency's resources may not be focused on imported foods posing the greater safety risk.

The Food and Drug Administration's procedures for ensuring that unsafe imported foods do not reach U.S. consumers are vulnerable to abuse by

unscrupulous importers. For example, when an exporting firm has a history of violations, the Food and Drug Administration detains shipments from that firm without sampling or analysis. Importers of these detained shipments have the right to present evidence, such as private laboratory tests, showing that the product complies with U.S. standards. However, because the Food and Drug Administration does not have the explicit authority to require importers to use certain laboratories, importers can choose the laboratories that select the samples and perform the tests to prove compliance. For other shipments, importers retain control of the goods while the Food and Drug Administration decides whether to inspect them or while tests are being conducted on them. In some cases, when the Food and Drug Administration decides to inspect shipments, the importers have already marketed the goods. In other cases, when the Food and Drug Administration finds contamination and calls for importers to return shipments to the Customs Service for destruction or reexport, importers ignore this requirement or substitute other goods for the original shipment. Such cases of noncompliance seldom result in a significant penalty.

Principal Findings

Lack of Equivalency Authority Diminishes FDA's Ability to Protect U.S. Consumers

FSIS has the statutory authority to require the exporters of meat and poultry products to have food safety systems equivalent to the system in the United States. In enforcing this requirement, FSIS has determined that 37 countries have food safety systems equivalent to the United States' and are therefore eligible to export meat and poultry products to this country. (App. II lists the eligible countries.) FDA's authority, on the other hand, requires imported foods to meet U.S. standards. FDA does not have the authority to require the exporting country to have an equivalent safety system in place. In 1997, administration initiatives on food safety proposed that FDA be given this "equivalency authority."

FSIS has used its equivalency authority to shift the primary responsibility for food safety to the exporting countries. In so doing, the agency can leverage its resources by reviewing exporting countries' compliance with U.S. requirements, rather than by depending on resource-intensive inspections at ports of entry. FDA, on the other hand, relies on selecting and testing import samples at ports of entry to ensure that foods are safe. Such an approach, when used as the sole means of assessing the safety of

foods, has been widely discredited as an effective protective measure by the Food and Agriculture Organization of the United Nations, an FDA advisory committee, and GAO for a number of reasons. For example, individual products tested at ports of entry may not represent the health risks of the entire shipment. The ineffectiveness of FDA's approach is magnified by its inability to keep pace with a rising level of imports. FDA's coverage of import shipments has fallen from an estimated 8 percent in fiscal year 1992 to an estimated 1.7 percent in fiscal year 1997.

Agencies Could More Effectively Target Resources on Unsafe Foods

Although both FSIS and FDA use computer systems to screen each import shipment and to help identify the import shipments requiring inspectors to take action, the agencies have not designed their systems to take the best advantage of available data so that they can target those imported foods posing the greater health risks. FSIS relies primarily on the violation history of previous shipments from the exporting firm to target entries for inspectors' action; this violation history may not always indicate the shipments more likely to pose health threats. For example, many violations, such as incorrect shipping labels, may not directly affect consumers' safety. As a result, FSIS is using some inspection resources to review shipments that pose lower food safety risks. However, information is available on the relative health risks of specific types of imported foods, such as ground or deboned beef, that would enable FSIS to further improve its computer screening system.

FDA's system for selecting imports for examination relies primarily on inspectors' judgment, and FDA's guidance and information to aid inspectors' decisions are often not useful. FDA's annual work plan, which identifies, among other things, the number of imported food inspections and tests each field office is expected to conduct, guides inspectors' judgment; but the work plan is unrealistic because it does not make allowances for the time needed to investigate emergencies and consumers' complaints. Because the number of activities set out in the work plan is generally not attainable, the work plan is not useful when making inspection and testing decisions, according to managers in field locations who reported the views of inspectors. In addition, FDA's computer system for screening imported food shipments is not programmed to help inspectors effectively use laboratory test results, violation histories, and other information to identify shipments posing the greater food safety risks. Finally, the information identifying the contents of imported food shipments is entered directly into FDA's computer system by importers, some of whom have an incentive to misrepresent their goods in the

interest of avoiding inspectors' attention. After an importer demonstrates competency with the system, FDA retrospectively verifies a sample of the importer-provided information. Although the agency frequently identifies errors, it has recently taken no corrective action other than counseling the filer. Thus, FDA has no assurance that importers are accurately describing their goods and that it is identifying shipments that should be scrutinized.

Weaknesses in Import Controls Allow Entry of Unsafe Products

FDA and Customs have historically had problems stopping importers from distributing unsafe foods under FDA's jurisdiction. Recent investigations by Customs confirm that these problems continue. Nevertheless, the procedures for controlling suspect shipments continue to permit importers to easily circumvent them.

In particular, FDA does not maintain effective control over the products it automatically detains because of past violations. In lieu of requiring that these shipments be destroyed or reexported, FDA requires importers to establish that the contents are safe. As proof, FDA allows them to present evidence, such as private laboratory test results, to show that the shipments meet U.S. safety standards. However, because the agency does not have the explicit authority to require importers to use certain laboratories, importers are free to choose the laboratories that will perform the tests. While FDA expects these laboratories to follow the agency's written sampling guidelines and reviews the test results submitted to the agency, it does not control the selection of the samples tested by the private laboratories or certify acceptable private laboratories to perform these tests. FDA has found numerous discrepancies between its test results and those from private laboratories for the same shipments. Customs officials and FDA inspectors told GAO that importers have been known to substitute shipments that have been tested as safe for samples of other shipments that are suspect.

Unlike FSIS, which controls the storage of imported foods after they are presented for inspection until their release into the U.S. market, Customs usually allows importers to retain possession of their shipments until FDA and Customs clear them for entry into U.S. commerce. According to FDA and Customs officials, imported food shipments under FDA's jurisdiction are often not made available for FDA's inspection as required or are not properly disposed of when refused entry into U.S. commerce. Customs and FDA inspectors have found many instances in which importers substituted safe products for inspection, rather than the imported products FDA wanted to inspect. In other instances, when the tested

products failed laboratory tests, importers substituted other products for destruction, rather than the imported products FDA wanted to destroy. In each situation, FDA inspectors believe the original imported food was sold in the U.S. market and presumably consumed. A joint Customs-FDA operation to test controls over foods at one port found that evasion was common.

The evasion of safety requirements is seldom punished effectively. While FDA and Customs rely on the bonds presented by the importer, which cover the value of the shipment, as the principal deterrent against noncompliance with laws, the collection of damages against violators is uneven and uncertain. For example, at one port, Customs collected about 2 percent of the damages originally assessed in 24 cases in 1997. In a previous report, GAO found that even if the maximum damages had been collected, the importer would still have made a profit on the sale of the shipment.[2] Thus, the bonds do not represent an effective deterrent.

Recommendations

In order to strengthen FDA's ability to ensure the safety of imported foods, GAO recommends that the Congress require all foods eligible for import to the United States, not just meat and poultry, be produced under equivalent food safety systems.

In the body of this report, GAO also makes several recommendations to the Secretary of Health and Human Services and the Secretary of Agriculture to improve the effectiveness and efficiency of their import review systems and procedures by targeting inspection resources on foods posing greater health risks.

Agency Comments

GAO provided copies of a draft of this report to the Department of Health and Human Services' Food and Drug Administration, the U.S. Department of Agriculture's Food Safety and Inspection Service, and the Department of the Treasury's U.S. Customs Service for review and comment. Their comments and GAO's responses are in appendixes III, IV, and V, respectively. The Centers for Disease Control and Prevention provided technical comments in response to the draft report, and these have been incorporated as appropriate.

[2]Pesticides: Adulterated Imported Foods Are Reaching U.S. Grocery Shelves (GAO/RCED-92-205, Sept. 24, 1992).

FDA generally agreed with the report and said it raises a number of issues that need to be addressed. FDA agreed with GAO that FDA needs additional legislative authority to control the safety of imported foods, but the agency disagreed that any authority to require equivalency should be mandatory because such mandatory authority would disrupt trade if implemented at one time. GAO disagrees that FDA should have discretion over applying equivalency requirements and believes the agency could implement the requirements in stages. GAO believes that equivalency should be mandatory for all imported foods and could be implemented in a manner that would not unnecessarily or unfairly disrupt trade. Mandatory authority to require equivalency would address weaknesses in FDA's inspection approach at ports of entry, enable FDA to leverage its staff resources by sharing the responsibility for food safety with the exporting countries, and compel FDA to take a proactive approach in preventing food safety problems instead of requiring equivalency after problems are identified. The Congress could provide reasonable time frames that would allow equivalency to be implemented over a number of years.

FDA also generally agreed with the report's recommendation regarding its import screening system. FDA described planned actions to improve the efficiency of its automated import screening system and to take appropriate corrective actions in its electronic filer program. FDA did not agree with GAO's characterization of its system for communicating inspection priorities to its inspectors or the associated recommendation in GAO's draft report to improve this system. Specifically, FDA said that its annual work plan and compliance programs provide sufficient guidance to inspectors to help them make decisions about which shipments to inspect. GAO continues to believe that the priority-setting guidance provided to inspectors, even as it is described in FDA's comments, is confusing and inconsistent. As a result, inspectors may not be selecting shipments to inspect that pose the greater food safety risk to consumers. GAO has, however, modified its recommendation to better reflect the nature of the problem and to provide FDA with more flexibility to address it.

FSIS concurred with the facts in the report and stated that it will consider GAO's recommendation in its evaluation of port-of-entry inspection procedures and automat..d systems.

Customs also provided explanations of its actions to enforce requirements for controlling imported foods and raised concerns about the extent of the problem regarding the substitution of safe food products for actual products for inspection.

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Abbreviations

AIIS	Automated Import Information System
CDC	Centers for Disease Control and Prevention
CLEAN	Closing Loopholes to Ensure Acceptable Nutrition
FDA	Food and Drug Administration
FSIS	Food Safety and Inspection Service
GAO	General Accounting Office
HACCP	Hazard Analysis and Critical Control Point
HHS	U.S. Department of Health and Human Services
OASIS	Operational and Administrative System for Import Support
USDA	U.S. Department of Agriculture

Chapter 1

Introduction

Foodborne illnesses constitute a major public health problem in the United States. In May 1996, we reported that up to 81 million cases of foodborne illnesses and as many as 9,100 deaths associated with those illnesses are estimated to occur each year.[1] While foodborne illnesses are often temporary maladies that may not require medical treatment, they can sometimes cause acute and chronic illnesses, such as kidney failure in infants and young children, stillbirths, and various types of arthritis. According to the U.S. Department of Agriculture's Economic Research Service, in 1996, the estimated annual cost of medical treatments and productivity losses associated with these illnesses ranged from $6.5 billion to $37.1 billion. The actual number of foodborne illnesses, however, is unknown because many people who become ill do not seek treatment, and doctors may not associate the illnesses they do see with a food source or, if they do, report it to state or local health agencies.[2] Even when a foodborne illness is reported, health agencies may not be able to trace the illness to a specific food or its origin.

Imported Food's Growing Role in U.S. Food Supply

A growing percentage of the U.S. food supply is imported. The sheer volume of these imports, along with the difficulty in ensuring that they are safe, adds to the risk of foodborne illnesses.

As shown in table 1.1, the import share of some commonly consumed foods is increasing. For example, in 1995, one-third of all fresh fruits consumed in the United States were imported.

[1] Food Safety: Information on Foodborne Illnesses (GAO/RCED-96-96, May 8, 1996).

[2] Federal and state agencies began in 1996 to collect more comprehensive data on foodborne illness in the United States to overcome the scarcity of data. This effort will help identify the frequency with which specific foods are associated with certain pathogens, but it does not address the difficulties of tracing an adulterated food back to its country of origin.

Table 1.1: Import Share of Selected Foods Consumed in the United States, 1980-95

Import Item	Percentage of total U.S. consumption provided by imports				Percent change, 1980-95
	1980	1985	1990	1995	
Fish and shellfish	45.3	53.8	56.3	55.3	22.1
Fresh fruits	24.2	28.0	30.7	33.3	37.6
Fresh vegetables	7.6	8.9	8.4	11.7	53.9
Tomatoes for processing	1.4	7.0	5.7	3.5	150.0
Broccoli for processing	9.1	22.2	57.8	84.9	833.0

Source: U.S. Department of Agriculture, Economic Research Service.

Some imported foods pose a significant risk of foodborne illness. They can introduce pathogens previously uncommon in the United States, such as new strains of Salmonella and the Cyclospora parasite. Imported foods may also contain pathogens, such as hepatitis A, that cannot be easily detected until illness breaks out. (App. I provides information on selected recent outbreaks of foodborne illness related to imported foods.)

As the percentage of imported foods consumed in the United States increases, the importance of ensuring that these foods are safe increases as well. Ensuring food safety therefore cannot be achieved by focusing on domestic products exclusively.

Multiple Agencies Are Responsible for Ensuring the Safety of Imported Foods

Two federal agencies have the primary responsibility for ensuring the safety of imported foods. The Food Safety and Inspection Service (FSIS) in the U.S. Department of Agriculture (USDA) is responsible for meat, poultry, and some egg products. The Food and Drug Administration (FDA) in the Department of Health and Human Services (HHS) is responsible for all other foods.

Under the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act, as amended, FSIS works to ensure that products moving in interstate and foreign commerce are safe and wholesome, and correctly labeled and packaged. In calendar year 1997, FSIS used about 84 staff years, costing an estimated $3.2 million, to review about 118,000 import shipments and to determine that exporting countries met U.S. food safety requirements.

Under the Federal Food, Drug, and Cosmetics Act, as amended, FDA works to ensure that domestic and imported food products are safe, wholesome, and properly labeled.[3] In fiscal year 1997, FDA spent approximately 463 staff years (inspectors, laboratory staff, and support staff), at a cost of approximately $35.1 million, to ensure the safety of about 2.7 million imported food shipments.

To assist these agencies, the U.S. Customs Service (Customs) in the Department of the Treasury and HHS' Centers for Disease Control and Prevention (CDC) provide a number of services, including referring imported shipments for inspection and providing information on outbreaks of foodborne illnesses. Customs is the first federal agency to screen imported products, including food imports, when they enter the United States. Enforcing laws for over 40 federal agencies, Customs has, among other duties, the responsibility for collecting revenues from importers and enforcing various customs and related laws. Customs cooperates with FDA and FSIS in carrying out their regulatory roles in food safety.

CDC is the federal agency primarily responsible for monitoring the incidence of foodborne illness in the United States. CDC assists state and local health departments and other federal agencies in investigating outbreaks of foodborne illness, monitors information on foodborne illnesses, and conducts research related to these illnesses.

Since 1992, we have frequently reported on the fragmented and inconsistent organization of food safety responsibilities in the federal government.[4] These reviews have shown that inconsistencies and differences between the agencies' approaches and enforcement authorities undercut overall efforts to ensure a safe food supply. To address this problem, we recommended the formation of a single food agency. In the fiscal year 1998 appropriation act for USDA, the Congress provided $420,000 for a study by the National Academy of Sciences on the need to reorganize the federal food safety system.

[3]FDA is also responsible for ensuring that certain other products are safe. These products include drugs, cosmetics, medical devices, and electronic products that emit radiation, such as television sets.

[4]Food Safety and Quality: Uniform, Risk-Based Inspection System Needed to Ensure Safe Food Supply (GAO/RCED-92-152, June 26, 1992); Food Safety: A Unified, Risk-Based System Needed to Enhance Food Safety (GAO/T-RCED-94-71, Nov. 4, 1993); Food Safety: A Unified, Risk-Based Food Safety System Needed (GAO/T-RCED-94-223, May 25, 1994); Food Safety: Changes Needed to Minimize Unsafe Chemicals in Food (GAO/RCED-94-192, Sept. 28, 1994); and Food Safety: Fundamental Changes Needed to Improve Food Safety (GAO/RCED-97-249R, Sept. 9, 1997).

How Import Control Processes Work

FDA and FSIS are the two agencies responsible for ensuring that the imported shipments of food entering the United States are safe. Their systems for inspecting, testing, and approving the release of these food import shipments operate independently of each other.

FDA's System for Allowing the Entry of Imported Foods

To ensure that FDA is notified of all imported food products under its jurisdiction, an importer must file both an import notice and certain shipping information and, for shipments valued over $1,250, a bond to cover the goods for release with Customs within 5 days of the shipment's arrival at a U.S. port of entry. The import documents or electronic entry data identify the type of food product, the importer, foreign manufacturer, and country of origin. The bond, which covers potential duties, taxes, and penalties, may allow the importer to retain control of the shipment until FDA decides to inspect samples, test, or release it. If an importer fails to make an import shipment available for FDA's inspection, fails to recondition,[5] or fails to destroy or re-export the shipment, as directed by FDA, Customs may collect penalties against all or part of the bond value.

FDA relies on several sources of information to determine whether an imported food shipment will be inspected or tested or can be released into U.S. commerce. Among these sources are the following:

- FDA's annual work plan. The annual work plan establishes, among other activities, the number of inspections and tests that each FDA district office is to conduct, which are derived from guidance in specific food programs.[6] For example, the work plan for fiscal year 1997 set inspection and testing activities for 10 imported food programs, such as imported low-acid/acidified canned foods and imported seafood,[7] in four major project areas related to food safety—Foodborne Biological Hazards; Pesticide and Chemical Contaminants; Molecular Biology and Natural Toxins; and Food and Color Additives.[8]

[5]Importers can recondition imported products that do not meet U.S. standards so that the products can enter the United States. Examples of reconditioning include changing labels and fumigating raw agricultural products.

[6]FDA refers to these programs as compliance programs.

[7]Low-acid canned foods are products like green beans, mushrooms, and tuna fish. Acidified canned foods are low-acid foods to which acid is added, such as pickles and marinated artichokes. Canned products with low acidity are more prone to bacterial growth and contamination.

[8]Technical Assistance is FDA's fifth major project area related to food safety, but FDA did not identify inspection and testing activities for programs in this area in 1997.

- FDA's Import Alert Retrieval System database. This database contains a list of products that FDA automatically detains because the exporter or the specific food products have shown a history of violations in previous shipments.[9] FDA will not approve the release into U.S. commerce of these automatically detained shipments until the importer shows that the product is not in violation, usually by providing the results of a private laboratory analysis. FDA disseminates information on automatic detentions to district offices through import alerts, which identify problem commodities and/or exporters, foreign firms, the country of origin, the reasons for detention, and the food safety risk.
- FDA's Low-Acid Canned Food database. This database contains information on foreign processors of low-acid and acidified canned foods registered with FDA. Foreign processors wishing to export these foods to the United States must submit descriptions of their canning processes to FDA before it will issue a registration number for the firm and permit the entry of the firm's shipments into U.S. commerce. The descriptions include the manufacturing methods used to prevent spoilage and contamination. FDA issues each foreign establishment a registration number to help track the firm's registration and processing records.

To assist FDA in reviewing all shipments, Customs' computer system uses the information provided by the importer and FDA-developed screening rates to determine which shipments to automatically release into domestic commerce and which shipments to review further. FDA sets the screening rates using several sources of information, such as the annual work plan, compliance programs, type of product, and past violations of products or shippers. Most shipments that are believed to pose minimal safety risks, such as candy and dried pasta products, are frequently released automatically because they have low screening rates. FDA releases these shipments a few minutes after the importer enters the information. Other shipments, such as some seafood and low-acid canned foods, are less frequently or never released automatically, because they pose greater potential risks.

Customs forwards information on products that are not automatically released to FDA for further review, through FDA's automated screening system, known as the Operational and Administrative System for Import Support (OASIS). This system was pilot-tested in 1992 and installed at all

[9]FDA uses the formal term "detention without physical examination" to identify those shipments that are automatically detained.

FDA's district offices by October 1997.[10] (Before OASIS was developed, FDA manually tracked shipments through entry documents submitted by importers to Customs.) Along with the electronic information provided by the importer, FDA officials use the information in OASIS and other sources as needed—such as the databases with information on products to be automatically detained and registration numbers for foreign firms—to determine which samples of imported food shipments should be held for further action, such as inspection and/or laboratory testing, and which can be released without further review. FDA releases most shipments not requiring further review within 3 hours after the importer enters the information. FDA does not visually check or inspect these released shipments.

FDA annually inspects or conducts laboratory analyses on a small percentage—currently less than 2 percent—of all types of imported food shipments. Inspections may occur at ports of entry and at warehouses or other business establishments. If FDA decides to test an imported food shipment, an FDA inspector collects a sample from the shipment and sends it to a FDA laboratory for analysis. (FDA maintains a record of all laboratory test results in its Laboratory Management System database.) For samples found to comply with U.S. standards, FDA notifies Customs and the importer that the shipment can be released. For samples found to violate these standards, FDA notifies Customs and the importer that the shipment has been refused entry into U.S. commerce. Importers generally have three options for handling shipments refused entry. If FDA concurs, importers can recondition the shipment. Otherwise, they must either destroy or re-export the shipment. Whatever option the importer chooses, Customs officials are required to supervise proper disposition of the refused shipment.

FSIS' System for Allowing the Entry of Imported Foods

Before foreign firms can export meat and poultry to the United States, FSIS must have determined that the exporting country has a food safety system for these products that is equivalent to the U.S. system. Unlike FDA, FSIS inspectors visually check every imported shipment of foods under their jurisdiction for correct documentation, transportation damage, and correct labeling at FSIS-approved import inspection stations. FSIS conducts more intensive inspections and tests on a portion of the imported shipments—about 20 percent in 1997—to verify the effectiveness of the foreign food safety system. FSIS calls this process "reinspection" because

[10]FDA began developing an automated system as early as 1987. OASIS succeeds an earlier version called the Import Support and Information System.

the product has already passed inspection by the exporting country's equivalent inspection system.

Importers of FSIS-regulated products, like importers of FDA-regulated products, must file an import notice and a bond with Customs within 5 days of the date that a shipment arrives at a port of entry to cover their goods for release. Unlike FDA, however, importers must hold shipments at FSIS-registered warehouses for FSIS' inspection until these shipments are released into the domestic market or refused entry.[11]

FSIS inspectors enter the information provided by importers—such as country of origin, foreign manufacturer, exporting country's health certification, and type of product—into a centralized computer system. This computer system, which was installed in 1979, is known as the Automated Import Information System (AIIS). The system scans the information it contains to determine if the country, plant, and product are eligible for import into the United States and whether the shipment will be allowed entry with only a visual check or be subjected to more intensive inspections and tests.

The AIIS system uses computer-assigned screening procedures and individual plants' performance histories to target shipments for more intensive inspection and testing. Under the system, one violation on the previous shipment of a particular product, such as boneless beef, triggers more intensive inspection and testing for the same type of product from the same foreign firm until FSIS has found at least 10 successive shipments that are free of violations and meet U.S. standards. Violations that generate more intensive inspections include food products that contain chemical residues or bone fragments, have misidentified products, or have microbial contamination. If the imported products do not meet U.S. requirements, they are stamped "U.S. Refused Entry" and must be exported, destroyed, or converted to animal food.[12] FSIS uses information on refused shipments to plan inspections in foreign countries.

Objectives, Scope, and Methodology

Concerned over recent foodborne illnesses associated with imported foods, the Chairman, Permanent Subcommittee on Investigations, Senate

[11]FDA officials stated that they lack the authority to require that shipments be held in a specific warehouse.

[12]Because of agreements with Canada, FSIS does not stamp refused entry on each load of refused imported meat and poultry shipments from Canada. Instead, FSIS notifies Canadian officials that the shipment was refused entry and is being returned.

Committee on Governmental Affairs, asked us to review federal programs' efforts to ensure the safety of imported foods. Specifically, this report discusses (1) the differences in the agencies' authorities and approaches for ensuring the safety of imported foods and (2) the agencies' efforts to target their resources. In addition, the report discusses weaknesses in controls over food imports.

Our work focused on the two principal federal agencies with responsibility for ensuring the safety of imported foods—FDA and FSIS. We also conducted work at Customs and CDC. We reviewed agency and public information on foodborne illnesses and their relationship to imported foods. We also spoke with FDA, FSIS, and CDC officials about the link between foodborne illnesses with imported foods. We reviewed information from USDA to determine the current level of food imports into the United States, the share of imported foods in the U.S. diet, and the costs associated with foodborne illnesses.

To examine the major authorities guiding the federal agencies responsible for imported food safety, we reviewed the federal laws and regulations governing imported foods. We also reviewed FDA's and FSIS' documents describing their procedures for ensuring the safety of imported foods, and we met with agency officials to discuss their approach to inspecting imports. We also discussed with FDA officials proposals to change FDA's statutory authority and to expand the import inspection program. We reviewed various studies on the effectiveness of different inspection approaches for ensuring the safety of imported foods. We analyzed agency data on resources used, import entries reviewed, and inspection actions taken.

To evaluate the approaches each agency uses to target imports for examination, we reviewed agencies' documents describing their import review procedures and the use of automated systems to screen imports. We discussed these procedures and systems with FDA and FSIS officials. We observed and analyzed the agencies' automated screening processes, physical inspections, and sample collections at FDA's and FSIS' field offices in California, Florida, New York, New Jersey, Texas, and Washington State. We visited three FDA laboratories to discuss and observe analysis procedures. We met with Customs officials in Laredo, Texas; Los Angeles and San Francisco, California; Miami, Florida; Port Elizabeth, New Jersey; and Seattle, Washington; to discuss and observe how FDA and FSIS work with Customs to handle the initial review of imported foods.

In the course of this review, we discussed and reviewed activities related to controls over imported foods in the field offices we visited. These activities included FDA's reliance on laboratory analysis provided by importers, and agencies' practices and procedures for (1) controlling imports before their release into domestic commerce, (2) ensuring that refused entries are properly disposed of, and (3) levying penalties against violators.

We performed our work from June 1997 through April 1998 in accordance with generally accepted government auditing standards.

FDA's Lack of Authority for Equivalent Inspection Systems in Exporting Countries Diminishes Its Ability to Protect Consumers From Unsafe Foods

FSIS shares the burden of ensuring the safety of the imported foods it regulates with the exporting country, while FDA primarily relies on inspections at the U.S. ports of entry to determine the safety of the imported foods under its jurisdiction. Before it will allow a country to export meat and poultry to the United States, FSIS is required to determine that the exporting country has a food safety inspection system for these products that is equivalent to the U.S. system. By ensuring that countries exporting meat and poultry to the United States have adopted practices that protect their products from contamination, FSIS can devote its energies to verifying the efficacy of these exporting countries' systems and thereby use its inspection resources more efficiently. FDA does not have the authority to impose such a requirement on foreign countries for fish, fruits, vegetables, and the other foods for which it is responsible. Lacking the authority to ensure that exporting countries are adopting safe practices, FDA has to rely on labor-intensive inspections of imported products at the port of entry as its primary line of defense against the entry of unsafe foods. Because FDA is currently able to inspect less than 2 percent of the foods imported under its jurisdiction there is reason to question whether this approach adequately protects U.S. consumers. Providing FDA with authority similar to FSIS' would allow it to leverage its resources and provide greater assurance that the imported foods it is responsible for are safe.

FSIS Requires Equivalent Food Safety Systems in Exporting Countries, but FDA Lacks Similar Authority

Federal laws on meat and poultry imports require that the products shipped to the United States meet U.S. standards for safety and wholesomeness, and comply with U.S. labeling and packaging requirements. Before a country can export meat and poultry to the United States, it must demonstrate that it has a food inspection system that is at least equivalent to the U.S. system. That is, the exporting country's inspection system must include, among other components, competent, qualified inspectors with the authority to enforce national food safety laws and regulations; administrative and technical support for these inspectors; and the implementation of inspection, sanitation, quality, microbiological, and residues standards equivalent to those applied to U.S. products.

In implementing this requirement, FSIS requires exporting countries to apply for eligibility to export meat and poultry products to the United States, to supply health certificates attesting to the safety of the product with each exported item, and to submit exports for inspection at the U.S. border to verify the effectiveness of the foreign inspection system. FSIS staff visit foreign countries and firms annually to verify the effectiveness

of their systems. In 1997, for example, FSIS staff visited 30 of the 37 eligible exporting countries to verify that the countries had changed their systems to include new safety procedures required for all domestic and foreign firms. These new procedures, called Hazard Analysis and Critical Control Point (HACCP), build science-based food safety controls into food production systems. Food firms incorporate controls into processing steps, maintain records of compliance with controls, and are subject to audits of their records to verify the program's effectiveness. As of January 1, 1998, FSIS had determined that 37 countries have food inspection systems equivalent to the United States' and are eligible to export meat and/or poultry products to this country.[1] Products from countries not on the list of eligible countries are automatically refused entry.

FDA does not have similar authority to accept only foods from countries with equivalent safety inspection systems. The Federal Food, Drug, and Cosmetics Act, which covers most food items other than meat and poultry, requires imported products to comply with U.S. standards for purity, wholesomeness, safety, and hygiene. It does not, however, require the exporting countries to have inspection systems equivalent to the U.S. system. Accordingly, FDA must, with few exceptions, rely on inspections and tests of selected imported foods at the U.S. port of entry as the only defense against unsafe foods entering the United States. For a few products (infant formula and low-acid and acidified canned foods), FDA may request that foreign exporting firms grant FDA inspectors access to their plants, but these inspectors actually conduct few foreign plant inspections. In fiscal year 1996, FDA planned 90 such inspections but carried out only 9. FDA planned 37 such inspections in fiscal year 1997, carrying out 29.

Although FDA cannot currently require countries to demonstrate that they have equivalent inspection systems before granting them authority to export to the United States, it can negotiate voluntary agreements with individual countries to establish equivalent inspection systems. For example, in 1997, FDA began an intensified effort to develop equivalency agreements, on a voluntary basis, with the major seafood exporting countries, in response to new regulations requiring all seafood producers selling to the U.S. market to use new HACCP procedures. However, FDA

[1]Since Jan. 1, 1998, FSIS has suspended Paraguay from exporting because FSIS found that the country had not implemented required pathogen reduction tests and had contaminated products in foreign plants. FSIS is considering action to withdraw several other countries from the list of eligible exporting countries because they do not comply with new regulations for testing for E. coli and implementing sanitary operating procedures.

officials said the agency has not strongly pursued equivalency agreements on a broad scale because the effort would require considerable resources to review foreign countries' food safety systems. In addition, a single agreement with each country might not be adequate because many countries have multiple food safety programs for different food products or even for different stages of preparation for the same product for export. For example, one foreign agency may be responsible for the safety of fresh produce, while another agency may be responsible for processed produce.

Nonetheless, FDA believes that equivalency authority provides significant benefits. In its 1997 draft Guidance on Equivalence Criteria for Food, developed to implement HACCP requirements for seafood processors, FDA stated,

> where equivalence has been determined to exist . . . the work of the foreign regulatory authority should serve to help ensure the safety of imports for U.S. consumers. Since the foreign inspection system will have been found to be equivalent to FDA's inspection system, FDA will be able to rely on the results for the foreign inspection system. . . . As equivalence is achieved, and agreements are reached recognizing the achievement of equivalence, trade is likely to flow more freely because of the reduced need by importing countries to engage in resource-intensive sampling and examination of products being offered for entry from countries with equivalent systems. For the United States, equivalency agreements will also mean that FDA will be able to target the limited resources it has for imports towards products from countries that have not been determined to be equivalent. Thus, FDA will be able to use its resources more efficiently and effectively.

In October 1997, as part of the administration's food safety initiative, the President directed FDA to seek new authority to require equivalency in food safety systems. In response, FDA developed proposed legislation for new discretionary authority that would allow the agency to prohibit imports of some foods, unless the exporting country demonstrates that the food safety system and conditions in the exporting country achieve the same level of protection as food prepared and packed in the United States. Legislation was introduced in the House of Representatives in November 1997 and in the U.S. Senate in March 1998, and is under consideration.[2] The legislation would allow FDA to determine that an imported food is adulterated, and thus cannot be imported, if the foreign system, conditions, or measures for preparing or packing the food product are not equivalent to the level of protection required for similar foods produced in the United States.

[2]H.R. 3052, the "Safety of Imported Food Act of 1997," and S. 1707, the "Safety of Imported Food Act of 1998." No action had been taken as of Apr. 10, 1998.

Equivalency Authority Allows for More Effective Use of Resources to Ensure Safety of Imported Foods

FSIS uses its equivalency authority to shift the primary responsibility for food safety to the exporting country. Rather than focusing on resource-intensive port-of-entry inspections, FSIS emphasizes reviews of exporting countries' compliance with U.S. requirements. In contrast, FDA relies on port-of-entry inspections to ensure that imported foods are safe. This approach does little to verify the safety of all imported foods because it does not account for the conditions under which the products were processed and packed. The efficacy of port-of-entry inspections therefore depends on inspecting an adequate sample of imports, an objective FDA has not been able to meet, particularly as import volumes have increased. In addition, inspections of imported foods may be insufficient to determine whether contamination has occurred. For example, both visual inspections and laboratory tests are inadequate to detect Cyclospora, according to CDC.

Equivalency Enables FSIS to Leverage Its Resources by Sharing Responsibility With the Exporting Countries

By requiring exporting countries to assume responsibility for the safety of meat and poultry products sent to the United States, FSIS can extend the coverage and enhance the effectiveness of its inspection resources. In 1997, FSIS had about 12 staff involved in reviewing the continuing eligibility of foreign countries to export their meat and poultry products to the United States, through document reviews and regular inspections in those countries. It also deployed about 75 inspectors to (1) ensure that each imported shipment had a health certificate from the exporting country, (2) visually check every shipment for transportation damage and accurate shipping labels, and (3) conduct intensive inspections and tests on a sample of products as a way of verifying the performance of the exporting country's system. This approach allows FSIS to transfer the primary food safety responsibility to the exporting country. FSIS considers the eligible foreign country's inspection system—not its own inspection at the port of entry—to be the primary control for ensuring that imported meat and poultry products meet U.S. standards. If a country fails to maintain an equivalent safety system, FSIS can suspend the eligibility of that country to export FSIS-regulated products to the United States.

FDA's Port-Of-Entry Inspections Provide Consumers Limited Protection Against Unsafe Imports

FDA's reliance on inspecting imported foods at the U.S. port of entry provides weak assurance that the foods it allows to enter the United States are safe. According to the United Nation's Food and Agriculture Organization, testing products at the port of entry involves a concentration of inspection resources on the imported product itself and is an attempt to compensate for a lack of knowledge about the processing, hygiene, and

sanitation practices of the producer. In addition, FDA's draft guidance on equivalency criteria states that, by itself, end-product inspection and testing at the port of entry cannot be relied upon to provide adequate protection because assurance that food will not present unacceptable risks requires effective processing controls that are periodically inspected and verified by a regulatory authority.

Similarly, a 1991 report by the Advisory Committee on the Food and Drug Administration called point-of-entry inspections an anachronism.[3] The process of inspecting a final product to determine if it conforms to standards and of rejecting those that do not has been "totally discredited," according to the committee, as a means of ensuring manufacturing quality or regulatory compliance for domestic products.

Likewise, in 1994, we reported that reliance on end-product testing was an ineffective, resource-intensive, and statistically invalid approach to ensuring that imported foods are not contaminated with unsafe levels of chemicals.[4] We recommended that the Congress change the federal government's role in ensuring food safety by moving away from end-product testing to an approach preventing contamination from occurring, such as the use of HACCP in production processes. In addition, we suggested the Congress consider requiring that all imported foods be produced under equivalent food safety systems. HACCP is now required for some products, such as seafood, and the Congress is considering legislation to provide FDA with equivalency authority.

The capabilities of FDA's inspection approach to protect consumers from unsafe products has been further called into question by the agency's inability to keep pace with rising import levels. Between 1992 and 1997, the number of imported food entries more than doubled, from 1.1 million to 2.7 million. As workloads increased, resources devoted to inspecting imported foods declined by 22 percent, from 328 staff years for inspectors in 1992 to 257 staff years for inspectors in 1997; thus, the average number of annual food shipments each inspector was responsible for increased from about 3,350 to about 10,500. As a result of these and other factors, FDA's inspection coverage of imported food entries has fallen from an estimated 8 percent of food entries in fiscal year 1992 to 1.7 percent in fiscal year 1997. Of the 2.7 million total food entries in 1997, 56 percent

[3]Final Report of the Advisory Committee on the Food and Drug Administration, Advisory Committee on the Food and Drug Administration, U.S. Department of Health and Human Services, May 1991.

[4]Food Safety: Changes Needed to Minimize Unsafe Chemicals in Food (GAO/RCED-94-192, Sept. 26, 1994).

were released after FDA's automated screening system reviewed the import information, 42.3 percent were released after an inspector reviewed electronic information or import documents, and the remaining 1.7 percent were held for inspection. Of the 1.7 percent held for inspection (46,295 entries), FDA conducted laboratory analyses on 16,048 entries, or 0.6 percent of the total number of food entries. (See table 2.1.)

Table 2.1: Disposition of Import Entries That Required FDA's Review, Fiscal Year 1997

Disposition	Number of entries	Percentage
Released automatically by Customs/FDA electronic screening	1,519,233	56.0
Released after FDA electronic or paperwork review	1,145,355	42.3
FDA inspections conducted	46,295	1.7
Total food entries requiring FDA's review	**2,710,883**	**100.0**

Source: FDA.

In contrast to the growing demands placed on FDA's inspection resources, FSIS' import inspectors have a more manageable and stable inspection burden. The number of import entries per FSIS inspector rose from about 1,236 in calendar year 1992 to about 1,645 in 1997. In addition to visually checking every shipment, FSIS performed more intensive inspections on about 20.2 percent of the 118,000 entries in 1997, somewhat less than its rate of 26.9 percent in 1992. FSIS also visited 30 countries and conducted 336 foreign plant inspections in 1997 as part of its ongoing equivalency reviews.

Conclusions

Given its lack of authority to require equivalency in foreign food safety systems, FDA relies primarily on port-of-entry inspections and tests to ensure the safety of imported foods. Because such port-of-entry inspection and testing has been widely discredited as an effective means for ensuring safety, FDA cannot realistically ensure that unsafe foods are kept out of U.S. commerce. Even if FDA could inspect more shipments at the ports of entry than it currently does, such an approach would still lack assurance that imported foods are picked, processed, and packed under sanitary conditions. An equivalency requirement would allow FDA to shift the primary burden of ensuring safety to the exporting country while achieving better assurance that food production and processing is safe and sanitary.

Recommendation to the Congress

To strengthen FDA's ability to ensure the safety of imported foods, we recommend that the Congress require all food eligible for importation to the United States, not just meat and poultry, be produced under equivalent food safety systems.

Agency Comments and Our Response

In commenting on a draft of this report, FDA agreed that it needs equivalency authority to control the safety of imported foods, but it did not agree that equivalence should be a requirement for the entry of imported foods. FDA believes the authority should be discretionary, not mandatory, so that equivalency could be applied where it is most appropriate without disrupting trade. We believe that equivalency should be mandatory for all imported foods and could be implemented in a manner that would not unnecessarily or unfairly disrupt trade. Mandatory authority to require equivalency would address weaknesses in FDA's port-of-entry inspection approach, enable FDA to leverage its staff resources by sharing the responsibility for food safety with the exporting countries, and compel FDA to take a proactive approach in preventing food safety problems instead of requiring equivalency after problems are identified. The Congress could provide reasonable time frames that would allow equivalency to be implemented over a number of years.

FDA and CDC provided technical comments that we incorporated where appropriate.

Agencies Have Not Effectively Targeted Their Resources on Imported Foods Posing Greater Risks

FSIS and FDA are not deploying their inspection resources to maximum advantage. With respect to FSIS, it is misdirecting some of its resources by targeting its inspections on the basis of all past violations—most of which are less concerned with food safety, such as missing shipping labels—rather than by focusing on violations directly related to food safety, such as contamination and decomposition. As a result, FSIS' resources are not being focused on imported foods posing the greater safety risk.

With respect to FDA, its system for identifying shipments for inspection is hampered by work plans that do not set clear priorities for inspectors in making selection decisions, a failure to make relevant health risk data readily available to its inspectors to help them select shipments to inspect, and a failure to ensure that importer-provided information on incoming shipments is accurate. Nationwide, FDA also cannot be assured that its limited resources are consistently targeting shipments posing the greater health risks.

FSIS Does Not Use Laboratory Results to Focus Its Inspections on Shipments Posing Food Safety Risks

FSIS' Automated Import Information System (AIIS) targets shipments for more intensive inspections and testing mainly on the basis of the violation history associated with the foreign firm producing the imported product. This overall violation history may be misleading, however, because AIIS treats all violations equally, except for transportation damage, in determining how much inspection attention will be provided to an importing firm's products.[1] As a result, violations not usually posing a direct health risk to consumers—such as a missing shipping label, incorrect weight, and misidentified product—could trigger a requirement for the agency to inspect every shipment from a foreign firm until the firm reestablished a good track record. In 1996, about 86 percent of the refused shipments, excluding those refused for transportation damage, were not directly related to health risks.[2] These violations triggered a series of inspections on subsequent shipments of the same product from the same exporting firm until at least 10 consecutive shipments were found to be in compliance. When limited resources are targeted in this fashion, fewer resources are available for products posing the greater health risk.

[1]Violations resulting from transportation damage do not trigger an automatic requirement for further inspections because they are not attributed to the exporting firm.

[2]Refusals with direct health risks include excessive residues; microbiological contamination; unsound condition, such as visual deterioration or odor; and defects caused by disease.

FSIS stores the test results associated with previous inspections of imported foods—data that would help identify shipments with the highest health risks—in AIIS, its automated screening system. However, the system does not use this information to identify patterns of violations, such as firms or countries with repeated problems, that are directly related to food safety. FSIS could further improve its automated screening system if it developed information on patterns of violations, which would allow it to determine whether Salmonella contamination, for example, was a recurrent problem in a particular country or exported product and increase its inspection frequencies for such shipments. In addition, FSIS could work with the exporting country to determine the extent of the problem and to take actions to correct it.

Several Key Problems Weaken FDA's System for Identifying Shipments to Target for Inspections

FDA's system for identifying shipments that should be targeted for inspection is undermined by problems in three key areas. First, FDA's annual work plan, which contains the number of inspections and tests each FDA district is to conduct, is not realistic. FDA inspectors attempt to use these numbers to guide their decisions on which products to inspect and test. Second, FDA's inspectors cannot readily obtain available health risk data that would help them choose the shipments likely to pose health risks. Third, FDA does not act to ensure that importer-provided information, which its screening system relies on to identify a shipment's contents, is correct. As a result of these problems, FDA's inspectors at ports of entry, working under significant time pressures to move shipments quickly into domestic commerce, make subjective decisions that may not target the riskiest shipments.

FDA's Annual Work Plan Is Not Useful in Making Selection Decisions in District Offices

FDA's annual work plan sets the number of activities, such as the number of inspections and tests, each FDA district is to conduct for the 10 specific food programs that cover imports. These programs, such as seafood, imported low-acid canned food, or imported cheese, are consolidated under the four major project areas related to food safety—Foodborne Biological Hazards, Pesticides and Chemical Contaminants, Molecular Biology and Natural Toxins, and Food Color and Additives. For example, for FDA's Seattle District, the fiscal year 1997 work plan called for 165 inspections and 583 laboratory tests of imported seafood products. For imported seafood products nationwide, the work plan called for 2,500 inspections and 9,432 laboratory tests.

Each day, FDA inspectors must decide which shipments of food imports to inspect. The inspectors at the locations we visited typically attempt to select shipments on the basis of the work plan's targets. However, regional and district FDA officials told us that the numbers for inspections and tests contained in the work plan were not realistic because they did not take into account the time required to investigate emergencies and consumer complaints, which invariably occur. In 1997, for example, FDA spent 6,274 hours investigating the outbreaks associated with Guatemalan raspberries—time not accounted for in the work plan. As a result, FDA inspectors are not able to complete the work plan and compliance program activities and therefore rely on their judgment when determining what to inspect and test.

Meeting the annual work plan targets is a problem nationwide. Table 3.1 shows the degree to which FDA inspectors fell short of completing the number of planned inspections and tests for fiscal years 1996 and 1997 in the four areas related to food safety. For example, in fiscal year 1997, 23,000 inspections and 19,432 laboratory analyses were planned for foodborne biological hazards. However, FDA was only able to conduct 11,587 inspections and 12,874 analyses. As a result, the inspections and tests conducted varied significantly among project areas.

Table 3.1: Planned and Completed FDA Import Inspection Activities, Fiscal Years 1996 and 1997

	Fiscal year 1996			Fiscal year 1997		
Inspection activities[a]	Planned	Completed	Percent completed	Planned	Completed	Percent completed
Foodborne Biological Hazards Project						
Foreign plant inspections	90	9	7	37	29	67
Import inspections conducted	26,250	11,983	46	23,000	11,587	50
Import samples analyzed	19,432	13,710	71	19,432	12,874	66
Pesticides and Chemicals Contaminants Project						
Import samples analyzed	8,794	6,228	71	8,294	5,675	68
Molecular Biology and Natural Toxins Project						
Import samples analyzed	555	386	70	1,380	564	41
Food and Color Additives Project						
Import samples analyzed	2,395	1,816	76	2,353	1,816	77

[a]A fifth area related to food safety, Technical Assistance, did not have planned inspection or testing activities for fiscal year 1997.

Source: FDA.

Inspectors use their own judgment in making decisions on inspections and laboratory analyses. We found that this judgment is highly subjective. For example, one inspector told us he believed one country did not have sanitary facilities and therefore assumed that all food products imported from that country are contaminated with filth. During our visit, he routinely selected samples of food from that country for filth tests, although the laboratory staff told us filth tests were not a high priority and, in fact, they sometimes did not conduct the tests because they already had a backlog of tests to conduct. Therefore, to the extent that the laboratory analyses were not conducted, the inspector wasted time collecting the samples.

FDA Inspectors Cannot Readily Access Relevant Health Risk Information

FDA retains information in a number of databases on the health risks presented by certain foods from a particular exporting country and/or an exporting company. These data include the results of the laboratory tests that FDA conducts on imported foods and lists of foreign products to be

detained because they have a history of violations. In addition, FDA maintains lists of foreign plants that have registered with FDA their processes for producing low-acid canned foods and acidified canned foods. If these products have not been produced with a registered process, they are banned from entry.

With respect to laboratory tests, FDA has not integrated its laboratory database with its OASIS system, the system used to screen imports. Therefore, inspectors do not have available the results of prior laboratory tests when considering possible actions to inspect imported products. FDA plans to integrate the laboratory database with OASIS in fiscal year 1998 to make better use of staff resources in targeting defective and dangerous products. Furthermore, FDA inspectors do not have ready access to some useful data in OASIS when deciding which products to inspect. For example, inspectors can obtain information on prior violations by foreign plants or countries, but the process for doing so can be cumbersome and time-consuming. To obtain these data, inspectors have to close their OASIS database and open another database. We observed two inspectors going through this process—which took 3 to 10 minutes per shipment—at a time when one of these inspectors had to process as many as 200 shipments per day. Not all inspectors will change databases to look for this information. Instead, inspectors told us they often rely on their memory of the information in the database or notes. Similarly, to obtain information on foreign registrations, inspectors have to close OASIS and open the registration database. Again, some inspectors find the process time-consuming and accordingly often choose to rely on memory. Because inspectors have these difficulties in obtaining needed data on health-related risks and are under time pressures, they may make decisions to select samples on the basis of incomplete information.

FDA has recognized the problems associated with difficulties in obtaining health risk data. In a 1993 hearing on food imports, FDA's Director of the New York District Office stated that FDA tries to funnel its limited inspection resources towards the imports that pose the greater risk and have the greatest likelihood of being adulterated or misbranded.[3] He added that including information, such as the data discussed above, in OASIS would be very useful in helping FDA inspectors make daily decisions on which import shipments to inspect and test. Two years later, in a 1995 FDA internal review, FDA's automated system was criticized for not providing inspectors with a means for accessing other FDA databases, such as the FDA

[3]FDA's Regulation of Food Imports, Hearings before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives, June 16, 1993 (Serial no. 103-28).

Import Alert Retrieval System database.[4] The review said that such access would improve inspectors' efficiency in identifying shipments that need to be detained. According to FDA officials, the agency received money to make these improvements in the screening system in fiscal year 1998 and will begin integrating the databases (Laboratory Management System, FDA Import Alert Retrieval System, and Low-Acid Canned Food database) with OASIS this year.

FDA Does Not Ensure the Accuracy of Importer-Provided Shipping Information

To facilitate the entry of imported foods under FDA's jurisdiction, importers enter data electronically on incoming shipments into OASIS after demonstrating competency with the system. Electronic filers that do not routinely have to provide actual shipping documents to FDA are called paperless filers. FDA inspectors rely on this electronic information in making their selections for inspections and laboratory analyses.

To ensure the accuracy of this information, FDA periodically requests the paperless filers to provide shipping documents on a sample of entries, and FDA then compares these documents against the electronically provided information for errors. Errors can include incorrectly identifying a product as exempt from FDA's regulation, entering the wrong FDA product code, or listing the wrong country of origin. Electronic filers exceeding the allowed 10-percent error rate may be removed from paperless status.

However, FDA records show that no corrective actions have been taken to remove even the most error-prone paperless filers from paperless status. According to a January 1998 FDA survey, 306, or 14.5 percent, of the 2,114 paperless filers audited had errors rates of 10 percent or greater, but none of these filers were removed from paperless status. For example, the paperless filer error rates for the New York District were 10 percent or more in 133 of the 251 audits conducted, but no electronic filers were removed from paperless status. Similarly, as of November 1997, none of the 16 electronic filers at the Miami field location with error rates of 10 percent or greater were removed from paperless filer status. In fact, the filer with the highest error rate—20 percent—has remained in paperless status without any follow-up audits since April 1996.

FDA officials at three locations we visited believed the error rates were high primarily because the product codes are complex for the importers to learn and use. In one case, for example, we found that an importer had

[4]Review of the Import Support and Information System (ISIS), FDA System Design Review Committee, June 21, 1995.

incorrectly entered the code for spaghetti, a form of pasta, instead of cappelletti, another form of pasta.

The failure to take corrective actions to remove filers from paperless status, as found in the January 1998 FDA survey, could affect decisions on selections for investigating food safety risks. Importers aware of FDA's inaction could evade FDA's inspections by incorrectly describing the contents of a shipment. For example, an FDA inspector at one port of entry said that, while most errors are accidental, he has encountered problems with importers who appeared to deliberately avoid FDA's inspections by using the wrong product code for swordfish, which is automatically held until the importer provides laboratory test results demonstrating that the product complies with U.S. standards. By entering a code for another type of fish, the importers hope that the on-screen review will not detect a discrepancy and the shipment will not be selected for inspection. Following an FDA investigation in 1993, an importer was prosecuted for deliberately misrepresenting imported foods. The importer was found guilty on 138 counts, mostly of misrepresenting the source of seafood in an attempt to avoid FDA's automatic detention.

FDA inspectors told us that when they encounter entry errors during evaluations, they inform the importer of the errors and offer help on entering the correct information. Even when these inspectors occasionally find incorrect entries that appear to be deliberate misrepresentations, they work with the importer to correct the entry problems and, in most cases, do not investigate the suspect filers further. They said that they view their role as teachers, not investigators.

Conclusions

Given the small fraction of import entries that FDA and FSIS can inspect, the agencies need to make the best use of all the information available to help select the right shipments to review. Both agencies have information to identify relationships between foodborne pathogens and specific food products, which would be a good indicator of the food safety risks associated with import shipments, but neither agency has used the information effectively or efficiently. As a result, FSIS is using its limited inspection resources to conduct inspections and tests triggered by violations that may not be related to safety. In addition, FDA's limited inspection resources may not be targeted to the riskiest shipments for a number of reasons. Reliance by FDA field offices on numerical inspection targets that are not closely linked to the risk-based priorities identified in the compliance programs impedes inspectors' effectiveness in selecting

imported food shipments for inspections and tests, key information on firms and products is not easily accessible and thus may be overlooked, and a shipment's contents may be misrepresented.

Recommendations

To help FSIS better identify the risks associated with specific foods and thereby further improve the Automated Import Information System's usefulness in selecting high-risk products to inspect, we recommend that the Secretary of Agriculture direct the Administrator, FSIS, to modify the Automated Import Information System so that the system can identify patterns between laboratory test results and specific foods, foreign firms, and exporting countries.

To provide more accurate and accessible information to FDA and thus minimize inconsistencies in inspectors' subjective decisions, we recommend that the Secretary of Health and Human Services direct the Commissioner, FDA, to

- clarify and emphasize the guidance inspectors should use when making decisions on which shipments to inspect and test;
- modify the Operational and Administrative System for Import Support system so that (1) it automatically reviews the Import Alert and Low-Acid Canned Food databases and recommends appropriate actions to inspectors and (2) inspectors can consider previous laboratory test results, which are stored in the Laboratory Management System database, in choosing shipments for inspections and tests; and
- ensure that the field offices are taking appropriate corrective action, when warranted, against importers that repeatedly enter incorrect shipping information into the Operational and Administrative System for Import Support database.

Agency Comments and Our Response

In commenting on a draft of this report, FSIS agreed with our recommendation. The agency stated that it will be evaluating its port-of-entry inspection procedures and its automated systems, and will consider our recommendation during this evaluation.

FDA agreed with our recommendation to link three databases— the Import Alert database, the Low-Acid Canned Food database, and the laboratory database— to its automated import screening system, the Operational and Administrative System for Import Support (OASIS), for use by inspectors when choosing shipments for inspections and tests. FDA stated that the

automatic review of the Import Alert database and the Low-Acid Canned Food database is under development. The agency stated further that it is developing software that will allow inspectors to review previous laboratory test results through OASIS. FDA expects all these improvements will be completed and operating by the end of fiscal year 1998. FDA also agreed with our recommendation to ensure that district offices are taking appropriate corrective action against importers that repeatedly enter incorrect shipping information in OASIS.

FDA also generally agreed with the report's recommendation regarding its import screening system. FDA described planned actions to improve the efficiency of its automated import screening system and to take appropriate corrective actions in its electronic filer program. FDA did not agree with our characterization of its system for communicating inspection priorities to its inspectors or the associated recommendation in our draft report to improve this system. Specifically, FDA said that its annual work plan and compliance programs provide sufficient guidance to inspectors to help them make decisions about which shipments to inspect. We continue to believe that the priority-setting guidance provided to inspectors, even as it is described in FDA's comments, is confusing and inconsistent. As a result, inspectors may not be selecting shipments to inspect that pose the greater food safety risk to consumers. We have, however, modified our recommendation to better reflect the nature of the problem and to give FDA more flexibility to address it.

We also incorporated technical comments from FSIS and FDA where appropriate.

Weaknesses in Controls Over Food Imports Enable Entry of Unsafe Products

In addition to the problems associated with its automated system for selecting food shipments for inspection, FDA has several weaknesses in its controls over imported products that have enabled some importers or their representatives to sell unsafe foods in the United States. First, FDA's system for automatically detaining suspicious products pending testing to confirm their safety may be easily subverted because FDA does not maintain control over the testing process. By allowing importers to choose their own laboratories to select samples and perform tests, FDA opens itself to the possibility of approving the entry of unsafe products on the basis of falsified test results. Second, FDA does not maintain control over products before releasing them into U.S. commerce. As a result, some importers have sent products to grocery stores before FDA has approved their release, and others have not returned and properly disposed of products that FDA has conditionally released but called back after testing showed them to be contaminated. In this connection, importers that violate FDA's and Customs' controls are frequently not penalized to deter such actions.

Some Importers Introduce Potentially Unsafe Foods Into U.S. Commerce

FDA's system for controlling the importation of unsafe foods has a history of circumvention by certain unscrupulous importers. For example, we reported in 1992 that about 10 importers had repeatedly distributed pesticide-adulterated shipments in disregard of FDA orders; in total, these importers distributed 73 shipments known to have been adulterated.[1] In all, about a third of the adulterated shipments that were identified reached the market.

A 1997 investigation by Customs confirmed that importers continue to evade import controls. Recognizing problems in controlling imported shipments, Customs launched a special operation at the port of San Francisco in 1997, known as Operation Bad Apple. Customs officials told us that of the shipments FDA ordered returned to Customs for destruction or reexport, 40 percent were never redelivered, and for half of those that were redelivered, other products had been substituted for the original contaminated products. Thus, 70 percent of the shipments ordered returned because they were unsafe presumably entered into commerce, contrary to FDA's orders. FDA and Customs officials developed a joint task force in November 1997, called CLEAN (Closing Loopholes to Ensure Acceptable Nutrition), to address the problems identified in Operation Bad Apple.

[1]Pesticides: Adulterated Imported Foods Are Reaching U.S. Grocery Shelves (GAO/RCED-92-206, Sept. 24, 1992).

FDA's System for Detaining Questionable Food Shipments Can Be Easily Evaded

FDA's automatic detention system is subject to evasion by unscrupulous importers. FDA automatically detains imported foods that, on the basis of prior violations, have a high potential for being contaminated. In these cases, rather than destroying or exporting the products, importers have the option of presenting the results of a private laboratory test to show that the detained products meet U.S. standards. However, FDA generally does not control the selection of the samples tested and cannot restrict the choice of the laboratories used to conduct the tests. According to FDA, the agency lacks explicit authority to require the use of specific laboratories importers can use. As such, importers can choose the laboratory, which selects the sample and conducts the analysis. While FDA expects these laboratories to comply with the agency's written guidance for collecting samples and performing tests, the agency generally does not control the selection of samples or witness laboratory analyses. This approach exposes FDA to the possibility that it will accept falsified test results or results from tests using improperly selected samples as a basis for releasing products into domestic commerce.

In fiscal year 1997, FDA detained 7,874 import shipments automatically. While FDA does not keep specific records, FDA officials said most shipments detained automatically are released after importers present their private laboratory results.

Customs and FDA officials are concerned about monitoring the accuracy of private laboratories chosen by importers in selecting and analyzing samples of imported foods that are on automatic detention status. Some Customs inspectors voiced concerns that some unscrupulous importers, to ensure their products meet U.S. requirements, share shipments that have already been tested and proven to be in compliance for sampling purposes—a concept referred to as "banking." FDA inspectors were also concerned about the uncontrolled sampling and testing of imported foods under FDA's jurisdiction. To verify the accuracy of tests performed by private laboratories, FDA laboratories occasionally select samples from the same shipments and perform identical tests. Officials at two field locations we visited told us that the FDA laboratories, in performing these tests, discovered violations that the private laboratory tests did not identify.

FDA is further increasing its reliance on the use of private laboratories for analyzing imported foods normally tested by FDA laboratories. Specifically, according to FDA's Procedures Manual, the increased scrutiny of import commodities and limitations on FDA resources are likely; therefore, FDA will expedite its enforcement efforts by using scientifically sound data

provided by private laboratories to determine if products should be allowed entry. In this regard, FDA is testing a new process to allow seafood importers the option of having a private laboratory select and analyze seafood samples for FDA's routine review of imported seafood. Under a pilot program at the Los Angeles District Office, if FDA selects the shipment for laboratory analysis, it will identify the product lots and sample sizes, and specify the type of analysis to be conducted, and the importer will choose the laboratory that will collect the samples and conduct the analysis.

While FDA is generally increasing its reliance on the test results of samples selected and analyzed by private laboratories, it has recognized that the practice of allowing importers to select their own product samples for testing is questionable. In this regard, importers of Guatemalan snow peas must now use third-party companies to select the laboratory samples because FDA test results have differed historically from the results of the importers' selected laboratory. In response to an internal report on the use of private laboratories, FDA approved new guidelines in March 1998 on the review of test results prepared by private laboratories. According to the guidelines, sample selection and laboratory analysis should be conducted by an independent party.[2]

FDA and Customs Maintain Insufficient Controls Over Known and Potentially Unsafe Products

Imported foods under FDA's jurisdiction, including foods that are of concern or are proven to be adulterated, are sold in domestic commerce before FDA has released them. This occurs because (1) importers either sell imported products before FDA has had a chance to inspect them or do not properly dispose of products that FDA has found to violate U.S. standards and (2) penalties against importers have not effectively deterred such actions.

Imported Foods Not Controlled Prior to Release

FDA-regulated foods are not controlled prior to inspection and release. Under the Federal Food, Drug, and Cosmetics Act, importers of FDA-regulated foods generally retain possession of the imported food shipments until FDA releases them and must make the shipments available for FDA's inspection if requested. In some cases, particularly for perishable items, FDA will select samples for testing and allow the shipments to continue in domestic transit—on the condition that the shipment be returned if FDA finds the shipment to be adulterated and refuses entry. If

[2]Private Laboratory Grassroots Meetings, 1996, A Final Report and Action Plan, sponsored by Division of Field Science, Office of Regional Operations, Office of Regulatory Affairs, U.S. Food and Drug Administration (undated).

importers of foods that FDA has refused entry cannot recondition the products to bring them into compliance with requirements, they have 90 days to (1) destroy the products or (2) reexport the products. The Customs Service is required to witness or attest to the fact that the refused shipment was disposed of properly, but FDA does not stamp "refused entry" on shipments found to violate safety standards, and it generally does not notify the destination country when such shipments are being reexported. According to FDA officials, FDA does not stamp refused shipments because it lacks the statutory authority to do so.

At the ports we visited, imported food shipments under FDA's jurisdiction often entered U.S. commerce before being delivered to FDA for inspection or were not properly disposed of when refused entry. For example, in Operation Bad Apple, which lasted 3 weeks, Customs officials identified 23 weaknesses in the controls over FDA-regulated imported foods. In this operation, Customs officials cited the following examples to illustrate these weaknesses.

- Substituting cargo that was en route to a holding area. On a shipment of frozen shrimp, Customs alleged that the importer removed a portion of the shipment that had thawed during transport before making the shipment available for FDA's inspection. If the thawed shrimp had not been removed, FDA would have refused entry for the entire shipment because the thawing indicated that the proper temperature controls were not maintained during transport, and thus the entire shipment may be contaminated.
- Not meeting FDA's request that the shipment be redelivered to Customs for disposition. According to Customs, about 40 percent of the imported foods released conditionally by FDA were found to violate U.S. standards during Operation Bad Apple, but were never redelivered to Customs. That is, they presumably entered into commerce and were not destroyed or reexported as required. Even when the shipments found to violate U.S. standards were redelivered, Customs officials said other products had been substituted for the violative products in about 50 percent of the shipments before redelivery. We found similar results for the nondelivery of shipments in 1992, when we reported that 60 percent of the perishable foods and 38 percent of the nonperishable foods that FDA found adulterated with illegal pesticides were released into U.S. markets and not returned to Customs for destruction or reexport.[3]

[3]Pesticides: Adulterated Imported Foods Are Reaching U.S. Grocery Shelves (GAO/RCED-92-205, Sept. 24, 1992).

Our work suggests that the evasion of imported food controls appears not to be isolated to a few importers at one port of entry. As part of Operation Bad Apple, Customs officials monitored cargo transferred from the vessel to the holding area, FDA sampled and tested the products, and did not give any conditional releases. Overall, while about 25 percent of the importers were viewed as suspicious, Customs anticipated that only 1 percent of these would be found to be evading controls. However, according to Customs officials, all of the "suspicious" importers were found to be out of compliance, and 25 percent of the other importers were also out of compliance. FDA and Customs officials told us that substitution of imported products or failure to redeliver products for inspection has been occurring at other ports.

Some Customs officials said they lack the resources needed to witness and thus ensure proper disposition of violative products refused entry. Accordingly, they generally verify only the number of containers—e.g., three containers were refused entry and three containers were reexported. Similarly, they frequently do not witness the destruction of the violative product and instead rely on a receipt from the landfill where it was disposed of. According to Customs officials, their regulations allow them to accept a receipt in lieu of witnessing the shipment's destruction.

Penalties Do Not Effectively Deter Illegal Distribution of Imported Foods

In addition to FDA's difficulties in controlling imported foods prior to releasing them into domestic commerce, FDA's economic deterrent to noncompliance with its requirements is inadequate. Lacking the authority to fine importers who distribute adulterated food shipments or fail to retain shipments for inspection, FDA relies on a bond agreement between Customs and the importer, for those shipments valued at more than $1,250 as a way to achieve compliance. Under the bond agreement, importers are required to pay all duties, taxes, and charges; to retain control over the shipment; and to properly dispose of the shipment if it is found to be unacceptable. The bond amount is based on the importer's declared value of the imported shipment, and penalties may be assessed at up to three times the value of the bond. However, we reported in 1992 that sometimes even assessed damages of three times the value of the shipment may not deter the illegal sale of imported goods because the value of the goods on the market is greater than the tripled bond amount.[4]

[4]Pesticides: Adulterated Imported Foods Are Reaching U.S. Grocery Shelves (GAO/RCED-92-205, Sept. 24, 1992).

Customs often does not collect full damages from importers that fail to comply with FDA's requirements. For example, in fiscal year 1997, Customs in Miami assessed and collected damages for about only 25 percent of the identified cases involving the improper distribution of food products for the previous 12 months. Customs and FDA attributed the low figure to (1) lax controls in communicating information about refused shipments between Customs and FDA, (2) unclear guidance for handling the shipments by Customs officials, (3) a malfunction of the Customs computer system for storing case files, and (4) a halt in collections pending the resolution of a court case involving the collection of liquidated damages. Even when damages were assessed, they were generally reduced to about 2 percent of the original assessment. For example, in one case, the damages were $100,000, based on the declared value of the import shipment, but Customs reduced the amount to $100. According to Customs headquarters officials, any reduction in damages must be in accordance with Customs guidelines, and both Customs and FDA must agree to reduce the damages when they involve the failure to redeliver shipments that were refused entry because they violated product purity and labeling requirements.

FDA's lack of authority to impose civil penalties, and its reliance on the importer's bond agreement with Customs, have left the agency without an adequate economic deterrent to the distribution of adulterated imports. We reported in 1992 that in fiscal years 1988 through 1990, importers at four locations had distributed 336 (34 percent) of the 989 shipments found to be adulterated with pesticides. Although this rate was lower than the rates of 50 percent and 45 percent that we found in 1979 and 1988, respectively, it indicated that adulterated imports continue to be distributed to American consumers. We recommended in that report and others that FDA be given authority to issue civil penalties to violators.[6] While FDA submitted legislative proposals seeking civil penalty authority in 1993, the Congress did not pass the legislation.

Conclusions

FDA's lack of controls over shipments selected for inspection leaves its inspection system vulnerable to unscrupulous importers. Without sufficient controls, some importers (1) may falsify laboratory test results on suspect foods to obtain an FDA release, (2) sell potentially unsafe imported foods before FDA can inspect them, and (3) sell imported foods that FDA found violative and barred from entry. Furthermore, importers'

[6]Pesticides: Adulterated Imported Foods Are Reaching U.S. Grocery Shelves (GAO/RCED-92-205, Sept. 24, 1992) and Pesticides: Status of FDA's Efforts to Improve Import Monitoring and Enforcement (GAO/T-RCED-93-55, June 16, 1993).

bonds are an ineffective deterrent against attempts to market contaminated products. As a result, FDA has little assurance that contaminated shipments are kept off U.S. grocery shelves, and it appears likely that certain importers will continue to circumvent controls over unsafe food products with impunity.

We are making no recommendations at this time because, as agreed with the Chairman, Permanent Subcommittee on Investigations, Senate Committee on Governmental Affairs, we are continuing work to identify specific actions needed to strengthen the controls over imported foods.

Agency Comments and Our Response

In commenting on a draft of this report, FDA agreed that it needs to exercise control over the practice of permitting importers to select a private laboratory to test shipments automatically detained due to a history of violations. FDA stated that it is issuing new instructions to its district offices regarding the use of independent laboratories. However, FDA further noted that the agency lacks the explicit authority to require importers to use certain laboratories or to provide a list of accredited laboratories to importers.

Customs provided comments to correct or clarify information about its responsibilities and practices. Customs stated that it is impossible to physically inspect the destruction or export of every refused shipment and said it is more logical to target their resources to those shipments and suspected importers posing the greater risk for noncompliance. Customs said the extent of substitution is probably limited to certain products and a small number of importers. However, we found that the substitution of products for inspection has occurred at ports of entry other than in the San Francisco example we provided. FDA and Customs officials have also acknowledged that substitution is occurring at other ports, although neither we nor they know the full extent of its occurrence. Finally, Customs disagreed with our statement that violators are seldom punished effectively and the damages against violators do not represent an effective deterrent; Customs stated that the current damages assessed against violators are adequate in most cases. However, on the basis of our work extending back to 1992,[6] we have found that liquidated damages do not appear to be an effective deterrent. In 1992, for example, we reported that the U.S. market value for selected products always exceeded the declared import value of the products we surveyed; thus, importers could and, in

[6]Pesticides: Adulterated Imported Foods Are Reaching U.S. Grocery Shelves (GAO/RCED-92-205, Sept. 24, 1992).

some cases, did profit from distributing refused products even after paying damages to Customs. The example we mention in this report, in which Customs assessed damages of $100 against an importer with a shipment having a declared value of $100,000, shows that the collected damages may be far less than the declared value of the shipment. We added information in the report to explain that, according to Customs officials in Washington, D.C., any decision to mitigate damages against importers for failure to redeliver shipments that were refused entry because of product purity or labeling problems requires agreement by both Customs and FDA.

Appendix I

Selected Outbreaks of Foodborne Illnesses Linked to Imported Foods, 1983-97

The Centers for Disease Control and Prevention (CDC) has linked several significant foodborne outbreaks to imported foods (see table I.1). According to CDC officials, the agency's investigation of recent outbreaks related to imported foods may indicate that food safety problems are more widespread than previously believed. For example, in the spring of 1996, multiple health departments reported cases of illness from Cyclospora, a pathogen that had not previously been proven to be transmitted by food. CDC and other public health officials were able to link illnesses from Cyclospora with raspberries from Guatemala; more than 1,000 people in various locations in the United States and Canada were affected. In 1997, additional illnesses from Cyclospora, also affecting more than 1,000 people, were also linked with raspberries from Guatemala. CDC and state and local health departments are not able to identify all cases of foodborne illness, however, because such illnesses are underreported and are difficult to trace to their source.

Table I.1: Information on Selected Outbreaks of Foodborne Illness, 1983-97

Year of outbreak	Number of illnesses	Pathogen	Source		Location
			Implicated food	Country of origin	
1997	1,012	Cyclospora	Raspberries	Guatemala	17 states; Washington, D.C.; and Canada
1997	270	Hepatitis A	Frozen strawberries	Mexico (implicated)	5 states
1996	9 14	Salmonella typhi, hepatitis A	Homemade cheese	Mexico	Florida
1996	1,465	Cyclospora	Raspberries	Guatemala	20 states; Washington, D.C.; and Canada
1995	242	Salmonella Stanley	Alfalfa sprouts	Seeds from Netherlands	17 states and Finland
1994	27	Salmonella Agona phage type 15	Kosher peanut-flavored savory snack	Israel	North America and United Kingdom
1994	171	Shigella flexneri, type 6 (SF6)	Green onions	Mexico (suspected)	Illinois
1994	12	Unidentified Norwalk-like agent	Raw limpets (molluscan shellfish)	Portugal	Massachusetts and Rhode Island
1992	74	Histamine poisoning (Scombroid)	"Fresh" tuna	Ecuador	Eastern seaboard
1991	4	Vibrio cholerae	Coconut milk in pudding	Thailand	Maryland
1991	12	Vibrio cholerae	Crab meat	Ecuador	New Jersey and New York
1991	400	Salmonella Poona	Cantaloupes	Mexico	23 states and Canada
1990	1,400	E. coli O153:H45	Raw scallops	South America	2 U.S. cruise ships
1989	99	Staphylococcal toxin—food poisoning	Canned mushrooms	Peoples Republic of China	3 states
1989	25,000	Salmonella Chester	Cantaloupes	Mexico	30 states
1988	202	Hepatitis A	Lettuce	Mexico (suspected)	Kentucky
1983	169	E. coli O27:H20	Semisoft cheese	France	4 states and Washington, D.C.

Source: CDC.

Countries Certified by Food Safety and Inspection Service to Export Meat and Poultry to the United States

As of January 1, 1998, the Food Safety and Inspection Service (FSIS) had determined that the countries listed below have food inspection systems equivalent to the United States' and are eligible to export meat and/or poultry products to this country. Since January 1, 1998, FSIS has suspended Paraguay from exporting meat and poultry products to the United States because its inspection system was not adequate to prevent contamination on repeated shipments.

Argentina
Australia
Austria
Belgium
Brazil
Canada
Costa Rica
Croatia
Czech Republic
Denmark
Dominican Republic
Finland
France
Germany
Guatemala
Honduras
Hong Kong
Hungary
Iceland
Ireland
Israel
Italy
Japan
Mexico
Netherlands
New Zealand
Nicaragua
Northern Ireland
Paraguay[1]
Poland
Romania
Slovenia
Spain

[1]Suspended as of January 1, 1998.

Sweden
Switzerland
United Kingdom
Uruguay

Source: FSIS.

Appendix III

Comments From the Food and Drug Administration

Note: GAO comments supplementing those in the report text appear at the end of this appendix.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

APR 3 1998

Mr. Robert A. Robinson
Director, Food and Agriculture Issues
General Accounting Office
441 G Street, N.W., Room 2T23
Washington, D.C. 20248

Dear Mr. Robinson:

Attached are the Food and Drug Administration's comments on the General Accounting Office draft report entitled, "FOOD SAFETY: Federal Efforts To Ensure Safety of Imported Foods Are Inconsistent And Unreliable, (GAO/RCED-98-103)."

Sincerely,

Diane E. Thompson
Associate Commissioner
For Legislative Affairs

Attachment

COMMENTS OF THE FOOD AND DRUG ADMINISTRATION ON THE GENERAL ACCOUNTING OFFICE DRAFT REPORT ENTITLED, FOOD SAFETY: Federal Efforts to Ensure Safety of Imported Foods Are Inconsistent And Unreliable GAO/RCED-98-103

Thank you for the opportunity to review the subject draft report. In general, we agree with the report, as the report raises a number of issues that need to be addressed, both by the Food and Drug Administration (FDA or Agency) and by the Congress. It is our hope that the report will provide an added impetus for resolving the issues it identifies. We strongly disagree, however, with the "Results in Brief" characterization of FDA's Workplan.

Specifically, the draft report has misinterpreted the purpose and function of FDA's Workplan. The Workplan is developed annually by Center Directors, the Office of Regional Operations, and the Office of financial Management. The plan reflects the allocation of field resources-based on a given year's established priorities. This tool is a guide for management in utilizing the field resources consistent with the established annual priorities. The Workplan is an implementing instrument for FDA's Program Management System (PMS) which incorporates all the Agency's activities into discrete, mutually exclusive programs, establishes their respective priorities, assigns the numbers of operations (e.g., wharf examinations, sample collections, and analyses) to be done, and allocates resources accordingly. The Workplan does not attempt to plan every operation that is performed by the field, nor does it provide guidance to enable inspectors to make decisions about which entries to examine or the admissibility of entries.

See comment 1.

The Compliance Programs, rather than the Workplan, provide guidance to inspectors making decisions about which entries to examine, whether an entry should be sampled and analyzed, and other relevant factors for determining an entry's compliance status. The Compliance Programs are the building blocks for the Workplan. Resources are distributed to the Compliance Programs through the Workplan, with higher-risk food programs given more resources. The risk factors have been incorporated into Operational and Administrative System for Import Support (OASIS), which automatically makes the initial decisions regarding entry admissibility. When there is a question as to which of two or more entries of equal priority to examine, inspectors refer to other guidance documents such as appropriate Compliance Programs, Import Alerts, the frequency at which a product has been examined, the country of origin, any available information about to the product, the importer, the shipper or the country of origin, and other relevant information.

The draft report characterizes the numbers of planned activities reflected in the Workplan as unrealistic, and links this alleged weakness with the difficulty inspectors have in deciding what to inspect and test. While FDA agrees that the planned number of operations most often is not achieved because inspectors may not be available to do routine import work if emergencies arise, the apparent discrepancy between planned and actual operations is not linked with individual decisions by inspectors at the import entry level. The Workplan is only a projection. The overall priorities established by the Workplan, however, remain the same for routine work, and inspectors are expected to make their decisions based on those priorities.

Moreover, there are a number of activities, such as recall and investigations of consumer complaints, for which time is allocated outside of the Workplan. In other words, the hours in these activities are considered separately from those contemplated in the Workplan. While FDA believes that the best approach is to plan for full utilization of its workforce, such planning, of course, includes consideration of the resources that might need to be directed to emergencies and consumer complaints. Emergencies are dealt with immediately, regardless of where or when they occur. Decisions are made after the fact about which category or Compliance Program will be tapped for the resources that were utilized.

AREAS OF AGREEMENT

NEED FOR STATUTORY AUTHORITY

See comment 2.

We agree that FDA needs additional authority for controlling the safety of imported foods. Legislation has been introduced in both the House of Representatives and the Senate to expand FDA authority to ensure the safety of imported food. The legislation applies to food safety systems of control. Before an action can be taken against an imported food product, the Secretary must determine that the product does not meet the U.S. food safety requirements or otherwise achieve the level of protection required. The legislation permits the Secretary to consider a refusal to allow necessary inspection, testing, or other relevant factors in determining whether imported food products meet U.S. food safety requirements or otherwise achieve the level of protection required. GAO's support of this legislation is welcomed.

UPDATES TO THE OPERATIONAL AND ADMINISTRATIVE SYSTEM FOR IMPORT SUPPORT (OASIS)

FDA currently is updating OASIS to incorporate automatic review of the Import Alert and Low Acid Canned Food (LACF) databases. The Agency also is incorporating access to the Laboratory Management System database into OASIS. Both will be completed by the end of FY1998. We agree with the General Accounting Office (GAO) that these enhancements will make the system more user friendly and reduce the amount of inspector time required to determine which entries to examine and/or sample.

THIRD PARTY SAMPLING

See comment 3.

In general, we agree with GAO that FDA needs to exercise control over the practice of permitting importers of articles subject to Detention Without Physical Examination (DWPE), which are identified on the Import Alert List, to select a laboratory to analyze their products and to certify such products do not violate the Federal Food, Drug, and Cosmetic Act (FFDCA or the Act.) To that end, FDA is issuing new instructions to the Districts regarding the use of independent laboratories. While it has been FDA's policy to accept only analyses done by well-qualified laboratories, and even then to verify the results, this policy is stated more explicitly in the new guidance. Nevertheless, the report should make it clear that FDA does not have explicit authority

to require importers to use certain laboratories, nor to provide a list of accredited laboratories to importers who may inquire. We do provide, however, the laboratory performance guidance used by the Agency upon request. This guidance should help importers select laboratories based on the qualifications of the analysts and how well the laboratories are equipped to do the particular analyses.

TAKE CORRECTIVE ACTION WHEN FILERS HAVE UNACCEPTABLY HIGH ERROR RATES

FDA is in agreement with GAO that corrective action should be taken against filers (importers and brokers) who continue to submit erroneous entry data to FDA. Since implementation of the automated electronic entry processing system, FDA has been working with the filers to help them learn the system in order to submit correct data consistently. We believe this has been an appropriate approach in light of the recent implementation and complexity of the system. To reduce filer problems in determining the correct product code to use for an entry, filers have been furnished a copy of FDA software that enables them to determine the correct product codes. As GAO is aware, FDA conducted two surveys in 1997 to determine how well filers were complying with the new electronic filing requirements. The surveys showed that the error rates were still unacceptably high overall, with some filers consistently exceeding the acceptable error rate of 10%. Consequently, on March 6, 1998 the Director of the Office of Regional Operations directed all District Directors to work with FDA's Division of Import Operations to identify filers who fail to meet the requirements and to determine what action should be taken by the Agency to improve compliance. Such action could include removing the error-prone filers from the paperless entry system by requiring that they submit both paper documentation and electronic data until they demonstrate their ability to meet the requirements for electronic filing. This dual filing approach should provide a strong incentive for improvement, because submitting paper documentation delays entries by several days.

GAO RECOMMENDATION TO CONGRESS

To strengthen FDA's ability to ensure the safety of imported foods, we recommend that the Congress require all food eligible for import to the United States, not just meat and poultry, be produced under equivalent food safety systems.

See comment 4.

FDA COMMENT

FDA has the authority, based on the implementing legislation for the World Trade Organization's Agreement on the Application of Sanitary/Phytosanitary Measures, to enter into equivalency agreements with other countries. We do not require such agreements, however, before trade can occur. The wording in the recommendation as written seems to require a finding of equivalence as a precondition of entry. If this is GAO's intent, we do not concur. Such a requirement could have the undesirable effect of forcing FDA to bar entry to imports from most of the world until such time as the Agency could make a determination of equivalency, a process which must be

done on a country-by-country basis, and potentially, a product-by product basis. In contrast, the Administration's proposed import legislation introduced in both House of Congress (S1707/HR3052) would give FDA the authority to deny entry to a food product that has been prepared, packed, or held under conditions, or subject to systems or measures that do not meet U.S. food safety requirements or otherwise achieve the U.S. level of protection. The legislation would not require that FDA have evaluated such systems, conditions, or measures and made an equivalency determination as a condition precedent to entry of imports.

GAO RECOMMENDATION

To provide more accurate and accessible information to FDA and thus minimize inconsistencies in inspectors' subjective decisions, we recommend that the Secretary of Health and Human Services direct the Commissioner, FDA, to

> make annual Workplans more realistic by setting aside time for unplanned activities, such as investigating emergencies and consumer complaints.

FDA COMMENT

See comment 1.

We do not concur. For the reasons stated above, FDA continues to believe that the current Workplan approach most clearly reflects priorities while permitting flexibility to handle emergencies as they arise.

GAO RECOMMENDATION

> Modify the Operational and Administrative System for Import Support system so that (1) it automatically reviews the Import Alert and low acid canned food databases and recommends appropriate actions to inspectors and (2) inspectors can consider previous laboratory test results, which are stored in the Laboratory Management System database, in choosing shipments for inspections and tests.

FDA COMMENT

We concur. The automatic review of the Import Alert data already is in place, and the automatic review of the low acid canned food database is under development. FDA also is developing the necessary software to provide inspectors with the capability to review previous laboratory test results through OASIS. Both of these enhancements to the system will be completed and operational by the end of FY1998.

GAO RECOMMENDATION

Ensure that district offices are taking appropriate corrective action, when warranted, against importers that repeatedly enter incorrect shipping information into [the] Operational and Administrative System for Import Support.

FDA COMMENT

We concur. As stated above, FDA District Directors were reminded recently of the Agency's policy that non-compliant filers should be identified and appropriate corrective action taken, including removal of filers from paperless filing status. We also continue to believe that it is incumbent on the Agency to work with the filers through education and training, which is a form of corrective action, to improve compliance.

The following are GAO's comments on the Food and Drug Administration's letter dated April 3, 1998.

GAO Comments

1. While we agree with FDA that the compliance programs contain specific guidance on inspection requirements, we found that FDA inspectors rely on the numerical inspection targets set forth in the annual work plan for guidance. These targets are sometimes inconsistent with the directions for the compliance program. We agree that FDA needs flexibility to deal with emergencies as they arise, but we disagree that the current work plan "clearly reflects priorities." The inconsistency we identified often leads inspectors to rely on subjective judgment, which may lead to inspectors' selecting shipments that do not pose the greater food safety risk to consumers.

2. We have not evaluated nor endorsed this legislation. Instead, this report addresses the need for FDA's equivalency authority. This authority would enable FDA to shift the primary responsibility for ensuring the safety of imported foods to the exporting country and to make more efficient and effective use of its limited resources.

3. We have modified the report to reflect FDA's comment that it does not have explicit authority to require importers to use certain laboratories nor to provide a list of accredited laboratories to importers.

4. Our recommendation was not intended to require the immediate implementation of equivalency requirements. Instead, we envision that such equivalency requirements would be phased in over time in a manner that would not unnecessarily disrupt trade. The mandatory authority to require equivalency would address weaknesses in FDA's approach to inspections at the port of entry, enable FDA to leverage its staff resources by sharing the responsibility for food safety with the exporting countries, and compel FDA to take an active approach in preventing food safety problems instead of requiring equivalency after problems are identified. The Congress could provide reasonable time frames that would allow equivalency to be implemented over a number of years.

We modified the report to address FDA's technical comments where appropriate.

Appendix IV

Comments From the Food Safety and Inspection Service

Note: GAO comments supplementing those in the report text appear at the end of this appendix.

United States Department of Agriculture | Food Safety and Inspection Service | Washington, D.C. 20250

APR 7 1998

Mr. Robert A. Robinson
Director, RCED Division
Food and Agriculture Issues
U. S. General Accounting Office
441 G Street, NW, Room 2T23
Washington, D. C. 20548

Dear Mr. Robinson:

This letter provides Agency comments on the Draft Report, "Food Safety: Federal Efforts to Ensure Safety of Imported Foods Are Inconsistent and Unreliable." We appreciate the opportunity to review the draft and for the full discussion of the audit provided by the exit conference the General Accounting Office (GAO) held with the Agency on March 5, 1998.

As noted in the draft report, the Food Safety and Inspection Service (FSIS) has a powerful system for inspecting imported meat and poultry. We believe the system is well designed and operates effectively and efficiently. We agree that it is an excellent model for assuring the safety of all imported foods.

The draft report notes that FSIS calls inspection at import "reinspection" because the product has already passed inspection by the exporting countries equivalent inspection system. In fact, import reinspection coupled with on-site audits in foreign countries are the principal techniques used by FSIS to verify an exporting countries inspection system is continuing to operate at an acceptable level.

The information obtained through import reinspection tells a lot about the overall operation of foreign countries inspection system. We think all of this information is informative, including specific information on food safety hazards. Nevertheless, FSIS appreciates the need to focus its inspection resources on risks in meat and poultry that are directly related to public health. The Automated Import Information System (AIIS) permits FSIS to focus on risks presented by a particular product from a particular country. As noted in this report, the AIIS data could be used by FSIS to develop profiles for individual countries, exporting establishments, or product groups. With the implementation of Hazard Analysis and Critical Control Point, FSIS will be evaluating port-of-entry procedures and automated systems, and the recommendations of the GAO will be taken into account.

See comment 1.

We do not, however, understand the basis for a statement in Chapter 3 of the draft that "in 1996, more than 97 percent of all the violations identified were not directly related to health risk problems." Our AIIS data for 1996 shows that more than 80 percent of the

Mr. Robert A. Robinson 2

violations were the result of health risk problems such as laboratory analyses showing excessive residues and microbiological contamination; product examination showing unwholesome products with organoleptic defects; and lack of container integrity. The remainder of the data shows that less than 20 percent of the violations were for incorrect weight, missing shipping marks, or labeling defects.

If you have any questions or need further assistance, please contact Vincent Fayne, Director, Internal Control Staff, at (202) 720-5959.

Sincerely,

Thomas J. Billy
Administrator

cc:
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M. Manis, OPPDE
K. Stuck, OPPDE
S. Strattmoen, OPPDE
C. Danford, OPPDE
R. Beck, OPO
E. Walker, OPHS

The following is GAO's comment on the Food Safety and Inspection Service's letter dated April 7, 1998.

GAO Comment

1. In response to FSIS' comment, we (1) expanded the list of reasons for refusal that are directly related to health risks to include unsound condition and residues, as FSIS cited in its comments, and (2) excluded all refusals resulting from transportation damage because FSIS officials said these refusals do not trigger requirements for FSIS to conduct subsequent inspections. Using this expanded definition, we recalculated the percentage of rejected shipments that were not directly related to health risk. As a result, in our final report, we changed the percentage of refused shipments not related to health risk from 97 percent to 86 percent.

Appendix V

Comments From the U.S. Customs Service

Note: GAO comments supplementing those in the report text appear at the end of this appendix.

DEPARTMENT OF THE TREASURY

U.S. CUSTOMS SERVICE

APR 6 1998

AUD-1-OP TDM

Mr. Robert A. Robinson
Director
Food and Agriculture Issues
General Accounting Office
Washington, D.C. 20548

Dear Mr. Robinson:

Thank you for the opportunity to review your draft report entitled "FOOD SAFETY: Federal Efforts to Ensure Safety of Imported Foods Are Inconsistent and Unreliable".

We have the following comments for your consideration:

1) **Export of Destruction of FDA Refused Products (see Pg. 52, Paragraph 2 of GAO Report)**

Pursuant to 19 CFR 101.2, Customs Port Directors may choose the level of supervision of FDA-refused products which must be exported or destroyed. Due to workload constraints, it is obvious that Customs cannot physically inspect every FDA-refused product destined for export or destruction. Instead, it appears logical to target intensive Customs supervision for those products and suspected importers posing the greatest risk and to utilize compliance measurement techniques in this regard, as deemed appropriate.

2) **Substitution Scheme by Importers (see Pg. 8, Paragraph 1 and Pg. 51, last Paragraph of GAO Report)**

See comment 1.

Customs questions GAO's allegation of many instances in which importers substituted safe food products for the actual imported products for inspection. While this might be true with respect to a "special enforcement operation" such as "Operation Bad Apple", it would not be true when one considers the totality of all redelivery actions for FDA-refused goods.

In the case of the latter GAO claim, the extent of this occurrence is also probably limited in scope with respect to certain particular categories of merchandise and a small number of importers involved. Nevertheless, Customs will work closely with FDA to close whatever enforcement loopholes might exist in this regard.

3) **Customs Collection of Liquidated Damages in 1997 (see Pg. 53, last Paragraph of GAO Report)**

See comment 2.

The decrease in such collections in FY97 in Miami is attributed to both a seven-month automation programming problem with our electronic case system called SEACATS ("Seized Assets and Case Tracking System") and the halting of case collections due to the impact of the Customs liquidated damage legal case with sureties currently before the Court.

In addition, in order to enhance communication between Customs and FDA at the Port of Miami and improve the above situation, the two agencies have established the first joint Customs and FDA Team in the country. In the past, several Import Specialists handled FDA refusals. By creating one centrally located team, multiple handling of the Customs and FDA documents has now ceased to exist. The staff for Import Team 488 at that location now consists of a Customs and FDA official both sharing the responsibility of creating well-documented cases.

4) **Customs Mitigation of Liquidated Damage Cases/Customs Bond Deterrence (see Pg. 8 of GAO Report)**

GAO alleges the following regarding these issues:

- violators are seldom effectively punished
- Customs collections of damages against violators are uneven and uncertain
- Customs bond default assessments do not represent an effective deterrent

See comment 3.

With respect to the assessment of liquidated damages for failure to redeliver, it should be noted that such assessment is intended to compensate the Government for a breach for which money damages cannot be easily calculated. They are not intended to penalize the bond principal although clearly the report concludes this is the consequence. In addition, if Customs bond default and mitigation guidelines are considered too lenient for contaminated food shipments, Customs would be willing to further study the need for more severe assessments as an increased deterrent. However, it should be noted that Customs is of the opinion that the current liquidated damage assessment for non-redelivery of contaminated food products is definitely adequate in most cases, i.e., three times the value of the goods.

5) **Customs Mitigation Case (from $100,000 to $100, see Pg. 53, last Paragraph of GAO Report**

See comment 3.

GAO cites this case as proof that our Agency is being too lenient on violators. However, we assume that the violation was minor, not a contaminated food violation and, therefore, in accordance with Customs mitigation guidelines. The GAO Report does not refer to the fact that Customs and FDA must be in agreement on the issuance of any mitigation decision that involves failure to redeliver and involves the purity or labeling of the product.

We note that there are no specific recommendations for the Customs Service in this draft report. However, Customs is committed to improving its efforts with regard to safety of imported foods and will take into account the findings in this report and the implementation of any future GAO recommendations.

We appreciate the opportunity to comment on your draft report. If you need any additional information on this matter, please contact Mr. J. Tony Del Moral, Director, Evaluation Oversight Staff at (202) 927-0194.

Sincerely,

William F. Riley
Director, Office of Planning

The following are GAO's comments on the U.S. Customs Services' letter dated April 6, 1998.

GAO Comments

1. We disagree with Customs' comment questioning our assertion about the extent to which importers substitute safe food products for imported products for inspection. Customs officials in San Francisco provided us the figures on import substitution to illustrate the weaknesses in controls over FDA-regulated imported foods found in Operation Bad Apple. We modified the language in the report to clarify that the 50-percent substitution rate was attributed to Operation Bad Apple. Furthermore, while we cannot report on the exact extent of product substitution, Customs and FDA officials have acknowledged that it is occurring at other ports of entry. We also found that product substitution was occurring at four of the six ports we visited.

2. We have expanded the report to reflect Customs' comment on the reasons for a decrease in collections at the Miami port of entry.

3. We do not share Customs' view that the current liquidated damage assessment for failure to redeliver contaminated food products is an adequate deterrent. Our work, beginning in 1992,[1] indicates a pattern of problems in the deterrence and punishment of violators. In 1992, for example, we reported that the U.S. market value for selected products always exceeded the declared import value of the products we surveyed; thus, importers could and, in some cases, did profit from distributing illegal products even after paying damages to Customs. The case we mentioned in this report, in which Customs assessed damages of $100 against an importer with a shipment having a declared value of $100,000, shows that the collected damages may be far less than the declared value of the shipment. We modified the report to provide further information on the reason for mitigating damages against importers.

[1]Pesticides: Adulterated Imported Foods Are Reaching U.S. Grocery Shelves (GAO/RCED-92-205, Sept. 24, 1992).

Appendix VI

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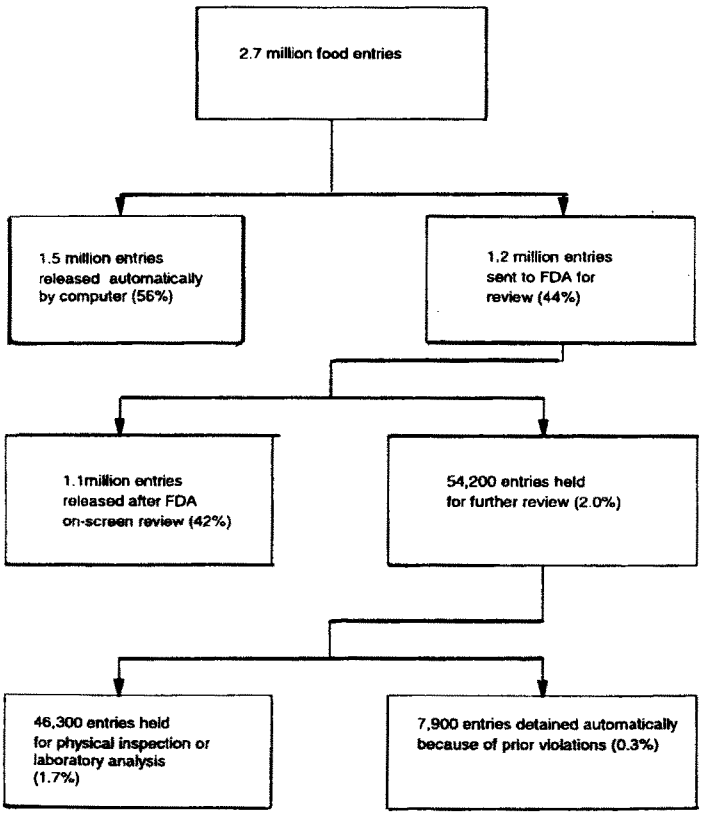
Senate Permanent Subcommittee
on Investigations

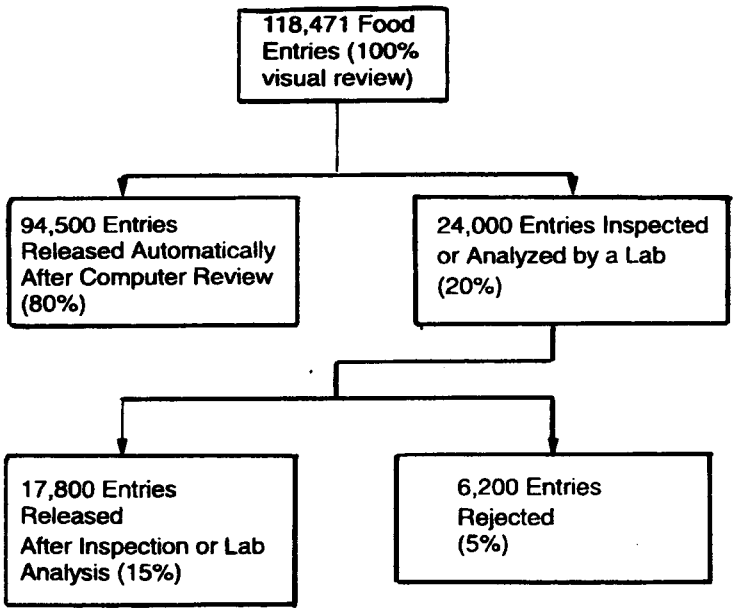
EXHIBIT # 4a.

Actions Taken on Imported Food Entries, FDA, FY 1997



Senate Permanent Subcommittee
on Investigations
EXHIBIT # 4b.

Actions Taken on Imported Food Entries Regulated by FSIS, CY 1997



Senate Permanent Subcommittee
on Investigations
EXHIBIT # 5

American Frozen Food Institute • 2000 Corporate Ridge, Suite 1000 • McLean, Virginia 22102
Telephone (703) 821-0770 • Fax (703) 821-1350 • E-Mail AFFI@POP.DN.NET

May 11, 1998

The Honorable Susan Collins
Chairman
Permanent Subcommittee on Investigations
United States Senate
Washington, D.C. 20510

Dear Chairman Collins:

Thank you for inviting the American Frozen Food Institute (AFFI) to provide a written statement to be included in the record of the May 14, 1998, hearing of the Permanent Subcommittee on Investigations regarding the adequacy of the systems and procedures used by Federal agencies to ensure the safety of food imported into the United States. I am pleased to provide the following comments on behalf of the members of the American Frozen Food Institute.

As you know, AFFI is the national trade association that represents the frozen food industry, including processors of frozen food products, as well as frozen food marketers and suppliers. AFFI's 580 members are responsible for approximately 90 percent of the frozen food produced annually in the United States, valued at some $60 billion. AFFI members manufacture products domestically as well as abroad, and in doing so may import and export both ingredients and finished food products.

OVERVIEW

The primary goal of the entire frozen food industry is to produce safe, wholesome and high-quality food products for the world's consumers. AFFI believes that if a food product is not safe, it should not be sold. Due to the diligence of AFFI members, as well as others in the food industry and throughout the food delivery chain, the U.S. food supply is the safest in the world. AFFI member companies take great pride in their products, their brand names and the fact that they are able to allow consumers in the U.S. the opportunity to enjoy safer products at a lower cost than consumers anywhere else in the world. In doing so, the companies comply scrupulously not only with all applicable laws and regulations, but also with their even more stringent corporate standards. This holds true equally for domestically-produced and imported food products.

The frozen food industry supports a strong Federal commitment to ensuring the American food supply remains the safest and most wholesome in the world. In that regard, AFFI supports the Federal government's efforts to ensure that food products imported into this country are as safe and wholesome as those produced and processed domestically. The industry encourages the two primary Federal food regulating agencies, the Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA), to utilize to the fullest their existing statutory authorities and resources toward this objective.

AFFI does not believe, however, that additional statutory authority is necessary for either agency to achieve its food safety objectives and AFFI is concerned that the imposition on imported products of additional inspection or labeling requirements could be deemed to create non-tariff trade barriers that will hinder the country's fair trade objectives to the detriment of U.S. agriculture, industry and consumers.

IMPORTED FOODS BENEFIT CONSUMERS

U.S. consumers benefit from the wide range of food products avai' 'e 'ear-round due, at least in part, to the increased availability of imported foods. These ' ..s include enhanced quality and selection of food products, as well as more affordable prices and increased ability to maintain a more healthful diet consistent with the Federal government's dietary guidelines. For example, the National Cancer Institute (NCI) has recommended that consumers strive to consume a minimum of five servings of fruits and vegetables each day to prevent cancer and other diet-related diseases. Imported produce, both processed and raw, has allowed consumers the opportunity to increase consumption of fruits and vegetables throughout the year both with convenience and at a reasonable cost. Federal actions that limit the availability of fruits and vegetables on a consistent basis or that result in their being cost-prohibitive to many Americans would be totally inconsistent with both the NCI and Federal recommended goals of achieving "5 a Day -- for Better Health."

In addition, domestic frozen food manufacturers often rely on foreign ingredients at various times of the year to allow for a continuous supply of inputs and a uniform, high quality output. Utilization of imported products also provides sourcing flexibility that may be necessary to combat a particular weather crisis or other condition that could affect the availability or price of a specific good.

Moreover, U.S. consumers also benefit from innovations derived from export markets, such as increased diversity of products. As discussed in more detail later in this document, increased global trade in food also equates to new markets for domestically-produced products. Growing export opportunities for U.S. food products will help ensure the continued profitability of the domestic food industry which in turn means more jobs for Americans.

STATUTORY REQUIREMENTS ARE APPLICABLE EQUALLY TO IMPORTED AND DOMESTIC FOOD PRODUCTS

In addition to the myriad safeguards required to ensure the safety and quality of domestically-produced foods, foods imported into the U.S. also are subject to a number of statutory and regulatory requirements intended to ensure that, when sold to the consumer, they are as safe as products produced domestically. Responsibility for enforcing these requirements falls on USDA and FDA, depending on the particular food. USDA, under the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA), has jurisdiction to regulate most meat and poultry products; and FDA, under the Federal Food, Drug, and Cosmetic Act (FFDCA), has the authority to regulate all other food products.

Imported and Domestic Meat and Poultry Products Covered Statutorily

The FMIA provides that no meat or meat products may be imported into the U.S. if they are adulterated or misbranded. Meat products of foreign origin also are barred from entry unless they comply with all provisions of the law and regulations to which domestically-produced meat and meat products are subject. The intent of the law in this regard is clearly spelled out in Section 620(f) of the FMIA which provides in pertinent part that all meat and meat products offered for import into the U.S. "shall be subject to the inspection, sanitary, quality, species verification, and residue standards applied to products produced in the United States. Any such imported meat articles that do not meet such standards shall not be permitted entry into the United States."

Any country seeking to export meat products to the U.S. must obtain certification from USDA that it maintains a program using reliable analytical methods to ensure compliance with

U.S. residue standards. In evaluating applications for certification, USDA is required to inspect individual foreign establishments.

The PPIA includes similar provisions for imported poultry products. The law requires that imported poultry products be "processed in facilities and under conditions that achieve a level of sanitary protection equivalent to that achieved under United States standards."

USDA's Food Safety Inspection Service (FSIS) has jurisdiction over the inspection and labeling of all meat and poultry products in the U.S. Such products from outside the U.S. are eligible for entry into this country provided the inspection system in the exporting country has been evaluated and found acceptable by FSIS. To be found acceptable, the system must have a program administered by the foreign national government and must provide standards equivalent to those required in the U.S. In addition, the legal authority for the inspection system must impose requirements at least equivalent to those governing the U.S. meat and poultry inspection system with respect to ante- and post-mortem inspections performed under the supervision of veterinarians, direct and continuous supervision of slaughtering and product preparation, sanitation, and Hazard Analysis and Critical Control Point (HACCP) systems.

Other Imported and Domestic Food Products Covered in Food Safety Statutes

The FFDCA authorizes the Secretary of Health and Human Services (HHS) to refuse admission to articles, including foods, that appear to be adulterated or misbranded, or that appear to have been manufactured under unsanitary conditions. The Secretary also has authority to refuse entry of foods that are illegal or subject to restrictions in the country in which they were produced or from which they were exported. HHS, acting through FDA, may

request from the U.S. Customs Service (Customs) samples of any food product offered for entry.

Pending a decision regarding the admission of an article proposed to be imported, delivery of the product to the owner may be authorized by Customs, provided the owner executes a bond. If a product that appears to be adulterated or misbranded can be brought into compliance or *rendered other than a food*, an application may be filed to do so. Otherwise, the article must be exported or destroyed.

Regulations Applied to Both Imported and Domestic Food Products

As the statutory language indicates, Congressional intent regarding the treatment of imported food products is comprehensive and precise. The regulations under which these statutes are implemented also are detailed and precise and are both designed to and do ensure that imported products undergo an appropriate amount of scrutiny.

Imported Meat and Poultry Products Under Strict Regulatory Regime

FSIS evaluates the eligibility of a country to export to the U.S. by performing a document review of the country's laws, regulations, and any other information FSIS may require. In addition, officials from FSIS perform an initial on-site review of the system. Approval of a country to export to the U.S. may be withdrawn if FSIS determines the system of inspection in the country does not ensure compliance with requirements equivalent to those imposed on establishments in the U.S.

Once a country is deemed eligible to export to the U.S., individual plants in the exporting country must be certified by national officials of the foreign country's meat inspection

system. Importers must apply to FSIS for inspection in advance of arrival of the shipment, and also must comply with U.S. Customs Service standard procedures for importing merchandise into the U.S.

Meat and poultry products offered for entry into the U.S. must be accompanied by a foreign meat inspection certificate when imported and must conform with U.S. labeling requirements. Labeling requirements include marking the immediate container with information regarding its country of origin, product name and foreign establishment number.

All products imported into the U.S. must undergo reinspection by an FSIS inspector within 72 hours of arrival. Following reinspection, the product is marked appropriately, either with the official inspection legend if it is eligible for entry or, if not, with a mark designating that it was refused entry into the U.S. The refused product must be exported, destroyed or used for animal food uses (if permitted by FDA).

Once a meat or poultry product has passed inspection and gained entry into the U.S., it is treated as a domestic product and is subject to all provisions of the FMIA, PPIA, and their implementing regulations. In being so treated, the imported product must meet the same standards of quality, wholesomeness, nutrient content, and labeling to which domestically produced products are subject.

Currently, approximately 40 countries are approved to export meat products to the U.S. and five countries are approved to export poultry products to this country.

Other Food Products Under Strict Regulatory Regime

FDA is responsible for ensuring that all imported foods meet the same safety and labeling standards as domestically-produced food products. Imported foods, like domestic

products, must be pure, wholesome, safe to eat, and produced under sanitary conditions. In addition, FDA has the authority to refuse entry into the U.S. of foods found to contain pesticide residues in excess of U.S. tolerance levels for such pesticides or for which no U.S. tolerance has been established.

FDA makes a determination whether to inspect a product by wharf, physical or sample examination. FDA determines the appropriate method of inspection based on its priorities and the past history of the commodity in question, as well as other information pertaining to the nature of the product. If it is determined a sample inspection is not warranted, the article is released into U.S. commerce. If FDA decides to inspect the product, the shipment is held intact so that a sample may be taken and analyzed. The shipment is held until the results of the analysis are available. In some cases, FDA may automatically place the product on detention until the importer can demonstrate that the product is in compliance with U.S. standards.

If the results of the laboratory analysis indicate the product is in compliance with U.S. requirements, the product is released into commerce. If the product is found to be in violation of U.S. requirements, the product is refused entry into the U.S. A refused product can either be brought into compliance, re-exported or destroyed.

It is important to note in this regard that imported food products in fact may be subject to more stringent standards than domestically-produced products. Imported meat and poultry products, for example, are inspected and approved two times before they are allowed entry into the U.S., first in a U.S.-equivalent foreign inspection system and then by FSIS in the U.S. In addition, an imported meat or poultry product used in a further processed product, such as an imported ground beef ingredient for a domestically-produced frozen lasagna, is then subject to additional inspection during the manufacture of the finished product. Other food products used

as ingredients in further processed foods, such as imported carrots used in a frozen vegetable blend, also are inspected in the domestic processing facility. In this regard, imported food products under the jurisdiction of FDA may be administratively detained prior to entry pending the results of laboratory analysis. FDA does not have the authority to detain domestic products in this manner.

As demonstrated in the foregoing discussion, Congress, by statute, and federal food safety agencies, by regulation, have adopted a comprehensive system of laws and regulations that place imported food products under a set of consumer protections as stringent as those applied to domestically-produced food products and, in some instances, even more stringent than those applied to domestic food production. On this basis, AFFI believes proposals which would establish new enforcement mechanisms directed at imported foods are unnecessary and should be rejected in favor of technology enhancement programs directed at detection and prevention of food contamination. For example, AFFI suggests that instead of directing FDA potentially to ban the import of food from a particular growing region, as proposed in S. 1707, the *Safety of Imported Food Act of 1998,* U.S. consumers would be better served by a directive to encourage FDA to work in partnership with importing countries to ensure their products are grown, processed and stored in an environment conducive to the highest food safety standards.

INTERNATIONAL GUIDELINES ADD TO FOOD SAFETY PROTECTION

In addition to strict domestic food safety laws and regulations, most foods imported into the U.S. also benefit from the code of food standards developed and maintained by the Codex Alimentarius Commission (Codex). Codex was established in 1962 as an international commission by the Food and Agriculture Organization of the United Nations and the World

Health Organization. The stated purpose of Codex, as designated in *Codex Alimentarius General Requirements,* Volume 1, is to "guide and promote the elaboration and establishment of definitions and requirements for foods, to assist in their harmonization and, in doing so, to facilitate international trade."

The Codex Commission's 146 member countries, including the United States and all its major trading partners, operate under a harmonized system of 237 food commodity standards and 41 hygienic and technological practice codes. The standards contain "requirements for food aimed at ensuring the consumer a sound, wholesome food product free from adulteration, correctly labeled and presented." These practices, and those that currently are evolving through the Codex structure, help ensure that foods imported into the U.S. meet the highest safety standards. Codex standards, in effect, serve as a backstop for the U.S. regulatory system in ensuring the safety of imported foods by placing the Commission's 146 member countries under a stringent code of food safety practices.

As international agreements reached under the World Trade Organization (WTO) lead to increased global trading of agricultural products in general and food products specifically, the role of Codex is becoming even more important in serving as the world's preeminent regulatory body for food safety standards. Countries including members of the European Union and many emerging nations increasingly are taking an active interest and participatory role in Codex activities and issues. AFFI believes it is essential, therefore, for the U.S. to continue serve in a leadership role in Codex and that increased government resources, including both financial and personnel, should be allocated for this purpose.

SCIENCE AND RISK-BASED INSPECTION SYSTEM IS THE FIRST DEFENSE

In evaluating the efficacy of existing food safety systems, AFFI maintains that a move to a more science- and risk-based food safety inspection system should be the goal of all Federal food regulations. In this regard, regulations that address imports should be established and applied no differently than those which address domestically-produced foods or any other type of regulation designed to protect human health. Moreover, investment in government and industry research to develop better testing and detection methods, as well as a focus on new preventive measures, such as irradiation, are important keys to reducing incidence of foodborne illness in the U.S. Making such enhanced technology available to domestic and non-U.S. entities throughout the food chain will be essential to future progress in the fight against both existing and emerging pathogens, as well as other food contaminants.

One proposal which AFFI believes begins to address this need is S. 1597, the *Safe Food Action Plan of 1998*. Sponsored by Senator Carl Levin (D-MI), this measure would foster food safety research at USDA and would allow public-private partnerships to develop and offer for sale new food safety technologies and products. AFFI supports the concepts contained in this measure and urges the consideration of this type of proposal for other Federal agencies with food safety responsibilities or authorities.

In addition to enhanced technology, AFFI suggests a risk-based regulatory approach should be applied to ensure Federal agency resources are directed appropriately at those products which present the greatest threat of contamination. AFFI maintains that low-risk foods should not be given the same level of day-to-day regulatory attention as those that present a higher food safety risk. Similarly, in addressing imported foods, AFFI believes resources should be devoted to reducing the level of food safety issues in the areas where they are most

prevalent. Ultimately, resources expended against preventive measures, rather than post-production enforcement, will yield the greatest benefit to consumers in the form of an even safer food supply.

AFFI believes a second important key in the process is increased education of all parties in the food chain, including industry members, consumers, food handlers, and those engaged in the foodservice sector. Some industry resources, in conjunction with those of government, have been allocated to promote consumer awareness of food safety issues; however, basic food safety education still is lacking in the U.S. educational system and should be incorporated into the appropriate curricula.

HACCP IS A FOOD SAFETY TOOL

The term "Hazard Analysis and Critical Control Point" (HACCP) refers to a food safety assurance system developed by food industry personnel to identify and control potential food safety risks reasonably likely to occur during food processing. Many food manufacturers have incorporated HACCP plans as an integral part of their food safety systems. Additionally, HACCP has been mandated by USDA for use in meat and poultry facilities, and by FDA for use in seafood facilities.

AFFI has endorsed HACCP as a useful tool for food plant personnel in minimizing food safety hazards. AFFI supports the inclusion of HACCP in regulatory programs on a voluntary basis, except in those instances in which there is a clearly defined and scientifically substantiated risk to public health. In the latter cases, AFFI believes a HACCP mandate *may* be appropriate. Further, AFFI has recommended its members establish their own HACCP programs. This approach is appropriate for both imported and domestic food production.

HACCP in itself, however, is not a cure-all for food product contamination. Food processors, whether operating within this country or outside it, utilize a broad spectrum of programs, including HACCP, to ensure product safety. Applied appropriately to identify and control food safety risks reasonably likely to occur during production, HACCP can be an effective food safety tool but should not be perceived as a panacea for eliminating all food safety hazards.

COUNTRY OF ORIGIN MARKING CURRENTLY IS REQUIRED FOR PROCESSED FOODS

Much has been made in recent months and years about U.S. country of origin . arking policies for food products and their potential relevance for food safety in this country. AFFI suggests that in the context of its May 14 hearing, it is critical that the Senate Permanent Subcommittee on Investigations be focused on the facts, rather than the rhetoric surrounding this issue.

As you may know, the Tariff Act of 1930, as amended, requires that country of origin marking be included on products with imported content, including processed food products. Most AFFI members' products are included in the Tariff Act definition and, therefore, frozen food products of foreign origin or those with imported content may be required to be marked with the product's country of origin. The Tariff Act requires specifically that the country of origin marking be "in a conspicuous place as legibly, indelibly, and permanently as the nature of the container(s) will permit."

AFFI does not, nor has it ever, objected to the Tariff Act marking requirements for country of origin. This requirement has been in place in the U.S. for nearly 70 years.

Moreover, AFFI is aware that similar requirements are placed on U.S. exports of frozen products by most recipient countries.

U.S. Customs Service Proposal for Imported Frozen Produce -- Unnecessary, Arbitrary, Capricious and Inconsistent with U.S. Trade Policy

AFFI does take strong exception, however, to a pending U.S. Customs Service proposal which would mandate that frozen produce with imported content display the country of origin marking on the front, or principle display, panel of the product's package. This proposal originally stemmed from a Section 516 Domestic Interested Party petition filed in 1993 by three domestic vegetable producers who requested that Customs make a determination that country of origin marking for frozen produce with imported content would not be deemed conspicuous unless located on the front, or principle display, panel of product packages. In this context it is critical to note that in August 1997, the last remaining of the three original petitioners withdrew its support for the original Section 516 request.

The proposed Customs regulation, issued July 23, 1996, goes far beyond the requirements of the marking statute, Section 304 of the Tariff Act, which directs that marking be located in *a conspicuous place*, but as indicated in the statutory language, *not* necessarily the *most conspicuous* place, on an article of foreign origin. The adoption of this requirement for frozen produce would be arbitrary and discriminatory. It would mandate a different and stricter interpretation of Section 304 of the Tariff Act as it applies to one small segment of the food industry, frozen produce with imported content. All other classes of food products would continue to be marked according to the *conspicuous* requirement, allowing flexibility for placement.

More importantly, the Customs proposal would provide no new or additional consumer benefit, yet compliance by individual companies could be quite costly. Consumers who wish to determine the country of origin of a frozen food product can do so now since the frozen food industry has been in compliance with the marking statute and regulations for many years by including such markings on the back or side panels of product packaging near the nutrition information required to be located there by the Nutrition Labeling and Education Act of 1990. Mandating that such a marking appear on the front, or principle display, panel of frozen produce would not add to the already available knowledge about the product.

If adopted, the Customs proposal would require virtually every producer and packer of foreign-origin produce to redesign its labels, regardless of the degree of conspicuousness of the country of origin marking that already appears on such labels. An informal AFFI survey of its members determined costs associated with relabeling products to be as much as $1 million per year. AFFI believes this cost imposition is unwarranted because it has no real consumer value. Adoption of the Customs proposal would place an economic burden on one segment of the food industry while providing consumers with no new information.

In addition, another AFFI survey, undertaken by an independent, objective consumer polling company, determined that consumers of frozen produce, in making purchasing decisions, by and large do not take country of origin labeling into account. Rather, they make purchasing decisions regarding frozen produce based on price, perceived quality, and brand identification. Country of origin was identified by less than one percent of those surveyed as a purchasing decision factor.

By the close of the comment period for the July 1996 proposal, Customs has received just over 400 comments, only one of which supported the proposal. AFFI believed at that time

Customs would withdraw its proposal based on its lack of support. Instead, a group called the American Alliance for Honest Labeling, created by Edelman Public Relations, was formed in January 1997, by those in favor of the Customs proposal to gain additional support for the measure. The Alliance was successful in generating media, consumer and Congressional attention for the Customs proposal.

Customs, in July 1997, took the highly unusual step of reopening the comment period on the front panel proposal for an additional 60 days. This step was taken despite the fact that no new or relevant information had been brought to light since the proposal initially was issued and appears to be a move by Customs to incorporate into the docket positive comments regarding the proposal received subsequent to the closing of the original comment period. Due in large part to the lobbying activities of the Alliance, an additional 3400 comments were received during this second comment period.

As of this date, Customs has yet to act on its proposal, although AFFI repeatedly has urged its withdrawal because it is unnecessary, arbitrary, capricious and inconsistent with U.S. trade and regulatory policies. AFFI's comments to Customs dated September 23, 1996, and October 17, 1997, are attached to this submission. AFFI respectfully requests that both documents be entered into the record as part of this statement.

Country of Origin Marking Requirements for Meat Products Should Be Consistent with Current Laws

AFFI also opposes proposals to require new country of origin marking requirements for processed meat products. Pending legislation such as S. 617, the *Imported Meat Labeling Act of 1997*, would require labeling of meat and meat products imported into the U.S., as well as U.S.-processed products derived from livestock born or raised outside the U.S. For AFFI

member companies, this proposal would result in a mandate of ingredient labeling for the meat component of a particular food product. For example, a frozen lasagna processed in the U.S., which contains ground beef sourced from outside the U.S., or sourced from a domestic supplier that purchased the derivative livestock or carcass from outside the U.S., would be deemed a product of the U.S., but would be labeled to indicate the meat component is of foreign origin.

This proposal is in direct conflict with U.S. rules of origin, which state that a product can have only one country of origin. It also conflicts with USDA's practices, as described in the regulation of imports section. In addition, this measure is not consistent with the World Customs Organization's (WCO) ongoing efforts to harmonize rules of origin requirements on a global basis. Finally, S. 617 would serve only to confuse consumers, providing no real useful information.

THE GLOBAL FOOD MARKETPLACE IS THE GROWTH MARKET FOR FROZEN FOODS

Despite the urging of some sectors, the regulation of food products imported into the U.S. cannot be contemplated without taking into account U.S. international treaty obligations and the increasing dependence of the U.S. economy on global sourcing as well as export markets. While ensuring the safety of the U.S. food supply is of paramount importance, the U.S. cannot and should not unilaterally impose restrictions on particular food imports or a particular region of the world without inviting similarly restrictive treatment for U.S. exports. This delicate balance must be foremost in any debate about new regulations concerning the ability of other countries to import products into U.S. markets.

In addition, it should be noted that many of the pending proposals to place new labeling or other regulatory burdens on imports are merely thinly disguised attempts by a particular

domestic industry to gain a marketing advantage over foreign competitors. The U.S. regulatory system should not be distorted to this end; rather, competitive issues of this nature should be settled in the marketplace.

AFFI believes U.S. consumers are sufficiently sophisticated and currently have enough information to make food purchasing decisions based on their individual priorities. Those who seek to gain an advantage by misleading consumers to believe domestic production equates with a higher standard of safety should be reminded that scare tactics regarding the safety of the food supply are not to be condoned.

CONCLUSION

U.S. consumers should continue to have confidence in the food supply, whether it be produced domestically or imported. Although an increased focus on improving scientific knowledge and technology capabilities to reduce the incidence of foodborne illness and other food contamination should be undertaken, imported food products by and large are subject currently to an acceptable level of regulatory scrutiny. Proposals that subject imports to new restrictions should be rejected in favor of programs that enhance the safety of the food supply worldwide.

Thank you for this opportunity to submit written testimony to the Subcommittee. Please do not hesitate to contact me if AFFI can provide any additional input.

Respectfully submitted,

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October 17, 1997

BY HAND DELIVERY

Mr. Samuel H. Banks
Acting Commissioner of Customs
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Attn: Regulations Branch
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Re: Proposed Country of Origin Marking Requirements for Frozen Imported Produce—61 Fed. Reg. 38119 (July 23, 1996)

Dear Commissioner Banks:

This submission on behalf of the members of the American Frozen Food Institute ("AFFI") provides additional comment concerning the subject Notice of Proposed Rulemaking, which would establish a new "front-panel" requirement for placement of country of origin marking on packages of frozen produce with imported content. 61 Fed. Reg. 38119 (July 23, 1996); 62 Fed. Reg. 43958 (Aug. 18, 1997) (instituting a second comment period and inserting into the record comments filed after the close of the first comment period).

AFFI has commented in opposition to a mandatory front-panel marking rule at every opportunity in the past and most recently, in a detailed comment submission filed for the record on September 23, 1996, expressed its opposition to the current proposal. AFFI remains strongly opposed to this unnecessary, discriminatory, and burdensome regulatory measure and hereby reiterates the points made in its September 23, 1996, submission. In this submission, AFFI takes the opportunity to offer additional views, including rebuttal of certain arguments that have been offered in support of the proposed regulation.

AFFI Exceeding The Expectation

AFFI is the national trade association representing manufacturers and processors of frozen food products, including frozen produce, as well as their marketers and suppliers, throughout the United States. AFFI's more than 560 member companies account for more than 90 percent of the total annual production of frozen food in the United States, valued at approximately $60 billion. AFFI's membership has a continuing interest in ensuring that any new regulations affecting the frozen produce industry are necessary and are consistent with law and sound regulatory policy.

I. THE PUBLIC INTEREST REQUIRES IMMEDIATE TERMINATION OF THIS RULEMAKING PROCEEDING BY A WITHDRAWAL OF THE PROPOSAL

The Customs Service has chosen to continue this rulemaking proceeding by re-opening the comment period. 62 Fed. Reg. 43958 (Aug. 18, 1997). It is unfortunate Customs chose to take this irregular procedural step because the evidence of record establishes that any further continuation of this rulemaking proceeding is contrary to the public interest. AFFI submits that the public interest compels an immediate termination of this rulemaking and a withdrawal of the proposed regulation.

A. The Proposal Is Unnecessary, Arbitrary, Capricious, and Inconsistent with U.S. Trade and Regulatory Policies

As discussed in detail in AFFI's submission dated September 23, 1996, the proposed front-panel marking regulation is unnecessary, discriminatory, arbitrary, and capricious. It needlessly would impose substantial re-labeling costs on the frozen produce industry without providing any benefit to the public. Current law already requires that country of origin marking on packages of frozen produce be legible, permanent, and located in a conspicuous place.

The proposed regulation goes far beyond the requirements of the marking statute, Section 304 of the Tariff Act of 1930 as amended (19 U.S.C. § 1304), which directs that marking be located in "*a* conspicuous place," but not necessarily the *most* conspicuous place, on an article of foreign origin. The proposal abandons the decades-long Customs Service precedent of interpreting Section 304 to permit marking in any place on an article or container that will satisfactorily inform the ultimate purchaser of the country of origin. In doing so, the proposal arbitrarily and capriciously would force the frozen produce industry to comply with a new "most conspicuous place" and "consistent place" requirement that Customs never before has imposed, and is not proposing to impose, on the products of any other

industry. 1/

Moreover, the proposed new requirement violates established principles of sound regulatory policy. Under the established policies of this Administration, agencies are to regulate only when necessary and to the extent necessary to effectuate the intent of Congress. Executive Order 12866 explicitly requires an agency to justify its decision to regulate by demonstrating a "compelling public need." Customs has failed to meet that requirement. In fact, Customs has yet to demonstrate there is *any* need for the proposed measure.

The proposal also violates Executive Order 12866 by failing to include a cost-benefit analysis and an adequate consideration of non-regulatory alternatives. Customs claims the regulation is justified by alleged levels of non-compliance with the marking law of frozen produce packages, an allegation not supported by the record. Moreover, Customs fails to provide any explanation for its failure to consider use of its regulatory compliance and enforcement authority as the more appropriate response.

Rather than enhance compliance, the proposed measure would establish an unwise precedent for the country of origin marking of other packaged goods. This precedent will encourage the filing of additional frivolous petitions under 19 U.S.C. §1516 by domestic producers of various products that seek to inflict regulatory compliance costs on their competitors.

The regulation also would invite retaliation against U.S. exports by this country's trading partners, some of whom already have objected to the proposal. For reasons discussed herein, it also would violate obligations of the United States established by the Uruguay Round Agreements of the World Trade Organization.

Finally, the manner in which this rulemaking proceeding has been conducted has unfairly prejudiced the frozen produce industry. As a result, AFFI urges the Treasury Department and Customs Service to terminate the proceeding at this time.

1/ A letter to Representative John Tanner (D-TN) dated January 21, 1997, and signed by former Customs Commissioner Weise, states that "Customs has no proposals under consideration regarding the country of origin marking of any other frozen food products." Representative Tanner's letter to Customs, dated January 2, 1997, inquired specifically whether there is any intention on the part of Customs to expand the proposed regulation to include other frozen food products. As AFFI has maintained since the "front panel" issue first arose, there is no basis or justification for imposing a mandatory front-panel marking requirement on any class of frozen food products.

B. This Rulemaking Has Been Conducted In a Manner Unfair and Prejudicial to the Opponents of a Front-Panel Marking Regulation

When the original comment period closed in September 1996, more than 400 comments had been filed in opposition to the proposed regulation. The commenters opposing the measure included frozen food industry representatives, members of Congress, and public interest organizations. Only one commenter, a U.S. processor of frozen produce, expressed support for the proposal; every other comment was submitted in opposition to it. Based on the record, that processor would appear to be the only member of the frozen produce industry that supports the proposal.

Following the closing of the comment period, the lone supporting commenter engaged the services of an international public relations firm, Edelman Public Relations Worldwide, to establish the "American Alliance for Honest Labeling" (hereinafter, the "Alliance") for the purpose of generating expressions of congressional support for the proposed front-panel rule. Edelman and the U.S. frozen produce processor, through the newly-established Alliance, sought and obtained from some members of Congress letters of support for the front-panel proposal. These letters were submitted to the Customs Service and Department of the Treasury after the close of the official comment period on September 23, 1996. In reopening the comment period, the Customs Service expressly announced it would include in the public record comments filed after the comment deadline.

The re-opening of the comment period is unfair to commenters who complied with the procedural requirements of this rulemaking. Indeed, in the Notice of Proposed Rulemaking, the Customs Service gave all parties specific notice that the comment period was *not* likely to be extended, having concluded that the 60-day period, in conjunction with the previous opportunities to comment provided by Customs, including publication of an Advance Notice of Proposed Rulemaking (ANPRM), would afford a full opportunity for all interested and affected parties to be heard. 61 Fed. Reg. at 38126. Rather than extend an ongoing comment period, as is customary, Customs has taken the highly irregular steps of re-instituting a comment period even though nearly a year had passed since the original comment period expired, and of admitting untimely-filed comments into the record.

The re-opening of the comment period is the latest development in a long procedural history that has been characterized by evidence of bias on the part of the Treasury Department in favor of an unprecedented and unnecessary "front-panel" marking regulation directed against the frozen produce industry. This bias is manifest in the Department's actions to reverse the position of the Customs Service, which on three separate occasions had declined to adopt a front-panel marking requirement. The first occasion was in 1988, when

the Customs Service, having been squarely presented the issue whether front-panel marking on packages of frozen produce was necessary, concluded correctly that neither the marking statute (19 U.S.C. § 1304) nor the Customs Regulation (19 C.F.R. Part 134) required marking to appear on the front panel. Headquarters Ruling Letter ("HRL") 731830 (Nov. 21, 1988).

Customs reaffirmed the holding of HRL 731830 in 1993, at the conclusion of litigation brought against the Customs Service to contest that ruling. The decision of the Court of International Trade in *Norcal/Crosetti Foods, Inc. v. U.S. Customs Service* ("*Norcal I*"), 2/ which had held that front-panel marking on frozen produce packages was required by 19 U.S.C. § 1304, was subsequently reversed by the Court of Appeals for the Federal Circuit in *Norcal II*. 3/

This action occurred subsequent to the filing, in January 1993, of a "Section 516" domestic interested party petition by two U.S. processors of frozen produce who had been plaintiffs in the litigation and who advocated adoption of a mandatory front-panel rule for frozen produce. It is important to note that both these U.S. producers subsequently withdrew their support for the petition.

After *Norcal I* had been rendered a legal nullity, the complaint of plaintiffs therein having been dismissed by the CIT as directed by the decision of the Federal Circuit in *Norcal II*, Customs reinstated HRL 731830 and suspended T.D. 91-48, the ruling requiring front-panel marking that Customs had issued to comply with the order of the CIT in *Norcal I*. 4/

Customs considered the front-panel issue a third time in late 1993, upon reviewing the comments, including comments of AFFI and other industry members, submitted in the administrative review procedure initiated by the filing of the Section 516 petition. The Customs Service again was prepared to rule that current law did not require front-panel marking for frozen produce but apparently was reversed by its parent Treasury Department, which in late 1993 reached a decision resulting in the issuance of a rule that interpreted 19 U.S.C. § 1304 to require front-panel marking on packages of frozen produce but made no such determination with respect to any other class of products. 5/ Specifically, this

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2/ 15 CIT 60, 758 F. Supp. 729 (Ct. Int'l Trade 1991).

3/ *Norcal/Crosetti Foods, Inc. v. U.S. Customs Service*, 963 F.2d 356 (Fed. Cir. 1992).

4/ 58 Fed. Reg. 47413 (Sept. 9, 1993).

5/ Counsel for AFFI was informed in late 1993 by an official of the Customs Service's Office of Regulations and Rulings that the Office of Regulations and Rulings had decided

"interpretive rule," issued December 29, 1993, as Treasury Decision ("T.D.") 94-5, required frozen produce packages to display country of origin marking on the front panel, in specific type sizes far larger than was necessary to inform the ultimate purchaser of the country of origin. The marking requirements in T.D. 94-5 were determined by the Treasury Department in consultation with a member of the staff of Representative Sam Farr (D-CA).

T.D. 94-5 subsequently was invalidated by the Court of International Trade in *American Frozen Food Institute, Inc. v. United States*, 855 F. Supp. 388 (Ct. Int'l Trade 1994). AFFI and three co-plaintiffs brought this suit to challenge T.D. 94-5 on the basis that this interpretive rule was issued in violation of the Administrative Procedure Act (APA) and was developed improperly as the product of a political agreement between Treasury officials and one or more members of Congress to secure support for enactment of legislation implementing the North American Free Trade Agreement, an issue unrelated to T.D. 94-5. The CIT determined that T.D. 94-5 had been promulgated unlawfully, the notice and comment procedures having been insufficient to satisfy Administrative Procedure Act requirements. 855 F. Supp. at 398. In the opinion, the court also addressed the "political agreement" issue:

> It is unclear whether, from the point of view of the Congressman [Representative Sam Farr], this was a *quid pro quo* (emphasis added). What is important, however, is that after the NAFTA vote, and after discussion with Congressional staff, one or more officials in the Treasury Department with significant responsibility for the 516 decision [i.e., the decision leading to issuance of T.D. 94-5] felt bound to resolve the matter in a manner which would meet with the Congressman's approval.

855 F. Supp. at 397, n.15 (emphasis added).

There is no doubt that the court, once it was aware of the history of the rulemaking proceeding resulting in T.D. 94-5, regarded that proceeding as improperly tainted. With respect to the need to follow proper APA procedures in any future rulemaking, the court stated that "[f]ollowing APA rulemaking procedures also will help ensure that, despite this history, all comments will be taken into consideration before a final rule is adopted." 855 F. Supp. at 397.

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against the position advocated in the Section 516 petition.

AFFI is concerned that, despite the court's expectation of future fairness, the consideration of comments in this rulemaking to date has lacked any semblance of balance or fairness. AFFI notes the Treasury Department has chosen to continue this rulemaking process despite the overwhelming opposition to the proposal that was expressed in the standard 60-day comment period, and this is despite the fact that no Section 516 petition is now pending on the issue, all parties having withdrawn from that petition.

AFFI also notes the one-sidedness of the Notice of Proposed Rulemaking, which adopted practically all the arguments of the relatively few proponents of front-panel marking who commented on the ANPRM, at times practically verbatim, while arbitrarily and summarily dismissing, or ignoring altogether, the points of the many opponents of the front-panel measure. In its entirety, the text of the Notice of Proposed Rulemaking demonstrates an intention by Customs to punish the frozen produce industry for alleged past noncompliance with the marking law by imposing, on *only* that industry, a burdensome and discriminatory new labeling requirement that the industry opposes. 6/ AFFI's previous comment submission in this rulemaking identifies the many errors of fact and law characterizing the Notice of Proposed Rulemaking.

In place of the punitive, discriminatory position directed against the frozen produce industry in the Notice of Proposed Rulemaking, AFFI urges that the Treasury Department and the Customs Service begin at once to approach this issue in an even-handed manner. Because the marking statute does not require front-panel marking, the issue that this rulemaking attempts to address is properly left to the Congress. The sweeping change in law and Customs Service precedent represented by a mandatory front-panel regulation has implications for the labeling of all packaged goods subject to the marking requirement. There is no basis or justification for a harsh, arbitrary, capricious, and discriminatory measure directed against a single class of products. In fact, to our knowledge, the Customs Service has never before threatened to inflict on any other industry an unnecessary and discriminatory

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6/ As AFFI pointed out on page 6 of its submission of September 23, 1996, Customs in the Notice of Proposed Rulemaking alleged significant noncompliance with the marking law but had made no effort to determine the industry's level of compliance or compare that level with the compliance of other industries. Whatever the actual level of compliance may be, it can be no justification for singling out the frozen produce industry and imposing on that industry a unique and arbitrary new marking requirement. As AFFI and industry members repeatedly have pointed out, Customs has all the regulatory and enforcement authority it needs to take action against produce labels found not to comply with 19 U.S.C. § 1304 and the regulations promulgated thereunder.

marking regulation of this type.

In summary, the administrative history of T.D. 94-5, the predecessor to the current proposed regulation, illustrates that the Treasury Department's motivation for imposing a front-panel marking rule on the frozen produce industry was neither a recommendation of the Customs Service nor in the public interest, but instead was the result of a desire to resolve the issue of the location of marking on frozen produce packages in a way that would meet with the approval of one or more members of Congress whose support the Administration had sought for the passage of the North American Free Trade Agreement Implementation Act of 1993. Based on the slanted approach taken in the Notice of Proposed Rulemaking, the bias that earlier tainted T.D. 94-5 appears to continue to affect this rulemaking proceeding.

For these reasons, AFFI submits that the only acceptable course of action is immediate termination of this rulemaking proceeding through a withdrawal of this misguided and prejudicial proposal.

II. THE ARGUMENTS OFFERED BY PROPONENTS OF A FRONT-PANEL MARKING RULE ARE INCORRECT AND MISLEADING

As discussed previously, during the original 60-day comment period, only one interested party submitted a comment in favor of mandatory front-panel marking for frozen produce. The other parties who since have advocated a front-panel marking regulation consist of the following: the aforementioned Alliance, the members of Congress and agricultural groups who have commented on behalf of or at the request of the Alliance, and the International Brotherhood of Teamsters. None of these commenters has offered an adequate justification for the position that the Customs Service should impose a new front-panel marking requirement on the frozen produce industry. To the contrary, their arguments are incorrect, misleading, and irrelevant, and even occasionally disingenuous.

The Institute also has examined the comments filed to date in response to the reopening of the comment period and believes the majority of comments received in support of the proposal should be discounted for a number of reasons. First, it is clear when reading these comments that the vast majority of the supporters of the proposal lack a basic understanding of the issue and also lack a personal stake in the issue. The large preponderance of comments are form letters and/or post cards on which commenters merely signed their name and address. In addition, as is consistent with the Alliance propaganda, the comments do not address the primary issue of this rulemaking, specifically whether the "conspicuous" requirement of the Tariff Act of 1930, as amended, may be satisfied by country

of origin marking appearing on the back panel of frozen produce packages with imported content. The arguments contained in the form letters and post cards are incorrect, misleading and irrelevant, and should be discounted when Customs assesses the comment record.

A. The Congressional Letters Supporting the Front-Panel Regulation Make No Valid Points in Support of the Proposed Regulation

Illustrative of the weakness in the arguments advanced by the Alliance is a letter to Treasury Secretary Robert Rubin dated May 23, 1997, signed by Representatives Marcy Kaptur (D-OH), Richard Gephardt (D-MO), and 40 other members of the House of Representatives. This letter is comprised of a collection of practically all the arguments contained in the various letters submitted in this proceeding by members of Congress and agricultural groups on behalf of or at the request of the Alliance. For this reason, AFFI in this submission presents its rebuttal of each of the arguments in the May 23, 1997, letter; the same points in rebuttal apply to the various similar letters submitted by members of Congress and agricultural groups that purport to incorporate or support the Alliance's position.

First, the May 23, 1997, letter falsely and misleadingly characterizes the Customs proposal as a measure to "clarify" current law. **Nothing in current law requires front-panel marking of frozen produce.** In fact, the holding of the Court of International Trade in *American Frozen Food Institute, Inc. v. United States, supra,* confirms that 19 U.S.C. § 1304 does not require front-panel country of origin marking on packages of imported frozen produce. Far from a clarification, the proposed measure is an unnecessary and discriminatory **new** regulatory requirement that Customs has never imposed on the products of any other industry.

Second, the letter attempts to justify this new front-panel frozen produce marking requirement by contending that "frozen produce brought into the United States to be re-packaged is often re-packaged without country of origin labeling." This contention, whether or not accurate, is wholly irrelevant to the front-panel marking issue. No regulation on the required placement of marking can have any relevance or effect whatsoever in circumstances in which the goods are not marked at all.

Equally irrelevant is the third claim in the letter, which notes that "[i]n instances in which packages are labeled, the size of type, location of the label, or poor quality of the ink make it impossible for consumers or Customs inspectors to verify compliance with the law." This allegation is patently false and disparaging of all U.S. producers of frozen produce that are in full compliance with the marking law. For those packages of frozen produce for which marking does not comply with the marking law, Customs has the full

regulatory authority and capability to take corrective enforcement action. Imposing a burdensome new requirement that will require re-labeling by the entire industry is wasteful and prejudicial to all the companies now in full compliance with the law. Moreover, it will do nothing to promote compliance in the future.

In asserting that absent a front-panel marking requirement, Customs inspectors cannot determine whether a frozen produce package has been marked for country of origin in compliance with the marking law, the letter makes the absurd argument that Customs inspectors are incapable of doing what they do routinely, which is to make the determination of compliance that the marking law requires them to make. They now make this determination for all the classes of products subject to the marking requirement, none of which is subject to a front-panel marking regulation. With respect to frozen produce in particular, the Notice of Proposed Rulemaking acknowledges that even were a mandatory front-panel marking rule adopted, Customs still would need to perform case-by-case examination of packages to determine compliance. 61 Fed. Reg. at 38123.

Fourth, the Kaptur, Gephart, et al. letter makes false statements concerning the administrative record in this proceeding by stating as follows:

> Despite the importance of this issue and the right of all Americans to be informed about where the frozen produce they buy for their families is from, Customs' proposed regulation received little public attention and few public comments during the comment period last summer. In fact, only about 50 independent comments were received: the majority were from food growers and processors in other countries.

This characterization of the comment record is completely and demonstrably false. In fact, a great number of U.S. producers of frozen produce objected to the proposal, either by filing an individual comment submission in opposition to it or by commenting in opposition to it through one or more of the major U.S. food producer associations that submitted comments against the proposal. The comment record provides details regarding the number of companies, and in many cases, number of employees, represented by these trade associations.

For example, as noted previously, AFFI's membership alone accounts for more than 530 member companies that produce more than 90 percent of the total annual production of frozen food in the United States. By further example, as stated in their comment submissions, the more than 130 companies which comprise the Grocery Manufacturers of

America, Inc., employ more than 2.9 million people nationwide, and the 265 companies which comprise the Food Distributors International "employ a work force of over 350,000 and in combination with their independently-owned customer firms, provide employment for several million people."

The comment record speaks for itself. The overwhelming majority of U.S. food companies, encompassing thousands of companies and millions of employees, through their membership in regional and national trade associations, oppose the front panel proposal. Only one U.S. food producer favored the proposal.

The final point in the letter concerns survey information obtained by the Alliance, which purports to indicate as follows:

> A national poll conducted after the comment period closed last year found that nearly 70% of American consumers would favor a government regulation requiring country-of-origin labeling of frozen produce, and 73% stated they would be most likely to notice the label if it appeared on the front panel of a package. Remarkably, the survey found that 83% of consumers had never noticed a country-of-origin label on a package of frozen vegetables.

AFFI submits the survey results in question were obtained by an organization with the goal of promoting front panel marking and were based on a biased methodology. Nevertheless, even taken at their face value, the survey results fail to make any case for mandatory front-panel marking.

The contention that 70 percent of American consumers favor country of origin labeling of frozen produce merely indicates they support current law. It says nothing about whether Customs should adopt a front-panel marking requirement. Since such markings already are required by law, the statistic is irrelevant to this debate.

The contention that 73 percent of American consumers would be more likely to notice a front-panel mark is also irrelevant, since it shows only that the front panel might be considered by some purchasers to be a more conspicuous place than other locations on the package. However, Customs has no statutory authority to require marking in the ***most*** conspicuous place on a product. The statute requires marking in ***a*** conspicuous place. The survey results failed to establish that marking in a location other than the front panel is not in a conspicuous place for purposes of 19 U.S.C. § 1304.

Moreover, the contention that 83 percent of consumers had never noticed a country of origin label on a package of frozen vegetables also is irrelevant to this debate since it provides no insight as to whether consumers care enough about the origin of such products to even seek this information via labeling.

In short, the survey results quoted by the Alliance are not persuasive nor are they reliable.

As discussed in AFFI's September 23, 1996, submission, however, the Institute commissioned a telephone survey by the independent polling group Opinion Research Corporation involving a national probability sample of 1014 adults, including 505 men and 509 women aged 18 years or older, all of whom were living in private U.S. households. Of the total, 656 indicated they had purchased frozen fruits and/or frozen vegetables in the previous three months.

Among the questions asked the latter group of respondents was the following: "What are the main things that influence which frozen fruits or frozen vegetables you purchase?" Only one respondent out of the 656 cited the origin of a product as an important factor in his or her purchasing decision.

When asked the question, "Is nutrition information on frozen fruits and vegetables more, less, or of equal importance to you than the same information on other food products?," 79 percent of the 656 individuals responded that nutrition information on frozen fruits and vegetables was either equally important, or more important, than the same information on other food products.

Their responses demonstrate, contrary to the contentions of the Alliance and the Customs Service, that consumers know to look to the back panel of food product packaging, including that of frozen produce, for important information. Their responses also show that nutrition information, which is required by the Nutrition Labeling and Education Act of 1992 to be located on the back panel of food packages, is regarded by consumers of frozen produce as *more* significant than country of origin information.

In summary, the letter dated May 23, 1997, by Representatives Kaptur, Gephardt *et al.* fails to make a single valid argument in favor of a mandatory front-panel marking rule for frozen produce. All the points contained in the letter are either false, misleading, irrelevant, or illogical. Versions of this same basic letter, signed by other members of the Congress, were also submitted after the close of the original comment period. These other letters vary somewhat in terms of wording but present no additional arguments.

B. Other Letters, Including Some of the Congressional Letters, Cite the Hepatitis Episode that Occurred Earlier this Year, Which Also Is Irrelevant to this Debate

Certain other letters submitted after the close of the comment period set forth one or more arguments included in the Kaptur-Gephardt letter dated May 23, 1997, but also make an additional argument that Customs should impose a front-panel country of origin marking rule on frozen produce because of the nationally-publicized outbreak of Hepatitis A earlier this year. This point typically has been made in letters submitted by or on behalf of the Teamsters.

Not only is the "Hepatitis" argument that the Alliance and the Teamsters have put forward irrelevant to the issue whether Customs should require front-panel country of origin marking, but it is irresponsible for these parties to have done so. It constitutes regrettable "scare mongering" directed against all imported produce products.

It is important to remember that the United States government agencies responsible for the outbreak did not determine that contamination of the strawberries occurred in Mexico. 7/ In fact, in a May 30, 1997, letter to Senator Richard Lugar regarding the hepatitis outbreak, Secretary of Health and Human Services Donna Shalala stated,

> **"The source of the contamination is not known and may never be known...The investigation did not identify a single event, food handler or contaminated water source to explain the source of the contamination of the strawberries."**

The country of origin marking law established by Section 304 of the Tariff Act of 1930 is intended to inform consumers of the country of origin of the product they are considering for purchase, and they may choose to purchase or not purchase it based on the country of origin as well as other factors. The marking requirement is not *intended to*, and indeed is not *capable of*, providing protection to the public from unsafe or contaminated food products. Because an unsafe or contaminated food product, whether of foreign or domestic origin, may not lawfully be offered for sale at all, the question of compliance of such a product with either the current marking law or an unprecedented new "front-panel" marking

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7/ That outbreak could have resulted from contamination in the United States or in a foreign country; there is simply no evidence implicating foreign produce in the occurrence. Whatever its cause, it has no relationship to the front-panel marking issue. The attempt by the proponents of the proposal to link these unrelated matters is unprincipled and misleading.

law is meaningless.

Even if a given consumer, based on some subjective belief, regarded foods grown in a particular country as unsafe, the marking law would not, and is not intended to, inform that consumer each time a food product of that country, or a food product containing ingredients from that country, is offered for purchase. Many produce products, including practically all fresh produce products and all produce products with foreign ingredients so processed as to result in a product of the United States, are exempt from the marking requirement altogether. As is clear from the operation of rules of origin, the country of origin of a processed food product is not necessarily the country in which each ingredient was grown or processed. Moreover, to the extent the marking law would assist such a hypothetical consumer in avoiding products of a given country, it already does so, based on the legal requirement that country of origin marking be located in a conspicuous place. A change in law to require frozen produce to be marked on the front panel simply has no relevance to the issue.

In summary, citing the recent hepatitis outbreak or similar occurrence in an attempt to advocate a front-panel marking requirement is unconvincing at best and scare-mongering at worst. (The Florida Tomato Exchange submitted a letter making a similarly unconvincing argument concerning a *cyclospora* outbreak.) Of course, contamination episodes occasionally do occur, affecting food of both domestic and foreign origin; the protection the law provides is effectuated under statutes administered by the Food and Drug Administration and the U.S. Department of Agriculture. Citing a particular disease episode to advocate a change in the country of origin marking law adds nothing to a meaningful debate on the issue presented in this rulemaking.

III. COMPELLING TRADE POLICY CONSIDERATIONS REQUIRE WITHDRAWAL OF THE FRONT-PANEL MARKING PROPOSAL

As AFFI has stated in previous submissions, the front-panel marking proposal is inconsistent with U.S. international trade obligations and will invite retaliation by foreign governments at a time when the United States is urging its trading partners to refrain from the use of unnecessary or unnecessarily-restrictive labeling laws as non-tariff trade barriers. The governments of Canada and Mexico already have objected to the front-panel proposal. This and other recent developments illustrate the necessity, from the standpoint of U.S. international trade policy and objectives, of withdrawing the proposal at this time.

A. The Subject Proposal Violates the Uruguay Round Agreement on Technical Barriers to Trade

The Uruguay Round Agreement on Technical Barriers to Trade, in Article 2.2, requires the United States and other members of the World Trade Organization (WTO) to ensure that "technical regulations" (a term that expressly includes regulations and standards on packaging, marking, and labeling) "are not prepared, adopted, or applied with a view to or with the effect of creating unnecessary obstacles to international trade." In addition, Article 2.2 provides that the regulation may not be "more trade-restrictive than necessary to fulfill a legitimate objective."

The subject front-panel marking proposal would create an unnecessary obstacle to international trade by requiring frozen produce products of foreign origin to be labeled according to a country of origin marking standard that is more restrictive than necessary to achieve the statutory objective. The standard it would apply to frozen produce is much more stringent than that applied generally under the U.S. marking law. On no other class of products subject to 19 U.S.C. § 1304 does the United States insist, or propose to insist, that marking occur in a uniform, "consistent" place, or in the "most conspicuous place."

With respect to the WTO requirement that the standard be no more trade-restrictive than necessary, the United States will be able to offer no convincing rationale for the Customs Service's premise that the front panel is the only location on a package of frozen produce that can be considered "a conspicuous place" within the meaning of the marking statute. Any rationale that the Customs Service might offer is undermined by the fact that the United States has never seen fit to impose this standard on any other class of goods. Nor is Customs able to cite any recognized international country of origin marking standard to support its new "consistent place" and "most conspicuous place" standards for country of origin marking of produce or any other products.

B. The Customs Proposal Violates Established U.S. Policy of Opposing Front Panel Country of Origin Marking

The United States Objected Strenuously to Regulations of the Republic of Korea that Required Front-Panel Country of Origin Marking

Notably, when other countries seek to impose a "front panel" labeling standard, the United States can be expected to object under the Uruguay Round Agreement on Technical Barriers to Trade, and indeed has done so. In March 1994, the U.S. government instructed the U.S. Embassy in Seoul, Korea, to voice strong opposition to two front panel

country of origin marking regulations issued by the Republic of Korea on a vast array of pre-packaged food products (issued by the Ministry of Agriculture, Forestry and Fisheries and the Korean Customs Administration, respectively), as discussed in the unclassified State Department cable attached as an exhibit to this submission.

As discussed in the cable, the United States objected to both sets of regulations on the basis of substantive violations of the GATT (now WTO) Agreement on Technical Barriers to Trade and on procedural grounds that the Korean government failed to notify the GATT Secretariat of these regulations. The cable states as follows:

> KCA [Korean Customs Administration] recently announced its own COO [country of origin] regulations that require the COO mark on the front of the package. This requirement seems to recreate an earlier MAFF [Ministry of Agriculture, Forestry and Fisheries] COO regulation that had been rescinded after the USG [United States Government] complained that consumers right to know the COO is well satisfied by declaring it together with other information on the package. The ROKG [Republic of Korea Government] also failed to notify the new KCA regulations to the GATT Secretariat as required under Article I of the Standards Code.

The cable concludes with the observation that "The ROKG COO system has been the subject of extensive debate and criticism at meetings of the Committee on Technical Barriers to Trade in Geneva by a number of delegations."

The government of the Republic of Korea subsequently rescinded the mandatory front-panel country of origin marking regulations promulgated by the Korean Customs Administration, as it had earlier done with respect to the parallel regulations of the Ministry of Agriculture, Forestry and Fisheries. Having strenuously objected to the two mandatory front-panel marking regulations by the Korean government, the United States is in a particularly vulnerable position should it now promulgate a mandatory front-panel labeling regulation of its own. The parties who stand to lose from U.S. issuance of such a regulation would include not only the U.S. frozen produce industry, but U.S. exporters of various products, who will be prejudiced by unjustified new front-panel marking requirements likely to be imposed by Korea and other foreign governments.

In summary, the United States, in its consultations with Korea, took the correct position that requiring marking for country of origin on the front panel of a product is

unnecessary for the purpose of satisfying (in the words of the cable) "the consumer's right to know." In the view of the United States, the Korean regulations were "prepared, adopted, or applied with a view to or with the effect of creating unnecessary obstacles to international trade."

The State Department cable demonstrates the inconsistency of the Customs proposal with established U.S. policy of opposing non-tariff trade barriers and, specifically, front panel country of origin marking requirements. AFFI believes it also is worth noting that a senior Department of Agriculture official reportedly voiced the Department's objection to the U.S. Customs Service front panel country of origin proposal while participating in a trade mission in Latin America this summer.

Accordingly, the United States will have no credibility, and no success, in attempting to defend to its trading partners the contemplated Customs Service front-panel marking requirement. Immediate withdrawal of the subject proposal is the only reasonable course of action.

C. The Proposal Would Harm U.S. Exports

Mandatory front panel marking will create trade barriers and as a result, will potentially harm, rather than help, American growers, manufacturers and consumers. The potential trade ramifications of this proposal are enormous. The tremendous growth in exports of frozen produce enjoyed by the U.S. industry could come to a halt. For example, frozen vegetable exports from the U.S. nearly doubled between 1990 and 1996 -- from 469.2 million pounds to 933.5 million pounds.

Current U.S. regulations mandating country of origin marking on frozen produce are consistent with requirements of our nation's largest trading partners. In this regard, the U.S. Department of Agriculture recently conducted an informal survey of U.S. Agricultural Trade Offices regarding foreign governments' requirements for country of origin marking. Contrary to assertions made by the Alliance, none of the United States' major trading partners require front panel country of origin marking for frozen fruits and vegetables with imported content.

In fact, in a memorandum to Congressional Legislative Staff, Timothy Galvin, Acting Administrator of the Foreign Agricultural Service, stated,

> **"Most countries require country of origin labels on consumer packaged and processed foods. However, in almost every instance, no specific location on the package is specified in their requirements. Generally, the only proviso is that it must be clearly visible and conspicuous on the product."**

If the U.S. government moves forward with mandating front panel marking for frozen produce, it will be interpreting the word "conspicuous" in a more stringent manner than has been done by our trading partners. Adoption of the proposed rule would establish a dangerous precedent for U.S. sanctioning of anti-competitive behavior. The results could be disastrous, as other countries likely will follow suit by requiring similar country of origin marking for food products exported to their countries -- harming American agriculture, business and employees.

* * *

For all the above-stated reasons and reasons set forth in AFFI's previous submissions on the subject issue, AFFI urges that the Customs Service terminate this rulemaking by publishing a notice withdrawing the proposed front-panel marking country of origin regulations applicable to frozen produce.

Respectfully submitted,

Steven C. Anderson
President and Chief Executive Officer

Exhibit: State Department cable on disputes concerning front-panel country of origin marking regulations of the Republic of Korea.

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FAS INFO: APHIS DLPD ERS_CABLES FAA_ASIA
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AGRIC:FAS:ITP:KROBERTS (DRAFT) AGRIC:FAS:FAA:WBEEGHLY
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FOR ECON JEAN BONILLA, FOR AGMIN COUNS

E.O. 12356: N/A
TAGS: EAGR, ETRA, KS
SUBJECT: COUNTRY OF ORIGIN DEMARCHE

REFS: (A). STATE SEOUL 11745, (B). COMMERCE SEOUL 00305

1. SUMMARY: THE USG CONTINUES TO HAVE SERIOUS CONCERNS WITH ROKG COUNTRY OF ORIGIN (COO) REGULATIONS. THE ROKG, MINISTRY OF AGRICULTURE, FORESTRY AND FISHERIES' (MAFF) REVISION OF ITS COO REQUIREMENTS WERE PUBLISHED ITHE KOREAN GOVERNMENT GAZETTE 12571 ON OVEMBER 19, 1993, EFFECTIVE JANUARY 1, 1994. THE ROKG FAILED TO NOTIFY THESE NEW REGULATIONS AS REQUIRED UNDER ARTICLE II OF THE AGREEMENT ON TECHNICAL BARRIERS TO TRADE (STANDARDS CODE). THE PROPOSED REGULATIONS WERE REVISED TO RESPOND TO USG CONCERNS THAT THESE REGULATIONS COULD IN PRACTICE RESULT IN DISCRIMINATION AGAINST IMPORTS. HOWEVER, THE ROKG CUSTOMS ADMINISTRATION (KCA) RECENTLY ANNOUNCED ITS OWN COO REGULATIONS WHICH SEEM TO REVIVE ISSUES THE USG BELIEVED RESOLVED AFTER MAFF REVISED THEIR ORIGINAL COO

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GUIDELINES. ROKG HAS ALSO FAILED TO NOTIFY THE NEW KCA COO REGULATIONS.

IT IS NOTED THAT OVER THE PAST THREE YEARS, FOUR DIFFERENT ROKG MINISTRIES HAVE ISSUED SEPARATE AND SOMETIMES CONFLICTING COO REQUIREMENTS.

2. ACTION REQUESTED: EMBASSY IS REQUESTED TO DRAW UPON THE FOLLOWING TALKING POINTS AND BACKGROUND TO DELIVER A DEMARCHE TO APPROPRIATE AGENCIES. P4EASE REPORT ROKG RESPONSES.

BEGIN UNDERLINE TALKING POINTS CONCERNING ROKG'S FAILURE TO NOTIFY NEW REGULATIONS TO THE GATT END UNDERLINE:

-- WHILE THE USG APPRECIATES ROKG'S DECISION TO MAKE CHANGES IN SOME OF THE INITIAL MAFF DRAFT COO REQUIREMENTS ADDRESSING CONCERNS EXPRESSED BY THE USG, WE CONTINUE TO BE VERY CONCERNED ABOUT ROKG FAILURE TO NOTIFY NEW COO REQUIREMENTS THROUGH THE GATT STANDARDS PROCESS (BOTH MAFF AND KCA COO REQUIREMENTS).

-- IN RECENT MEETINGS IN GENEVA, WASHINGTON AND SEOUL, THE ROKG HAS BEEN PRESSED ONITS GATT OBLIGATIONS. THE ROKG ASSURED THE USG THAT IT FULLY INTENDS TO DO MUCH BETTER IN THE FUTURE TO NOTIFY ANY PROPOSED MANDATORY REGULATIONS SUCH AS THE NEW MAFF COO REQUIREMENTS.

-- WE CONTINUE TO BELIEVE THAT THE ROKG SHOULD NOTIFY BOTH THE NEW MAFF AND KCA COO REQUIREMENTS THROUGH THE GATT STANDARDS CODE PROCESS AND CONSIDER GATT SIGNATORY COMMENTS BEFORE IMPLEMENTATION. AN APPROPRIATE GRACE PERIOD SHOULD BE GIVEN BEFORE IMPLEMENTATION TO ENSURE A SMOOTHCONVERSION TO THE NEW REQUIREMENTS BY INDUSTRY.

"- THE MINISTRY OF HEALTH AND SOCIAL AFFAIRS (MOHSA) COO REGULATIONS, GATT NOTIFICATION TBT 93.13, ISSUED ON JANUARY 15, 1993 AND SCHEDULED TO GO INTO EFFECT FEBRUARY 15, 1993 WAS CANCELED ACCORDING TO ROKG. HOWEVER, NO OFFICIAL NOTIFICATION OF ITS CANCELLATION HAS BEENREPORTED THROUGH THE GATT PROCESS AS REQUIRED UNDER ARTICLES 2.5 AND 1.5.

- BY WORKING IN COMPLIANCE WITH THE STANDARDS CODE GUIDELINES AND THE PRESIDENTS' ECONOMIC INITIATIVE (PEI) RECOMMENDATIONS, WE BELIEVE DUPLICATIONS AND

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CONTRADICTIONS WOULD BE AVOIDED SINCE THESE AGREEMENTS ALLOW THE PRIVATE TRADE TO REVIEW AND COMMENT ON PROPOSED LEGISLATION.

BEGIN UNDERLINE TALKING POINTS CONCERNING MAFF AND KCA COO REGULATIONS END UNDERLINE:

-- RECENTLY ANNOUNCED COO REGULATIONS WERE ISSUED BY THE KOREAN CUSTOMS ADMINISTRATION (KCA) WITHOUT NOTIFICATION TO GATT SECRETARIAT AS REQUIRED UNDER THE TBT AGREEMENT. THIS HAS DENIED THE USG THE RIGHT TO COMMENT ON REGULATORY ISSUES WHILE STILL IN THE PROPOSAL STAGE.

-- THE USG CONTINUES TO OPPOSE THE REQUIREMENT THAT THE COO MARK BE PROMINENTLY DISPLAYED ON THE FRONT OF THE PRODUCT LABEL. WE BELIEVED THIS ISSUE WAS RESOLVED AFTER MAFF REVISED THEIR FINAL COO REGULATIONS. THE USG REQUESTS THAT KCA RESCIND THE REQUIREMENT FOR THE LOCATION OF THE COO MARK ON THE FRONT PART OF THE LABEL.

-- THE USG BELIEVES THAT MAFF'S RECENT ANNOUNCEMENT THAT IT WILL REQUIRE COO TO BE DECLARED ALONGSIDE THE PERCENTAGES OF THE IMPORTED INGREDIENT CONTAINED IN A COMPOUND PRODUCT ON PRODUCTS PROCESSED INKOREA COULD LEAD TO UNNECESSARY AND DISCRIMINATORY PERCENTAGE INGREDIENT LABELING ONIMPORTED PROCESSED FOOD PRODUCTS AND INGREDIENTS.

-- THE USG WOULD LIKE TO RECEIVE DETAILS FROM ROKG ON WHO AND HOW AN INSPECTION BODY WILL MONITOR AND ENFORCE COO REQUIREMENTS CONSISTENT WITH INITIATIVE'S UNDERTAKEN IN PEI RECOMMENDATIONS. WE UNDERSTAND THAT MAFF PROPOSES TO USE THE STAFF OF THE NATIONAL AGRICULTURAL COOPERATIVES FEDERATION (NACF), NATIONAL LIVESTOCK COOPERATIVES FEDERATION (NLCF), AND NATIONAL FISHERIES COOPERATIVES FEDERATION (NFCF) TO SERVE AS COO INSPECTORS. WE QUESTION THE APPROPRIATENESS OF DESIGNATING DOMESTIC COOPERATIVE ORGANIZATIONS ENGAGED IN BUSINESS TO PERFORM GOVERNMENT FUNCTIONS AND REQUEST THAT THE ROKG RECONSIDER THIS DECISION. AS YOU KNOW, THIS IS AN ACTIVE DISCUSSION IN THE DEC COMPETITION POLICY GROUP.

-- THE USG IS VERY CONCERNED THAT NEW MAFF AND KCA COO REQUIREMENTS, IF WRONGLY INTERPRETED BY KOREAN CUSTOMS OFFICIALS, KOREAN IMPORTERS, AND/OR RETAILERS, COULD DISCOURAGE SALES OF IMPORTED PRODUCTS.

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3. BACKGROUND:

OVER THE PAST THREE YEARS, FOUR SEPARATE ROKG MINISTRIES ISSUED SEPARATE AND SOMETIMES CONFLICTING REGULATIONS AFFECTING COO: MAFF, KCA, MINISTRY OF TRADE, INDUSTRY, AND ENERGY (MOTIE), AND MOHSA. THE COO PROPOSAL BY MOHSA IS NOW SAID TO BE TECHNICALLY DEFUNCT.

MAFF PUBLISHED, IN THE GOVERNMENT GAZETTE 11933 (NOTICE 91-47) DATED OCTOBER 2, 1991. THE ROKG FAILED TO NOTIFY THE NEW MAFF MANDATORY COO REQUIREMENT TO THE GATT SECRETARIAT AS REQUIRED UNDER ARTICLE I OF THE STANDARDS CODE, DESPITE EXPLICIT STATEMENTS FROM ROKG OFFICIALS THAT THEY WOULD NOTIFY ALL SUCH PROPOSED CHANGES IN IMPORT REGULATIONS. INITIALLY, FIVE HUNDRED AND THIRTY IMPORTED ITEMS WERE REQUIRED TO DISPLAY THE MARK OF ORIGIN ON THE PRODUCT CONTAINER/PACKAGE OR AT THE POINT-OF-SALE. THE USG EXPRESSED CONCERN TO THE ROKG THAT THE NEW DRAFT MANDATORY COO REQUIREMENTS COULD RESULT IN DISCOURAGING THE SALE OF IMPORTED PRODUCT BY DIFFERENTIATING IMPORTS FROM DOMESTIC PRODUCT TO THE KOREAN CONSUMER.

THE ROKG ANNOUNCED THE FINAL MAFF COO REGULATION IN THE GOVERNMENT GAZETTE 12571 ON NOVEMBER 19, 1993. THE FINAL MAFF COO REQUIREMENT DID NOT AFFECT AGRICULTURAL PRODUCTS MARKETED IN THE SAME FORM AS CLEARED KOREAN CUSTOMS.

KCA RECENTLY ANNOUNCED ITS OWN COO REGULATIONS THAT REQUIRE THE COO MARK ON THE FRONT OF THE PACKAGE. THIS REQUIREMENT SEEMS TO RECREATE AN EARLIER MAFF COO REGULATION THAT HAD BEEN RESCINDED AFTER THE USG COMPLAINED THAT THE CONSUMERS RIGHT TO KNOW THE COO IS WELL SATISFIED BY DECLARING IT TOGETHER WITH OTHER INFORMATION ON THE PACKAGE. THE ROKG ALSO FAILED TO NOTIFY THE NEW KCA REGULATIONS TO THE GATT SECRETARIAT AS REQUIRED UNDER ARTICLE I OF THE STANDARDS CODE.

A MINIMUM OF THREE YEARS IMPRISONMENT OR 30 MILLION WON, BEGINNING APRIL 1994, AGAINST VIOLATORS OF THE COO REGULATIONS. MAFF PLANS TO APPOINT THE STAFF OF NACF, NLCF, AND NFCF, FARM COOPERATIVES/TRADE ORGANIZATION, TO SERVE AS COO INSPECTORS.

MOTIE ISSUED FOUR COO NOTIFICATIONS TO THE GATT STANDARDS CODE. ON JULY 3, 1992 TBT 91.191 REQUIRED

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COO MARKINGS FOR 323 IMPORTED PRODUCTS; JANUARY 27, 1992 TBT 92.7 INCREASED THE LIST TO 530 ITEMS; AND, MAY 18, 1993 TBT 93.34 INCREASED THE LIST TO 675 ITEMS. ALSO ON MAY 18, 1993 TBT 93.164 REVISED THE COO SYSTEM TO PROTECT BUSINESS DOCUMENT CONFIDENTIALITY AND TO DEFINE CRITERIA FOR EXEMPTION OF SOME PRODUCTS FROM COO DECLARATION.

ON JANUARY 15, 1993, MOHSA INDEPENDENTLY ISSUED A CONTROVERSIAL SET OF COO REQUIREMENTS, TBT NOTIFICATION 93.13. THIS NOTIFICATION WAS SCHEDULED TO GO INTO EFFECT FEBRUARY 15, 1993, AND REQUIRED PRODUCTS TO DECLARE THE COO MARK ON THE FRONT DISPLAY PANEL OF THE PRODUCT LABEL IN LETTERING EXCEEDING 14 POINT TYPE. THE USG EXPRESSED BOTH CONCERN OVER THE CONFUSION CAUSED BY CONFLICTING COO PROPOSALS ISSUED BY MOTIE AND MOHSA, AND OPPOSITION TO THE REQUIREMENT TO DECLARE COUNTRY OF ORIGIN SO PROMINENTLY ON A PRODUCT LABEL. DURING THE OCTOBER 1993 TRADE SUBGROUP MEETINGS THE ROKG INFORMED THE USG THAT MOHSA'S COO PROPOSAL WAS DEAD. HOWEVER, NO NOTIFICATION OF ITS CANCELLATION HAS BEEN GEN THROUGH THE GATT PROCESS.

.IE ROKG COO SYSTEM HAS BEEN THE SUBJECT OF EXTENSIVE DEBATE AND CRITICISM AT MEETINGS OF THE COMMITTEE ON TECHNICAL BARRIERS TO TRADE IN GENEVA BY A NUMBER OF DELEGATIONS. ROKG HAS NOT BEEN COMPLETELY FORTHCOMING IN ITS RESPONSE TO THESE CRITICISM.

CHRISTOPHER

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September 23, 1996

BY HAND DELIVERY

The Honorable George J. Weise
Commissioner of Customs
1301 Constitution Avenue, N.W.
Washington, D.C. 20229

Attention:
Regulations Branch
Office of Regulations and Rulings
Franklin Court
Suite 4000
Washington, D.C.

Re: Proposed Country of Origin Marking Requirements for Frozen Imported Produce—61 Fed. Reg. 38119 (July 23, 1996)

Dear Commissioner Weise:

On behalf of the members of the American Frozen Food Institute ("AFFI"), I appreciate the opportunity to submit these comments in response to the U.S. Customs Service's ("Customs Service," or "Customs") Notice of Proposed Rulemaking entitled "Country of Origin Marking Requirements for Frozen Imported Produce." 61 Fed. Reg. 38119 (July 23, 1996) (the "Proposed Regulation").

Introduction and Summary

AFFI is the national trade association representing manufacturers and processors of frozen food products, including frozen produce products, as well as their marketers and suppliers, throughout the United States. AFFI's more than 530 member companies account for more than 90 percent of the total annual production of frozen food in the United States, valued at approximately $60 billion. AFFI's membership has a continuing interest in ensuring that any new regulations affecting the frozen produce industry are necessary and consistent with law and sound regulatory policy.

AFFI is strongly opposed to the Proposed Regulation on numerous grounds and urges that the proposal be withdrawn immediately. The Proposed Regulation is unnecessary, discriminatory, arbitrary and capricious. It would impose needless and substantial relabeling costs on the frozen produce industry without providing any benefit to the public. It arbitrarily and capriciously discriminates against the frozen produce industry by imposing a new "most conspicuous place" requirement and a new "consistent place" requirement, neither of which is provided for by statute, and neither of which Customs has ever imposed on any other class of products.

Moreover, the Proposed Regulation is inconsistent with the Clinton Administration's established regulatory policies because it is unjustified by either a compelling public need or an appropriate cost-benefit analysis. An agency is obligated to regulate only when necessary and to the extent necessary to effectuate the intent of the Congress. Consistent with established Administration policy and sound regulatory practice, this rulemaking proceeding should be terminated immediately.

Customs states in its notice that the proposed regulatory action is necessary to address that which Customs alleges constitutes instances in which markings on frozen produce packages are not sufficiently conspicuous. However, Customs has made no effort to address the alleged problem through non-regulatory alternatives and fails to establish that its existing regulatory, administrative and enforcement authority is insufficient to address any compliance problems which may exist.

The notice of proposed rulemaking cites a proceeding under Section 516 of the Tariff Act of 1930, as amended (19 U.S.C. § 1516; or "Section 516") as the justification for proceeding with a proposed rule. However, no Section 516 petition currently is pending before the Customs Service; therefore, there no longer is a basis for considering the action proposed in the notice of proposed rulemaking. The proposal, therefore, should be withdrawn, with no further regulatory action taken.

The record of comments submitted in response to the Customs Service's advance notice of proposed rulemaking on frozen produce marking reveals that the proposal is strongly opposed by the affected industry and favored by a very small number of parties, some of whom support the proposal purely with anticompetitive and protectionist motives. In fact, only one producer of frozen produce appears to support the Proposed Regulation.

For all these reasons, AFFI urges Customs to take immediate action to withdraw the Proposed Regulation and terminate the rulemaking proceeding. AFFI's specific objections to the Proposed Regulation are discussed below.

No Section 516 Petition Is Pending Before the Customs Service on the Issue of Front-Panel Marking of Frozen Produce Packages

As Customs acknowledges in its notice of proposed rulemaking, this rulemaking proceeding has a long history and stems from a petition submitted under Section 516 by two U.S. processors and packers of frozen produce. Both petitioners have withdrawn their joint petition. As a result, there exists no petitioner on whose behalf this rulemaking proceeding may be continued.

The International Brotherhood of Teamsters (Teamsters) is not a petitioner in this proceeding. Although the Teamsters submitted a letter to the Customs Service, dated February 24, 1993, that letter does not constitute a petition under Section 516. Instead, that letter requested, "pursuant to 19 CFR § 117.23(c)" (apparently intended as a reference to § 177.23(c), which applies to rulings pertaining to government procurement) that Customs issue a ruling holding that certain packages of frozen produce mixtures did not comply with 19 C.F.R. § 134.46, the special marking rule applying to product labels bearing U.S. references.

In any event, the Teamsters' letter is irrelevant to this rulemaking proceeding because it raises an issue that is outside the scope of this proceeding and which already has been addressed by Customs in a private letter ruling issued in 1993 (HRL 735085 (June 4, 1993)). Moreover, the Teamsters' support for the frozen produce processors' petition is a moot point because that petition has now been withdrawn by action of both co-petitioners. Therefore, no matters presented in the Teamsters' letter of February 24, 1993 remain pending before Customs.

Finally, the frozen produce processors' petition itself did not raise the broader issue of a mandatory front-panel marking requirement applicable to all frozen produce subject to the marking requirement under Section 304. The letter of January 13, 1993, filed on behalf of the petitioners limits the petition to produce imported in the package in which it will be sold to consumers. In fact, the petitioners stated specifically as follows:

> It is important to note that the requested ruling only applies to produce imported into this country in its consumer package, and does not apply to the importation of bulk frozen product which undergoes further processing and/or packaging in this country.

As noted previously, that petition, regardless of its scope, has been withdrawn in its entirety. Given the absence of a Section 516 petitioner, this rulemaking proceeding should be terminated immediately.

The Proposed Regulation Serves No Valid Purpose

Executive Order 12866 requires an agency to justify its decision to regulate by demonstrating a "compelling public need." The Executive Order also requires a cost-benefit analysis and full consideration of non-regulatory alternatives. The Proposed Regulation does not meet either of these requirements and, therefore, violates the letter and spirit of the Executive Order.

Section 304 and the regulations implementing it already require that marking be legible, indelible and located in a conspicuous place. Customs already possesses the regulatory, administrative, and enforcement authority it needs to ensure that *all* articles of foreign origin subject to the Section 304 marking requirement are marked in a conspicuous place.

Nevertheless, Customs alleges in the proposal that a mandatory front-panel marking requirement is necessary for frozen produce because allowing marking on the side or back panel would require Customs to issue "elaborate conditions or regulations specifying, e.g., type size or other details of the marking." 61 Fed. Reg. at 38124. Customs further states that "the back panel (as well as the side panel), with its manifold distractions and without qualifications or graphic highlighting, is not a "conspicuous place." *Id.* These statements in the proposal display an improper unwillingness on the part of Customs to exercise the case-by-case enforcement discretion it is required to exercise with respect to all products subject to the marking requirement. That which Customs derogatorily terms "manifold distractions" are in fact other types of product information, including government-mandated information. Such information appears on practically all packaged goods and certainly on all packaged foods, yet Customs is proposing a front-panel rule only for frozen produce.

Moreover, Customs acknowledges in the notice that it will continue to use case-by-case enforcement discretion even if it imposes a mandatory front-panel requirement. 61 Fed. Reg. at 38123, 38126. In fact, Customs notes it will rely on case-by-case enforcement, rather than new regulations, to respond to that which it finds to be certain unacceptable marking practices on frozen produce, as follows: stamped marking that is smeared, upside down, sideways, or placed over other text or graphics. 61 Fed. Reg. at 38126. No credible explanation is presented as to why case-by-case enforcement is not also sufficient to ensure general compliance with the conspicuous place requirement.

Customs also alleges that a front-panel rule will conserve its enforcement resources and be "less burdensome to industry than the government injecting itself into the minutiae of label graphics on the back or information panel." 61 Fed. Reg. at 38124. As for burden to the government, frozen produce constitutes a minuscule percentage of all packaged goods subject to the marking requirement. No measurable level of government resources, therefore, possibly

could be saved by a front-panel rule, particularly when, as noted above, Customs has stated not only that it must, but also that it intends to, continue to use case-by-case discretion regarding frozen produce compliance.

With regard to burden on industry, the U.S. frozen produce industry is a more reliable judge than is Customs of the costs and burdens of the alternatives discussed in the notice. AFFI does not believe increasing the ease of operations for the U.S. Customs Service justifies the promulgation of additional regulatory burdens on industry which are not contemplated by the U.S. Congress. Moreover, as discussed below, a mandatory front-panel rule will impose substantial costs and burdens on the affected U.S. companies.

The Proposed Regulation Would Impose Substantial and Unwarranted Costs on the Frozen Produce Industry

If a regulation is unjustified by a showing of compelling public need and serves no public purpose, it is not to be issued regardless of whether the costs and burdens it imposes on affected parties are heavy, light, or moderate. The Proposed Regulation, which as discussed above serves no public purpose, is particularly egregious in that it would require virtually *every* producer and packer of frozen-origin produce to redesign its labels, *regardless of the degree of conspicuousness of the country of origin marking that already appears on such labels.*

AFFI surveyed its membership to obtain information on the cost and extent of the relabeling that the Proposed Regulation would impose. Contrary to the premises on which Customs stated it based its Proposed Regulation, the responses to AFFI's survey establish that Customs has underestimated the cost and burden that would result from the Proposed Regulation, as well as the number of source countries from which U.S. producers obtain fruits and vegetables.

The respondents' estimates of their compliance costs ranged from $15,000 to more than $1 million for a one-year period. The number of product lines for which they source foreign produce ranged from 3 to 47, and the percentage that these product lines constitute of a respondent's total number of product lines ranged from less than five percent to 100 percent. The respondents informed AFFI that the number of countries outside the United States from which they are likely to source foreign fruits and vegetables in an average year ranged from one to 12. The countries listed included Argentina, Australia, Belgium, Bosnia, Brazil, Canada, Chile, China, Costa Rica, Ecuador, El Salvador, Fiji, France, Fuji, Guatemala, Honduras, India, Indonesia, Israel, Mauritius, Mexico, New Zealand, Paraguay, Peru, Poland, Serbia, Spain, Taiwan, United Kingdom, and Vietnam.

The data provided by AFFI's membership establishes that compliance with a mandatory front-panel country of origin marking rule will impose substantial costs and burdens on the affected companies. These costs and burdens are entirely unjustified in that they would be incurred for no public benefit.

The Proposed Regulation Would Establish an Unprecedented "Consistent Place" Requirement for Marking that Is Not Required by Section 304

The Proposed Regulation is further misguided in its adoption of the position that marking has to be located in a *consistent* place on all packages of a particular good, in this case, frozen produce. In this regard, the notice of proposed rulemaking, in an attempt to explain Customs' rejection of the option of allowing marking on the back panel, states as follows:

> While this option would offer the regulated party some flexibility, it was rejected in part because of its potential for confusing the ultimate purchaser who would not have *a consistent place* on the package to look for country of origin marking.

61 Fed. Reg. at 38124 (emphasis added).

Customs apparently would abandon its long-standing position, under which goods may be marked anywhere on the article or container, provided the ultimate purchaser is "able to find the marking easily and read it without strain." 19 C.F.R. § 134.41. Had Congress intended to require every class of product, or particular classes of products, to be marked in a consistent place, it would have so provided. Needless to say, if Customs is now going to require that all packaged goods, and indeed all articles, subject to Section 304 be marked in a consistent place, it is effecting a major change in the marking law, with serious costs and consequences for U.S. industries. The considerations attending any such change are clearly a matter for the Congress. AFFI notes that the Proposed Regulation is particularly unwelcome at the current time, when the Committee on Ways and Means of the U.S. House of Representatives is considering the need for comprehensive revisions to the marking law.

Section 304 requires neither that marking appear in a "consistent" place nor that it appear in the *most* conspicuous place on an article or container. Customs must exercise its regulatory discretion within the boundaries established by the Congress. The Proposed Regulation goes beyond those boundaries in forcing the frozen produce industry to meet a requirement not present in the statute and not necessary for effectuation of the congressional purpose.

The Proposed Regulation Is Arbitrary, Capricious, and Discriminatory

Customs is not proposing to force industries other than the frozen produce industry to comply with a front-panel marking requirement, even though the same considerations that apply to the marking of frozen produce apply equally to packaged goods generally, whether frozen or unfrozen. Customs cites alleged non-compliance with the conspicuous place requirement on some frozen produce packages as a rationale for proceeding with a regulation limited to frozen produce packages, stating that its mandatory front-panel rule "should afford a definitive solution to a problem which has been demonstrated to be extensive." 61 Fed. Reg. at 38123.

As a threshold matter, alleged noncompliance with a current rule by some industry members is not, nor has it ever been, considered a proper justification for imposing a more onerous rule on an entire industry, particularly an onerous rule that Customs never has applied to any other industry. As discussed above, Executive Order 12866 requires that an agency refrain from regulating except in cases of compelling public need and also requires a cost-benefit analysis and full consideration of non-regulatory alternatives. Alleged noncompliance by some producers is not a justification that satisfies the requirements of the Executive Order.

Additionally, Customs has failed even to establish the existence of what it terms "a problem which has been demonstrated to be extensive." Customs does not compare the compliance rate of the frozen produce industry with that of any other industry. The evidence of noncompliance on which Customs relies appears to have been provided by the former petitioners, each of whom, as discussed above, has withdrawn from the petition and no longer supports a mandatory front-panel rule.

AFFI notes, furthermore, that Customs has not taken any steps to work cooperatively with the frozen produce industry in addressing the compliance problems Customs considers to exist. Assuming, *arguendo,* that Customs could identify a significant level of noncompliance, the appropriate action would not be a regulation of general applicability, but might instead include the pursuit of alternatives to regulation desired to bring about "informed compliance." The preamble to the Proposed Regulation suggests that Customs was unwilling to give serious consideration to non-regulatory alternatives out of an attitude of mistrust of the frozen produce industry:

> With regard to a basic issue raised in the ANPRM, that is, whether rulemaking is needed, Customs determined that not to proceed with a marking proposal would leave the country of origin marking situation no better than it was prior to *Norcal I.* Manufacturers of frozen produce would still be free to choose marking options that could make it

> difficult for the average consumer to learn the origin of the product prior to purchase, contrary to clear Congressional intent in the law.

61 Fed. Reg. at 38123.

The mistrustful attitude is demonstrated elsewhere in the notice as well. Customs states that it rejected the option of allowing marking on the back panel because "it affords many opportunities to bury the origin information in other information or graphic devices." *Id.*

Similarly, later in the notice Customs states as follows:

> Consideration was also given to providing the manufacturer with a choice: (1) Provide a simple and legible marking on the front panel or (2) submit to a more detailed set of guidelines for marking on the back panel as in the foregoing option. While this option would offer the regulated industry *some flexibility*, it was rejected in part because of its potential for confusing the ultimate purchaser who would not have a consistent place on the package to look for country of origin marking.

Under current regulations implementing Section 304, all industries have *complete flexibility* with respect to placement of marking, provided that marking satisfies the general requirements of the statute. Customs states in the quoted language that it is unwilling to allow the frozen produce industry even "*some* flexibility," citing a purported "consistent place" requirement that, as discussed previously, is not contemplated in the marking statute, the legislative history or even Customs' own previous long-standing practice.

The mistrustful and discriminatory attitude exhibited toward the frozen produce industry in the notice is unfortunate and misplaced, particularly in that Customs has made no effort to determine the level of compliance, or comparative level of compliance, on an industry basis. Regardless of the compliance level that may exist, the Customs Service's posture in seeking to punish an industry with a new, more burdensome regulation that is applied to no other industry, on the premise that the industry cannot be trusted to comply with existing regulations, is improper and an abuse of discretion. For this reason as well, the Proposed Regulation should be withdrawn at once.

The Customs Service's mention of the fact that frozen produce is cold to the touch and displayed for retail sale in freezers is not sufficient to cure the arbitrariness and capriciousness of the Proposed Regulation. Customs presumes that the coldness of the package is a basis on which the marking should be required to appear on the front panel, even though frozen produce packages are not so cold as to preclude handling by the consumer. Additionally,

requiring labeling on the front panel will not satisfy the objective Customs claims to serve. Produce is displayed in various ways in retail freezers, including methods in which the side panel faces the consumer. Even in circumstances in which the front panel faces the prospective purchaser, the consumer in most instances still must handle the package to examine *any* information on the label. Customs proceeds under the false assumption that a consumer interested in receiving information on the product considered for purchase will not examine the package. Under such an erroneous assumption, it is difficult to appreciate how any reasonable method of marking on any package could ever suffice.

Customs not only is erroneous in applying the "coldness" factor in this rulemaking, but is arbitrary and capricious in doing so as well. Customs is not proposing to apply the requirement to all frozen goods, but instead is proposing to single out frozen fruits and vegetables for the unique "consistent place" rule it applies in no other situations.

In this regard, part of the Customs Service's justification for disallowing back panel marking is it conclusion that marking located close to the required nutrition information would not necessarily be conspicuous. Customs concludes, on the basis of no evidence on the record, that consumers are less interested in nutrition information about frozen produce than they are about nutrition information on other classes of products. 61 Fed. Reg. at 38125. This unsupported assumption is beyond the expertise or jurisdiction of Customs. Moreover, it is false.

AFFI recently commissioned a telephone survey conducted by Opinion Research Corporation, involving a national probability sample of 1014 adults (505 men, 509 women) 18 years of age or older, all of whom were living in private U.S. households. Of the total sample, 656 indicated they had purchased frozen fruits and/or vegetables in the previous three months. The latter group of respondents were asked the following question:

> Is nutrition information on frozen fruits and vegetables more, less, or of equal importance to you than the same information on other food products?

Seventy-nine percent of the 656 responded that nutrition information on frozen fruits and vegetables was either equally important, or more important, than the same information on other food products. Their responses show, contrary to the assumptions of Customs, that consumers know to look to the back panel for important information.

In fact, the responses of the participants strongly suggest that nutrition information is regarded by consumers as *more* significant than country of origin information. When asked, "What are the main things that influence which frozen fruits or frozen vegetables you purchase?", only

one respondent out of the 656 -- less than one percent -- cited the country where a product is from as an important factor in his or her purchasing decision.

The Opinion Research Corporation results reaffirm the results of a previous U.S. Food and Drug Administration (FDA) survey with regard to the importance of country of origin information to consumers. In 1978, FDA sponsored a Consumer Food Labeling Survey. Respondents were asked, "What information, if any, printed on food packages and cans do you pay particular attention to or find helpful in any way?" Forty one percent named ingredient information, 22 percent named nutritional information and 18 percent named size/quantity information. Less than one percent named country of origin information.

The Proposal Is Unsound as a Matter of Regulatory and Trade Policy

The United States has an obligation to its trading partners not to use the country of origin marking requirement as a non-tariff barrier. The Proposed Regulation is inconsistent with this obligation because it imposes a marking requirement that is not reasonably necessary under U.S. marking law and that arbitrarily disadvantages U.S. processors that use imported fruits and vegetables in frozen products.

AFFI notes that the Government of Canada rightfully has objected to the Proposed Rule on several grounds, including the obligation of parties to the North American Free Trade Agreement ("NAFTA") to "accept any reasonable method of marking" of a good of another party. The Government of Canada also noted the NAFTA definition of "conspicuous" for purposes of marking "capable of being easily seen with normal handling of the good or container." Discriminatory and unduly burdensome marking requirements, such as those contemplated by the Proposed Rule, are a well-recognized non-tariff barrier and must be avoided. If the U.S. Government proceeds with the Proposed Rule, it can expect its trading partners to impose similarly unfair labeling requirements.

Equally objectionable are the domestic regulatory consequences of the Proposed Regulation. If adopted, the administrative precedent established under Section 304 for front-panel marking can be expected to be cited in future Section 516 petitions by various interests for anticompetitive purposes; these parties would seek the opportunity to impose the costs and burdens of a major relabeling requirement on their domestic competitors.

For the aforementioned reasons, AFFI urges the Treasury Department to terminate immediately the rulemaking proceeding it has initiated on country of origin marking of frozen fruits and vegetables. No justification exists for the continuation of a rulemaking concerning a new regulatory requirement that is unnecessary, arbitrary and capricious, harmful and discriminatory with respect to the affected industry, and unsupported by any current petition under Section 516 of the Tariff Act, as amended.

Sincerely,

Steven C. Anderson
President and Chief Executive Officer

Senate Permanent Subcommittee
on Investigations

EXHIBIT # 6

Testimony of
American Meat Institute
to the
Permanent Subcommittee on Investigations
Committee on Governmental Affairs
May 8, 1998

The American Meat Institute is the national organization representing meat packers and processors and their suppliers throughout North America. This testimony focuses on meat and poultry slaughterers and processors and USDA, the government agency that intensely regulates our industry.

Today's meat and poultry inspection program has its origin in the Federal Meat Inspection Act of 1906. At that time, the primary public health concerns were diseased animals and unsanitary conditions in meat packing plants. The law requires all cattle, sheep, swine, goats and equines and their carcasses and parts be inspected and passed as human food for distribution in interstate commerce. The 1957 Poultry Products Inspection Act extended to chickens, turkeys, ducks, geese and guineas many of the same requirements mandated for meat. The Wholesome Meat Act of 1967 further extended inspection programs to the state level by establishing a federal-state cooperative inspection program for plants that produce and distribute meat and poultry products within state boundaries. Twenty-five states currently maintain inspection programs that are required to be at least equal to federal standards. Similar requirements also apply to imports from foreign countries, which must have equivalent inspection systems. The primary goal of these inspection programs is to prevent unwholesome, adulterated or misbranded products from being sold as human food, and to ensure meat and poultry products are slaughtered and processed under sanitary conditions.

USDA's legal responsibilities are primarily focused on slaughter and processing facilities. It maintains jurisdiction over federally inspected meat and poultry products during storage, distribution and sale, but the federal law exempts retail and restaurant operations from the type of food safety inspection required in federal and state inspected packing and processing plants. Moreover, current meat and poultry inspection statutes give USDA no food safety jurisdiction on farms, ranches, feedlots or other live animal production facilities. While it is true that no inspection system can eliminate all foodborne illness risks from meat and poultry, there is a growing consensus that food safety can best be ensured through oversight programs that are coordinated from production through consumption.

USDA's Food Safety and Inspection Service uses significant resources to carry out its responsibilities. FSIS has a total staff approaching 10,000 employees. More than 8,000 field inspectors and supervisors inspect approximately 6,500 plants. The estimated cost to operate this massive, labor-intensive program in fiscal year 1998 is $675 million, or approximately $100 thousand per federally inspected facility. In contrast, FDA has a budget slightly over $200 million for food safety activities and approximately 900 employees to regulate an estimated 53,000 establishments that produce, process or store food. That translates to an expenditure of

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approximately $4,000 per FDA inspected facility. These statistics demonstrate that meat and poultry manufacturers are the most intensely regulated segment of the U. S. food industry.
Existing governmental resources devoted to food safety are disproportionately directed at meat and poultry manufacturers because federal laws require continuous animal-by-animal inspection and a daily inspection presence in processing facilities. Current statutes coupled with FSIS inspector opposition restrict the agency's flexibility to shift its resources in response to changing health risks. The ability of FSIS to tailor its inspection frequency based on the risks presented by the type of animal, processing technology or other risk factors is limited. FSIS's effectiveness and efficiency could be enhanced if the agency focused its resources on products and processes that present the most significant public health risks.

FSIS has a broad range of enforcement powers to prevent unwholesome, adulterated or mislabeled meat and poultry from reaching the public. Plants are prohibited from operating unless the government provides inspection services. FSIS often exercises its authority to withhold or suspend inspection if plants are not meeting their statutory or regulatory obligations. Such actions shut down plant operations.

It is also illegal to sell or transport adulterated or misbranded products. Unsafe products can be condemned and removed from the market. Violation of the federal meat and poultry laws can result in substantial fines as well as imprisonment.

Over the past two decades, USDA has asked Congress for additional statutory authority to mandate product recalls without obtaining court orders, to summarily withdraw inspection services from companies USDA believes have violated the law and to unilaterally impose civil fines on companies that fail to comply with the laws, regulations, or agency's orders. In light of the scope and breadth of USDA's existing enforcement arsenal, and the absence of any proof that the tools currently available to USDA are inadequate, additional authority is not necessary. Moreover, because of the potential administrative abuse these requested sanctions would present, new enforcement authority would be contrary to sound public policy. More punitive measures will not and cannot make food safer.

On January 27, 1997 the federal government and industry began a several year process to dramatically change the way meat and poultry is inspected. This new regulatory program commonly referred to as Hazard Analysis Critical Control Points, or HACCP, more clearly defines the responsibilities of the regulator and the regulated industry. Meat and poultry companies are required to have a plan for producing safe food. The government's regulatory role is to set food safety performance standards and to verify through its inspection activities that the company meets those performance standards. Federal inspectors maintain a continuous presence in plants. But where inspectors previously looked for problems that had already occurred, under the new system, they monitor plant activities to be sure appropriate steps are being taken to prevent problems. It is a fundamental shift in the priorities of the federal government.

The transition to this new HACCP-based regulatory program has created several implementation challenges. Many FSIS personnel find it difficult to abandon traditional "command and control" inspection tactics. Many inspectors with no scientific training continue to dictate how a plant's production process is designed and operated. FSIS needs to improve its inspector performance to achieve fair and uniform enforcement of the regulations. A more in-depth understanding of food safety manufacturing principles and the agency's inspection modernization process is needed. USDA's credibility and the ultimate success or failure of its new regulatory program depends on allowing companies to produce products in a manner that

results in uncompromising food safety. FSIS should focus on verifying products are safe and abandon the practice of mandating how product safety is achieved.

Regulatory and policy changes are also needed to create an environment that is consistent with HACCP-based inspection. FSIS began a regulatory review process in 1995 to revise or repeal existing regulations that impede implementation of a scientifically designed HACCP program. FSIS has made limited progress in discarding old, outdated regulations. The result is a new HACCP-based inspection program layered over the traditional regulatory compliance program. Inspectors are using new procedures to determine compliance with old regulations. FSIS should complete its regulatory review process as soon as possible. Otherwise, the new HACCP-based inspection program will be scientifically indefensible and inhibit the adoption of new technologies and innovations that can improve the safety of meat and poultry products.

Consumer and food handler education is an extremely important element of a production to consumption food safety system. The American Meat Institute Foundation has trained thousands of meat and poultry industry workers in HACCP principles and basic food safety. Joint training in these areas between industry and government employees would be even more beneficial. Last year, industry, consumers, and the federal government formed the Partnership for Food Safety Education and launched a consumer education program called Fight BAC!™ It is hoped that this campaign will persuade consumers to improve risky food handling behavior and prevent food borne illnesses.

The meat and poultry industry is committed to doing everything within its powers to ensure that the food it processes, distributes and serves to American consumers is the safest and most wholesome in the world. Companies strive every day to make their food safety systems better. Manufacturers of meat and poultry products routinely employ many state-of-the-art practices to minimize the risks of foods causing human illness, but we cannot guarantee all food products are free from all risks. By the same token, no food inspection system or testing program can guarantee zero risks.

One central question facing this committee is the organizational structure of the U.S. food safety regulatory system. The American Meat Institute believes the current organizational structure is adequate to maintain the safety of the food supply. We are far more concerned about having a scientifically supportable meat and poultry inspection program than where it is located within the federal bureaucracy. However, if others deem organizational changes necessary, then we would support the establishment of a single food agency at USDA that is statutorily permitted to allocate its resources to areas that pose the most significant public health risks. USDA should have jurisdictional authority because of its long history and experience in addressing agricultural issues, and its vast infrastructure that extends throughout the food chain.

The fundamental elements of a sound food safety system are in place today. Food manufacturers and distributors willingly accept their responsibilities to produce safe food. Government has a valuable regulatory role, but it must expand its leadership and investment in other areas such as food safety research, education and technology development. Food safety is a shared responsibility. Maintaining the safety of the U. S. food supply depends on all participants in the food chain--from producers to consumers--taking appropriate measures to prevent foodborne diseases.

Thank you for the opportunity to present AMI's perspective.

Senate Permanent Subcommittee
on Investigations

EXHIBIT # 7

FOOD MARKETING INSTITUTE

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May 13, 1998

The Honorable Susan M. Collins
Chairwoman
Permanent Subcommittee on Investigations
Senate Governmental Affairs Committee
United States Senate
Washington, DC 20510-6250

Dear Senator Collins:

The Food Marketing Institute appreciates the opportunity to comment on the issues of the safety of imported foods.

The Food Marketing Institute (FMI) is a nonprofit association conducting programs in research, education, industry relations and public affairs on behalf of its 1,500 members including their subsidiaries — food retailers and wholesalers and their customers in the United States and around the world. FMI's domestic member companies operate approximately 21,000 retail food stores with a combined annual sales volume of $220 billion — more than half of all grocery store sales in the United States. FMI's retail membership is composed of large multi-store chains, small regional firms and independent supermarkets. Its international membership includes 200 members from 60 countries.

The General Accounting Office report does not say that imported foods are unsafe, but the report did focus on the differences and inefficiencies among the various federal agencies that have food safety responsibilities.

It is the federal government's job to make certain that food in the distribution system is safe and wholesome, whether the food products are domestically produced or imported. If better coordination and resources are needed for the federal government to more effectively act with one voice, we encourage it.

In your letter you specifically seek the merits of initiatives, such as additional country of origin labeling. In fact, S. 1042, "The Imported Produce Labeling Act," mandates retailers to label by country of origin produce at the initial point of sale. FMI opposes this bill for the following reasons:

- The average produce department carries over 340 items year round. Displays change constantly due to supplies and the perishable nature of the product. Country of origin signs would have to be constantly changed and updated. Retailers would face a nearly impossible task to put the right label or sign in place at the right time. In almost all cases, produce department employees cannot tell country of origin simply by looking at a product. At times, it is not uncommon to have the same product from different countries in the store at the same time. Additional costs would be incurred in added labor, signage and display space. Inevitably, these costs would be reflected in consumer prices.

- The American Cancer Society, the American Heart Association and others are encouraging consumers to eat more fruits and vegetables. The *5 A Day for Better Health* program has promoted healthful eating. The "Shopping for Health" research by FMI and the Prevention Magazine shows that survey respondents are eating more fruits and vegetables. A recent survey by *Produce Merchandising* indicates that the three most important characteristics that consumers look for when selecting fresh produce are freshness; quality and appearance; and price.

- The clear objective of this proposed legislation is to restrain U. S. produce imports. The great majority of imported produce enters this country to satisfy consumer demand for year-round availability of fresh fruits and vegetables. For many commodities, such as grapes, winter vegetables and specialty tropical fruits, there is simply not enough domestic product to meet consumer needs.

Some proponents of this legislation argue that the labeling is necessary to assure the safety of imported foods. Country of origin labeling does not address the issue of food safety in any way. If the food is not safe, it should be prohibited from entering this country. Country of origin labels will not in any way help consumers determine on their own if a product is safe.

U.S. growers and shippers are not restricted from voluntarily placing stickers on their own produce identifying it as "Grown In The U.S.A.". In fact, one example of voluntary labeling is the Washington apple industry. They are using their own labeling to help promote and merchandise their product. This makes more sense then asking Congress to pass protectionistic, country of origin labeling legislation.

If you have any questions, please feel free to contact me.

Sincerely,

John Motley
Senior Vice President
Government and Public Affairs

Senate Permanent Subcommittee
on Investigations

EXHIBIT # 8

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TESTIMONY OF THE

GROCERY MANUFACTURERS OF AMERICA

BEFORE THE

PERMANENT SUBCOMMITTEE ON INVESTIGATIONS
SENATE GOVERNMENT AFFAIRS COMMITTEE

The Adequacy of Systems and Procedures Used by Federal Agencies to Ensure the Safety of Foods Imported into the United States

MAY 14, 1998

The Grocery Manufacturers of America (GMA) appreciates the opportunity to submit testimony to the Permanent Subcommittee on Investigations of the Senate Government Affairs Committee regarding the regulation of foods imported into the United States GMA is the world's largest association of food, beverage and consumer brand companies. With U.S. sales of more than $430 billion annually, GMA members employ more than 2.5 million workers in all 50 states. The organization applies legal, scientific and political expertise from its member companies to vital food, nutrition, and public policy issues affecting the industry. Led by a board of 44 Chief Executive Officers, GMA speaks for food and consumer product manufacturers at the state, federal and international levels on legislative and regulatory issues. The association also leads efforts to increase productivity and efficiency in the food industry.

BACKGROUND

Although the safety of the food supply has been a topic of increased discussion in recent years, the U.S. food supply remains the safest and most abundant in the world. More than 750 million meals are consumed in the United States daily, and American consumers enjoy a wide variety of food products that are abundant, affordable, and the safest in the world. The food industry has a great deal at stake in ensuring the safety of its products. And, the industry continually strives for improvement.

The Adequacy of Domestic and International Food Standards, Codes of Practice and Other Guidelines With Regards to Imported Foods.

In December 1997, GMA formed a Task Force on Food Safety/Independent Food Agency, which was composed of 15 food industry trade associations, and 15 of our member companies. The purpose of the task force was to fully examine the food safety system, and make recommendations to the National Academy of Sciences (NAS). The NAS's report on the regulation of the U.S. food supply, as required by the FY 1998 Agriculture Appropriations bill, is expected to be sent to Congress in August 1998. GMA presented its findings to the NAS on Wednesday, April 29, 1998, along with other stakeholders. Attached to our testimony is one of the GMA task force white papers that was submitted to the NAS, entitled, "Food Safety Requirements Applicable to Food Products Imported into the United States."

Summary of the GMA Task Force White Paper on Food Imports

- Food imports into the United States are subject to a number of statutory and regulatory requirements that are intended to ensure that, when sold to the customer, they are as safe as products produced domestically. The two agencies who regulate the safety of the food supply are the U.S. Department of Agriculture (USDA) and the Food and Drug Administration (FDA).

- The primary statutes governing the safety of imported foods are the Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act (PPIA), and the Federal Food, Drug and Cosmetic Act (FFDCA).

- Meat and poultry products from foreign countries are eligible for entry into the United States provided the foreign country's inspection system has been evaluated and found acceptable by FSIS. FSIS also evaluates the eligibility of a foreign country by reviewing the country's laws, regulations and other information the FSIS may need. Officials from FSIS perform an initial on-site review of the system. Approval of a country's system may be withdrawn if FSIS determines that the system does not ensure equivalent standards with the U.S.

- Once a country is deemed eligible to export meat and poultry products into the United States, officials of the foreign country must certify individual plants in the exporting country. The certification must be renewed annually.

- The shipping container for the meat and poultry product must contain the following: product name, foreign establishment number and country of origin. All products imported into the United States must undergo reinspection within 72 hours of arrival. Once a product has passed inspection and is in the United States, it is treated as a domestic product and is subject to all provisions of the FMIA and the PPIA.

Currently, approximately 40 countries are approved to export meat products to the U.S. and five countries are approved to export poultry products.

- Although the Food and Drug Administration has no explicit authority under the FFDCA to inspect foreign food establishments, the agency does inspect some foreign establishments on a voluntary basis. FDA has also entered into MOUs with several foreign governments. These MOUs ensure that food products produced in those countries are manufactured under sanitary conditions, meet U.S. quality requirements and are tested and sampled before export.

- The FFDCA authorizes FDA to refuse admission to articles, including foods, which appear to be adulterated or misbranded, or that appear to have been manufactured under unsanitary conditions. The FDA is responsible for ensuring that all imported foods meet the same safety and labeling standards as domestic food products. FDA makes a determination whether to inspect a product by wharf examination, physical examination or sample examination. This determination is based on information pertaining to the nature of the product, FDA priorities, and past history of the commodity.

- To streamline its import monitoring activities, FDA routinely issues import alerts to its district offices. These alerts identify products and importers that have repeatedly been found to violate federal law and regulations. FDA inspectors are instructed to

pay close attention to these products and, in certain cases, to refuse entry of all such products without sampling or analysis. Any product refused entry to the U.S. must either be re-exported or destroyed under approval supervision.

As you can see from the white paper, both FDA and FSIS have ample legal authority to regulated imported foods. While bills such as the "Safety of Imported Food Act of 1998", S. 1707, introduced by Senator Barbara Mikulski, and other proposals to increase statutory authorities for federal agencies have good intentions, GMA is concerned about the potential negative ramifications of these bills. The costs of trying to police the entire world are not justified by the real food safety risks to date. It could open U.S. manufacturers to requirements from other countries that they be allowed to inspect U.S. plants exporting to their respective countries as a condition of import. In addition, inspection itself is not a guarantee of food safety domestically or internationally. Finally, GMA is concerned that the FDA proposal would lead to entire country "blacklisting" regardless of the safety systems employed by GMA member companies. What agencies such as FDA and FSIS need are resources and direction to focus most effectively and efficiently on those food safety concerns presenting the most significant risks to public health.

FDA needs adequate funding for its science-based activities, strong leadership and adequate staffing. The food industry and consumers both are best served by a strong

FDA that develops policy based on the best science, and enhances public confidence in the safety of the food supply. Equally, the Food Safety and Inspection Service (FSIS)'s effectiveness and efficiency could be enhanced considerably by streamlining the current inspection system, and focusing scarce resources on products, processes and facilities presenting the most significant risks.

Importance of a Science and Risk-Based Import Inspection System

GMA believes that the food safety standards and related requirements (or equivalent ones) enforced by the agencies within the food regulatory system should be applicable to products at all levels of distribution, including imported products. GMA supports the continuation of a strong FDA and FSIS with standards and related requirements that should be scientifically based. For example, developing better detection systems in certain types of foods. Many companies rely heavily on tight specifications with respect to production and distribution.

The agencies within the food safety system responsible for product regulation should be provided the necessary supporting scientific expertise and research. The emphasis should be put on focusing available resources of government and industry on the key science-based preventive systems for food safety and on the voluntary use of government inspections and consultations with foreign suppliers where serious issues of food safety are identified.

Merits, if any, of Various Initiatives, such as Requiring the use of (i) Trace-back Mechanisms to the Farm of Origin, (ii) Country of Origin Labeling, and (iii) Hazard Analysis and Critical Control Point System.

GMA believes that mandating trace-back or country-of-origin labeling would be tremendously burdensome and unnecessary, and would do nothing to increase the safety of the food supply. Proposals for country-of origin labeling are misleading, will raise food prices, and run the risk of retaliation from other countries.

The United States has an obligation to its trading partners not to use country of origin marking requirements as non-tariff trade barriers. Adoption of country of origin labeling would establish a dangerous precedent for the United States' staunch opposition to anti-competitive behavior. In the past, several trading partners have indicated that such a non-tariff trade barrier could spark retaliatory action against U.S. agricultural exports harming agriculture, business, employees and consumers. With regards to trace back, any product that is imported into the United States must satisfy all applicable requirements imposed on domestic products, which includes the name and place of business of the manufacturer, packer or distributor. There is no need for further record-keeping of details about lots or sub-lots that would make for an unmanageable implementation in manufacturing and distribution.

Finally, GMA strongly believes that HACCP should be voluntary for most food categories as part of the food industry approach to a safe food system. Grocery manufacturers are among the most enthusiastic promoters and actual users of the HACCP approach to food safety assurance. In fact, a GMA member company developed HACCP in the 1960s, in cooperation with the national aerospace program, to ensure that food prepared for astronauts was safe. HACCP provides a common set of principles and procedures that are theoretically appropriate to every situation. But its actual application at the company, plant or foodservice level must be product and process specific. However, where it is currently mandated, or safety assurance is mandated for domestic products, the same should apply to imported products.

GMA appreciates the opportunity to provide comments to you today.

FOOD SAFETY REQUIREMENTS APPLICABLE TO FOOD PRODUCTS IMPORTED INTO THE UNITED STATES

Foods imported into the United States are subject to a number of statutory and regulatory requirements that are intended to ensure that, when sold to the consumer, they are as safe as products produced domestically. Responsibility for enforcing these requirements falls on the U.S. Department of Agriculture or the Food and Drug Administration, depending upon the particular food product imported.

The primary statutes governing the safety of food imported into the United States are the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA), granting the U.S. Department of Agriculture (USDA) jurisdiction to regulate most meat and poultry products; and the Federal Food, Drug, and Cosmetic Act (FFDCA), granting the Department of Health and Human Services (HHS) authority to regulate all other food products. USDA's Food Safety and Inspection Service (FSIS) and HHS' Food and Drug Administration (FDA) have promulgated regulations implementing the Departments' authority under these statutes. This memorandum provides a general overview of the statutory and regulatory requirements already in place to ensure the safety of food products imported into the United States. 1/

Statutory Requirements Applicable To Imported Meat and Poultry Products

The FMIA 2/ provides that no meat or meat products may be imported into the United States if they are adulterated or misbranded. Meat products of foreign origin are also barred from entry unless they comply with all provisions of the law and regulations to which domestically produced meat and meat products are subject. 3/ The intent of the law in this regard is clearly spelled out in Section 620(f) of the FMIA, which provides that all meat and meat products offered for importation into the United States:

> shall be subject to the inspection, sanitary, quality, species verification, and residue standards applied to products produced in the United States. Any such imported meat articles that do not meet such standards shall not be permitted entry into the United States.4/

1/ This memorandum only provides a general overview of the basic requirements for broad food classes. It is not intended to provide detailed information on importing procedures, nor to provide information on categories or types of food products that are subject to more specific requirements.

2/ 21 U.S.C. §§ 601 et seq. (1967).

3/ *Id.* at § 620(a).

4/ *Id.* at § 620(f).

Any country seeking to export meat products to the United States must obtain a certification from USDA that it maintains a program using reliable analytical methods to ensure compliance with U.S. residue standards. In evaluating applications for certification, USDA is required to inspect individual foreign establishments. 5/ Meat and meat products from foreign countries that have not obtained such certification may not enter the U.S.

Similarly, the PPIA 6/ prohibits the importation of adulterated poultry (and poultry products) and subjects imported poultry to the inspection, sanitary, quality species verification, and residue standards applicable to domestically produced poultry. Moreover, the law requires that imported poultry have been "processed in facilities and under conditions that achieve a level of sanitary protection equivalent to that achieved under United States standards." 7/ Poultry and poultry products that fail to meet these standards may not enter the U.S. To enforce this, the PPIA gives USDA authority to conduct random inspections and sampling at the point of slaughter. 8/

Regulations Applicable to Imported Meat and Poultry Products

FSIS, an agency within USDA, has jurisdiction over the inspection and labeling of all meat and poultry products, which include products from cattle, sheep, swine, goats, equines and from any domesticated bird, including chickens, turkeys, ducks, geese, or guineas. 9/ Meat and poultry products from foreign countries are eligible for entry to the U.S., provided the inspection system in the foreign country has been evaluated and found acceptable by FSIS. 10/ To be found acceptable, the system must have a program administered by the foreign national government and provide standards equivalent to those required in the United States. 11/ This includes, inter alia, government control, adequate staffing, qualified inspectors, adequate administrative and technical support, and inspection, sanitation, quality, species verification, and residue standards applied to products produced in the U.S. 12/

In addition, the legal authority for the inspection system must impose requirements equivalent to those governing the U.S. meat and poultry inspection system with

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5/ *Id.*

6/ 21 U.S.C. §§ 451 et seq.(1957).

7/ *Id.* at § 466(d)(1)(A) and (B).

8/ *Id.* at § 466(d)(4)(A) and (B).

9/ 9 CFR § 301.2 (rr), 9 CFR § 381.1(b)(40).

10/ 9 CFR § 327.2(a)(2), 9 CFR § 381.196(a)(2).

11/ 9 CFR § 327.2(a)(2)(i),9 CFR § 381.196(a)(2)(i).

12/ *Id.*

respect to ante- and post-mortem inspections performed under the supervision of veterinarians, direct and continuous supervision of slaughtering and product preparation, sanitation, and Hazard Analysis and Critical Control Point (HACCP) systems. 13/ The program must be maintained to ensure equivalency to the U.S. system and must include periodic supervisory visits and written reports by a representative of the foreign inspection system and random sampling and testing of carcasses intended for export to the U.S. 14/

FSIS evaluates the eligibility of a country to export to the U.S. by performing a document review of the country's laws, regulations, and any other information FSIS may require. 15/ In addition, officials from FSIS perform an initial on-site review of the system, including plant facilities and equipment, laboratories, training programs, and in-plant inspection operations. 16/ Approval of a country to export to the U.S. may be withdrawn if FSIS determines that the system of inspection in the country does not ensure compliance with requirements equivalent to those imposed on establishments in the U.S. 17/

Once a country is deemed eligible to import into the United States, individual plants in the exporting country must be certified by national officials of the foreign country's meat inspection system to import products to the U.S. That certification must be renewed annually. 18/

Meat and poultry products offered for entry into the U.S. must be accompanied by a foreign meat inspection certificate when imported. 19/ Labeling which conforms to U.S. labeling requirements and indicates the exporting country and the establishment number assigned by the foreign inspection system is required for both the immediate product and the shipping container. 20/ The immediate container must have the following information: product name, foreign establishment number, and country of origin. All labels must be in English and must be approved in accordance with FSIS' general labeling regulations. 21/ The means of transporting

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13/ 9 CFR § 327.2(a)(2)(ii), 9 CFR § 381.196(a)(2)(ii).

14/ 9 CFR § 327.2(a)(2)(iv), 9 CFR § 381.196 (a)(2)(iv).

15/ 9 CFR § 327.2(a)(2)(iii), 9 CFR 381.196(a)(2)(iii). This review focuses on five risk areas: contamination, disease, processing, residues, and compliance and economic fraud.

16/ 9 CFR § 327.2(a)(2)(iii) and(iv), 9 CFR § 381.196 (a)(2)(iii)and (iv).

17/ 9 CFR § 327.2(a)(4), 9 CFR § 381.196(a)(4).

18/ 9 CFR § 327.2(a)(3), 9 CFR § 381.196(a)(3).

19/ 9 CFR § 327.4, 9 CFR § 381.197.

20/ 9 CFR § 327.14, 9 CFR § 381.205.

21/ 9 CFR § 327.15, 9 CFR § 381.206.

the product, including all devices used in moving and handling it, must be maintained in a sanitary condition. 22/

To ensure that FSIS knows that a product is being imported, importers must apply to FSIS for inspection in advance of arrival of the shipment. 23/ The importer must also follow standard procedures for bringing merchandise into the U.S., as established by the U.S. Customs Service. This entails the filing of appropriate entry forms within 5 working days after the shipment arrives at port and acquiring a bond for release of the goods from Customs custody. 24/

All products imported into the U.S. must undergo reinspection. 25/ This reinspection is administered within 72 hours of arrival by an FSIS inspector at a designated official import inspection establishment. The designation of the facility is dependent upon the type of product which is to be inspected and the capacity of the facility. 26/

After documents are checked to ensure proper certification by the exporting country, each lot of product undergoes a routine visual inspection for appearance, condition, certification, and labeling compliance. 27/ The Automated Import Information System (AIIS), a centralized computer information system, assigns specific levels and procedures for manual inspection based on established sampling plans and established product and plant history. 28/ Several types of inspection may be assigned by the AIIS in which a sample is collected by random selection. Some samples are examined by visual inspection, while others are sent to FSIS laboratories for analysis. 29/ If a plant has had previous problems or is suspect, the shipment is held until the laboratory results are known.

Following reinspection, the product is marked accordingly, either with the official inspection legend if it is eligible for entry or, if not, with a mark designating that it was refused entry into the U.S. 30/ Within 45 days, the refused product must be exported, destroyed under

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22/ 9 CFR § 327.8, 9 CFR § 381.201.

23/ 9 CFR § 327.5, 9 CFR § 381.198(a).

24/ For additional information on retention in U.S. Customs custody, delivery under bond and movement prior to inspection, *see* 9 CFR § 327.7, 9 CFR § 381.200.

25/ 9 CFR § 327.6(a)(1), 9 CFR § 381.199(a)(1). Canada has "streamlined" procedures to follow for importation of meat and poultry products. *See* 9 CFR § 327.5, 9 CFR § 381.198(b).

26/ 9 CFR § 327.6(b).

27/ 9 CFR § 327.6(a)(2), 9 CFR § 381.199(a)(2).

28/ 9 CFR § 327.6(a)(3), 9 CFR § 381.199(a)(3).

29/ Canned products have additional inspection requirements, *see* 9 CFR § 327.6(j), 9 CFR § 381.199(d).

30/ 9 CFR § 327.26, 9 CFR § 381.204.

the supervision of an FSIS official, or used for animal food uses, if permitted by the Food and Drug Administration (FDA). 31/ The importer may appeal this decision. 32/ However, if a product was refused entry solely due to misbranding, it may be brought into compliance under authorized supervision. 33/

Once a product has passed inspection and gained entry into the U.S., it is treated as a domestic product and is, therefore, subject to all provisions of the FMIA, PPIA, and their implementing regulations. Accordingly, imported products must meet the same standards of quality, wholesomeness, nutrient content, and labeling to which domestically produced products are subject. 34/

Currently, approximately 40 countries 35/ are approved to export meat products to the United States and five countries 36/ are approved to export poultry products. The list of approved countries may change based on trade restrictions with particular countries or the presence of animal disease conditions, as determined by the USDA Animal and Plant Health Inspection Service (APHIS). Examples of the types of diseases which could make a country ineligible include foot-and-mouth disease in meat and exotic Newcastle disease in poultry. However, some products from countries in which these diseases occur may be eligible for importation if the product is processed in accordance with requirements set by APHIS. 37/

Statutory Requirements Applicable to All Other Imported Food Products

With very limited exceptions, the Food and Drug Administration has no explicit authority under the FFDCA to inspect foreign food establishments. 38/ However, the agency

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31/ 9 CFR § 327.25, 9 CFR § 381.202(a)(2) and (4).

32/ 9 CFR § 327.24, 9 CFR § 381.202(d).

33/ *See* 9 CFR § 327.25, 9 CFR § 381.202 for more detailed information on the handling of shipments which are refused entry.

34/ 9 CFR § 327.18, 9 CFR § 381.208.

35/ 9 CFR § 327.2(b). Traditionally, the largest exporting countries are Australia, Canada, New Zealand, Denmark, Argentina, Brazil, and Costa Rica.

36/ 9 CFR § 381.196(b). The countries are Canada, France, Great Britain, Hong Kong, and Israel.

37/ 9 CFR § 94.

38/ When read together with the definition of "interstate commerce" under Section 201(b)(1) of the FFDCA, FDA's general inspection authority under Section 704(a)(1) could be interpreted as extending to foreign establishments. 21 U.S.C. §§ 374(a), 321(b)(1). Agency practice, and the fact that FDA is seeking additional authority with regard to imported foods, suggests, however, that FDA does not interpret its authority so broadly or is unwilling to assert it.

FDA does have explicit authority to inspect the premises of foreign commercial processors of acidified foods and low-acid canned foods when FDA has determined that such products "may result in the distribution in

does inspect some foreign establishments on a voluntary basis. Moreover, FDA has entered into Memoranda of Understanding (MOUs) with several foreign governments. These MOUs ensure that food products produced in those countries are manufactured under sanitary conditions, meet United States quality requirements, and are tested and sampled before export.

Although the FFDCA provides FDA with no express foreign establishment inspection authority, it does authorize FDA to refuse admission to articles, including foods, that appear to be adulterated or misbranded, or that appear to have been manufactured under unsanitary conditions. 39/ Theoretically, this standard is actually easier for the agency to meet than the standard for seizure and detention of domestic foods. A condemnation order from a federal court may be obtained for products in domestic commerce that are shown to be adulterated or misbranded, not foods that *appear to be* adulterated or misbranded. 40/ The Secretary also has authority to refuse entry to foods that are illegal or subject to restrictions in the country in which they were produced or from which they were exported. 41/

HHS, acting through FDA, may request from U.S. Customs samples of any food product offered for entry. Customs must provide such samples and notify the owner. Pending a decision as to the admission of an article being imported, delivery of the product to the owner may be authorized by U.S. Customs, provided the owner executes a bond. If a product that appears to be adulterated or misbranded can be brought into compliance (by "relabeling" or other action) or "rendered other than a food," the Secretary may authorize the owner to do so if a timely application is filed and a bond posted. 42/ Otherwise, the article must be exported within 90 days or destroyed.

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interstate commerce of processed foods that may be injurious to health." See 21 U.S.C. § 344; 21 C.F.R. § 108.25(j), 108.35(k).

39/ 21 U.S.C. § 381(a)(3).

40/ 21 U.S.C. § 334.

41/ *Id.* at § 381(a).

42/ *Id.* at § 381(b).

Regulations Applicable to All Other Imported Food Products

The Food and Drug Administration (FDA) is responsible for ensuring that all imported foods meet the same safety and labeling standards as domestic food products. Therefore, imported foods, like domestic products, must be pure, wholesome, safe to eat, and produced under sanitary conditions. 43/ Additionally, FDA can refuse entry of shipments into the U.S. of food found to contain pesticide residues in excess of U.S. tolerances or for which no U.S. tolerance is established. 44/

An importer of food products must follow standard procedures for bringing merchandise into the U.S., as prescribed by the U.S. Customs Service. This entails filing appropriate entry documents 45/ within five working days after the shipment arrives at port and acquiring a bond for release of the goods. Customs notifies FDA of such filings. 46/

FDA makes a determination whether to inspect a product by wharf examination, physical examination, or sample examination. This determination is based on information pertaining to the nature of the product, FDA priorities, and past history of the commodity. If it is determined that a sample inspection is not warranted, the article is released into U.S. commerce. If FDA decides to inspect the product, the shipment is held intact so that a sample can be taken and forwarded to an FDA laboratory for analysis. 47/ The shipment is held until the results of the analysis are available.

To streamline its import monitoring activities, FDA routinely issues import alerts to its district offices. These alerts identify products and importers that have repeatedly been found to violate federal law and regulations. FDA inspectors are instructed to pay close attention to these products and, in certain cases, to refuse entry of all such products without sampling or analysis. The effect of such an automatic detention alert is to place the burden on the importers to show that the product meets FDA requirements or otherwise overcomes the appearance of a violation before it is released in the United States. 48/

If the results of the laboratory analysis indicate that the product is in compliance with U.S. requirements, the product is released into commerce. If the product is found to be in violation of U.S. requirements, the product is refused entry into the U.S. In the case of a refusal,

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43/ *See* 21 CFR Parts 100-199.

44/ FDA monitors pesticide residues through their "sampling" procedures to assure compliance.

45/ In addition to entry forms, FDA may require specific information on certain products, such as low-acid canned food and milk and cream products.

46/ *See* 21 CFR § 1.97 for more information on bond requirements.

47/ *See* 21 CFR § 1.90.

48/ *See* FDA Regulatory Procedures Manual for details on automatic detention.

FDA must give the importer an opportunity to provide evidence relating to the admissibility of the product or in support of an application to relabel or otherwise recondition the product to bring it into compliance with U.S. requirements. 49/ If the importer is granted permission to bring the product into compliance, FDA specifies the procedure to be followed, the timeframe in which it must be completed, and any other conditions deemed necessary. This "reconditioning" must be done under the supervision of an FDA or Customs official. Following such reconditioning, another sample is taken to determine compliance. 50/ If the second sample is in compliance, FDA releases the product into U.S. commerce. If not, the importer is given a notice of refusal. Any product refused entry to the U.S. must either be re-exported or destroyed under approved supervision. 51/

49/ 21 CFR § 1.94 and 1.95.

50/ 21 CFR § 1.96. *See* 21 CFR § 1.99 for chargeable costs for relabeling and reconditioning product.

51/ FDA has placed emphasis on: establishing cooperative programs with state regulatory agencies for surveillance of imported products; conducting "blitzes," short-term intensified surveillance of a specific product; initiating civil and criminal judicial action against both importers and foreign exporters who repeatedly violate FDA regulations; and, educating importers on their responsibilities in adhering to FDA regulations.

National Broiler Council

Senate Permanent Subcommittee on Investigations

EXHIBIT # 9

May 11, 1998

Ms. Susan M. Collins
Chairman
Permanent Subcommittee on Investigations
Committee on Government Affairs
United States Senate
Washington, DC 20510-6250

Dear Chairman Collins:

Thank you for the opportunity to provide our input regarding the very critical issue of the Federal systems and procedures used to ensure the safety of imported foods. We appreciate being asked to submit the following comments for your Committee's consideration as you work toward the difficult balance of adequately protecting consumers while enabling international commerce to function fairly and efficiently.

You ask that comments address three specific areas of issues. Since our statement is a blend of these issues, the following comments should be considered as covering the three topics outlined in your April 28 letter.

In a recent consumer trends survey conducted by the Food Marketing Institute, consumers reported they have great confidence in poultry with respect to food safety. We are pleased by these findings because U.S. poultry producer/processors have worked long, diligently, and with a very focused vision to build consumer loyalty and confidence in poultry. Brand names for poultry products are very important and a brand's good reputation takes years to attain.

U.S. poultry processors are implementing USDA's Hazard Analysis and Critical Control Point/ Pathogen Reduction Program. Although the transition period has been a challenge, poultry companies continue to embrace the new approach to ensuring the wholesomeness of poultry. Using good science and good management can improve any already high level of quality and food safety. Because the U.S. broiler industry is vertically-integrated in structure, any question of a live bird's condition can be readily identified and traced. Such a structure and coordinated method of production/processing/marketing has helped establish a very enviable record of food safety for chicken.

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Countries wishing to export their poultry to the United States must meet the very high standards applicable to domestically produced poultry if they are to be permitted into our market. Both the health of live birds and the adequacy of the country's veterinary inspection system must be demonstrated to the satisfaction of the U.S. Department of Agriculture before a country is certified as being equivalent to U.S. system. In addition, plants desiring to export to the United States must comply with the U.S. regulations. These requirements are as they should be. Anything less than true equivalency could jeopardize the confidence U.S. consumers have in poultry and threaten the safety of imported products sold to American consumers. Such confidence is relatively delicate and, as recent situations have demonstrated, can be shaken with even perceived, rather than real, problems.

U.S. poultry producers are efficient and operate in a very competitive environment. At the same time, it is realized that certain countries view the U.S. poultry market as potentially very rewarding. As world trade of poultry continues to increase and as the United States increasingly becomes a poultry market being sought by other countries, it is vitally important that the high standards required of U.S. poultry producers/processors not be compromised.

U.S. government regulators have been faithful in requiring sufficient and necessary documentation and evidence when another country seeks certification to export poultry to the United States. Such diligence must be continued and not adjusted to meet certain political expediencies or agendas.

We look forward to continuing to work with your committee to achieve a successful outcome for the issue of ensuring the safety of imported poultry and other foods. Please advise us if we can provide more information regarding our views and comments.

Sincerely,

W. P. Roenigk

William P. Roenigk
Senior Vice President

WPR:dw
Enclosure

Senate Permanent Subcommittee on Investigations

EXHIBIT # 10

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May 11, 1998

The Honorable Susan M. Collins
Chairman
Permanent Subcommittee on Investigations
United States Senate
Committee on Governmental Affairs
Washington, DC 20510-6250

Dear Senator Collins:

The National Consumers League (NCL), the nations's oldest nonprofit consumer advocacy organization, would like to thank you for giving us this opportunity to comment on the systems and procedures used to ensure the safety of imported foods into the United States.

We appreciate that there are considerable time constraints involved in your investigative process, thus, will keep our remarks brief and to the point. If you need further information during or after the hearings, NCL will be more than willing to provide it. The three issues to be addressed are as follows:

- Adequacy of domestic and international food standards, codes of practice, and other guidelines with regard to imported foods;
- Importance of a science and risk-based import inspection system;
- Merits, if any, of various initiatives, such as requiring the use of (I) trace-back mechanisms to the farm of origin, (ii) country-of-origin labeling, and (iii) Hazard Analysis and Critical Control Point system.

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Domestic and international food standards: America has the safest food supply in the world; however, there is still more that needs to be done to ensure that food borne illness is reduced. Overall, the standards are adequate, however, there are specific areas that need to be strengthened:

- The level of inspection for FDA inspected plants is inadequate. With more than 50,000 plants that fall under FDA jurisdiction and approximately 700 inspectors, some plants are inspected at an average of once every ten years.

- The acceptable levels (performance standards) of Salmonella and Campylobacter for poultry, pork, beef, and eggs is too high. Poultry remains the major concern with Salmonella and Campylobacter, and USDA allowable levels of around 40% of product contaminated is too high.

- The disconnect between FDA inspected products and USDA inspected products is also a problem that should be addressed. A single food safety agency would better serve the needs of consumers to ensure that our food supply is safe and that all federal food safety oversight is coordinated.

- Imported food inspection--With the increasing reliance on imported foods, particularly produce, added emphasis on inspection of imported foods at the border, as well as at the source country needs to be strengthened. There is a problem with "easy access" ports and

points of entry that are well-known for either being understaffed or more lenient in food inspection.

- Equivalence--American consumers expect, and the government should insist, that imported foods be produced under sanitary conditions and other good agricultural practices equivalent to our own. Understanding that we cannot mandate that sovereign countries adhere to our exact requirements for domestic production, processing, and distribution, we can, however, require that they operate systems that are at least equivalent--ensuring that they meet similar organoleptic and microbial/pathogen performance standards.

- Codes of Practice--NCL believes that certain rules of practice need to be clarified, particularly as they apply to FSIS and govern the refusal, suspension, or withdrawal of inspections services. Establishments should be provided better notice and certainty regarding FSIS enforcement activities; however, we do not believe that the improved procedural rights of establishments should take precedence over the consumers' rights to safe meat and poultry. (Plants should not be allowed to operate while an appeal of FSIS decision to withdraw is pending. The burden of showing product poses an "imminent hazard to health" should be on the plant, not government).

- FDA and USDA need mandatory recall authority and ability to impose civil penalties on processors.

Importance of a science and risk-based import inspection system: Microbial contamination is an ever-increasing problem in our food supply, especially as we continue to increase the supply of imported food. Since contamination by pathogens cannot be detected by sight, smell, or touch, it is imperative that a science and risk-based approach to food safety and inspection be administered.

- The recent outbreaks of Cyclospora, Crypto sporidium, E. Coli 0157:H7, and other pathogens from imported produce (i.e., Guatemalan raspberries, Mexican strawberries) highlights the need for an increased emphasis on science-based approaches, including microbial testing, for imported food.

- Inspectors cannot detect microbial contamination in food, thus, testing is essential. Further, additional emphasis should be placed on specific products, or products from specific countries that are at a higher risk of contamination due to the nature of the agricultural practices of that country or the nature of the product itself.

Merits of various initiatives such as trace-back, country-of-origin labeling, and HACCP: NCL believes that all three of these initiatives are essential to any food safety and inspection system for both domestic and imported foods.

- Trace-back mechanisms--NCL supports trace-back mechanisms to the farm of origin. We feel that trace-back is vital to pinpointing the source of contamination, particularly for ground beef. Processing plants generally combine product from several suppliers, which makes it extremely difficult to determine which product, if any, is contaminated. Trace-

back mechanisms will allow the contaminated product to be more easily identified. For produce, trace-back is equally important, as many pathogens have now "jumped" to produce (i.e., E. coli 0157:H7 on lettuce and alfalfa sprouts), and different batches of lettuce or sprouts may be combined at different points along the chain from farm to table.

- Country-of-origin labeling--Country-of-origin labeling does not directly prevent food-borne pathogens or contamination, yet it does give consumers more information about the products they are buying, and this may help to prevent food borne illness. It will allow consumers to avoid buying products from countries where sub-standard sanitation and inspection practices exist, or pesticide laws are not as stringent as ours. Examples of how country-of-origin labeling better informs consumers and possibly prevents food borne illness are the bans on British beef (risk of BSE), and the outbreaks of Cyclospora and Salmonella on Guatemalan raspberries and Mexican cantaloupes.

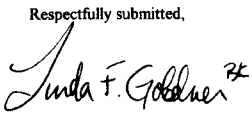
- HACCP--NCL strongly supports the HACCP system and feels that it is a modern solution to modern problems that exist in the food supply. However, we do have concerns that putting the onus on the companies to police themselves may have drawbacks if government agencies are not extremely vigilant. Federal inspectors need to remain in the plants at all times (USDA), conducting carcass-by-carcass inspection. Further, reliance on inspection of record-keeping alone (government inspection of records kept by plant employees) will not suffice. Finally, for HACCP to work, whistle-blower protections for plant employees must be put into place. If employees fear reprisal for calling attention to systems failures, and other problems, then they will not call attention to these problems

which may go undetected, resulting in possible release of contaminated product to consumers.

- FDA needs to adopt HACCP systems that are more equivalent and compatible to those currently employed by USDA.

The National Consumers League thanks this Committee for its hard work and commitment to keeping America's food supply the safest in the world. If you have any further questions or need additional information, please contact Brett Kay at (202) 835-3323.

Respectfully submitted,



LINDA F. GOLODNER
President

Senate Permanent Subcommittee
on Investigations

EXHIBIT # 11

National
Fisheries
Institute

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May 15, 1998

The Honorable Susan M. Collins
United States Senate
Washington, DC 20510-1904

Re: Safety of Imported Foods into the U.S.

Dear Senator Collins:

Thank you for the opportunity to provide you with our views and comments on the adequacy of the systems and procedures used by Federal agencies to ensure the safety of foods imported into the United States.

The National Fisheries Institute represents over 1,000 companies engaged in all aspects of the U.S. fish and seafood industry. Our comments are directed to the federal programs which directly concern fish or seafood.

In our view, the International Food Standards and Codes of Practice, as negotiated at Codex, are an excellent basis on which to establish minimum acceptable standards. U.S. acceptance of these standards has been frustrated, however, by the practice of the FDA in adding more to these standards than is intended.

Today's food marketplace is global and the World Trade Organization will be using Codex standards and codes to judge acceptance in country-to-country disputes. U.S. continued participation in Codex standard setting and adoption of international standards, therefore, is important.

The world is rapidly accepting the use of Hazard Analysis Critical Control Point systems to ensure food safety. HACCP systems are science-based and are universally used in the U.S. fish and seafood industry. The FDA is to be commended for its success in introducing HACCP into our industry. At this point, risk analysis and management should be further developed by FDA to conserve personnel and resources in the inspection of imported products. New legislation is not needed. Instead, what must be fostered is a new attitude - one directed at avoiding problems before they occur rather than reacting once problems arise. Also needed are international agreements to ensure that food exported to the United States is processed consistent with U.S. requirements. Product sampling and testing at the port of entry should not continue to be our first line of defense against unsafe imported food.

While extending trace-back mechanisms to the farm level is an interesting idea, it is impractical from an operating sense. Country of origin marking is already required. Where marks are placed should be of little consequence from a food safety perspective.

Using the HACCP based approach for imported foods will aid the safety concern of the regulatory agencies, lessen the number of samples to be analyzed, lessen delays at ports of entry and achieve consumer confidence in these products. It is our strong suggestion that more government effort should be put into preventative measures such as HACCP and in obtaining Memorandums of Understanding (MOU) with our trading partners.

The financial risk associated with importing food commodities is great and falls on the U.S. businessmen. Detentions of these products and our inability to re-export them impose a substantial cost upon seafood firms. These added costs translate into higher food costs for Americans. Destroying product rather than shipping it back to the overseas supplier should be a regulatory option.

Sincerely,

Richard Gutting, Jr.
Executive Vice President

Senate Permanent Subcommittee
on Investigations

EXHIBIT # 12

NATIONAL
FOOD
PROCESSORS
ASSOCIATION

Statement of
The National Food Processors Association
on the
Safety of Foods Imported into the United States
Presented to the
Permanent Subcommittee on Investigations
Committee on Governmental Affairs
United States Senate

May 14, 1998

The National Food Processors Association (NFPA) is pleased to provide testimony to the Senate Permanent Subcommittee on Investigations on the adequacy of systems and procedures used by federal agencies to ensure the safety of foods imported into the United States.

NFPA is the voice of the $430 billion food processing industry on scientific and public policy issues involving food safety, nutrition, technical and regulatory matters and consumer affairs. NFPA's three scientific centers, its scientists and professional staff represent food industry interests on government and regulatory affairs and provide research, technical services, education, communications and crisis management support for the association's US and international members. NFPA's members produce processed and packaged fruits and vegetables, meat and poultry, seafoods, drinks, and juices or provide supplies and services to food manufacturers.

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202 639 5900

<u>The adequacy of domestic and international food standards, codes of practice, and other guidelines with regard to imported foods:</u>

Americans enjoy one of the safest food supplies in the world. NFPA strongly supports current requirements for an equivalent level of safety for both imported and domestic foods. In the US there are a variety of regulations and guidelines that foods and food manufacturers must meet. These requirements, coupled with a food industry that takes seriously its obligation to provide foods that are safe to consume, help ensure that the US maintains a food supply in which we can continue to have confidence.

Foremost among our food safety "standards" are the recently implemented requirements for development of Hazard Analysis and Critical Control Point (HACCP) systems. The HACCP system, developed by industry as a risk-based food safety management system, is rapidly gaining worldwide recognition as the preferred method for assuring food safety. Within the past year, the US has begun implementing requirements that mandate the use of HACCP by manufacturers of meat and poultry products and by manufacturers and importers of seafood products to assure the safety of these products. Seafood product importers are required to provide evidence of compliance by foreign processors, upon demand.

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Other requirements for all foods sold in the US include the umbrella Good Manufacturing Practices (GMPs), and additional regulations that assure the safe production of canned foods. In addition, substances used in and on foods must be approved under provisions of a wide range of laws including the Federal Food Drug and Cosmetic Act, Federal Insecticide, Fungicide and Rodenticide Act, and The Food Quality Protection Act. All these US standards apply to imported foods as well as domestic foods. These standards provide the framework that has resulted in the current level of food safety that America's consumers enjoy.

Admittedly, food safety standards that exist internationally show much diversity. Many countries, however, feel that their laws are at least as stringent as those in the US and that their foods are as safe if not safer than those produced within the US. Since 1962, countries (including the US) with a common interest in food safety have been developing model standards, guidelines and codes of practice related to the safe and hygienic production of foods within the Codex Alimentarius Commission. Over the years, the Codex process has developed many guidance documents on food safety and wholesomeness. All of these consensus documents have had strong input by the US government and are felt to provide an equivalent level of protection for consumers. The US is an active participant in a number of Codex Committees that produce these guidelines. Codex documents that reflect good food safety practices are very useful for developing countries that may lack the government infrastructures to develop their own documents. The Codex process has resulted in a general increase in food safety standards worldwide.

Considering the high level of consumer protection inherent in current US policy and in the standards and guidelines developed through the Codex process, NFPA feels that efforts should be focused on ensuring a level of consumer protection equivalent to that provided by US domestic food safety standards. Food safety standards need not be identical—they do need to be equivalent, however. Gaining assurance that consumers are appropriately protected is best accomplished through an approach that focuses on the presence and use of food safety systems rather than a dependence on inspection/testing of finished goods. To accomplish this, US authorities must focus on assessments of the ability of different national systems to assure an appropriate level of protection for consumers. NFPA feels that the basis for making such determinations exists in current US statutory authority and within internationally available guidelines. The result of such determinations should be Equivalence Agreements, Memoranda of Understanding (MOUs), and/or Mutual Recognition Agreements (MRAs) between governments as appropriate.

Importance of a science and risk-based import inspection system:

NFPA believes that a scientific evaluation of risk is necessary for authorities to determine priorities for inspections, whether for imported or domestic products. A risk-based inspection system will allow authorities to focus limited resources in those areas where greatest benefit to public health can be derived. The main focus of a risk-based food safety assurance system for imported products must be on equivalence of consumer protection afforded by the sanitary measures in place in each country.

It would be wrong to rely solely on increased sampling and testing of foods for contaminants of various types to increase food safety assurance. Sampling and testing of products has been shown statistically to have very limited utility in assuring the safety of foods. Thus, NFPA favors a risk-based, safety management system focused on prevention of potential hazards, rather than increasing emphasis on sampling and testing alone. The latter constitutes the "needle in the haystack" approach to eliminating food safety hazards, and as noted above it does not work. Rather, focus should be directed to establishing equivalence which, through MOUs or other appropriate vehicles, will provide recognition between governments that products meet appropriate levels of protection. Such a system will ultimately provide greater confidence in the safety of imported foods.

Merit, if any, of various initiatives, such as requiring the use of:

- Trace-back mechanisms to the farm of origin:
  NFPA has, in the past supported efforts to formalize trace-back systems when there is a documented public health need to do so and the probability of developing a successful scheme seems feasible. NFPA encourages voluntary efforts wherever possible to enhance the ability to trace raw materials back to a farm of origin. We strongly support efforts to educate growers and ranchers in the practices they can utilize to best minimize downstream food safety problems from their raw materials. However, it must be recognized that the cost and the practicality of such programs will vary widely between food industry segments, between species of animals and from one fruit or vegetable variety to the next. Before there should be any effort to mandate trace-back requirements, there should be studies to clearly demonstrate that the food safety benefits of such requirements would warrant the costs for their development and implementation. Perceived food safety benefits should be very clearly defined.

- Country-of-Origin labeling:
  There has been much speculation recently that imported products pose a greater risk to consumers than those products produced domestically. NFPA can find no substantiation in the public health literature for this perception. While there have been outbreaks of foodborne disease from imported foods, particularly produce items, there have also been outbreaks associated with domestic products. Thus NFPA views country-of-origin labeling as an ineffective means of addressing food safety problems. In fact, such a measure could be viewed as protectionist policy that is inconsistent with US trade commitments and with international standards. NFPA recommends a science-based approach to food safety policy that focuses on solving problems rather than seeking politically attractive solutions.

- HACCP:
  As noted above, the HACCP system was developed by industry as a risk-based food safety management system. HACCP is rapidly gaining worldwide recognition as the preferred method for assuring food safety. NFPA endorses the use of HACCP where it can be effective in assuring the safety of certain food products. HACCP is best used where: (1) there is evidence that rigorous oversight is needed to control a food safety hazard; and (2) technology and processes exist to control the food safety hazard with confidence. The application of HACCP where these considerations do not apply will likely result in undue hardship to the processor and importer, without measurable improvement in safety.

Application of HACCP requirements to imported products should depend on the need to employ this system to meet US standards of consumer protection.

Processed seafood is an example of the appropriate use of HACCP. However, the safety of raw produce, where definitive intervention procedures do not currently exist, is probably best managed at this time through the application of Good Agricultural Practices.

Recent efforts in the US have focused on the safety of vegetables and fruits. Guidance on Good Agricultural Practices is being developed within the produce industry and by FDA. In order for such guidance to be effective both domestically and for imports, it will be necessary to implement educational programs. The regulatory agencies should be given additional resources to work with industry, the States and, where appropriate, foreign governments to develop and implement educational programs at both the domestic and foreign level.

Comments on "Safety of Imported Food Act"

On March 3rd, 1998 Senator Barbara Mikulski introduced S. 1707, the Safety of Imported Food Act, to give FDA the authority to halt the importation of foods from countries which deny FDA access to inspect their food safety systems. While NFPA recognizes the desire of the bill's proponents to provide FDA with additional statutory authority to address possible food safety problems associated with imported foods, significant questions exist regarding specific outcomes which are likely to result from the proposed legislation. NFPA believes FDA's existing authority should be fully utilized before concluding that the Agency's statutory authority should be expanded.

FDA already possesses the authority to halt the import of foods that appear misbranded or adulterated, and to promulgate additional regulations if necessary. NFPA believes FDA should initiate promptly such a rulemaking if the Agency makes a scientifically-based determination that additional regulations are necessary to prevent food safety problems associated with imported foods. To date, the proponents of the Safety of Imported Food Act, including FDA, have not adequately explained what specific new regulatory activities would be authorized or expected to result from the legislation.

In the meantime, NFPA supports continuing negotiations with our country's trading partners through the Codex Alimentarius to develop worldwide guidelines to achieve food safety systems in other nations that offer equivalent protection to that of the U.S. This cooperative process is one of the best means of improving worldwide food safety systems without creating artificial trade barriers. In the meantime, NFPA stands ready to work with FDA in joint government and industry efforts to provide education and technical assistance to foreign producers to improve their food safety production systems.

NFPA appreciates the opportunity to submit testimony on this important issue. We are very interested in the deliberations and the conclusions of the Subcommittee and we offer our assistance to you anytime during this process.

Senate Permanent Subcommittee
on Investigations

EXHIBIT # 13

Representing, Educating and Promoting the Restaurant/Hospitality Industry

1200 SEVENTEENTH STREET NW, WASHINGTON DC 20036-3097 202/331-5900 FAX: 202/331-2429

NATIONAL RESTAURANT ASSOCIATION.

STATEMENT
of the
NATIONAL RESTAURANT ASSOCIATION
on
U.S. PROCEDURES TO ENSURE THE SAFETY OF IMPORTED FOODS
for the
PERMANENT SUBCOMMITTEE ON INVESTIGATIONS
of the
COMMITTEE ON GOVERNMENTAL AFFAIRS
UNITED STATES SENATE
May 14, 1998

The National Restaurant Association appreciates the opportunity to submit its views in this written statement for the record on the adequacy of the systems and procedures used by federal agencies to ensure the safety of imported foods. As the leaders of the hospitality industry, restaurants have had a long-standing commitment to food safety and the protection of our customers.

The National Restaurant Association is the leading business authority for the nation's $336 billion restaurant industry comprised of over 799,000 restaurant locations. Our members operate full-service restaurants, quick-service units and cafeterias, and provide food service for such institutions as hospitals, universities and military clubs.

The U.S. restaurant industry has made a multi-million dollar investment in developing and improving food safety education over the past 25 years and continues that substantial investment, commitment and hard work today. In cooperation with federal and state health officials, the National Restaurant Association has developed state-of-the-art regulations and educational and informational materials based upon current science, risk and Hazard Analysis Critical Control Point (HACCP). We have actively disseminated information to the restaurant industry and our customers and have worked with state and local officials to adopt new food safety regulations such as the FDA Food Code.

The Association has certified over one million managers in our ServSafe® training program, and we are currently training and certifying approximately 150,000 managers a year. ServSafe® has been translated into two foreign languages and is currently being licensed in additional countries and languages. It was developed through input and cooperation with regulatory officials, academia and industry professionals. ServSafe® is just one of multiple training programs available within the restaurant industry.

Food-borne illness has become a major public policy issue over the past six years, and while we understand the attention, not all of the public perceptions or proposed solutions are science-based or sound. Any long-term improvement in food safety must be science- and risk-based. The best way to currently incorporate this approach into food safety systems is through the industry-developed HACCP approach. HACCP is not a one-size-fits-all measure and will require industry cooperation and participation to work effectively. Voluntary HACCP with government assistance and incentives has proven to be the most effective way to incorporate HACCP and improve food safety.

Because imported foods have become such a large segment of the foods we buy, we are strongly interested in the safety and the continued easy availability of imported foods. No single comment can accurately describe the sanitary conditions found in all international food-producing countries. The conditions in individual countries will vary greatly as will the conditions on individual farms within countries. Many of the major restaurant chains and suppliers to the restaurant industry today have developed complex supplier audit systems where they inspect, set specifications and take microbiological samples of imported products. These systems are based upon HACCP and are implemented to improve safety and quality. The audits include international farm, processor and transportation inspections; microbiological sampling; and strict quality control from farm to restaurant.

We believe that the current federal system of imported food inspection is in need of logical focus and has not been adequately funded to conduct the number of science-based inspections and microbiological samples necessary to reliably assure international food safety. There are good and bad operators in all countries, and we should be able to rely on the federal government's inspection programs at FDA to identify the bad operators and remove unsafe products from the system. This level of assurance will require application of science-based concepts and increased funding over the current levels. We are not convinced, however, that these improvements warrant creation of a single food safety agency or that a single agency would be more effective than proactive coordination and harmonization of regulatory agencies' food safety standards.

We strongly encourage the development of a science- and risk-based import inspection system for imported foods. We should not continue to waste valuable resources on visual, often inadequate inspections. The maximum benefit and greatest assurance of safety will be gained by focusing on those individual products and countries that have historically posed the greatest illness risk. Increased federal microbiological sampling must also be conducted using scientific statistical assurance techniques and not the currently used minimum or "shotgun" approaches.

Current initiatives such as trace-back to the farm of origin and country-of-origin labeling have not demonstrated that the economic impact will justify the minimal gain in food safety. These proposals concentrate efforts on identifying imported products and assessing responsibility after an illness happens. Identification of imported products may inadvertently sensationalize

unfounded fears of the unknown with regard to a foreign country's sanitary conditions. From a practical standpoint in our industry, country-of-origin labeling in restaurants would be unworkable and cost-prohibitive because of the changing daily supply of menu items.

Trace-back is a system to assess blame after the illness outbreak. We strongly recommend that the committee take a more proactive view, as discussed previously, and explore more science-based solutions to prevent contaminated food from reaching the U.S. market.

The National Restaurant Association takes a great interest in the systems and procedures used by federal agencies to ensure the safety of imported foods because, like consumers, restaurateurs rely on what is available in the marketplace. We believe that it is in our best interest to work with government, suppliers and others in the food industry to fully and honestly address this issue and assure food safety. We thank you for the opportunity to comment on these important proposals and would be happy to provide any additional information regarding our remarks or specific concerns of the committee.

Senate Permanent Subcommittee
on Investigations
14

Western Growers Association
Serving the California and Arizona Fresh Produce Industry

Statement for the Senate Subcommittee on Investigations

Thank you for the opportunity to present these comments to you. Western Growers Association (WGA) is an agricultural trade association which represents the fresh fruit, vegetable, and nut industry in California and Arizona. WGA's 3400 members grow, pack, ship, and process over 90% of the fresh vegetables and over 60% of the fresh fruits and nuts grown, packed, shipped, and processed in Arizona and California. Approximately 54% of the fresh fruits, vegetables, and nuts consumed in the United States are produced by WGA members.

Food safety is a critically important matter for Western Growers Association and its membership. Our membership prides itself on its ability to provide to United States and international consumers the safest, the most nutritious, and least expensive fresh fruits, vegetables and nuts.

WGA has been on the leading edge of food safety activities, and we are proud of the fact that WGA developed and published, in partnership with the International Fresh-cut Produce Association (IFPA), the widely acclaimed, disseminated, and used Voluntary Food Safety Guidelines for Fresh Produce. WGA has been an active participant in all federal and state food safety issues and discussions.

There are several points which we believe must be stressed at the outset:

1. Production agriculture is not responsible for the bulk of food safety outbreaks. According to the most recent Center for Disease Control statistics, fresh produce contributes less than 7% to all food-borne illnesses. The overwhelming majority of

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food-borne illnesses, over 70%, are caused by post-harvest, post-purchase food handling practices, most commonly by uninformed consumers.

2. Virtually every health expert, including the National Cancer Institute and federal and state government experts and agencies, strongly advocate the increased consumption of fresh fruits and vegetables as the single most important step American consumers should take to prevent cancer as well as weight problems and related illnesses such as diabetes. The benefits of eating at least five servings a day of fresh fruits and vegetables far outweigh any risks associated with food-borne microbial pathogens.

In spite of the fact that fresh produce is not a major contributor to food borne outbreaks, the United States produce industry — particularly in California and Arizona — began almost a year and a half ago to develop the food safety voluntary guidelines for farm practices that have been connected to food-borne illnesses. We believe strongly that while we produce the safest fresh produce anywhere in the world, we owe it to ourselves and to our consumer customers to do everything possible to minimize wherever possible, any potential for microbial contamination of our fresh produce.

Interestingly, a large percentage of fresh fruits and vegetables produced in Mexico is produced in joint ventures or in partnerships with United States producers predominately from California and Arizona, and predominantly WGA members. Because of our members interests in Mexico, and in the spirit of positive cross-border relationships, WGA and IFPA have disseminated a Spanish language version of the Voluntary Food Safety Guidelines for Fresh Produce to Mexican state government officials and fresh produce associations and growers. In addition, WGA has met with and will continue to meet with produce association executives from the major fresh produce growing states in Mexico to discuss, develop, and implement cross-border food

safety strategies.

It is our strongest belief that by taking a bottoms-up cross-border approach, grower to grower, trade association to trade association, rather than a federally mandated top down program, United States and Mexican producers have and will employ the most rigorous food safety standards found anywhere in the world. We strongly believe that the existing guidance documents, as well as the industry developed guidelines are more than sufficient to implement stringent food safety practices in Mexico as well as in the United States. There is no need for additional laws relating to food safety.

Although the fresh produce industry is always trying to do a better food safety job, it is necessary to recognize that no standard, code, or guideline will ever ensure that the United States supply of fresh fruits and vegetables is completely free from microbial contamination. Such a goal, while laudable, is not realistic. We can, and are, doing everything possible to minimize the potential for such contamination. We do not live in a risk free society. If we did, airplanes would never crash, automobiles accidents would not occur, and medical operations would always be 100% successful. That is not the case.

Even federal laws, regulations and other mandates cannot change this fundamental fact. However, the airline industry, the automobile industry, the medical profession, as well as the fresh produce industry, are attempting to achieve, through hard work and with a lot of resources, a risk-free environment.

In response to the question of the importance of a scientifically sound import inspection system, WGA believes that it is absolutely imperative that any system designed for the inspection and possible prohibition of imports be based on the best available science. An inspection system which is based on anything less will be

severely criticized by our international trading partners, and may even be in violation of United States international trade obligations.

It is our belief that establishing an unscientifically sound inspection system may create additional trade tension and unnecessary retaliation by our trading partners. The whole area of sanitary and phytosanitary measures as artificial trade barriers to imports was the subject of intense debate in the Uruguay Round. The international community is still discussing these issues.

WGA has had as one of its highest priorities, and for many years has advocated breaking down sanitary and phytosanitary barriers in our potential export markets where those barriers were not based on sound science. For example, Japan had for years kept California tomatoes from coming into Japan because of a "phytosanitary" concern. When the United States was finally able, after seven years of tests, to show that the Japanese concern was not grounded in sound science, United States produced fresh tomatoes were able to gain access to Japan's multi-million-dollar tomato market.

If we are to continue to open new markets for United States products, we must not be guilty of establishing import measures which we would oppose in other countries.

Another international issue in which WGA believes strongly has to do with labeling and marking of United States produced products. We have and will continue to advocate for international harmonization of country of origin labeling and product marketing. To do otherwise may again create unnecessary artificial trade barriers with our international trading partners.

On another issue, WGA strongly favors development of a trace-back mechanism from field to the table. WGA has been working with representatives of the retail sector as well as its own members to develop a "model" trace-back system. There has been progress. However, because of a wide variety of issues, trace back may not be

achievable for some commodities, especially where product from many growers is commingled or pooled. Nevertheless, WGA is aggressively working to develop as comprehensive a trace back system as is possible given current agricultural practices and technology.

WGA also strongly believes that to a HACCP or HACCP-type system in the field or packing house environment is not feasible or practical. HACCP, by its definition, requires a microbial pathogen kill step. In production agriculture, there is no current science or other technical methodology to kill a microbial contaminant.

Production agriculture is by definition conducted in an environment that is exposed to a great many natural phenomena such a wind, rain, soil and its necessary living organisms, as well as wildlife in many forms. The HACCP concept works well in a controlled environment, but it does not translate in any significant way to a natural exposed environment such as production agriculture.

However, this point takes us back to the beginning of this statement. While we cannot at the field level "kill" microbial contaminants, we can do everything possible to minimize microbial contamination. We believe that there are practices which every responsible grower should follow and it is these practices that are precisely the focus of the WGA-IFPA voluntary guidelines effort.

Lastly, WGA very strongly believes that a set of guidelines developed, written, implemented, and advocated by trade associations has the greatest chance of being accepted and implemented at the grower level. In contrast, any set of guidelines that are imposed top-down from the federal government to local growers will encounter a very long and tortuous road to acceptance.

Thank you for the opportunity to comment to the Subcommittee. We welcome the chance to provide our views and comments based on our extremely proactive and positive food safety efforts and experiences.

Senate Permanent Subcommittee
on Investigations

EXHIBIT # 15

Wild Blueberry Commission OF MAINE
5715 Coburn Hall, Orono, Maine 04469-5715
TEL: 207-581-1475
FAX: 207-581-3499

May 13, 1998

The Honorable Susan Collins, Chairman
Permanent Subcommittee on Investigations
Committee on Governmental Affairs
United States Senate
Washington, DC 20310-6250

Via Fax, 2 pages
207-224-7042

RE: Safety of Imported Foods

Dear Senator Collins:

The following are written comments to be added to the record of your subcommittee's investigation into the adequacy of systems to ensure the safety of imported foods.

Imported food should be held to the same standards of safety as domestically produced food as the consumer will assume that all food sold in this country will be of the same quality. It is also important that U.S. producers have a level playing field so standards must be harmonized. Consistent (the same) standards for domestic and imported food is good for both agriculture and trade.

Any standard should be workable and enforceable to insure a minimum level of health protection. Standards should be based on industry standards such as good agricultural practices and good manufacturing practices and should only become regulations when it is necessary (the only way) to protect public health. When change in practices is necessary, industry standards can change faster than regulatory rule making or legislation.

Imported food should meet standards at ports of entry. It is not unreasonable to put the burden of proof on the importing entity such that the cost of analysis or inspection is certified by an independent entity with compliance oversight by one agency. In other words, standards should be met but trade should not be restricted. Ensuring standards are met before the food enters the U.S. distribution system will ensure safe food for our country's citizens. It is difficult for buyers to trace back suppliers beyond our shores so safety should be maintained when the food is imported. This will also protect an importer if the food is mishandled in this country.

The practicality of trace back mechanisms focused on the overseas producer and/or primary processor is questionable because food safety/food quality problems can arise from handling by intermediaries. How do you know where the problem developed? Was it unsanitary practices in the field or during shipping?

Any food safety regulations and enforcement should be handled by one or two existing agencies. It might make sense for one agency to be responsible for on farm and fresh packing/processing and one other entity that had responsibility for all processed food all the way from the fresh receiving dock at the processing plant right through to the consumer be it at a store, restaurant, vending machine or some other food service entity. By having one entity involved they would have both the big picture and the technical expertise to prevent problems consistently across the whole market. With more and more meals eaten out on a regular basis by Americans, food safety does not apply just to the grocery store and home kitchen.

Thank you for the opportunity to provide input.

Sincerely,

David Bell

David K. Bell
Executive Director

cc: Sanford Kelley, Chairman, Wild Blueberry Commission of Maine

Food Industry Trade Coalition

U.S. Food Industry Feeding the World

Senate Permanent Subcommittee on Investigations

EXHIBIT # 16

May 14, 1998

The Honorable Susan M. Collins
Chairwoman
Permanent Subcommittee on Investigations
Senate Governmental Affairs Committee
United States Senate
Washington, DC 20510-6250

Dear Senator Collins:

The Food Industry Trade Coalition (FITC) supports policies which enhance opportunities for international trade in food products and their ingredients. Trade increases U.S. jobs and strengthens U.S. competitiveness in an increasingly global marketplace. Our members include companies and trade associations involved in processing, manufacturing, distributing, and marketing food products in U.S. and foreign markets.

We are writing to express our concern over congressional proposals that would mandate new country-of-origin labeling requirements on food products. Existing U.S. law already establishes requirements for identifying the country-of-origin of imports, including food products. New requirements, which add to or complicate existing rules, merely impose additional burdens on U.S. firms and workers with no meaningful consumer benefit.

For example, S. 617, the "Imported Meat Labeling Act of 1997" -- would require identifying not simply the country of origin of the meat product (as current law requires) but also the country of origin of the animal(s) from which the meat is derived. This requirement imposes an incredible burden and cost on parties throughout the production, processing, and marketing chain of meat products and food products that may contain meat. Companies would have to make huge investments to segregate, track and label product inventories as they move from one link in the chain to the next, from cattle to canned soup. All this additional cost is for what benefit?

Certainly not food safety. Imported food products are already subject to inspections at our ports of entry. There is simply no evidence that existing requirements fail to protect food safety concerns in a manner which new country-of-origin labeling will fix. In fact, a recent U.S. Department of Agriculture Foreign Agriculture Service report on trade agreements and food safety says: "Country-of-origin labeling does not address the issue of food safety. If a food product is not safe, it should be prohibited from entering the United States. Country-of-origin labels will not help consumers determine if a product is safe."

Another example is S. 1042, the "Imported Produce Labeling Act of 1997," which calls for retail grocers to label imported produce by country of origin at the final point of sale. It imposes monetary penalties for failure to do so. This bill overlooks the practical difficulties, if not impossibility, for the average produce department, which carries over 340 items year round, to constantly divide produce items of the same type from different countries and identify different sources with ever-changing signs.

The great majority of imported produce enters the U.S. market to satisfy consumer demand for year-round availability of fresh fruits and vegetables. For many commodities there is simply not enough domestic product to meet consumer needs. Protectionistic country-of-origin requirements will do nothing to increase inadequate domestic supplies but surely will end up increasing consumer costs.

Similar concerns are raised by a U.S. Customs Service proposal to require front panel country-of-origin marketing for frozen produce with imported content. That proposal also should be rejected.

Proponents of new or stricter requirements on country-of-origin labeling often rely on the consumer's "right to know" as justification. However, they fail to produce any real evidence of the value of country-of-origin information to consumers, or how it affects their purchasing decisions. To the extent that consumers do attach a premium value to products from a particular country, the marketplace provides an economic incentive for such identification. It is unnecessary and patronizing for the federal government to micromanage Americans' food dollars by mandating costly labeling requirements with no overriding value to the consumer.

Increased regulation will also bring increased costs for government enforcement. In a period of declining budgets and rationalization of government programs, how can we justify increased enforcement costs with no clear benefit?

Increased regulation of country-of-origin labeling makes little sense in terms of U.S. trade policy interests. The United States has been a leader in the world trading community in seeking elimination of trade barriers and policies that discriminate against U.S. goods and services. We have made significant progress in improving multilateral trading rules and using the dispute settlement system to overturn foreign countries' protectionist policies.

Pending U.S. legislative proposals on country-of-origin labeling are examples of measures we would criticize if adopted by another country. The extension of labeling requirements into the area of ingredient origin is particularly troublesome, as it sets a precedent with broad ramifications for U.S. export interests.

American food products are second to none in terms of price, quality, variety and wholesomeness. Our strong competitive edge in food and agriculture is amply reflected in our expanding presence overseas, with U.S. agricultural exports exceeding a record $60 billion last year. Let's not shoot ourselves in the foot by enacting regulatory hurdles at home that we would neither benefit from nor tolerate if adopted by another country.

We urge the committee to reject proposals to mandate new country-of-origin labeling requirements on food products and their ingredients. We respectfully request that this letter be made a part of the hearing record for the May 14, 1998 hearing discussing the adequacy of the systems and procedures used by Federal agencies to ensure the safety of foods imported into the United States.

Sincerely,

AMERICAN BAKERS ASSOCIATION
AMERICAN FROZEN FOOD INSTITUTE
AMERICAN MEAT INSTITUTE
ASSOCIATION OF SALES & MARKETING COMPANIES
CHILEAN EXPORTERS ASSOCIATION
CHILEAN FRESH FRUIT ASSOCIATION
CONSUMERS FOR WORLD TRADE
FOOD DISTRIBUTORS INTERNATIONAL
FOOD MARKETING INSTITUTE
GROCERY MANUFACTURERS OF AMERICA INC.
INTERNATIONAL BANANA ASSOCIATION
INTERNATIONAL DAIRY FOODS ASSOCIATION
INTERNATIONAL MASS RETAIL ASSOCIATION
NATIONAL GROCERS ASSOCIATION
MEAT IMPORTERS COUNCIL OF AMERICA, INC.
NATIONAL FISHERIES INSTITUTE
NATIONAL FOOD PROCESSORS ASSOCIATION
NATIONAL MEAT ASSOCIATION
NATIONAL TURKEY FEDERATION
NORTH AMERICAN MEAT PROCESSORS ASSOCIATION
SNACK FOOD ASSOCIATION
U.S. CHAMBER OF COMMERCE

and their member food companies

Senate Permanent Subcommittee
on Investigations
EXHIBIT # 17

TESTIMONY SUBMITTED FOR THE RECORD
OF DR. FRANCISCO GURRIA TREVINO
BEFORE THE SENATE GOVERNMENTAL AFFAIRS COMMITTEE
PERMANENT SUBCOMMITTEE ON INVESTIGATIONS
HEARING ON THE SAFETY OF FOOD IMPORTS
May 14, 1998

On behalf of the Government of Mexico, and in my capacity as Deputy Secretary of Secretaria de Agricultura, Ganaderia y Desarrollo Rural ("SAGAR"), I am honored to present these comments to the Senate Governmental Affairs Permanent Subcommittee on Investigations. Mexico's ministries of health, agriculture, and others, which oversee food safety standards in Mexico, have asked me to initiate a comprehensive food safety partnership with the United States. Mexico is committed to working with the United States to develop appropriate Guidance for the production, processing and packing of our agriculural exports.

Mexico takes food safety very seriously. As you know, Mexico's strawberries were implicated in last year's outbreak of hepatis A. While I remind the Subcommittee that the United States has not determined whether the contamination originated in Mexico, our farmers have responded to the incident in an aggressive and positive way. To prevent future outbreaks, agricultural workers in the strawberry fields are required to shower before working the crops. The fields are now specifically delineated and workers are prohibited from eating inside the fields. Toilets -- rather than privies -- are provided for the strawberry workers. I believe these aggressive, proactive, costly actions demonstrate our commitment to safe and sanitary products.

To build on this positive response, in my capacity as leader of Mexico's food safety partnership effort, I am seeking to finalize a formal, comprehensive partnership agreement with the United States to ensure cooperation on research, surveillance, monitoring, technology and information-sharing and other aspects of the President's Food Safety Initiative ("FSI"). Mexico believes its food safety standards and enforcement will meet U.S. food safety standards and is committed to working with the United States, Canada and other countries around the world to secure and sustain the confidence of the U.S. and global consumers in the safety and wholesomeness of the international food supply.

Like the United States, Mexico is committed to science-based food safety standards. Food safety is an important international public health issue, and the protection of public health remains one of the most cherished responsibilities of every nation. Like the United States, Mexico also strongly believes food safety should not become a trade issue. Valid public health issues should not be used by competitors to disrupt the flow of trade. SAGAR urges the Congress and the Administration to take care to ensure that any and all food safety regulations and procedures be based on verifiable science and that their enforcement be carried out in an objective, non-biased, and structured manner. Food safety rules should not be available as tools to convey a competitive advantage.

As we offered in previous meetings with your staff, we stand ready to assist the Subcommittee in its ongoing investigation of the U.S. food supply and would welcome your visiting Mexico to see our production facilities.

Senate Permanent Subcommittee
on Investigations

EXHIBIT # 18

FRESH PRODUCE ASSOCIATION OF THE AMERICAS
30 North Hudgins Street, Nogales, Arizona 85621
520-287-2707 Fax 520-287-2948/287-5430

Statement

FRESH PRODUCE ASSOCIATION OF THE AMERICAS

Lee Frankel, President, and James Cathey, Chairman

Permanent Subcommittee on Investigations
Senate Committee on Government Affairs

Hearing on May 14, 1998
"The Safety of Food Imports"

The Fresh Produce Association of the Americas (FPAA) commends the Permanent Subcommittee on Investigations for taking a systematic and patient approach to examining the issue of food safety today. Much misinformation and sensationalism, mixed with politically charged rhetoric, have given the public a sense of unease about the food they consume. A need exists for truth and unbiased advice, therefore, to give back to the American public the confidence they had in food safety until self-serving headline-seekers took isolated incidents and turned them into widespread food scares.

FPAA would like to call the Subcommittee's attention to the following:

Fresh vs. Processed. *Clear distinction should be made between fresh fruits and vegetables (produce) which have their skins and peels intact and processed foods that have been cut, cooked, squeezed, and otherwise handled and prepared by humans and machines prior to consumption.*

Unfortunately, the GAO report (paged 47) mixes various types of foods and lumps them together as selected causes of outbreaks. For example, "frozen strawberries" are not fresh produce. The frozen strawberries implicated in the Hepatitis A outbreak in 1997 were washed, sliced, and frozen. They were extensively handled and processed, and were not fresh strawberries which are touched only when they are picked.

During the hearing, witnesses and subcommittee members made very little distinction between fresh produce and processed foods. Witness Reggie Jang discussed imported foods but almost completely spoke about processed foods. Subcommittee members also did not make the distinction during their questions.

Most food borne illnesses are caused by cooked, processed, cut, and prepared foods that have been improperly handled. Illnesses caused solely by fresh produce are uncommon in the United States. Raspberries and sprouts were two rare exceptions.

It may be worthwhile to note that fresh produce consumed in some foreign countries cause illnesses because of poor water quality, not necessarily because the produce is inherently contaminated. The cleanest US produce if washed, prepared and consumed in some foreign countries could cause illnesses due to poor water quality or worker hygiene.

It is also important to distinguish between the various types of factors that make foods unsafe, such as microbiological contamination, chemical (pesticide) contamination, heavy metals, poisonous compounds, inedibles. Most of the discussion at the hearing focused on microbiological contamination, but there were times when chemical contamination was discussed simultaneously. In discussing the "safety of food imports," appropriate attention should be paid to all types and kinds of contaminants as well as foods that are by nature unsafe. For example, fish can contain heavy metals, and certain plant foods may be poisonous or just unhealthy and inappropriate to consume. The American public is entitled to know about the safety of all foods under all circumstances.

"Equivalency." *The US could require an exporting country to have an equivalent level of food safety as the US only if the US had such a standard. At present, the US does not have a food safety standard for fresh produce.*

In case of *meat and poultry*, the US has strict standards and regulations. Other countries can be expected to have "equivalent" ones. Furthermore, the number of exporting companies and countries are limited in number and, therefore, easier to control and inspect.

The same cannot be said for *fresh produce*. There are no specific rules, standards or regulations that cover microbiological contamination. The only requirement is that the produce should be clean and wholesome. Virtually every country would have a similar requirement so that an "equivalency" would be meaningless.

Even if fresh produce standards existed, there would be so many exporting countries that the US government would have great difficulty checking for "equivalency." The number of US government inspectors would have to increase dramatically.

There would be a problem in defining equivalency. For example, if a foreign food regulation specified an allowable e. coli bacteria count on fresh produce (in the same way the FDA allows a maximum number of insect parts in some commodities), would that be considered "clean and wholesome" or would that be reason to keep out the import? In turn, how would foreign governments treat American fresh produce exports when the US has no standard.

Country-specific approvals and regional approvals for equivalency. The reality of food contamination is that it can occur to any farmer at any time, and that contamination can be very localized and limited. One sick farm worker or food handler can cause a limited outbreak among those who consume the food he has touched. On the other hand, an unsanitary food processing plant can cause a widespread outbreak.

It is unfair to indict a whole country or an entire industry for the mistake or carelessness of one person or one company.

Conversely, it may be inappropriate to grant a general "equivalency" approval of a whole country when only certain companies, farms or regions might merit that designation.

The solution may be a conditional or limited approval of equivalency.

While many farms and food processing operations in the US are clean and sanitary, there will be exceptions. The same would be true overseas. In some cases, the overall sanitary standards of a foreign country might not match those of the US, but specific regions might be fully compatible. In such cases, it would be unfair for the US to ban exports from that country when exports come only from the region, area, or farms that meet US standards. Consequently, *the US should provide for a process by which equivalency can be established for regions and growing areas, if not specific farms.*

There is precedence for this type of approval. USDA's Animal and Plant Health Inspection Service (APHIS) has approved seasonal importation of avocados from Mexico from certain approved orchards. The restriction is for the control of pests but there is no reason that similar limited approvals cannot be given to regions, areas, or farms that meet science-based international "equivalency" standards. Such a system would be fair and most likely internationally acceptable.

The FDA should not be asked to waste its resources by visiting, inspecting, and validating the equivalency of numerous countries with which the US might have little or no trade. The FDA might better serve US consumers and improve food safety if it concentrated its efforts and attention only on major exporters of fresh produce to the US.

An over-zealous application of equivalency might be to the disadvantage of American consumers. There is no statistical reason to state that imported fruits and vegetables are any less safe than domestic produce. The FDA says, as part of its current effort to develop a guideline to minimize microbial contamination of fresh produce, that domestic produce is not safer that imports. There is no reason, therefore, to make the importation of fruits and vegetables especially difficult in an effort to achieve some degree of higher level of safety. American consumer like the wide variety of produce now available through imports, and American consumers are eating a variety of fresh produce. Limiting imports will go against the current trend, and will deprive American consumers of the healthful benefits of eating fresh fruits and vegetables year round.

As part of the hearing, attention was focused on illegal activities, such as smuggling, port shopping, and forgery. While some of those activities might relate to food safety, much of them point back to the administrative and management tasks of the regulatory agencies--FDA, USDA, and US Customs Service. While the FSIS of USDA seemed to get high grades, the FDA came under much criticism. The US Customs Service seemed to escape scrutiny for the moment. *It is unfair to criticize the FDA when it has not been given adequate resources to carry out its work. FDA does not have the manpower or the physical facilities to intensely inspect imported foods because Congress has not provided the funds.* The FDA has a wide range of responsibilities and while it might be "politically fashionable" to attack the FDA, the criticisms are unfair--especially if they come from those who believe that the government that governs least is the best government.

Port shopping, smuggling, and other illegal activities do not make much sense for fresh produce because of the relatively low unit value and bulk of the commodities, not to mention perishability. Such activities, however, might be profitable for high-value processed foods with long shelf-life. The OASIS system works well and tracks imports so that illegal maneuvering becomes quite difficult.

In Nogales, Arizona, the port through which the majority of fresh winter vegetables from Mexico enter the US, there is a close working relationship between the FDA and US Customs Service. As a result, in Nogales *the disposal rate of items rejected by the FDA is basically 100 percent.* The system works because there is a legitimate threat of government action for non-compliance. As a result, the system works.

It should be noted that all Federal inspectors have full access to the entire shipment of fresh produce brought into the US. The importer is required to allow full access to FDA inspectors and to off-load pallets from any part of the truck at their expense if requested by the FDA.

It would be unfair to impose fines that have no relationship to the declared value or in excess of the financial stake of the importer. Recommendation was made at the hearing to dramatically increase the fine from three times the declared value of the shipment to a much greater level because the market value of the shipment is considerably higher. It should be noted that the retail value does not necessarily reflect the money received by the grower/shipper or the importer. The retail price reflects the costs of domestic transportation, distribution and marketing costs, and markup by the retailer. It would be unfair in most instances to impose fines that have no relationship to the declared value. If additional or different penalties are to be considered, the importer might be restricted or prohibited from importing the commodity in question for a specific period of time depending on the type of commodity, i.e., perishable vs. non-perishable.

Food safety is not simply the responsibility of the grower, the importer or the retailer. There is a chain of responsibilities that reach from the farm to the table in assuring the safety of foods. The farmer must grow, pack, and ship clean, wholesome produce. The distributor, shipper, and retailer must make sure the food stays clean. The consumer must not contaminate or cross contaminate the food at home. Fresh fruits and vegetables that leave the farm in a perfectly clean condition can become contaminated in route or through handling at the retail level, including the consumer with unwashed hands that pinches, fondles, and otherwise handles fresh produce at the store. Food safety, therefore, is everyone's responsibility. The hearings before the Subcommittee, therefore, must not allow witnesses to find scapegoats and thereby escape their responsibilities.

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Senate Permanent Subcommittee
on Investigations
EXHIBIT # 19
98-400 STM

CRS Report for Congress

Food Safety: Recommendations for Changes in the Organization of Federal Food Safety Responsibilities, 1949-1997

April 21, 1998

Donna U. Vogt
Analyst in Social Sciences
Science, Technology, and Medicine Division

Congressional Research Service • The Library of Congress

ABSTRACT

This report describes recommendations to change the structure of federal food safety responsibilities and gives the reader background information on the debate over the last five decades over which structure would best improve the system for ensuring "safe" food for U.S. consumers. The report lists all the major efforts that were made from 1949 through 1997 by groups inside and outside the federal government. The sets of recommendations are placed chronologically under one of four categories, depending on which organizational structure the group thought would improve food safety. The categories of organization are as follows: an independent single food safety agency, the U.S. Department of Agriculture, or the Food and Drug Administration, or with the Consumer Product Safety Commission. This product will be updated periodically. See also CRS Issue Brief 98009, Food Safety Issues in the 105th Congress.

Food Safety: Recommendations for Changes in the Organization of Federal Food Safety Responsibilities, 1949-1997

Summary

This report summarizes twenty-one sets of recommendations, made in the last five decades, for changing the organization of federal food safety responsibilities. Since 1906, food safety responsibilities and inspections have been split by product under different laws. Congress passed the Pure Food Act and the Meat Inspection Act on June 30, 1906. Both Acts placed the responsibility for food safety in the U.S. Department of Agriculture (USDA), Division of Chemistry (later Bureau). That Bureau later became the Food and Drug Administration. Over time, USDA kept responsibility for meat safety, while most other foods came to be regulated by the Food and Drug Administration (FDA) of the Public Health Service in the Department of Health and Human Services (DHHS).

Recommendations for changing the federal food safety system can be fit into one of four categories. The recommendations proposed that 1) a single, independent institution be given responsibility for all food safety; 2) responsibility for all food products should be returned to USDA; 3) responsibility for all food products should be given to FDA; or 4) responsibility for all food products should be given to the Consumer Product Safety Commission (CPSC).

Most of the recommendations had both supporters and critics. Supporters of the first recommendation claim that the agency could promulgate consistent risk-based regulations and inspections for all types of foods, whether meats or canned foods, and increase the confidence of consumers in the U.S. food supply. Critics claim that a single, independent food safety agency would have large start-up costs in an era of tight budgets and would not be able to take advantage of the long-term experience and regulatory organization developed for different foods by USDA and FDA.

Supporters of the second recommendation claim that USDA could utilize its nationwide network for new research and enforcement. Critics claim that USDA has little institutional culture to support legal regulatory work. They are also concerned that USDA's mission of supporting and promoting agriculture would interfere with its ability to take regulatory action when needed.

Supporters of the third recommendation feel that FDA could use its long-term expertise in combining law and science to regulate consumer products. Critics argue that FDA is not organized to regulate all foods, would have to completely change its orientation, and could be overwhelmed by the process.

Supporters of the fourth recommendation claim that under the CPSC, the fragmented federal authority for food safety could be modernized and focused on protecting U.S. consumers by strengthening the links to federal and state public health departments. Critics are concerned that food is unlike other products that the CPSC has regulated and may not receive the attention it deserves.

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Food Safety: Recommendations for Changes in the Organization of Federal Food Safety Responsibilities, 1949-1997[1]

Introduction

At times, consumers have questioned whether the organization of federal food safety efforts works well enough or whether a different system may better serve consumer needs. Questions often revolve around which standards are used when judging whether food is considered safe, and how the federal government should be organized to respond appropriately to food safety concerns. During the past five decades, those concerns have led the executive branch and Congress to consider recommendations for changes in the organization of federal food safety efforts.

This report summarizes twenty-one sets of recommendations, presented to the President or to Congress between 1949 and 1997 to change the structure of food safety responsibilities. These recommendations were developed by entities inside and outside the federal government. They have included Presidential and other official commissions, Members and committees of Congress, the U.S. General Accounting Office (GAO), and prominent food policy representatives. All recommendations have influenced the debate on restructuring the federal organization of food safety.

Background[2]

The federal government's role in food safety began when safety questions about food were referred to the Division (later Bureau) of Chemistry within a newly created Department of Agriculture (USDA) in the latter half of the nineteenth century. USDA's role began to increase when, at the turn of the century, developments in transportation systems increasingly brought processed food into growing cities. The residents of those cities lost the ability that villagers had possessed of being first-hand judges of the food they ate. U.S. consumers began questioning the safety of what they were buying in stores and expressed concern about the safety of chemical preservatives being used by commercial food processors to extend the life of meats, dairy products, and vegetables, and sometimes to mask their decomposition.

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[1] CRS Report 93-955, which this report supersedes, was coauthored by Karen L. Alderson, Library Services Division, Congressional Research Service.

[2] Most of the historical material used to prepare this section was provided by Suzanne White Junod, Ph.D. History Office, Food and Drug Administration.

The conditions of some foods led the Bureau of Chemistry to conduct studies of the extent to which adulterated foods had begun to permeate the nation's food supply. While the chief chemist of USDA at that time, Dr. Harvey W. Wiley, estimated that less than 5% of the nation's food was adulterated, he surmised that the overuse of chemical preservatives such as borax, formaldehyde, benzoate of soda, salicylic acid, and copper salts, commonly used as additives in food, could be harmful to health. Those studies convinced Congress to appropriate funds for Dr. Wiley's famous "poison squad." The squad consisted of a group of young men who were given increasing doses of the chemicals to discover their effects on the human metabolism. Many of the young men became ill when they consumed foods containing preservatives in amounts commonly used at that time. The scientific value of the studies remained questionable, but the effect on the public was dramatic when the results were reported. The "poison squad" stories provoked interest in food safety throughout the country. The time was ripe for federal action.

Under pressure from consumer groups and from President Theodore Roosevelt, Congress passed the 1906 Food and Drugs Act on June 30, 1906.[3] That Act set up the regulatory role of the federal government for foods other than meat and poultry by prohibiting from interstate commerce the sale of food and drugs that were adulterated and/or misbranded. Adulteration in the act was defined as

> ...the intermixture or substitution of substances reducing quality, the abstraction of valuable constituents, the concealment of damage or inferiority, the addition of deleterious ingredients, and the use of spoiled animal or vegetable products.[4]

Misbranding meant placing false or misleading statements on the label. Yet, food safety involved more than adulteration and misbranding. The 1906 Food and Drugs Act also had a provision for enforcement. It required that adulterated foods not only be seized but also destroyed.

In 1905, Upton Sinclair published *The Jungle*, a book about the way meat was mishandled in Chicago's slaughterhouses. It had a major impact on consumers with meat sales falling around the country by nearly a third almost overnight. Congress appointed a commission to examine the charges made in the book. The commission found that while some of the allegations might have been slightly exaggerated, other evidence showed situations actually worse than portrayed by Sinclair. That evidence was used to convince lawmakers to pass the Meat Inspection Act of 1906[5], which set sanitary standards for slaughter of animals and for meat sold in interstate commerce.[6]

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[3]P.L. 59-384, 34 Stat. 768 (1906).

[4]Lauffer Hayes and Frank Ruff, "The Administration of the Federal Food and Drugs Act," in *Food and Drug Law: Cases and Materials*, ed. Peter Barton Hutt and Richard A. Merrill. 2nd ed. (Westbury, New York: The Foundation Press, Inc., 1991), 9.

[5] P.L. 59-242, 21 U.S.C. §601 et seq.

[6]Meat had been separated from other food for special legislative treatment in 1890 and 1891. Federal inspection began as a means of reassuring European nations that U.S. meats were safe. Europe had banned imports of U.S. pork on the charge that it had caused

(continued...)

With the passage of the 1906 Act, USDA began a system of continuous daily inspection in slaughterhouses using organoleptic (sight, smell, touch) means to detect problems. If problems were found, inspectors could instantly condemn carcasses.

With the signing of the 1906 Food and Drugs Act, USDA officials in the Bureau of Chemistry emphasized the development of detection methods to find chemical problems in foods. During the 1920's, conflicts sometimes occurred within the department between officials who were charged with promoting the use of chemicals to produce food and regulators who were concerned about food being adulterated by those chemicals. For example, California apple growers at the time used large quantities of arsenic on apples to fight pests. USDA chemists had set a limit for the maximum amount of arsenic residue that could be left on the fruit. Some of the apples had residues that exceeded that limit. The regulators wanted to declare the apples adulterated; other officials did not.

The conflict in mission began early in the century. The following statement characterizes it:

> The Bureau of Chemistry had originated as a research bureau and law enforcement was a superimposed responsibility. The task of undertaking research designated to improve the methods of utilizing agricultural products was frequently in striking conflict with enforcement of the Pure Food and Drugs law. These conflicts arose, first, because there was a constant tendency to stop a research project so as to permit the scientist to assist in acquiring evidence immediately needed in a lawsuit and second, because the objectives of law enforcement frequently did not coincide with increasing the utilization of a particular agricultural product, but instead might retard its utilization.[7]

In 1927, Dr. Walter Campbell of the Bureau of Chemistry recommended that the Secretary of Agriculture separate the functions of agricultural research and enforcement. At the time, USDA was enforcing several other laws.[8] Campbell suggested that the Secretary of Agriculture create a Food, Drug, and Insecticide Administration (FDIA) within the Department. Congress supported this suggestion and the 1927 appropriations bill created the FDIA and gave it the responsibility to

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[6](...continued)
epidemics of trichinosis. A newspaper scare arose during the Spanish-American War when U.S. packers were blamed for shipping "embalmed beef" that sickened the troops. Investigation attributed some of the trouble to the rapid growth of bacteria in meat exposed to the hot Cuban sun. James Harvey Young, "The Long Struggle for the 1906 Law," *FDA Consumer*, v. 15, no. 5, June 1981, 16.

[7]Michael Brannon,"Organizing and Reorganizing FDA," in *Seventy-Fifth Anniversary Commemorative Volume of Food and Drug Law*, Food and Drug Law Institute Series, (Washington, D.C., Food Drug Law Institute, 1984), 142.

[8]Laws included the Food and Drugs Act (34 Stat. 768 (1906)), the Insecticide Act (7 U.S.C. §121-134), the Caustic Poison Act (15 U.S.C. §410-411), Naval Stores Act (7 U.S.C. §91 et seq.), Federal Import Milk Act (21 U.S.C. §141 et seq.), Filled Milk Act(21 U.S.C. §61 et seq.), and Tea Importation Act(21 U.S.C. §41 et seq.).

enforce the 1906 Pure Foods Act.[9] Simultaneously, the Secretary created a soil and chemistry bureau to handle research functions. In 1930, USDA dropped "insecticide" from the agency's title, and its name became the Food and Drug Administration (FDA).

FDA's new enforcement responsibilities continued to grow as did the agency's commitment to consumer protection. In 1930, Congress passed an act setting standards for canned foods, but excluding canned meat and milk products from those standards. As the New Deal began in 1933, pressures mounted to pass a new law that would fill the gaps in the 1906 Pure Food and Drugs Act. A tragedy occurred in 1937 that resulted in strengthening the federal role of premarket review of drugs. At least 73, and perhaps over 90, persons died as a result of taking "Elixir Sulfanilamide." Franklin Roosevelt's son had recovered from a near fatal infection using sulfanilamide, a European wonder drug. Problems developed when the producer began using diethylene glycol as a solvent for sulfanilamide without first determining that the solvent was safe. The disaster prompted passage of the 1938 amendments to the law, requiring manufacturers to prove a drug's safety to FDA before marketing the drug. Consumers began to support the idea that there should be federal premarket approval for both drugs and substances added to foods.

On June 25, 1938, President Roosevelt signed into law the Federal Food, Drug, and Cosmetic Act of 1938[10] (FFDCA) that today remains the basic authorizing legislation for food safety. Even though USDA had primary responsibility for food safety for almost 80 years, the new law defined more clearly USDA's authority to regulate livestock and poultry feeds and drugs used in animal disease control. After the 1938 law was passed, President Roosevelt said,

> "The work of the Food and Drug Administration is unrelated to the basic function of the Department of Agriculture," and he expressed his belief that "the opportunity for the Food and Drug Administration to develop along increasingly constructive lines" lay in the Federal Security Administration.[11]

In 1940, the President moved FDA out of USDA and into the Federal Security Agency (FSA), a separate part of the executive branch. FSA was a new agency; it had been in existence for only one year. At the time, the FSA mission was to protect the public health, and it had under its jurisdiction the Public Health Service, the Office of Education, the Civilian Conservation Corps, and the Social Security Administration, among other agencies. FDA's responsibilities within the FSA included regulating food quality, sanitation, and consumer protection. Under the new FFDCA, FDA was also given the authority to test the safety of new products and was given research responsibilities. The agency focused on whether a given substance in foods was "poisonous or deleterious" within the meaning of section 406 of the statute. As an operational rule, FDA sought to ban in the diet any substance that proved toxic to laboratory animals at 1% of their diet.

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[9]Donald R. Whitnah, ed., *Government Agencies*. (Westport, CT: Greenwood Press, 1983), 251.

[10]21 U.S.C. §301-392

[11]Brannon, *Organizing and Reorganizing FDA*, 158.

Not everyone agreed with the President's decision about reorganizing FDA. Secretary of Agriculture Henry A. Wallace argued that the meat inspection work of USDA's Bureau of Animal Industry also should be transferred. He claimed,

> This activity might be associated with other health or public welfare work. Meat inspection is of course a technical job and it seems logical to have the technical inspectors attached to the bureau most competent in this field.[12]

However, President Roosevelt was not persuaded; meat and poultry inspection remained within USDA. The USDA meat inspection system had developed on a parallel track within USDA's Bureau of Chemistry for over 50 years. Veterinarians within the Bureau trained inspectors to spot animal diseases. Those inspectors performed continuous inspections of animals before slaughter and examined every carcass for disease and contamination after slaughter. The system positioned the United States to supply meat to the world during World War II.

The war effort was not confined to USDA. Even after FDA was transferred out of USDA, FDA was charged with ensuring the enrichment of breads in 1942 for the soldiers serving in World War II. Several years later (1953), the FSA became the Department of Health, Education, and Welfare (HEW). In 1968, FDA became part of the Public Health Service (PHS) where it added a focus on health and nutrition to its food safety responsibilities.

Since the start of federal regulation, food safety has been the primary responsibility of either of two different cabinet agencies, USDA and Department of Health and Human Services (DHHS). **Table 1** shows which statute and consequently which organization and department has been responsible for carrying out the statutes' mandates for food safety since the federal government became involved.

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[12]Memo to President Franklin D. Roosevelt from Henry Wallace, 20 April 1939. Found in Senate Committee on Governmental Affairs, "Food Regulation: A Case Study of USDA and FDA," Chapter 4, *Study on Federal Regulation*, 95th Cong., 2nd sess., December 1977. S. Rept. 95-91,140.

Table 1. Institutional Chronology of Food Safety Responsibilities, 1862-1998

Years	Statute/plan	Name of Organization	Department
1890-1901	Act of March 3, 1891 and Act of March 2, 1895 on exported meats	Division of Chemistry	USDA
1901-1927	1906 Pure Food Act 1906 Appropriations Act	Bureau of Chemistry and Bureau of Animal Industry	USDA
1927-1930	1906 Pure Food Act 1906 Appropriations Act	Food, Drug, and Insecticide Administration	USDA
1930-1940[13]	1938 Federal Food, Drug, and Cosmetic Act (FFDCA)	Food and Drug Administration	USDA
1940-1953	Reorganization Plan No. 4, effective June 3, 1940.	Food and Drug Administration	Federal Security Agency
1953-1970	1954 Miller Pesticide Act and 1958 Food Additives Amendment (Delaney Clause) 1960 Color Additives Amendment (Delaney Clause)	Food and Drug Administration	Department of Health, Education, and Welfare
(1958-1968)	1958 Humane Slaughter Act; 1967 Wholesome Meat Act; 1968 Poultry Products Act	Meat Inspection Branch of Agricultural Research Service	USDA
1970-1979	Reorganization Plan No. 3 of 1970; sect. 346, 346a, 348, and 408 of FFDCA and 135-135k of FIFRA	All pesticide regulation responsibilities were transferred to EPA as were all functions of Environmental Quality Branch, Plant Protection Division of Agricultural Research Service	Environ-mental Protection Agency (EPA)
(1972)	1972 Meat and Poultry Inspection	Food Safety and Inspection Service	USDA
(1968-1979)	Reorganization Plan of March 1968. Public Health Service Act	Food and Drug Administration Public Health Service	Department of Health, Education, and Welfare
1980-		Food and Drug Administration Public Health Service	Department of Health and Human Services

Source: Peter Barton Hutt and Richard A. Merrill, eds. *Food and Drug Law: Cases and Materials*, 2nd ed., (Westbury, New York: The Foundation Press, Inc., 1991), 4-5.

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[13]The name "Food and Drug Administration" was first used in the Agriculture Appropriation Act of 1931 (46 Stat. 32).

Current Federal Food Safety Responsibilities

Historically, Congress passed laws in reaction to immediate food safety problems. Those laws assigned food safety responsibilities to several executive departments. Today, the primary federal agencies responsible for regulating the safety of the U.S. food supply are the Food and Drug Administration (FDA) under the Public Health Service of the Department of Health and Human Services (DHHS), and the Food Safety and Inspection Service (FSIS) under the U.S. Department of Agriculture (USDA). FDA and USDA together try to ensure that food products, as sold in the United States, will not adversely affect human health.

FDA is charged with ensuring that foods (except meat, poultry, and certain egg products) are safe, nutritious, sanitary, wholesome, and honestly labeled. The primary statute governing FDA's food safety activities is the Federal Food, Drug, and Cosmetic Act (FFDCA).[14] FDA monitors whether food manufacturers are adhering to their legal responsibility of ensuring that foods are not defective, unsafe, filthy, or produced under unsanitary conditions. USDA is responsible for monitoring meat, poultry, and commercially processed egg products under the Federal Meat Inspection Act, as amended, the Poultry Products Inspection Act, as amended, and the Egg Products Inspection Act, as amended. FSIS is directly responsible for the daily inspection of all meat and poultry entering U.S. commerce. FSIS also shares responsibility with FDA on combination products such as stews and pizzas. For example, FSIS regulates all products that contain 2% or more of poultry and poultry products and 3% or more of red meat or red meat products. FDA regulates all other foods.

In total, thirteen agencies in the federal government have food safety responsibilities.[15] FDA has three centers conducting and supporting food safety activities: Center for Food Safety and Applied Nutrition (CFSAN), Center for Veterinary Medicine (CVM), and the National Center for Toxicological Research (NCTR). Besides FSIS, the USDA agencies with food safety responsibilities are the Animal and Plant Health Inspection Service (APHIS),which has regulatory programs to protect animals and plants from pests and disease; the Agricultural Research Service (ARS), which conducts a wide range of food safety related research; the Cooperative State Research, Education, and Extension Service (CSREES), which carries out a program of fundamental and applied research in several areas, including

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[14]Other relevant statutes are the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (P.L. 104-61,Stat.163-172,1947, 7 U.S.C. §136 et seq.); the Public Health Service Act (Chapter 288, 37 Stat. 309 (1912), 7 U.S.C. §201 et seq.); the Fair Packaging and Labeling Act, as amended (P.L. 89-755, 15 U.S.C. §1451 et seq.); the Federal Meat Inspection Act, as amended (P.L. 90-201, 21 U.S.C. §601 et seq.); the Poultry Products Inspection Act (P.L.85-172, 21 U.S.C. §451 et seq.); Federal Import Milk Act (P.L. 69-625, 21 U.S.C. §141 et seq.); Plant Quarantine Act , as amended (P.L 85-36, 7 U.S.C. §150 et seq.) and the Pesticide Monitoring Improvements Act (P.L.100-418, 21 U.S.C. §1401, et seq.).

[15]Detailed information on those responsibilities can be found in Congressional Research Service, *Food Safety Agencies and Authorities: A Primer*, by Jean Rawson and Donna U. Vogt. Report No. 98-91 ENR, 5 February 1998, 6.

food safety and health; and the Economic Research Service (ERS), which provides cost and benefit information on food-borne illnesses. The National Center for Infectious Diseases of the Centers for Disease Control and Prevention (CDC), under DHHS, monitors and investigates food-borne illnesses and diseases and shares that information with the other agencies.

The Environmental Protection Agency (EPA) regulates pesticides and is charged with setting pesticide-residue tolerances for each pesticide-food combination. The Bureau of Alcohol, Tobacco, and Firearms (BATF), of the U.S. Treasury Department, regulates production, distribution, and labeling of alcoholic beverages.[16] The National Marine Fisheries Service (NMFS) of the U.S. Department of Commerce conducts a voluntary fee-for-service seafood inspection program. The Federal Trade Commission (FTC) regulates advertising of food products. The U.S. Customs Service of the Department of the Treasury assists FDA by notifying FDA of incoming shipments of products under FDA jurisdiction. FDA officials examine all paperwork and electronic submissions related to these imports and at times collect samples.

In addition, federal agencies work in close collaboration with state officials. Often, federal agencies such as FDA will train and contract with state enforcement officials to conduct food plant inspections. FDA also developed a model ordinance for milk sanitation and a "Food Code" for retail food store and restaurant sanitation to be adopted by state legislatures. FDA also works with groups such as the Association of Food and Drug Officials of the United States and the Association of Official Analytical Chemists.[17] FDA, in conjunction with the states, regulates animal feed ingredients and feeds as part of the American Association of Feed Control Officials.[18]

Overlapping Responsibilities

Critics charge that part of the "food safety problem" is that U.S. food safety laws and regulations are fragmentary and inconsistent and are not comprehensive. Critics also claim that too many agencies are responsible for food safety activities. Foods posing similar health risks may be inspected by different agencies at different frequencies. The roles that these agencies play depend for the most part on their statutory authority and their resources. One former official who served in both USDA and FDA said that the fragmentation and diversity of the agencies' authority undercuts the government's accountability for food safety, and he added:

> FDA has jurisdiction over plants producing cheese pizza, but rarely inspects such plants. USDA has jurisdiction over plants producing pepperoni pizza, and inspects such plants on a daily basis, after having already inspected both the

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[16]FDA is responsible for all nonalcoholic beverages, and wine beverages (i.e. fermented fruit juices) containing less than 7% alcohol.

[17]James T. O'Reilly, *Food and Drug Administration* (Colorado Springs, Colorado: Shepard's/McGraw-Hill, Inc., Oct. 1993).

[18]Edward L. Korwek, *1997 United States Biotechnology Regulations Handbook*, vol. 1, (Washington, D.C.:Food and Drug Law Institute, 1997), 112.

> animal from which the pepperoni was made and the processing of the meat into pepperoni.[19]

Other examples abound. USDA daily inspects meat and poultry for contamination of various pathogens, including *Listeria monocytogenes* and *E. coli* O157:H7. At the same time, FDA may inspect once every ten years soft cheeses or apple juice in which those same pathogens have been found. Some believe that it is inappropriate for separate agencies using different risk and inspection criteria to regulate the nation's food supply. These critics also think that the same or similar risk criteria should be used by all federal agencies to prevent microbial contamination on all foods.[20]

Others charge that safety cannot be properly regulated when food safety responsibility is placed in the hands of the same agency in charge also of promoting regulated products. Many think that an organization that promotes and subsidizes production agriculture and other consumer products should be separate from one that watches over food safety.

The meaning of "food safety" responsibilities continues to expand. Food safety functions of federal agencies have come to signify certain responsibilities regarding foods. The responsibilities were aptly defined in an FDA report to Congress:

> Under the foods program, FDA sets food standards; evaluates food additives and packaging for potential health hazards; conducts research to reduce food-borne disease to determine specific health impacts of hazardous substances in food and to develop methods for detecting them in foods; and maintains surveillance over foods through plant inspections, laboratory analyses, and legal action where necessary.[21]

USDA carries out similar functions for meats, poultry, and certain egg products.

Whether all food should be regulated by the same or different agencies is currently under debate. Some argue that a clearer direction to food safety policy could emerge if a single, independent agency were charged with administering all food safety programs. Others oppose forming a single agency, asserting that the various agencies with differing expertise strike a balance among divergent interests.

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[19]Michael R. Taylor, "Preparing America's Food Safety System for the Twenty-First Century — Who is Responsible for What When it Comes to Meeting the Food Safety Challenges of the Consumer-Driven Global Economy?" in *Food and Drug Law Journal*, vol. 52, n.1, (Washington, D.C.:Food and Drug Law Institute, 1997) 13.

[20]Dr. Sanford Miller, Professor and Dean, Graduate School of Biomedical Sciences, The University of Texas Health Science Center at San Antonio, telephone conversation with the author, 17 September 1993, (210) 567-3709.

[21]Senate Committee on Agriculture, Rural Development, and Related Agencies, *Appropriation Bill, 1990*, 101st Cong., 2nd sess., 1989, S.Rept. 101-84, as found in Peter Barton Hutt and Richard A. Merrill, *Food and Drug Law: Cases and Materials*, 2nd ed. (Westbury, New York: The Foundation Press, Inc., 1991) 21.

Recommendations for Changes in the Federal Organization of Food Safety Responsibilities

This report contains 21 separate sets of recommendations that have had a significant impact on the debate over whether the federal organization that ensures safe food needs to be changed. This debate has recurred over 48 years with long periods when little interest was expressed in changing the organization for federal food safety. The debate has been carried on by a range of different entities from major government bodies such as presidential commissions, agency commissions, congressional Members, the General Accounting Office (GAO), to interested parties or influential food policy experts.

The recommendations are grouped chronologically into four categories:

- a separate, independent food safety agency or some modification of that idea;
- all food safety functions given to USDA;
- all food safety functions given to FDA;
- all food safety functions be given to the Consumer Product Safety Commission.

The recommendations described in this report were selected because each expresses a position on how the federal organization of food safety could be improved or changed. Each recommendation was acknowledged as contributing to the debate in later documents discussing changes in the organization for federal food safety. The gaps in the chronology represent the fluctuating nature of the debate. The recommendations listed also represent all the major official bodies that debated this issue in the last five decades.

No President or Congress has adopted these recommendations. However, the reports and publicity surrounding each set has added to the debate and helped define current food safety responsibilities. Eight sets of the recommendations would have created some type of independent federal entity for the regulation of food safety, with responsibility for all foods. Two would have given all responsibility to USDA, and 10 would have FDA reorganize and regulate the safety of all foods including meat and poultry. One would have the Consumer Product Safety Commission carry out all food safety functions. The most recent proposals appear to be evenly divided between giving food safety responsibility to a single, independent agency or to a reorganized FDA that links food safety explicitly to public health. Table 2, at the end of the report, summarizes in chronological order the selected sets of recommendations presented to Presidents and Congresses from 1949 to 1997 period.

Most of the reports or recommendations examine what are perceived to be five separate issues in food safety:

- Should food safety be considered to be a public health responsibility only or should it also be linked with research and development of new standards that not only protect consumers but also lead to the development and marketing of new products?

- Will the cost to the federal government increase or decrease if all activities related to regulating food are combined into a single food safety agency?

- By competing among each other for food safety resources, have agencies become more or less efficient in carrying out their food safety functions?

- If Congress and the Administration chose to create an independent food safety agency, should such an agency be independent of or located within the Public Health Service?

- Would U.S. consumers be better protected by having a uniform set of regulations and laws that covered all foods and were enforced by a single agency?

Some believe that one food safety agency could apply consistent and strong food standards that would assist in building public confidence in the federal system of food safety. Others argue that, although some consumers are very vocal in their distress with the current regulatory framework, it does provide some of the safest, most abundant, and least expensive food in the world.

Most believe that pressures for change will continue focusing mainly on streamlining policies for food, nutrition, and veterinary drug activities. There have always been threads that link the different food safety programs with those of production agriculture and nutrition research.

Food Safety Under a Single, Independent Agency

Popular Name and Date

White House Conference on Food, 1969.[22]

Description and Mission of Group Making Recommendations

President Nixon asked a large group of experts to meet and make recommendations on revising the federal regulatory policy for food and on certain aspects of food, nutrition, and health policy. He requested recommendations regarding administration and operations, community affairs, information, and education. The Conference was chaired by Dr. Jean Mayer, and the deputy chairman was James D. Grant.

Summary of Recommendations

The Conference recommended that there should be one federal regulatory policy with respect to safety, sanitation, identity, and labeling of foods. The Conference also recommended that the Secretary of Health, Education, and Welfare (HEW) issue an order establishing a separate interdepartmental coordinating committee on federal food regulatory policy with the aim of implementing national nutritional and health goals. The committee would be comprised of representatives of all federal departments and agencies having jurisdiction over safety, sanitation, identity, and labeling of any food. Within certain schedules, the committee should issue reports on the progress of reconciling all pertinent federal food policies and practices. The committee should initially consider the question of whether a single federal regulatory agency for foods should be established, and particularly whether the jurisdiction of USDA over food products derived from or utilizing inspected meat and poultry should be transferred to HEW.

Dissenting views

Not Available

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[22] *White House Conference on Food, Nutrition, and Health. Final Report*. (Washington, D.C.: White House, 1969), 118-119.

Popular Name and Date

GAO Food Inspection Report, 1970.[23]

Description and Mission of Group Making Recommendations

In a letter to the President of the Senate and the Speaker of the House of Representatives, the Comptroller General of the United States presented the results of a review of the roles of federal organizations involved in inspecting food. GAO's authority to conduct the review was contained in the Budget and Accounting Act of 1921 (31 U.S.C. 53); the Accounting and Auditing Act of 1950 (31 U.S.C. 67); and the authority of the Comptroller General to examine contractor's records as set forth in 10 U.S.C. 231(b).

Summary of Recommendations

Federal food inspection evolved from piecemeal legislation and regulations, designed to solve specific problems when they arose. The report claimed that current practice at the time did not clearly express an overall federal policy on food inspection. Many federal, state, and local organizations performed different parts of the food inspection process. Such a process led to some overlap in responsibility and caused dissatisfaction among members of the food industry. Some of the dissatisfaction related to inspections being made for different purposes and with varying intensity. The GAO recommended that the different agencies arrange agreements among themselves to use the skills and experience of each to establish clearer lines of responsibility, and to reduce overlap. The report did concede that those agreements would be time-consuming to arrange and difficult to administer.

Although the report did not specifically recommend consolidation, it criticized the overlapping inspection activities of USDA, FDA, and other federal agencies and the lack of consistency in their requirements, procedures, and concepts. GAO recommended that the Director, Bureau of the Budget, make a detailed evaluation of the federal food inspection system to see how to improve its administration and determine if it was feasible to consolidate some of the inspection efforts.

Dissenting views

Most of the federal agencies responsible for food inspections agreed to evaluate their separate functions. However, USDA's comments indicated that agency officials believed that GAO had not properly characterized certain USDA inspection functions. In its response letter, as published in the GAO report, it stated,

> Meat inspection, for example, is looked upon primarily as a program for consumer protection or benefit. This it is, but we believe it also facilitates interstate commerce in meats and enhances the market for farm animals sold for meat.

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[23]General Accounting Office, *Need to Reassess Food Inspection Roles of Federal Organizations. Department of Agriculture, Department of Defense, Department of Health Education, and Welfare, Department of the Interior*, Rept. No. B-168966, 30 June 1970.

Similarly meat grading, while it may be primarily looked upon as a program for facilitating marketing or dealing in meat, is recognized by consumers as a purchasing tool and, we believe as well, benefits the farmer by giving him added assurance of a return related to the quality of the animals sold. On the other hand, the consumer benefits from grading of grain are quite indirect. Performance standards are designed to be uniform whether the service is mandatory or voluntary. Thus procedures and regulations are geared to the particular need. The consumer's interests are expected to be recognized and protected in each case. It is the needs, and not whether the primary beneficiary is the producer, consumer, or industry that determines requirements and methods.

Popular Name and Date

Hearings on S. 3419, Consumer Safety Act of 1972.[24]

Description and Mission of Group Making Recommendations

Three committees of the Senate held hearings to discuss S. 3419, the Consumer Safety Act of 1972 and its proposal to restructure food safety responsibilities in the federal government. The Commerce Committee held a hearing on April 13, 1972. The Committee on Government Operations, Subcommittee on Executive Reorganization and Government Research held hearings on April 20, 21, May 2, 3, 1972. The Senate Labor and Public Welfare Committee, Subcommittee of Health held hearings on May 2, 3, 1972.

Summary of Recommendations

The report of the Senate Committee on Labor and Public Welfare stated that the purpose of S. 3419, the Consumer Safety Act of 1972, was to establish an independent agency to regulate foods, drugs, and consumer products. The bill would have combined several different responsibilities under a single agency. For example, all FDA's authority to regulate foods and drugs would be transferred, as would the authority, at that time, of the Center for Disease Control over the licensing of certain clinical laboratories. The Department of Commerce and the Federal Trade Commission authority over flammable fabrics and refrigerator doors would be transferred as would USDA's authority over meat and poultry inspection and animal biological drugs. The purpose of this independent Consumer Safety Agency was to have been to protect consumers against unreasonable risk of injury from hazardous products. The independent agency would have had responsibility to set product safety standards for all consumer products representing unreasonable risk of injury or death.

S. 3419 became the Food, Drug, and Consumer Product Safety Act of 1972.[25] It passed the Senate on June 21. 1972. However, the House did not agree with the transfer of functions administered by FDA. In conference, legislators exempted all food, drugs, devices, and cosmetics as defined in the FFDCA from the jurisdiction of the new Consumer Product Safety Commission.

Dissenting Views

The Nixon Administration thought that the establishment of an independent consumer safety agency would prove to be regressive rather than progressive and

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[24]Senate Committee on Commerce, *Consumer Safety Act of 1972*, 92nd Cong., 2nd sess., 1972, S.Rept. 92-749. Senate Committee on Government Operations, Subcommittee on Executive Reorganization and Government Research, *S.3419, The Consumer Safety Act of 1972*, 92nd Cong., 2nd sess., S.Rept. 92-2. Senate Committee on Labor and Public Welfare, *Food, Drug, and Consumer Product Safety Act of 1972*, 92nd Cong., 2nd sess., S.Rept. 92-835.

[25]P.L. 92-573.

opposed establishment of an independent "Consumer Safety Agency." On March 16, 1972, in a press release on S. 3419, Secretary of Health, Education, and Welfare Richardson stated,

> I think...that if the Food and Drug Administration is going to have any problems of digestion of new responsibilities, the problems would be multiplied several fold by the effort to create a new agency duplicating administrative authorities and having to seek scientific capabilities and resources that are already within the Food and Drug Administration. ... It is ... much greater if we build upon the experience and capabilities of the Food and Drug Administration, than if we start all over again through the creation of comparatively small, isolated outside body. [26]

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[26]Senate Committee on Commerce, *Consumer Safety Act of 1972*, 92nd Cong., 2nd sess., 1972, S.Rept. 92-749; Senate Committee on Government Operations, Subcommittee on Executive Reorganization and Government Research, *S.3419, The Consumer Safety Act of 1972*, 92nd Cong., 2nd sess., S.Rept. 92-2; Senate Committee on Labor and Public Welfare, *Food, Drug, and Consumer Product Safety Act of 1972*, 92nd Cong., 2nd sess., S.Rept. 92-835.

Popular Name and Year of Document

Ralph Nader Report, Sowing the Wind, 1972.[27]

Description and Mission of Group Making Recommendations

This report, sponsored by the Center for Study of Responsive Law, was conducted by an interdisciplinary task force of young professionals trained in law and science. Its members conducted research on a wide range of issues, from the fat and chemical content of hot dogs to the potential birth-defect hazards of pesticides. Ralph Nader wrote the introduction to the report. It had some influence on consumer opinion about certain food hazards.

Summary of Recommendations

The report found that food inspection "remains embarrassed by departmental conflicts of interest and overlapping jurisdictions in USDA and FDA." In its conclusions, the report recommended that meat inspection and chemical monitoring by USDA and FDA should be transferred to a new food safety agency where the goal of protecting public health would be consolidated. It also suggested that food inspection be included in the responsibilities of the independent "consumer safety agency" under consideration at the time in Congress.

Dissenting Views

Not Available

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[27]Harrison Wellford, *Sowing the Wind: A Report from Ralph Nader's Center for Study of Responsive Law on Food Safety and the Chemical Harvest*, (New York: Grossman Publishers, 1972) 354.

Popular Name and Date

GAO's Risk-Based Inspection Report, 1992.[28]

Description and Mission of Group Making Recommendations

GAO published this report in response to a request from the Honorable John D. Dingell, Chairman Subcommittee on Oversight and Investigations, House Committee on Energy and Commerce. GAO's mandate was to examine the consistency, efficiency, and effectiveness of the federal food safety inspection system.

Summary of Recommendations

GAO found that 12 agencies that were involved in food safety inspect similar foods posing similar risks at inconsistent frequencies and under different enforcement authorities. It also found long-standing problems whereby those agencies use their inspection resources inefficiently and do not effectively coordinate with each other. GAO recommended that "Congress hold oversight hearings to evaluate options for revamping the federal food safety and quality system, including creating a single food safety agency responsible for administering a uniform set of food safety laws."

On October 8, 1997, a GAO division director advocated before the Senate Agriculture Committee that all federal food safety functions be assigned to a new agency. He stated that GAO "believes the existing federal food safety structure needs to be replaced with a uniform, risk-based inspection system under a single food safety agency. While some administrative actions can be taken to improve the system, the fundamental changes that are needed will require legislative action."[29]

Dissenting Views

DHHS officials responded to this GAO report by stating that there was no reason to believe that creating a new single agency would improve basic food safety. FDA, through DHHS, suggested that it could, without new legislation, formally establish regulations that could address the nature and extent of problems encountered by the food production industry; the food industry could be held accountable for self-regulation to an even greater degree; and a policy that compares risks could be established through regulation. The response implied that an independent agency was unnecessary. In addition, FDA claimed that the GAO report failed to analyze some major issues for the food industry such as whether the food industry needs uniformity in regulations by states and international harmonization of standards among countries; whether market promotion activities should be commingled with safety regulation; and whether the potential impact of new food technologies, both in producing and

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[28]General Accounting Office, *Food Safety and Quality: Uniform, Risk-based Inspection System Needed to Ensure Safe Food Supply*, GAO/RCED-92-152, June 1992.

[29]Robert A. Robinson, Director, Food and Agriculture Issues, RCED/GAO, "Food Safety: Fundamental Changes Needed to Improve the Nation's Food Safety System," statement for the record before the Senate Committee on Agriculture, Nutrition, and Forestry, 8 October 1997.

developing new and novel foods, would affect how regulations could ensure food safety.

Popular Name and Date

The Durenberger Food Safety Bill, 1993.[30]

Description and Mission of Group Making Recommendations

On August 3, 1993, Senator Durenberger introduced S. 1349, the Food Safety and Inspection Agency Act of 1993. It was referred to the Senate Committee on Governmental Affairs. There were no hearings on this bill.

Summary of Recommendations

The act, if passed, would have placed all food safety and inspection activities in a single, independent agency that, with the guidance of a 15-person expert commission, would have set uniform risk-based inspection standards by which food safety could be ensured. It also would have established a state-federal communications network to educate consumers on potential microbial diseases.

Dissenting Views

Some critics claimed that the proposed bill did not clearly define what a uniform risk-based safety system was or how the existing two separate field-inspection systems would be organized. Also, critics claimed that this bill would have cost the federal government more to create a new agency than to transfer responsibility to an existing agency.

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[30]S. 1349 was introduced by Senator Durenberger on 3 August 1993.

Popular Name and Date

The Torricelli/Bradley Food Safety Bill, 1994.[31]

Description and Mission of the Group Making Recommendations

The Katie O'Connell Safe Food Act (H.R. 3751) was introduced on January 26, 1994, by Representative Robert G. Torricelli. It was referred to the House Committees on Energy and Commerce and Agriculture. On February 1, 1994, it was referred to the Agriculture Subcommittees on Livestock, and Departmental Operations and Nutrition; and on February 24, 1994, it was referred to the Commerce Subcommittee on Health and the Environment. On August 2, 1994, Senator Bradley introduced the Katie O'Connell Safe Food Act (S. 2350); it was referred to the Senate Committee on Agriculture, Nutrition, and Forestry. No hearings were held on either bill. The bills received only a few cosponsors: three for H.R. 3751 and one for S. 2350.

Summary of Recommendations

The act, if it had passed, would have transferred responsibility for enforcing meat, poultry, and egg inspections from FSIS of USDA to an independent federal health agency called the Meat, Poultry and Eggs Inspection Agency. It would have created a position of director of meat, poultry, and eggs inspection and authorized 8 assistant directors. It also would have established an advisory commission made up of representatives from federal and state governments, industry, and the scientific community. This advisory commission would have recommended how the agency could improve inspection by using more technologically advanced techniques in meat, poultry, and egg product inspections.

Dissenting Views

No dissenting views available, but the bill had few cosponsors.

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[31]H.R. 3751 was introduced 26 January 1994; S.2350 was introduced 2 August 1994.

Popular Name and Date

The Fazio-Durbin Food Safety Administration Bill, 1997.[32]

Description and Mission of Group Making Recommendations

In November 1997, Representative Vic Fazio and Senator Richard Durbin introduced identical bills, the Safe Food Act of 1997. On November 4, 1997, H.R. 2801 was referred to the Committees on Agriculture and Commerce and, on November 14, 1997, to the Subcommittee on Health and the Environment. S. 1465 was introduced on November 9, 1997, and referred to the Committee on Government Affairs. So far, there have been no hearings.

Summary of Recommendations

This act, if passed, would consolidate all federal food safety, labeling, and inspection programs into a new independent agency known as the Food Safety Administration (FSA). The new agency would be funded by transferring appropriated funds that are currently designated for food safety functions of four agencies (FDA, USDA, EPA, and National Marine Fisheries Service). According to supporters, the purpose of the new agency would be to replace an outdated, fragmented, and overlapping food safety system. Supporters also say that a single food safety agency could identify the most serious public health risks from specific food-borne pathogens. In addition, resources could be used to develop better testing methods, conduct risk assessments, and identify the most cost-effective interventions without regard to the type of food or bureaucratic "turf."

Dissenting Views

Critics believe that the time is not right for major reform of the current food safety system. Some resist the formation of a new agency because of fear that a whole new FSA would cause dislocation and upheaval. It could also mean that the current parent agencies would have to relinquish their budget authority and control over functions related to food safety. Most opponents to an independent agency advocate allowing the Clinton Administration's 1997 food safety initiatives to take effect. They await the Administration's reports to Congress as to whether these new policies reduce incidences of food-borne illnesses. Other critics claim that the proposed legislation does not define a new food safety mandate to be carried out, but only reorganizes food safety functions by moving the current functions to the new FSA. They argue that a new FSA could be hindered in setting priorities for food safety activities because the bills would not amend or change the basic food safety statutes that establish the policies on which the current food safety system is based. For example, the meat and poultry statutes require that a government inspector be in continuous attendance and the food and drug statute grants FDA the authority to act only when adulterated and/or misbranded foods are found in interstate commerce.

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[32]H.R. 2801 was introduced 4 November 1997; S.1465 was introduced 9 November 1997.

Food Safety Under the U.S. Department of Agriculture

Popular Name and Date

The Hoover Commission Report, May 20, 1949.[33]

Description and Mission of the Group Making Recommendations

Headed by Herbert Hoover, former President of the United States, the Commission on Organization of the Executive Branch of the Government was established in accordance with P. L.80-162, approved July 7, 1947. It was created by unanimous vote of Congress in July 1947, and submitted a series of reports to Congress. The Lodge-Brown Act, which brought the commission into being, conceived of its mission as being bipartisan. Therefore it had six members from each party. Four Commissioners each were chosen by the President of the Senate, the Speaker of the House of Representatives, and President Truman. The Commission members consisted of Herbert Hoover, Chairman; Dean Acheson, Vice Chair; Arthur S. Flemming; James Forrestal; George H. Mead; George D. Aikin; Joseph P. Kennedy; John L. McClellan; James K. Pollock; Clarence J. Brown; Carter Manasco; and James H. Rowe, Jr.

Summary of Recommendations

The commission recommended that all regulatory functions relating to food products be transferred to the Department of Agriculture and that those relating to other products be placed under a reorganized Drug Bureau administered by a public health agency. At the time, four agencies (Federal Security Agency, Federal Trade Commission, the Bureau of Internal Revenue in the Treasury Department, and USDA) exercised food regulatory functions, and some manufacturers had to comply with the regulations of more than one federal agency. The commission noted that many regulations related to food were once the responsibility of the Department of Agriculture. The commission found that, "their separation from other departmental activities [meaning USDA's activities]...creates great overlap and also confuses the public." With food inspections scattered among four government agencies, the commission argued that too many agencies had jurisdiction over food and drug products.

Dissenting views

Two of the commissioners, James K. Pollock, and James H. Rowe, Jr., disagreed with the recommendation to transfer the food regulatory activities of the FDA to USDA. They claimed that the purpose of the food provisions of the FFDCA was to protect the consumer. They advocated that a unified program under the FDA part of the Federal Security Agency should be kept together. They also stated that one food safety system under the FDA, that "safeguarded" consumers from a series of common problems, would accomplish that purpose. The common problems were characterized

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[33] *The Hoover Commission report on organization of the Executive Branch of the Government (1947-1949)*. Westport, CT: Greenwood Press, 1970).

as "economic cheating (misleading and deceptive labels, substitution of cheaper ingredients, short weight); filth and other extraneous or obnoxious materials; harmful products or products containing harmful ingredients." The dissenting Commissioners also believed that splitting the regulatory functions of foods and drugs between two separate agencies would require two sets of laboratories and staffs working independently of each other and would limit the flexibility and economy of work assignments. These commissioners, the Committee on Medical Services, and the Brookings Institution recommended that the [food safety] function be continued as part of a reorganized public health service within the Federal Security Agency or its successor.

Popular Name and Date

Acts Restructuring Meat and Poultry Products Inspection: Wholesome Meat Act of 1967 and the Poultry Products Act of 1968.[34]

Description and Mission of Group Making Recommendations

The Wholesome Meat Act of 1967[35] substantially revised the 1906 Meat Act. Soon afterwards, the Wholesome Poultry Act[36], signed on August 18, 1968, extended to poultry inspection many aspects of the meat inspection act approved in 1967. These acts were the result of a long debate over the differences in federal, state, and local meat inspections. The federal system continued to be responsible for meats moving in interstate commerce and international trade, whereas state and local authorities oversaw meats consumed in their own jurisdictions. Thus, the control over all meat products was mixed; some areas had rigid standards, and others had lax standards. From this background came a call for legislation setting common standards from various interested groups.

The Talmadge-Aiken Act of 1962 had provided for cooperation among federal and state agencies in regulating the marketing of agricultural products. However, few states took advantage of the authority to enter into broad cooperative agreements for meat inspection with USDA. Under the Talmadge-Aiken Act, the states were to establish "equal to" meat inspection systems. In 1967, President Johnson urged that the law be amended to provide greater protection to consumers and federal assistance to states in developing state inspection programs.

Summary of Recommendations

Both Acts required states to have meat and poultry inspection programs "at least equal in rigor to" federally-run programs (under APHIS), even though the state-inspected plants could still market their products only within the state. Under deadlines of December 1969 (meat) and August 1970 (poultry), states could receive federal matching funds to bring their programs up to federal safety and purity standards. One-year extensions could be granted under certain conditions. The Acts encouraged uniformity in the inspection systems and closed loopholes in various phases of the inspection program. Annual reports to Congress on operations and effectiveness of the inspection system were required.

Interest in restructuring the meat and poultry inspection systems had grown as certain Members of Congress became aware that some food additives were becoming a safety problem. Members received letters from constituents concerned about the

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[34]Vivian Wiser, "Part V: Meat and Poultry Inspection in the United States Department of Agriculture," in, *100 Years of Animal Health. 1884-1984*, eds.Vivian Wiser, Larry Mark, and H. Graham Purchase (Beltsville, MD: The Associates of the National Agricultural Library, 1986).

[35]P.L. 90-201.

[36]P.L. 90-492.

presence of nitrosamine, a carcinogen, in bacon. Food processors added nitrite as a curing agent to pork, and that addition caused the formation of nitrosamine when the naturally occurring amine and nitrite combined. Consumers were also alarmed about meat safety when Canada prohibited meats from DES-treated animals (DES — Diethylstilbestrol — is a synthetic estrogenic drug) to be sold in its market. At the time, FDA considered banning its use altogether.

Dissenting views

There were charges that APHIS wanted the complete federalization of meat inspection. A number of representatives of the packing and processing industries joined others from some state agriculture departments opposing the new federal inspection programs. However, over time, the states dropped out of the meat inspection business because of its high cost. By 1976, APHIS inspectors monitored meat and poultry processing in 60% of the nation's plants.

Food Safety Under the Food and Drug Administration

Popular Name and Date

HEW Reorganization Directive of March 1968.[37]

Description and Mission of Group Making Recommendations

President Lyndon Johnson sent a message to Congress on March 4, 1968, with "Health Recommendations." Among the many proposals and recommendations was a directive to the Secretary of Health, Education, and Welfare to submit a "modern plan of organization to achieve the most efficient and economical operation of the health programs of the Federal Government." On March 13, 1968, the Secretary of Health, Education, and Welfare (HEW), Wilbur J. Cohen, announced his first step in carrying out the President's directive. He placed the FDA and the Public Health Service under the direction of Dr. Phillip R. Lee, the Assistant Secretary for Health and Scientific Affairs. The Commissioner of Food and Drugs would report directly to Dr. Lee, rather than to the Secretary. On June 14, 1968, Secretary Cohen's report to the President was made public and recommended the creation of a new Consumer Protection and Environmental Health Service (CPEHS) which would include FDA along with other agencies.

Summary of Recommendations

The rationale for making FDA a part of the newly created CPEHS was stated in the message from the Secretary to the President:

> The fact that similar or interacting contaminants manifest themselves in more than one type of environmental exposure argues strongly for focusing in a single agency the responsibility for identifying the hazards to health, developing and promulgating criteria and standards, and mounting programs that will promote compliance therewith. ... Retention of a separate FDA relates to its history as a regulatory agency with an operational pattern historically different from that of the Public Health Service (PHS). The historic role of the FDA has been primarily one of policing industry to assure compliance with provisions of the FFDCA. ... In the last two years, the FDA has markedly modified its policeman posture [with the food industry.]

The Secretary said that, with this new attitude and with states taking over most of the routine surveillance of industry practices, the justification of keeping FDA and PHS as separate agencies had disappeared.

Dissenting views

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[37]Wallace Janssen, "FDA Since 1962," in unpublished papers, *History of the Department of Health, Education and Welfare During the Presidency of Lyndon Baines Johnson, November 1963 - January 1969*, kept in the FDA History Office by John Swan.

In the 1968 reorganization Directive of the President, CPEHS was formed to deal with environmental problems, but it never received congressional authorization or appropriations. Other federal programs, funded at the time, contributed funding and positions. Dr. Winton Rankin, Deputy Commissioner of FDA reportedly commented: "We gave him [C.C. Johnson, Director of CPEHS] whatever bit of lip service we had to but didn't offer much cooperation. He finally went under." Dr. Rankin also said that he thought that if CPEHS succeeded, FDA would cease to exist.[38]

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[38]Brannon, *Organizing and Reorganizing FDA*, 135-174.

Popular Name and Date

The Malek Report, December 10, 1969.[39]

Description and Mission of Group Making Recommendations

On December 10, 1969, Frederick V. Malek, Deputy Undersecretary, Department of Health, Education, and Welfare became chairman of a Special Task Force on the Reorganization of the Consumer Protection Programs. The task force's report to Dr. Charles C. Edwards, FDA Commissioner, was called *Analysis and Recommendations: The Food and Drug Administration Organizational Review*. It contained an organizational and management study of the FDA. The report was delivered August 25, 1970.

Summary of Recommendations

The task force's report proposed a reorganization of FDA because of a growing concern over FDA's ability to carry out its consumer protection responsibilities. The report recommended that FDA become a separate health agency reporting to the Assistant Secretary for Health and Scientific Affairs, and a new Consumer Protection and Environmental Health Service be created separate from FDA. Within FDA, a new bureau for foods, pesticides, and product safety should be created along with a new drug bureau. Each should have full responsibility and authority from initial research to final regulatory action. The rationale was that the new Food Bureau could concentrate on its major product areas without jeopardizing other product areas and would create clearer lines of authority for FDA's compliance activities.

Dissenting Views

Not Available

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[39]House Committee on Interstate and Foreign Commerce, Subcommittee on Commerce and Finance, *Hearings on the Consumer Product Safety Act*, 92nd Cong., 1st and 2nd sess., part 3, Nov. 1, 1971-Feb. 3, 1972, H.Rept. 92-61.

Popular Name and Date

Senate Governmental Affairs Report on Federal Regulation, 1977.[40]

Description and Mission of Group Making Recommendations

The Chairman of the Senate Committee on Governmental Affairs, Abraham Ribicoff, submitted *Study on Federal Regulation* to Walter F. Mondale, President of the Senate on December 21, 1977. The report was prepared under the authority of Senate Resolution 71, which authorized the Governmental Affairs Committee to conduct a study on various aspects of the federal regulatory process.

Summary of Recommendations

Senator Ribicoff hoped that the report would provide a basis for congressional action. The report recommended a transfer of USDA food regulatory functions to FDA. The report stated, "Divided responsibility for regulating food production has resulted in a regulatory program which is often duplicative, sometimes contradictory, undeniably costly, and unduly complex." The report asserted an urgent need to combine and rationalize the dual food regulation system that had existed over 70 years. "We believe the bifurcated food regulatory system should be unified in a single agency."

Dissenting Views

The proposal would have split employees located throughout the country (known as the field force) between the two administrations. USDA officials claimed that USDA's greatest strength was its network of field offices in operation throughout the country, as well as the experience and skills of its field staff. USDA officials were concerned that the transfer of USDA employees to another agency would weaken the network system.

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[40]Senate Committee on Governmental Affairs, "V. Regulatory Organization" in *Study on Federal Regulation*, 95th Cong., 2d sess., December 1977, S Rept. 95-91, 140.

Popular Name and Date

President Carter's 1978 Government Reorganization Project or White House Study (never released).[41]

Description and Mission of Group Making Recommendations

In February 1978, during testimony before the Appropriations Subcommittee on Agriculture, Rural Development and Related Agencies, chaired by Representative Whitten, spokespersons for the Carter Administration referred to the President's White House Study for Reorganization. Two of the most prominent officials were the Secretary of Agriculture, R. Bergland, and D. Angelotti, Administrator of the Food Safety and Quality Service (FSQS) (a precursor of FSIS).

Summary of Recommendations

The project recommended consolidation of all federal food regulatory functions. The final report did not resolve where the new organization would be located, although the HEW Secretary Joseph Califano suggested that FDA take over USDA's meat and poultry inspection and labeling duties. In 1977, USDA had formed the FSQS. Its mission was to enhance coordination among food inspection activities as well as food grading, certification and purchasing. USDA made clear that it had reorganized itself along functional lines, and, therefore, it did not believe consolidation of its food safety functions with FDA functions would be beneficial.

Dissenting Views

USDA Secretary Bergland countered Secretary Califano's suggestion with the idea that FDA food inspection authority be transferred to the new FSQS. Secretary Bergland stated, "The President's Reorganization Task Force is reviewing the desirability of combining FDA food activities, and USDA food safety and quality activities operations." In November 1977, HEW proposed that USDA's meat and poultry inspection activities and the women-infants-children program be consolidated within HEW. In February 1978, USDA proposed an alternative arrangement of functions. No final reorganization was initiated.

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[41]House Committee on Appropriations, Subcommittee on Agriculture, Rural Development, and Related Agencies, *Hearings on Agriculture, Rural Development and Related Agencies Appropriations for 1979*, 95th Cong., 2nd sess., February 1978, 75 and 367-371.

Popular Name and Date

Lester Crawford, 1980.[42]

Description and Mission of Group Making Recommendations

From 1987 to 1991, Dr. Lester Crawford was the Administrator of USDA's Food Safety and Inspection Service. In a speech at the 1980 U.S. Animal Health Association annual meeting, he recommended that one agency would do a better job in formulating food regulatory policies.

Summary of Recommendations

Dr. Crawford stated, "Managerially unsound and duplicative systems of regulation will cause us all to still be spinning on our collective wheels decades from now." He suggested a number of alternatives: 1) consolidation of all food safety functions within DHHS; 2) transfer of FDA's Center of Food Safety and Applied Nutrition (CFSAN) and Center for Veterinary Medicine (CVM) to USDA; or 3) at least merge CFSAN with CVM.

Dissenting Views

Several food safety activists objected to moving all food safety responsibility to USDA, because USDA is not linked to the Public Health Service as is FDA. They argued that communication could be improved on food safety standards if all food safety agencies were affiliated with public health agencies such as the Centers for Disease Control and the National Institutes of Health.

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[42]Lester Crawford, "Critique of Animal Health Regulation," in *Proceedings of the 84th Annual Meeting*, (Washington, D.C., U.S. Animal Health Association, 1980.)

Popular Name and Date

Dr. Sanford Miller, 1989.[43]

Description and Mission of Group Making Recommendations

Dr. Sanford Miller was the director of the Center for Food Safety and Applied Nutrition at FDA from 1978 to 1987. He is a national voice on public policy relating to nutrition and food sciences.

Summary of Recommendations

In discussing the underlying philosophical dynamic for the leading food safety agencies, which he believed has led to unnecessary controversies, Dr. Miller recommended that it was time to review the structure of food regulation in the United States. He suggested that it would be reasonable for the President and Congress to appoint a very senior level commission to review the requirements for an optimal food regulatory process and make recommendations. Dr. Miller stated, "The commission might very well conclude that the current setup is the best that we can devise, or it may propose a single agency, perhaps at the level of EPA."

Dissenting views

Not Available

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[43]Sanford Miller, "Quest for Safe Food: Knowledge and Wisdom," 1989 S. B. Hendricks Memorial Lecture of the USDA, ARS presented before the American Chemical Society, Miami Beach, Florida, 11 September 1989, (Washington:GPO, 1990), 11.

Popular Name and Date

The Edwards FDA Advisory Committee, May 1991.[44]

Description and Mission of Group Making Recommendations

The committee was chaired by Dr. Charles C. Edwards, the former FDA Commissioner (1969-1973), and former Assistant Secretary for Health (1973-75). One of its members, Dr. David A. Kessler, later became the FDA Commissioner. The purpose of the committee was to examine FDA's mission, responsibility, and structure according to its legislative mandate, and to recommend how FDA could be strengthened to fulfill its mission. The committee was to provide advice accordingly to the Secretary of DHHS and to the Assistant Secretary for Health and did so in the *Final Report of the Advisory Committee on the Food and Drug Administration*.

Summary of Recommendations

The Committee recommended that FDA be removed from the Public Health Service (PHS) and that the FDA Commissioner report directly to the Secretary of Health and Human Services. It also recommended that the Secretary of DHHS directly delegate to the Commissioner the authority to issue regulations implementing all the laws that FDA administers and to manage the daily operations of the Agency.

The Food Policy Subcommittee of the Advisory Committee recommended that FDA move immediately to improve the Center for Food Safety and Applied Nutrition (CFSAN) management system, increase its resources, upgrade the development of its program planning, and delegate additional authority to the CFSAN director. It also recommended that the Commissioner establish one task force to ensure that FDA meet its nutrition labeling obligations and another to assist CFSAN in resolving scientific and technical issues. It also said that it found no evidence to show that FDA's performance would improve if its human food responsibilities were combined with those of USDA. It recommended the establishment of a consistent approach to risk assessment among regulatory agencies responsible for food safety (FDA, EPA, and USDA), including for food derived from animals.

Dissenting Views

The Secretary of DHHS responded that the location in Public Health Service (PHS) was not the source of FDA problems. The Secretary contended that FDA gained from the close scientific interaction with other PHS agencies on issues such as AIDS epidemiology and research, pertussis vaccine, outbreaks of *Salmonella* Enteritidis, dental amalgam problems, and food safety issues.

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[44]Department of Health and Human Services, *Advisory Committee on the Food and Drug Administration. Final Report.* May 1991. Charles C. Edwards. Chairman,, (Washington. 1991) iii-iv, 19-24.

Popular Name and Date

National Performance Review, September 1993.[45]

Description and Mission of Group Making Recommendations

Vice President Al Gore published his report of the National Performance Review (NPR) on September 7, 1993. He had been asked by President Clinton to undertake a 6-month study of the federal bureaucracy and make recommendations on how to create a government that works better and costs less.

Summary of Recommendations

The Review recommended that all federal food safety responsibilities be placed under the FDA.

Dissenting Views

A working group of government food safety officials advising the Vice-President's staff in preparing the NPR had recommended that an independent agency be created that would administer a science-based food safety system that would apply the same standards to all foods, thereby representing a more effective method of preventing food-borne illnesses. The working group also suggested that four policy initiatives were needed in conjunction with creating the new agency. The group suggested locating the new agency within the executive branch so that the congressional committees who would be responsible for oversight and the appropriation of its funds would be those "whose principal concerns are the health and economic welfare of this countries' citizens, and not those whose principal interests are in the economic welfare of the producers of food or the inspected food industries." The group also suggested that Congress should amend existing food safety laws to provide uniform regulatory authority that would be adequate to monitor and control food-borne health hazards at any point in the country's food production system. The group suggested that all food safety research functions be assigned to the single food safety agency. Finally, the group wanted the agency to fill each decision-making position with people who had appropriate scientific backgrounds.

None of those recommendations were in the final National Performance Review report. Some in Congress would have preferred that FSIS absorb all food and seafood inspection responsibilities. For example, House Speaker Thomas S. Foley said that, if USDA regulated all foods, the FDA would be free to concentrate on the safety of drugs.[46]

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[45]Al Gore, "From Red Tape to Results: Creating a Government That Works Better and Costs Less," in *Report of the National Performance Review*, (Washington, D.C., 7 September 1993), 101.

[46]Kenneth J. Cooper, "Hill Turf Fights May 'Reinvent' Gore Proposals," *Washington Post*, 13 September 1993, A19; Also see Rodney E. Leonard, "A Single Food Safety Agency," *Nutrition Week*, v. 23, September 1993, 2.

Popular Name and Date

Carol Tucker Foreman, Safe Food Coalition, October 6, 1993.[47]

Description and Mission of Group Making Recommendations

These recommendations, in the form of a press release issued by the Safe Food Coalition, reflect support for reorganizing food safety functions from the American Public Health Association, Center for Science in the Public Interest; Consumer Federation of America; Consumers Union; Food and Allied Service Trades AFL-CIO; Government Accountability Project; National Consumers League; Public Citizen; Public Voice for Food and Health Policy; United Food and Commodity Workers International Union. Ms. Foreman is a former Assistant Secretary of Agriculture.

Summary of Recommendations

The press release states that the Safe Food Coalition strongly endorses Vice President Gore's National Performance Review recommendation that would transfer USDA's meat and poultry inspection functions to FDA. The Coalition believes that the inspection of meat and poultry should be a public health program and should be within the responsibility of a public health agency. In supporting the consolidation of food safety functions within the FDA, the Coalition cited two concerns that they believed prevented USDA from effectively administering an adequate food safety inspection program. First, they believe that USDA knows more about animal health than human health, and second, that USDA cares more about promoting sales of agricultural products than it does about protecting consumers.

Dissenting Views

Giving the task of regulating meat and poultry to FDA would be similar to "the gnat swallowing the elephant," says a New York Times reporter, Marian Burros, in a newspaper article at the time.[48] FDA currently has about 1,042 full time equivalent (FTE) positions to do all types of inspection and to analyze food samples and other products, whereas FSIS of USDA has about 7,500 FTEs to inspect meat and poultry.

The types of inspections are somewhat different from one agency to the other. FDA staff pointed out that most FDA inspectors have extensive scientific training. FDA inspectors also make periodic inspections of food plants where they can take samples for laboratory analysis, check temperatures in canning processes, check machinery, and collect information in their evaluations to be able to support any regulatory action that may lead to a legal proceeding. FSIS staff explained that FSIS meat and poultry inspectors rely on constant and daily organoleptic inspection (based on sight, touch, or smell) of products as they flow by on the assembly line. FSIS

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[47]Safe Food Coalition, "Safe Food Coalition Endorses Gore Proposal to Consolidate Food Safety Functions," Press Release and Letter to Members of the House, 6 October 1993; Ms. Joy Stevens, FDA/OLA, conversation with author, 2 September 1993.

[48]Marian Burros, "Clinton Plan Would Move Meat and Poultry Inspections to FDA" *New York Times*, 13 September 1993, A18.

inspectors can immediately condemn carcasses that do not pass standards. They also can take samples and send them for laboratory analysis, and inspect both the product and the paperwork connected with exports and imports.[49] In addition to the organoleptic approach, FSIS inspectors check each meat or poultry plant's Hazard Analysis and Critical Control Point (HACCP) plan and records. Every meat and poultry plant must implement, by the year 2000, a HACCP plan that identifies where hazards occur and what steps are needed to control those hazards.[50]

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[49]Mrs. Joy Stevens, FDA/OLA, telephone conversation with author, 23 September 1993. Will Kerr, USDA/FSIS/BFPB, telephone conversation with author 24 September 1993.

[50]Congressional Research Service, *Food Safety Issues in the 105th Congress*, by Donna U. Vogt, IB98009, March 30, 1998; and *Meat and Poultry Inspection Issues*, by Jean Rawson, IB 95062, March 1998.

Popular Name and Date

Hearings in Support of the Vice President's National Performance Review Recommendations for Reinventing the Food Safety System, 1993-1994.[51]

Description and Mission of Group Making Recommendations

A series of five hearings of two subcommittees of the House Committee on Government Operations took place during both sessions of the 103rd Congress. The Subcommittee on Human Resources and Intergovernmental Relations held hearings on Nov. 4 and 19, 1993 (both were on USDA's progress in reforming meat and poultry inspection); May 25, 1994 (review of FDA's food safety programs); Sept 28, 1994 (chemical residues and contaminants in food); and a joint hearing with the Subcommittee on Information, Justice, Transportation, and Agriculture on June 16, 1994 (fresh versus frozen chickens and other issues involving USDA's regulation of poultry products).

Summary of Recommendations

The hearing records contain thousands of pages of testimony and submitted documents from hundreds of experts considering whether the current federal food safety system is adequately protecting U.S. consumers; whether the existing system has a comprehensive federal food safety mission and objective that protects the public's health; and whether Vice President Gore's National Performance Review recommendation to consolidate all federal food safety programs within FDA is warranted. Principally, most of the recommendations discussed the need to revise the food safety system to monitor for microbiological pathogens in the food supply and to prevent food-borne illnesses. Representative Edolphus Towns stated in his opening remarks, "The current federal food safety system is not just fragmented; it is broken. The system is not designed to prevent food-borne disease...There is no question about it. USDA has known for over 20 years that its inspection system cannot detect harmful microbes in meat and poultry, but did absolutely nothing about it." Several witnesses also testified on the need to transfer meat and poultry inspection functions to a "public health" agency because of the perceived conflict in USDA's dual mission, agriculture production and consumer protection.

Dissenting Views

USDA officials testified that they were implementing a "two track" approach for reforming the meat and poultry safety system: first, to maximize the performance of the current inspection system; and second, to design, test, and implement a regulatory program for the future. A key component of this approach was the Pathogen Reduction Program/Hazard Analysis and Critical Control Point system aimed at reducing the likelihood of harmful microorganisms that could enter the food system anywhere in the production, distribution, and consumption chain. USDA officials

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[51] House Committee on Government Operations, *Hearings on Reinventing the Federal Food Safety System*, 103rd Cong., 1st and 2nd sess, v. 1 and 2, 1995, Joint Committee Print.

and representatives from state agriculture and health departments testified that there was no need to reorganize food safety activities because, in carrying out food safety inspections and other activities, they were ensuring already that the foods under their jurisdictions were safe.

Food Safety Under the Consumer Product Safety Commission

Popular Name

The Metzenbaum Bill, 1993.[52]

Description and Mission of Group Making Recommendations

The Food Safety Reform Act of 1993 (S. 1750) was introduced on November 20, 1993, by Senator Metzenbaum and was referred to the Senate Committee on Governmental Affairs. S. 1750 had no cosponsors.

Summary of Recommendations

The act would have transferred to the Consumer Product Safety Commission (CPSC) all food safety and inspection functions of the USDA and the Departments of the Interior and Commerce, FDA, and EPA. It would have established the position of "Executive Director of Food Safety" in the CPSC, which would be charged with preparing and submitting to the appropriate congressional committees a plan for a nationwide food safety database and the implementation of food inspection techniques. The plan would include hazard analysis of critical control points, rapid pathogen detection, trace-back technology, food irradiation, and other necessary techniques. The purpose of this bill would have been to centralize responsibility for the management of all federal food safety activities into one existing agency to lessen the cost on the federal budget.

Dissenting Views

Not Available

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[52]S. 1750 was introduced 20 November 1993.

Table 2. Recommendations for Changes in the Federal Organization of Food Safety Responsibilities, 1949-1997
(In chronological order)

Name and Source	Proposed Changes in Organization
1949 The Hoover Commission Report. U.S. Commission on Organization of the Executive Branch of the Government (1947-1949). May 20, 1949. Westport, CT:Greenwood Press, 1970.	Recommended that all regulatory functions relating to food products to protect the consumer be transferred to USDA and that those relating to other products be placed under a reorganized Drug Bureau administered by the public health agency.
1968 Department of Health, Education, and Welfare Reorganization Directive of March. Found in: Janssen, Wallace. FDA Since 1962. Vol. 1. Unpublished papers entitled History of the Department of Health, Education and Welfare During the Presidency of Lyndon Baines Johnson. November 1963 - January 1969.	Placed FDA under the Public Health Service and in July 1968 made FDA a part of the newly created Consumer Protection and Environmental Health Service (CPEHS). FDA received resources devoted to pesticides, shellfish, product safety, and poison control from other Public Health agencies. FDA then began to operate under the Public Health Service Act.
1967-68 Acts Restructuring of Meat and Poultry Inspection: Wholesome Meat Act of 1967, and the Poultry Products Act of 1968. U.S. Department of Agriculture. Economic Research Service. National Economy and History Branch. Agriculture and Rural History Branch. Unpublished chapters from forthcoming history of the Food Safety and Inspection Service.	Both required states to have meat and poultry inspections programs "at least equal in rigor to" federally run programs (under APHIS), even though the state-inspected plants could still only market their products within the state. Under deadlines of December 1969 (meat) and August 1970 (poultry), states could receive federal matching funds to bring their programs up to federal safety and purity standards. One-year extensions were to be granted under certain conditions.
1969 White House Conference on Food, Nutrition, and Health. Final Report. Washington, D.C. 1969.	Recommended that there should be one federal regulatory policy with respect to safety, sanitation, identity, and labeling of foods.

Name and Source	Proposed Changes in Organization
1969 Malek Report. House Committee on Interstate and Foreign Commerce. Subcommittee on Commerce and Finance. Consumer Product Safety Act. Hearings, 92nd Congress, 2nd sess. Part 3, Nov. 1, 1971-Feb. 3, 1972. Serial No. 92-61. Washington, U.S. Govt. Print. Off., 1972.	Recommended that a new Consumer Protection and Environmental Health Service be created, separate from FDA, with FDA becoming a major health agency reporting to the Assistance Sec. for Health and Scientific Affairs. Within FDA, a new Bureau of Foods, Pesticides, and Product Safety and a Bureau of Drugs would be created, each with full responsibility and authority for all activities from initial research to final regulatory action.
1970 General Accounting Office, Need to Reassess Food Inspection Roles of Federal Organizations. Department of Agriculture, Department of Defense, Department of Health Education, and Welfare, Department of the Interior. Report to the Congress by the Comptroller General of the United States. Rept. No. B-168966. June 30, 1970.	Did not specifically recommend consolidation, but criticized the overlapping inspection activities among USDA, FDA, and other federal agencies. Instead, it recommended that the Director, Bureau of the Budget, make a detailed evaluation of the federal food inspection system to see how to improve its administration and determine if it was feasible to consolidate some of the inspections.
1972 Ralph Nader Report. Wellford, Harrison. Sowing the Wind: A Report from Ralph Nader's Center for Study of Responsive Law on Food Safety and the Chemical Harvest. (New York: Grossman Publishers, 1972), 354.	Found that food inspection "remains embarrassed by departmental conflicts of interest and overlapping jurisdictions in USDA and FDA." In its conclusions, the report recommended that meat inspection and chemical monitoring by USDA and the food inspection functions of FDA be transferred to a new food safety agency to improve the likelihood of protecting the public health.

Name and Source	Proposed Changes in Organization
1972 Hearings before the U.S. Senate on S. 3419. Senate Committee on Commerce, Consumer Safety Act of 1972, 92nd Cong., 2nd sess., 1972, S.Rept. 92-749. Senate Committee on Government Operations, Subcommittee on Executive Reorganization and Government Research, S.3419, The Consumer Safety Act of 1972, 92nd Cong., 2nd sess., S.Rept. 92-2. Senate Committee on Labor and Public Welfare, Food, Drug, and Consumer Product Safety Act of 1972, 92nd Cong., 2nd sess., S.Rept. 92-835.	The purpose of S. 3419, Consumer Safety Act of 1972, was to establish an independent agency to regulate foods, drugs, and consumer products. The bill would have combined under a single agency, a number of different responsibilities. The purpose of this independent Consumer Safety Agency was to have been to protect consumers against unreasonable risk of injury from hazardous products. The independent agency would have had responsibility to set product safety standards for all consumer products representing unreasonable risk of injury or death. S. 3419 became the umbrella legislation and was called the Food, Drug, and Consumer Product Safety Act of 1972. It passed the Senate on June 21, 1972.
1977, Senate Committee on Governmental Affairs Report. U.S. Congress. Senate. Committee on Governmental Affairs. Study on Federal Regulation. Senate Document No. 95-91, 95th Cong., 2d sess. vol. V. Regulatory Organization. December 1977. p. 140.	Recommended a transfer of USDA food regulatory functions to FDA.
1978 President Carter's Government Reorganization Project or White House Study (never released). U.S. Congress. House Committee on Appropriations, Subcommittee on Agriculture, Rural Development, and Related Agencies. Agriculture, Rural Development and Related Agencies Appropriations for 1979. Hearings, Parts 1 and 4, Feb., 1978. Washington, D.C., U.S. Govt. Print. Off., 1978. p. 75 (pt.1), p. 367-371 (pt. 4).	Recommended consolidation of all food regulatory functions of FDA.
1980 Lester Crawford Speech. Crawford, Dr. Lester. Critique of Animal Health Regulation. Proceedings of the 84th Annual Meeting. Washington, D.C., U.S. Animal Health Association, 1980.	Suggested consolidation of all food safety functions within DHHS, transfer of FDA's divisions of Center of Food Safety and Applied Nutrition (CFSAN) and Center for Veterinary Medicine (CVM) to USDA, or at least merge CFSAN with CVM.

Name and Source	Proposed Changes in Organization
1989 Dr. Sanford Miller. Quest for Safe Food: Knowledge and Wisdom. 1989 S. B. Hendricks Memorial Lecture presented by Dr. Sanford A. Miller by USDA, ARS before the American Chemical Society, Miami Beach, Florida. September 11, 1989. U.S. Department of Agriculture. Agricultural Research Service. Washington, D.C., U.S. Govt. Print. Off., 1990. p. 11.	Recommended that a special commission be set up to make recommendations on the optimal food safety regulatory process which may be a single agency.
1991 The Edwards Committee Report. U.S. Dept. of Health and Human Services. Advisory Committee on the Food and Drug Administration. Final Report. Charles C. Edwards, Chairman. May 1991. Washington, D.C., 1991. p. iii-iv, 19-24.	Recommended that FDA be removed from the Public Health Service (PHS) and the FDA Commissioner report directly to the Secretary of Health and Human Services
1992 Risk-Based Food Safety Inspection. U.S. General Accounting Office. Food Safety and Quality: Uniform, Risk-based Inspection system Needed to Ensure Safe Food Supply. GAO/RCED-92-152, June 1992.	Recommended that Congress hold oversight hearings to evaluate options for revamping the federal food safety and quality system, including creating a single food safety agency responsible for administering a uniform set of food safety laws.
1993 S. 1349, Food Safety and Inspection Agency Act was introduced by Senator Durenberger and referred to the Senate Committee on Governmental Affairs, August 3, 1993.	Would have placed all food safety and inspection activities in a single, independent agency which would, with the guidance of a 15-person expert commission, set uniform risk-based inspection standards by which food safety would be ensured. In addition, it would have established a state-federal communications network to educate consumers on potential microbial diseases.
1993. National Performance Review. Gore, Al. From Red Tape to Results: Creating a Government that Works Better and Costs Less. Report of the National Performance Review. Washington, D.C. September 7, 1993,101.	Recommended consolidating all federal food safety responsibilities under the FDA.

Name and Source	Proposed Changes in Organization
1993. Carol Tucker Foreman and the Safe Food Coalition, "Safe Food Coalition Endorses Gore Proposal to Consolidate Food Safety Functions," Press Release and Letter to Members of the House, 6 October 1993 in which they strongly supported the National Performance Review recommendation to move the food safety function of inspection of meat and poultry to the FDA. The Coalition is composed of members of the from the American Public Health Association; Center for Science in the Public Interest; Consumer Federation of America; Consumers Union; Food and Allied Service Trades, AFL-CIO; Government Accountability Project; National Consumers League; Public Citizen; Public Voice for Food and Health Policy; United Food and Commercial Workers International Union.	States that the Safe Food Coalition strongly endorses Vice President Gore's National Performance Review recommendation that would transfer USDA's meat and poultry inspection functions to FDA. The Coalition believes that the inspection of meat and poultry should be a public health program and should be within the responsibility of a public health agency. In supporting the consolidation of food safety functions within the FDA, the Coalition cited two concerns that they believed prevented USDA from effectively administering an adequate food safety inspection program. First, they believe that USDA knows more about animal health than human health, and second, that USDA cares more about promoting sales of agricultural products than it does about protecting consumers.
1993 and 1994 Hearings in Support of the Vice President's National Performance Review Recommendations for Reinventing the Food Safety System. House Committee on Government Operations, Hearings, *Reinventing the Federal Food Safety System*, 103rd Cong., 1st and 2nd Sess., Volume 1 and 2. Washington, D.C.:GPO, 1995.	Hearing experts discussed whether the current federal food safety system was adequately protecting U.S. consumers, whether the existing system has a comprehensive federal food safety mission and objective that can protect the public health, and whether Vice President Gore's National Performance Review recommendation to consolidate all federal food safety programs within FDA is warranted.
1993 The Food Safety Reform Act (S. 1750) was introduced on November 20, 1993 by Senator Metzenbaum and referred to the Senate Committee on Governmental Affairs.	Would have transferred to the Consumer Product Safety Commission (CPSC) all food safety and inspection functions of the USDA, and the Departments of the Interior and Commerce, FDA, and EPA.

Name and Source	Proposed Changes in Organization
1994 The Katie O'Connell Safe Food Act (H.R. 3751) was introduced on January 26, 1994 by Representative Robert G. Torricelli; it was referred to the House Committees on Energy and Commerce and Agriculture. On February 24, 1994, it was referred to the Commerce Subcommittee on Health and the Environment; and on Feb. 1, 1994 it was referred to the Agriculture Subcommittees on Livestock, and Departmental Operations and Nutrition. On August 2, 1994, Senator Bradley introduced the Katie O'Connell Safe Food Act (S. 2350); it was referred to the Senate Committee on Agriculture, Nutrition, and Forestry.	Would have transferred responsibility for enforcing meat, poultry, and egg inspections from FSIS of USDA to an independent federal health agency entitled the Meat, Poultry and Eggs Inspection Agency.
1997 The Safe Food Act of 1997 (H.R. 2801/S. 1465). Rep. Vic Fazio and Sen. Richard Durbin introduced identical bills. On Nov. 4, 1997, H.R. 2801 was referred to the Committees on Agriculture and Commerce and on Nov. 14, 1997, H.R. 2801 was referred to the Subcommittee on Health and the Environment. S. 1465 was introduced on Nov. 9, 1997, and referred to the Committee on Government Affairs.	Would consolidate all federal food safety, labeling, and inspection programs into a new single, independent agency known as the Food Safety Administration (FSA). The purpose of the agency would be to identify the most serious public health risks from specific food borne pathogens and use resources to develop improved testing methods, conduct risk assessments, and identify the most cost-effective interventions without regard to the type of food or bureaucratic "turf."