REVIEW OF THE IMPACT OF IMPORTED CONTAMINATED FOOD AND FEED INGREDIENTS AND OF RECENT FOOD SAFETY EMERGENCIES ON FOOD SAFETY AND ANIMAL HEALTH SYSTEMS

HEARING

BEFORE THE

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HOUSE OF REPRESENTATIVES

ONE HUNDRED TENTH CONGRESS

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C O N T E N T S

HEARING TO REVIEW THE IMPACT OF IMPORTED CONTAMINATED FOOD AND FEED INGREDIENTS AND OF RECENT FOOD SAFETY EMERGENCIES ON FOOD SAFETY AND ANIMAL HEALTH SYSTEMS

WEDNESDAY, MAY 9, 2007

HOUSE OF REPRESENTATIVES,
COMMITTEE ON AGRICULTURE,
SUBCOMMITTEE ON HORTICULTURE AND ORGANIC AGRICULTURE,
Washington, DC.

The Committee met, pursuant to call, at 11:00 a.m., in Room 1300 of the Longworth House Office Building, Hon. Collin C. Peterson [Chairman of the Committee] presiding.

Members present: Representatives Peterson, Holden, Etheridge, Boswell, Baca, Scott, Pomeroy, Kagen, Donnelly, Musgrave, Neugebauer, Boustany and Goodlatte.

Staff present: Rob Larew, Chandler Goule, Craig Jagger, Tyler Jameson, John Riley, Sharon Rusnak, April Slayton, Debbie Smith, Kristin Sosanie, Lindsey Correa, John Goldberg, Alise Kowalski, Kevin Kramp, Pam Miller, Pete Thomson, and Jamie Weyer.

STATEMENT OF HON. COLLIN C. PETERSON, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MINNESOTA

The CHAIRMAN. The committee will be in order. Welcome everybody. Good morning and welcome to today's hearing of the House Agriculture Committee. I will start by acknowledging our witnesses; Dr. Kenneth Petersen, with the USDA's Food Safety Inspection Service and Dr. David Acheson with the Food and Drug Administration. I want to thank you both for joining us today to update the committee about the current situation surrounding melamine tainted products from China that have been used in pet food and animal feed.

Based on what I have heard from USDA and FDA, I am relieved that contaminated feed does not pose a risk to the health of poultry, swine and farm fish that ate it, nor do the products from these animals pose a threat to the food supply or human health. However, the explanations from USDA and FDA leave me with the uncomfortable feeling that maybe we just got lucky this time. The next time tainted food or feed products slip through the very large cracks in our import inspection system, we may be forced to confront a much more serious situation in terms of animal or human health.

As food and feed imports from countries around the world continue to rise, the rate of inspection of those products entering this country has declined. According to recent newspaper reports, in the past five years, as food imports have grown by almost 50 percent. FDA has lost about 20 percent of its food inspectors. Today, FDA is inspecting only 1 percent of the products that enter the U.S. food supply that it is responsible for monitoring. This is a recipe for major problems down the road and the recalls and quarantines we have seen in response to mislabeled melamine tainted products are minor compared to what we could see in the future if this problem is not addressed.

There are many questions we need to answer as we move forward. First, I am interested to hear if USDA and FDA feel confident about the existing inspection procedures that are in place now. Are those procedures adequate to ensure the safety of imported foods and feed products? If changes need to be made or if additional resources are needed to make those changes, I think the committee should be aware of that.

Second, I am interested in the issue of who bears the ultimate responsibility for the safety and integrity of imported products. Who will ultimately be held responsible for the melamine tainted products? According to news reports, it was common knowledge amongst Chinese manufacturers that melamine was routinely used as an additive to spike protein levels, yet no company or government entity in the U.S. seemed to be aware of it.

For meat and poultry products, we only accept imports from countries with food safety systems that are equivalent to our own, giving consumers here a certain level of assurance about the integrity of those goods. With FDA-regulated food and feed products, however, we have no such assurance that producers in foreign countries are held to any safety standards, whatsoever, much less the kind of standards we expect from our domestic producers.

I hope that the seriousness of the recent risk assessment efforts undertaken by multiple government agencies in the wake of the melamine incidents are not lost on our trade negotiators. Advocates of free trade have done consumers a disservice by failing to address the simple fact that expanding trade with countries that fail to enforce food and safety and environmental standards make our domestic food supply less safe.

I do appreciate the efforts by USDA and FDA to keep the members of this committee and the public informed about the ongoing investigation related to contaminated food and feed products. However, moving forward, I am interested to hear not only how the agencies that reacted to and investigated the current situation, but also what lessons have been learned and what we can do to better detect and protect against adulterated, mislabeled and unsafe imports.

I look forward to hearing more about the current situation today and to addressing some of these serious questions about the safety of products that we are feeding our pets, our livestock and our families. And I would advise members that their opening statements will be made part of the record with the exception of one person, that is my good friend and the ranking member, Mr. Goodlatte

from Virginia. I will recognize him for an opening statement and then we will proceed to the witnesses.

STATEMENT OF HON. BOB GOODLATTE A REPRESENTATIVE IN CONGRESS FROM THE STATE OF VIRGINIA

Mr. GOODLATTE. Well, thank you, Mr. Chairman, and I thank you for calling this hearing. While the committee has been correctly focusing its efforts on the Farm Bill, the recent contamination of pet and livestock feed warrants our attention and continued oversight. It is important to note however, that the Food and Drug Administration and the U.S. Department of Agriculture are still conducting their investigations and there are still many unanswered questions. I appreciate the efforts of both departments to keep the members of the committee updated with the most recent information and look forward to learning the conclusions of their findings once the entire investigation is complete.

As the representative of a district that is heavily oriented towards animal agriculture, I am always interested in any issue that affects livestock feed. And like the rest of my colleagues, I have been approached by family and friends who are quite concerned about the health and safety of their pets. We all sympathize with those who have lost their pets or who have pets that have been adversely affected. As we continue to learn more about this matter, we have discovered that in addition to pets, some hogs and poultry may have also received contaminated feed.

As part of the pet food manufacturing process, there is a certain amount of excess product or ingredients that are sold into the livestock feed processing sector. As far as we know at this point, no one involved in the animal feed business knowingly sold or bought contaminated salvage material. Based on what we know so far, the livestock feed that had been contaminated was sold and consumed before anyone in the United States was aware of the problem. The fact and extent of this occurrence suggests that some attention to the food safety systems of our trading partners may be warranted.

I appreciate the actions thus far by the administration to resolve this issue, specifically the FDA's recent decision to take the extraordinary action of detaining all vegetable protein products imported from China. During the course of sampling various vegetable proteins and products made with vegetable proteins, the FDA has linked all of the samples testing positive for contamination to imports from China. As part of the FDA's investigation, they will identify the actual manufacturer or manufacturers of the contaminated products imported from China.

While the source of the contamination in China is currently unknown, I hope the FDA's detention order will send a strong signal to the Chinese industry and government that we are serious about this issue and will not tolerate violations of our food import standards. I look forward to the testimony of our witnesses and any light that they can shed on this issue. Thank you, Mr. Chairman.

The CHAIRMAN. I thank the gentleman and again want to thank our witnesses for being with us today. Your statements will be made part of the record in their entirety, so we would appreciate it if you could summarize the main points in 5 minutes and welcome to the Committee. Mr. Acheson.

STATEMENT OF DAVID ACHESON, ASSISTANT COMMISSIONER FOR FOOD PROTECTION, U.S. FOOD AND DRUG ADMINISTRATION

Dr. ACHESON. Good morning, Mr. Chairman and members of the committee. I am Dr. David Acheson, Assistant Commissioner for Food Protection at FDA. I am joined here today with my colleagues, Dr. Sundloff from Center for Veterinary Medicine, Dr. Solomon from the Office of Regulatory Affairs and Walter Batts from our Office of International Programs.

In my newly created position, Commissioner von Eschenbach has asked me to provide advice and counsel on strategic and substantive food safety and food defense matters based on my knowledge and experience in the science of food safety. I will discuss FDA's response to the importation of contaminated animal feed ingredients and the impact of this incident on food safety and animal health. But first let me share with you some of the broader complexities and challenges we face in regulating our Nation's food system.

At FDA, ensuring that products we regulate are safe and secure is a vital part of our public health mission. The agency regulates everything Americans eat except for meat, poultry and processed egg products, which are covered by USDA. FDA's responsibility extends to live food animals and animal feed. Through trans-agency cooperation and leveraging FDA public health resources, we are working to ensure that America's food supply is among the safest in the world.

However, we face significant challenges in our mission, such as the increased globalization of the food supply; changing consumer expectations for all foods; changes in farming, manufacturing and processing practices; an outdated infrastructure relative to the increasing complexities; the increased concern of a deliberate terrorist attack on the food supply; and challenges in tracking food rapidly when a problem does arise. The melamine case we are discussing today illustrates many of these challenges we face and highlights the need for new scientific and technological approaches to advanced food protection.

FDA's investigations into contaminated pet food and farm feed began in March 2007 and are an ongoing priority for the agency. As we obtain more investigative and scientific information, our assumptions and knowledge about the problem are constantly changing. The investigations have revealed that the underlying cause of the contamination was imported pet food ingredients which contained the industrial chemical melamine and melamine analogs.

FDA has identified the source, the importer, the supplier and other parties involved with the distribution of contaminated product declared, at entry, as wheat gluten, but which we now know was wheat flour. In mid-April, FDA became aware of a suspicious shipment of a product identified in labeling and import records as rice protein concentrate that was also used in the manufacture of pet foods. Upon inspection, FDA detected the presence of melamine and melamine analogs in the imported protein concentrate and the finished pet food and began its investigation to track and trace all uses of that material.

Some of this contaminated pet food was unknowingly sent as salvage feed to hog producers in several States. Additionally, FDA learned that pet food salvage containing contaminated wheat gluten was used in chicken feed on some farms in the States of Indiana, Missouri and Arkansas. During the past eight weeks we have aggressively worked to identify the sources and scope of the contamination, trace the distribution of contaminated products through the supply chain and assure their removal from store shelves.

FDA's response has been a team effort in which we have mobilized more than 400 employees to collect pet food and animal feed samples, monitor the recall and take consumer complaints; conduct numerous inspections of manufacturing facilities and warehouses to trace the contaminated product and analyze more than 700 pet food and ingredient samples in FDA field labs and our Forensic Chemistry Center. Additionally, we have instituted an import alert covering all vegetable protein products from China in which all entries are detained and examined. We have dispatched investigatory personnel to China and worked closely with agricultural and health agencies in all 50 States.

Finally, we have issued a high priority surveillance assignment for our field staff to examine imported plant protein ingredients and finished products commonly found in the United States' food and feed supply. These products include wheat gluten, corn gluten, corn meal, soy protein, rice bran and rice protein concentrate. At this time we have no evidence of harm to humans associated with the processed pork or poultry products from animals that consumed contaminated feed and we believe the likelihood of human illness from eating these products is very low.

This assessment is based on a number of factors, including dilution of the contaminants in the original protein concentrate as they move through the food system and the fact that the pet food is only part of the total feed given to the chickens and hogs. The assessment also takes into account that these food products are only a small part of the average American diet. The human health risk assessment completed with the input of scientists from FDA, CDC, USDA, EPA and DHS looks at the potential risk to human health from consuming meat from hogs and chickens known to have been fed the contaminated animal feed.

This team is now compiling a scientific assessment of the risk to animal health associated with ingestion of animal feed containing melamine in its compounds. As an added precaution, we have asked CDC to use a surveillance network to monitor for signs of human illness that could indicate a contamination of the human food supply. To further evaluate any potential harm to humans, FDA is developing and implementing additional tests and risk assessments based on the toxicity of melamine compounds and the amounts that consumers could be expected to consume. If any evidence surfaces to indicate there was potential harm to humans, appropriate and aggressive action will be taken.

FDA is examining recent incidents, as well as global food system trends to determine what changes are necessary to improve the safety of human and animal foods. We are focusing our food protection review in three key areas; prevention, intervention and re-

sponse; preventing contamination through strong science-based, risk-based preventative controls with key partners; improved intervention, using modern technology to establish a comprehensive, integrated food information system to analyze information and detect potential product contamination; and rapid response to improve product tracking and related lab research capacity.

We know that the future will require different resources, technology and science to effectively enhance the safety of all human and animal foods. We will continue to work closely with our food protection partners at each point in the supply chain to establish the most protective measures. Mr. Chairman, the animal feed investigation has been a massive effort that will continue until we are completely satisfied that the underlying cause has been determined, the scope is identified and full and complete corrective action has been implemented and found to be effective.

Thank you for the opportunity to discuss these important food safety issues with you. I will be glad to answer questions that you may have.

The CHAIRMAN. I thank the gentleman. I would like to welcome Dr. Petersen. Welcome to the Committee.

STATEMENT OF KENNETH E. PETERSEN, FOOD SAFETY INSPECTION SERVICE, UNITED STATES DEPARTMENT OF AGRICULTURE

Dr. PETERSEN. Good morning, Mr. Chairman, Congressman Goodlatte and other members of the committee. I am the Assistant Administrator for Field Operations for the Food Safety and Inspection Service of the United States Department of Agriculture. We do appreciate the opportunity to appear before you today to discuss this ongoing investigation of animal feed supplemented with pet food scraps containing melamine and melamine related compounds. I also am pleased to be here today with my colleague, Dr. David Acheson, from the Food and Drug Administration.

Before I get to the details, let me begin by emphasizing that FSIS takes very seriously its responsibilities to ensure the safety of meat, poultry and processed eggs products. We do not believe the current incident poses a threat to human health and we are not aware of any human illnesses that ever have been linked to melamine or melamine related compounds. Our mission at FSIS is to ensure that meat, poultry and processed egg products distributed in commerce for use as human food are safe, secure, wholesome and accurately labeled.

FSIS is charged with administering and enforcing the Federal Meat Inspection Act, the Poultry Products Inspection Act, the Egg Products Inspection Act, portions of the Agricultural Marketing Act and regulations that implement these laws. FSIS also ensures compliance with the Humane Methods of Slaughter Act, which requires that all livestock be handled and slaughtered in a humane manner. The agency is responsible for determining equivalence to Federal standards at the State level and among our foreign trading partners.

Essentially, our agency is charged with ensuring the safety of the meat, poultry and processed egg products supply once animals leave the farms for the slaughter and processing establishments.

We inspect each animal at slaughter before applying the mark of inspection. We also inspect all processing establishments on a daily basis to ensure sanitary and other regulatory requirements are met. Our inspection personnel form the backbone of FSIS public health infrastructure in laboratories, plants and import houses throughout the country.

In Fiscal Year 2006, the agency had approximately 7,600 full-time personnel protecting the public health in 6,000 federally inspected establishments nationwide where FSIS inspection personnel performed antemortem and postmortem inspection and processing inspection procedures to ensure public health requirements were met. This included the processing of over 46 billion pounds of livestock carcasses, almost 57 billion pounds of poultry carcasses and about 4.4 billion pounds of liquid egg products.

It has been estimated that approximately 60 cents of every food dollar in the United States is spent on products that FSIS inspects. In addition, during Fiscal Year 2006, approximately 3.9 billion pounds of meat and poultry and about 5.9 billion pounds of egg products were presented for import inspection at U.S. ports and borders. FSIS also has program inspectors nationwide who conduct food safety, food defense and outbreak investigators and enforcement.

FSIS has been working cooperatively with FDA on the investigation into the swine and poultry feed incident involving melamine and melamine related compounds. We were first alerted, at the field level, on April 17 and at the headquarters level on April 19 to the possibility that contaminated pet food scraps may have been used in animal feed by producers of food animals. Since that initial contact, FSIS has been assisting FDA with the investigation, including on-site visits to farms and daily communication with State and local officials.

By April 26, investigative results confirmed that a relatively limited number of hogs had consumed contaminated feed. At that time, FSIS joined FDA in alerting the public that this feed had been fed to some hogs and assured the public that those hogs would not be allowed to enter the food supply until we could conduct the necessary scientific work to make an appropriate safety determination. Due to the limited information available, USDA could not determine whether it was appropriate to place the mark of inspection on foods derived from those animals and so we did not do so at that time.

FSIS worked with States and producers to quarantine or hold animals until further notice. We also announced that if identified animals needed to be depopulated, producers would be appropriately compensated for any costs. On April 30, USDA and FDA announced that the agencies had learned the pet food scraps from pet food manufactured with the wheat flour contaminated with melamine and melamine compounds had been sold to a limited number of farms for use as supplements in chicken feed. As with the pork products, we believe that humans were highly unlikely to become ill from consuming products from poultry that had consumed this feed.

Likewise, as in the case of swine, we initiated appropriate controls in coordination with our Federal and State partners at the

farm level. As with the hogs, affected chickens on the affected farms were voluntarily held while we further assessed the situation. This past Monday, May 7, FSIS determined that the mark of inspection could now be placed on meat and poultry products when the animals were from farms where the feed that was fed to those animals tested negative for melamine and the melamine compounds. This determination was made after a risk assessment was conducted by scientists from FSIS, FDA, the Centers for Disease Control and Prevention, EPA and the Department of Homeland Security.

The risk assessment found that consuming meat from hogs and chickens known to have been fed the animal feed supplemented contaminated pet food scraps, represented a very low risk to human health. In the most extreme risk assessment scenario, the scientists assumed the unlikely event that all the solid food a person consumed in an entire day was contaminated with melamine. Even given that extreme assumption, the potential exposure was about 2500 times lower than the dose considered safe, well below any level of public health concern.

As I have already mentioned, FDA and USDA have confirmed that scraps of contaminated pet food that contained only low levels of melamine were distributed to farms in a limited number of States and added to the swine and poultry feed. These scraps constituted a small percentage of the farm animal rations. In addition, melamine is known to be rapidly excreted in the urine of the animal. When exposure levels are much higher, as was the case with cats and dogs, the melamine and its compounds appeared to cause the formation of crystals resulting in kidney damage. There is no such indication of kidney damage in hogs.

Both hogs and chickens known to have consumed the contaminated feed appear to be healthy. The assessment that the risk to human health is very low is based on several factors, including the dilution of contaminated feed from the original concentrate as it moved through the food system. First, it was a small component of the pet food. Second, that pet food was a small component of any of the feed given to hogs and poultry. Third, it is not known to accumulate in the body of animals and even if it was present in pork or chicken. Fourth, pork and poultry make a relatively small portion of a balanced American diet.

Neither FDA nor FSIS has uncovered any evidence of harm to swine or poultry that were fed the contaminated feed. This dilution factor was an important piece of data considered in the multi-agency science-based risk assessment and helped support the conclusion of a very low risk to human health from eating the animals.

As the investigation proceeded, we now know that in several cases, on-farm feed samples tested negative for melamine and melamine related compounds. Those tests were conducted in Federal and State laboratories.

USDA has concluded, based on the human health risk assessment and the inability to detect melamine in the feed sample, that those animals, where there is a negative feed test, no longer need to be quarantined or withheld from processing. In other cases, feed samples have tested positive or we simply do not have a feed sample available. Those animals continue to be withheld from proc-

essing but are not yet being culled, pending the results of an animal exposure risk assessment. That new information is expected shortly, likely this week.

USDA and FDA continue to work together in conducting a full and comprehensive investigation. As additional information is confirmed, updates will be provided and decisions will be made using the best available science with the singular goal of protecting the public health. We will also make the risk assessment available for public comment. The scientists that worked on the risk assessment are compiling scientific assessment of the risks to animals associated with the ingestion of this potentially contaminated feed.

We do recognize how important it is to communicate with all of our stakeholders, our partners and the general public in an open and transparent manner. Throughout the ongoing investigation with FDA, we have been sharing information with State Departments of Agriculture and State veterinarians. We continue to keep trading partners informed through the Foreign Agriculture Service. We have been updating our stakeholders from industry and consumer organizations. We have been working with FDA to keep the general public informed. We will continue to reach out to our stakeholders, our partners and the general public to keep them informed as the investigation continues. We will continue to keep Congress informed of our ongoing investigation, as well.

Thank you for providing us the opportunity to make these comments and we look forward to any questions you may have.

The CHAIRMAN. I thank the gentleman and thank both of the witnesses for their testimony. Now we will have a round of questions that I will start off. I think you folks have done a pretty good job since you discovered the situation, but if these pets not been affected, you wouldn't have even known about this contamination. We also saw this with the spinach situation, where until people got sick, we didn't know about it. So Mr. Acheson, you have been put in a new position, is that correct?

Dr. ACHESON. That is correct, yes.

The CHAIRMAN. So what are you, Assistant——

Dr. ACHESON. Assistant Commissioner of Food Protection at FDA.

The CHAIRMAN. Okay. And in your testimony, I don't believe you asked for any more inspectors or resources, am I right?

Dr. ACHESON. With regard to resources, part of my mission is to develop a strategic plan around food safety and food defense and a piece of that is going to be looking at what further resources we will need to get the job done.

The CHAIRMAN. Well, I would hope so, because I hope the response is not to create another level of bureaucracy, which is what we seem to do in government a lot of the time, instead of focusing on putting more people on the ground. So that leads me to my main question for Mr. Acheson. The imports that you folks regulate have gone up 213 percent from 1996 through 2005. We used to inspect 1.7 percent of those shipments, in 2005, it was 1.27 percent and now it is down to 1 percent.

There has been some increase in field employees, a 41 percent increase, but we can't even find out how many of them are involved in inspecting imported food. In 1995, we know there were 595 peo-

ple and we can't find out how many there are now. But even if you took all of the new employees and put them into inspecting imported food, you still wouldn't even come close to keeping up with the increase in imports that has happened here.

We have a similar situation in FSIS, although it is not quite as pronounced and, at least in the case of FSIS, I think they have changed the way they operate in terms of using methods that may require fewer employees. How do you respond to that lack of additional resources and people to deal with this big increase in imports that we have seen?

Dr. ACHESON. I think you asked a lot of questions in there and let me try to sort of phrase it around part of it, which is directed as 1 percent of imports are being inspected and is that enough? What the agency has done is to use a risk-based approach to focus inspections based on where the risk lies. We would never have the resources to be able to inspect and test 100 percent of imported food.

So it is clearly important that we use a risk-based strategy and that is what we have done. Over the years, we have moved away from testing foods that are considered to be lower risk and focused on areas that are higher risk. Food defense is a classic example of that, where through the Prior Notice Center, we have set up a system which is specifically designed to identify and target foods that are considered to be of higher risk.

As I develop this strategic plan with my colleagues at FDA, one of the things that we need to do, quite clearly, apart from building the scientific infrastructure for the agency, is to develop a sound, risk-based strategy that is going to focus both on imports and domestic foods to ensure their safety and security.

The CHAIRMAN. So how would you do that in China? I mean, are you going to go over there and inspect plants like we do with USDA, is that what you are considering?

Dr. ACHESON. Well, again, it is not resource feasible, with the best will in the world, to get an FDA inspector in every manufacturing facility in every part of the world. We have approximately 150,000 manufacturers registered as part of our registration database throughout the world. That is aside from the domestic, that is just foreign. So what we clearly need to do is to strategize on how to ensure that what the industry is doing and what the countries are doing is maintaining a level of food safety and security standard that is acceptable to the United States.

The CHAIRMAN. Just one last thing. I had a gentleman in my office who claims that he has got some kind of system where they can test the molecules and this would have identified the spinach problem. Are you familiar with this technology where they claim that they can actually find this stuff immediately? Do you know anything about that?

Dr. ACHESON. You are referring to melamine or are you referring to——

The CHAIRMAN. This is any kind of substance. This gentleman claimed that this would be a big help to us in trying to identify these problems and apparently he must be having some problem getting people to look at it but——Are you aware of anything available in the technology area that would help us with this?

Dr. ACHESON. One of the reasons that we need and try to maintain a sound scientific research infrastructure is to get at exactly that. Our scientists and researchers need to stay ahead of the curve on the modern technology. They need to understand what is up and coming through attending scientific meetings, interacting with scientists around the world. We are very open to new detection methodologies and in principle, you are exactly right, if we could develop a detection method that was rapid, sensitive, specific and could be operated at a simple level by an inspector in a field situation, that is heading towards the perfect type of methodology. But it has got to be validated. It has got to be shown to work, so that is all part of building and ensuring that this scientific infrastructure—because what you are talking about there is the basic science components which are the underpinnings for sound detection and then response.

The CHAIRMAN. Well, thank you and we will be very much interested in monitoring and being informed about your progress and hopefully, we will get something going here sooner rather than later, so thank you very much.

Dr. ACHESON. Thank you.

The CHAIRMAN. Mr. Goodlatte.

Mr. GOODLATTE. Dr. Petersen, the USDA has made the decision not to recall the meat and poultry products from hogs and chickens that have been fed this questionable feed, but that has already entered commerce and I have listened to your statement regarding your analysis of that and your conclusion that it is safe. What level of assurance would you give the American consumer that these products are safe?

Dr. PETERSEN. Thank you for the question. First of all, we made that decision after carefully considering the facts and we do consider the food supply to be safe. The facts we looked at, and I think it is important to understand them, are that on the first day, when we made the announcement that we were aware that some of the contaminated feed had gone to several swine producers, that is about all we knew, that there was some exposure to swine and so we took a very cautious approach on that day, which was April 26. With that limited set of facts and we took the cautious approach of not applying the mark of inspection to any of those animals, should they have come to slaughter.

On that day, we were not certain that any of the animals had already gone into commerce. It was over the course of the next two days, over the course of that weekend, April 28, where we did become aware that there were swine that had gone to the marketplace. And during that intervening two days, we did get some additional facts and they were facts such as the melamine is a very small component of the pet food and the pet food is a very small——

Mr. GOODLATTE. I don't want you to—I heard your testimony and I understand the analysis. What is your level of confidence that the decision not to recall the products assures the public of the safety of the products?

Dr. PETERSEN. Well, we are quite confident now——

Mr. GOODLATTE. Is it a high level of assurance or is it a low level of assurance? Is it, I think it is safe? What is your level of assurance?

Dr. PETERSEN. It is a high level of assurance, particularly in light of the human risk assessment that was completed the other day.

Mr. GOODLATTE. Great, great. Thank you. Now, my next question relates to what I think is the wider public concern which is, if this got into our food system from China, then the Chinese are not doing a very good job with their own food safety. And so I want to know what message the administration is sending to the Chinese government that exporting contaminated products of any kind to the United States will not be tolerated?

Dr. PETERSEN. Well, I will start and no doubt my colleague from FDA may want to mention their approach. Our message would be we are taking this extremely seriously and as we uncover the facts, the facts will lead where they lead. But the mere fact that this occurred and we are in this position of responding, shows we take this quite seriously and we are dealing with it through our equivalency system, which is a very rigorous approach before any country gets even approved to have the possibility of exporting any products to the U.S. China does not export meat or poultry products to the U.S. at this time. So that is our message as far as the approach with engagement on China on this particular issue. I would defer to my colleague.

Mr. GOODLATTE. Yes, let me ask Dr. Acheson about that. You have put a halt to all vegetable proteins being imported from China, is that correct? What are the terms and conditions of that halt? Is it contingent upon their making certain changes or is that subject to future negotiation? What is the status of that?

Dr. ACHESON. Thanks for the question. The status is that, as you point out, all vegetable-based protein concentrates imported from China are not allowed to enter the United States until we, at FDA, have evidence that it is safe to proceed. That evidence can be varied. It can be validated testing undertaken by the industry. It can be a number of factors. That will continue and we will continue to do that until we have assurance from a particular importer working with the Chinese authorities, AQSIQ, to ensure that the products that are being imported into the United States are, indeed, safe.

Mr. GOODLATTE. But at this stage in the investigation, do you have confidence that the Chinese government's food safety system is sufficient to assure U.S. consumers that Chinese products are safe for export?

Dr. ACHESON. At this point, that is part of what we are trying to seek. We are working very closely with AQSIQ on this. With regard specifically to the melamine, the Chinese authorities have made changes since this has occurred, with regard to making sure that all imports or exports from China to the United States and other parts of the world, I believe, go through AQSIQ to ensure that safety. Our team is over in China right now, working very closely with AQSIQ. The job is not done. We need to continue to work with AQSIQ and the Chinese authorities to further ensure the safety of imported food from China.

Mr. GOODLATTE. Thank you. The chairman has given me leave to ask you another question to follow up on that. The U.S. Department of Agriculture established equivalency agreements with nations that export meat and poultry products to the United States to ensure that the exporting country is meeting our food safety standards. Does the FDA have the capability of using a similar approach?

Dr. ACHESON. In theory, yes. FDA does have the capability of using equivalence, in theory. But I would like to point out that for FDA, the situation is significantly more complex than for USDA. We are having to deal with multiple products. It is not just meat, poultry and egg products. There is a huge spectrum of products that are under the control of a vast array of agencies, very often in different countries. I think, as we go down this road, an equivalence-type thinking or an equivalence-type approach is one aspect of what could be in the toolbox that we can use to ensure that imported goods, not just from China but from all parts of the world, are safe and secure.

Mr. GOODLATTE. Thank you, Mr. Chairman.

The CHAIRMAN. Thank the gentleman. I recognize the gentleman from Pennsylvania, Mr. Holden.

Mr. HOLDEN. Thank you, Mr. Chairman. Dr. Acheson, I realize you have limited resources, but I have a few questions about dairy imports and particularly on India. I understand that the imports from India are averaging about $47 million over the last 3 years and their level of pesticide approval is much higher than that of the U.S. I am just wondering what specific steps are you taking to monitor imports from India? It has come to my attention that the domestic dairy industry brought this to FDA's attention, but there has not even been any sampling that has been done so far.

Dr. ACHESON. There is an ongoing pesticide testing program in FDA. It is part of the total diet study and part of a separate assignment that we have, looking for pesticides. Frequently, when we find them, we issue import alerts and we have a number in place right now related to pesticides. I don't have specific facts on numbers of tests of pesticides related to imports of dairy products from India at my fingertips today. I would be happy to get those for the record.

Mr. HOLDEN. If you get them, Doctor, I would appreciate it.

Dr. ACHESON. Sure. I would be happy to do that.

Mr. HOLDEN. Okay. And second, Doctor, I understand that the FDA is trying to accelerate Grade A importation of dairy products through third party verification, is that true?

Dr. ACHESON. With regard to dairy products, I know that FDA is working closely with a number of other countries to try to ensure that there is importation of safe and secure dairy products into the United States. Again, if you want specifics on the current status of that discussion, I would be happy to provide that for the record.

Mr. HOLDEN. I would appreciate that, Doctor, and again, I realize that you have limited resources and you are looking for ways to crunch the dollars, but I would be concerned about the integrity of third party inspections and so if you could get that information to me, I would appreciate it.

Dr. ACHESON. Thank you. I understand.

Mr. HOLDEN. I yield back, Mr. Chairman.

The CHAIRMAN. Thank the gentleman. Gentleman from Texas, Mr. Neugebauer.

Mr. NEUGEBAUER. Thank you, Mr. Chairman. I agree with the chairman in that we don't need to create any new bureaucracy here. We need to make sure that we have food safety in our country. I think one of the things I want to follow up on is that other countries have been very punitive on the U.S. when there has been a question about the quality and the health safety of our products. For example, Japan with American beef. Are we taking a hard line with China for example, right now to make sure that they understand that if we can't satisfy ourselves that we are getting safe food products from them, then that could have some long-term ramifications?

Dr. ACHESON. Is that question directed to me?

Mr. NEUGEBAUER. Both of you.

Dr. ACHESON. Okay. Well, let me start out. First of all, I want to say that our focus is not solely on China with regard to imported foods. We cannot ignore the rest of the world. But right now, that is the current focus, on China. But whatever strategies we put in place have to be applicable globally and, as I said in my statement, we have got an increasingly global food supply and I suspect it is only going to get more global and diverse as time continues.

We do already have systems in place so that when situations, or problems, are identified, we can put import alerts out there which essentially stop something from coming into the country. That can be done in a very focused way and the melamine situation is an example of that. We started that, as an import alert, on the two companies from China that we knew for sure were problematic. As we learned more about this situation as it unfolded, we expanded that to include all vegetable protein concentrates. In theory, I believe, we could keep expanding it based on what we find, so we can, basically, put things in place that will stop the problem.

But I think the key question is how do you get one step further back? How do you deal with the preventative strategies in the country itself? Because the overall approach needs to be prevention Number 1, which needs to involve all stakeholders. It needs to involve industry participation, understanding suppliers. Where do you get your material from? What do you know about your supplier? And that is something we have worked with the industry on very closely with regard to food defense, raising awareness about your supplier through our alert program.

Then the other piece is how do you apply that, locally, into a country going globally? And that is part of the strategy that has to be figured out. And clearly, we need to make some changes.

Mr. NEUGEBAUER. I appreciate that. Mr. Petersen, as you know, we were put through a fairly rigorous process by the Japanese on our monitoring process so that they could rely it when we said U.S. beef was safe and that we have safety measures in place. I agree with you. It is the preventative side. We don't need to wait until animals start dying or God forbid, people start dying or having health issues to determine how we need to monitor that. So what are we doing, then, on a proactive basis, of putting a lot of pressure on these various countries of saying that they are going to have to

demonstrate to us that they have a process in place that we can rely on to ensure the product is safe when they allow that product out of their country and it is coming into our country?

Dr. ACHESON. Well, again, to take the micro example of melamine, we have that in place through the import alert. We will not allow importation or take people off that import alert until we have assurances from the country that product is safe. And again, it is broader than that. I think, possibly, one way to take that question is, which will be part of my analysis, strategically as we move forward, is do we need new authorities? Do we need to tweak current authorities to make sure that we meet that goal of prevention and ensuring prevention and pushing it back onto the countries who want to import food into the United States and the industries that want to do that. Because there is no way in the world we would ever get an FDA inspector in every manufacturing facility throughout the world. We just couldn't do it. And I don't think we should.

Mr. NEUGEBAUER. Does that also include some kind of verification of types of chemicals that are being used on agricultural products in those countries? Because one of the things I hear from fruit and vegetable people is that some of the vegetables and fruit that may be coming into our country, in fact, have chemicals being used in those countries that are prohibited in the U.S.?

Dr. ACHESON. It happens and that is why we have monitoring systems in place, to try to pick that up. The worse case is when you get human illness. That is the point at which you have got to respond, or animal illness. And then you backtrack and you figure out okay, we have got a problem. Our goal is to never get to that point and as I said, push it back on prevention; make sure that there is something in place that would prevent a product coming in which has been exposed to a pesticide which we don't consider safe. Then on top of that, there has got to be an intervention, inspectional testing, detection level to basically trust and verify in terms of the prevention. But there has got to be enough teeth in this to make sure that the rest of the world will pay attention to our standards.

Mr. NEUGEBAUER. After you have had a chance to analyze that, do you anticipate bringing something to this committee? If you need additional authority, do you think that is going to be necessary that legislatively? Do we need to look at some ways to give your agency broader powers to be able to interact in that way?

Dr. ACHESON. I would be happy to come back and report to you once we have made that assessment. Part of where we are trying to go strategically is to look at exactly those questions. And I want to phrase that in two ways; one is tweaking current authorities and the other is seeking new authorities. Frankly, we are not there yet, in terms of what that would look like, but I would be happy to report back to this committee once we have reached that point.

Mr. NEUGEBAUER. Thank you.

The CHAIRMAN. Thank the gentleman. The gentleman from North Carolina, Mr. Etheridge.

Mr. ETHERIDGE. Thank you, Mr. Chairman. Thank you for holding this hearing. I think it is important. Gentlemen, let me quickly go to some questions. My first is for both of you. Frankly, this entire incident is troubling. I think this will remind people of the im-

portance of our nation not being totally reliant on foreign sources of food. We have said many times that our food supply here in the United States is the safest and most abundant in the world and I hope this incident will sound something of a clear call for more diligent food inspection, as well as better lines of communication when an incident occurs.

I believe the lag time between when these animals first started dying and the official disclosure of tainted feed going to the farm, was entirely too long. My understanding is that we first knew about it in February. It took a month for anyone to acknowledge it. So my question is this, wheat gluten and some of the other products that have been put on hold and the test lists such as ryes and corn gluten go into far more products than pet food. Can either of you tell me within a degree of certainty that this product has not entered into the human food supply chain?

Dr. ACHESON. Let me first respond to that.

Mr. ETHERIDGE. Yes or no?

Dr. ACHESON. Yes, I can give you assurance that the wheat gluten and the rice protein concentrate that we now know was wheat flour that was used to make the contaminated pet food, has not, to date, to our awareness, entered the food supply chain. I want to also emphasize, though, that this is an ongoing investigation and I cannot predict where it is going to go. That is part of what we need to do, is to continue to trace out the tentacles. And I also want to point out, in that context, that we——

Mr. ETHERIDGE. I have a very limited amount of time and you have answered that one, so I don't want to take all my time filibustering.

Dr. PETERSEN. FDA, would of course, have the lead on how the contamination is moving on the wheat protein side of the spectrum. Everything we have seen as far as their investigation supports the statement that was just made. There is no direct information that we have seen that supports that it went into the human chain directly.

Mr. ETHERIDGE. All right. Thank you. USDA and FDA have both issued press releases that state that the risk to human health is very low. What does very low mean? And the reason I ask this question, I have a grandson who is two and a half years old and weighs about 27 pounds. How does that compare, that child, to say, a grown adult weighing 200 pounds? How does that compare? When you say very low, I think the American people want to know what does very low really mean?

Dr. ACHESON. Based on the risk assessment, one of the things that we look for is what is the margin of safety, as it is called, between the level that we see in the food and the level which we might expect anybody, infant or whatever, on a per kilogram basis, of body weight, to have a problem. And that risk assessment, worse case indicated that there was about a 2500-fold margin of safety between the level that we were seeing in the meat and the likelihood of an illness.

Mr. ETHERIDGE. Do you agree?

Dr. PETERSEN. Yes, we worked jointly on the risk assessment and that was using the most extreme assumptions that could theoreti-

cally happen, but are not expected to happen in the real world. A 2500-fold margin of safety is rather large.

Mr. ETHERIDGE. See, the reason I ask this, it is troubling because if you go back to the question the Chairman asked earlier, at the percentage of increase of feedstock coming into this country since 1996, with the reduction in the amount of inspections in that period of time, this is the first time it has shown up and it didn't show up until we had a death that we recognized in animals. I think I am understanding you now.

We really don't know what else is out there and yet, we have increased the amount of imports substantially with a reduction in the amount of inspections. So my next question is this, is it true that Menu Foods, the first company to notify USDA that there was a problem, first discovered the problem at the end of February? And why was the first hold on these imported products put in place, it took a month to take the action to put it in place, to put a hold on the imports?

Dr. ACHESON. The hold on the import was, as I said earlier, expanded from the companies that we first identified and once we had identified who the company was, what the problem was, the hold was put in place and that has expanded now. Part of what you are getting at is the need for, in terms of response, is what do we need within the system to be able to get a handle on an illness, whether it be human or animal, earlier? And that is public health infrastructure, to get to where we can take action faster.

Mr. ETHERIDGE. I hope you will share back with us that need. My final question, with the Chairman's indulgence, I have a stack of material I have been reading and obviously, a lot of it is from newspapers, the Washington Post, the New York Times, with the latest one out this morning about the number of the pigs that are dying in southeast China by the thousands, outside Hong Kong. And they started dying the first of the year. Have you had any input on that, any response with USDA or FDA? Because the question is that it is about the same time the tainted food started showing up.

Dr. PETERSEN. We don't have any direct information on that, but another agency within USDA, the Animal and Plant Health Inspection Service, remains vigilant on any animal diseases that could come into this country and so even if we were to receive product from that part of the world, which I am not aware that we do, their animal protection measures would immediately come into play with their is animal disease surveillance networks.

Mr. ETHERIDGE. The reason I follow that up is because it is from the region of China where SARS was, which refused to issue information then. Now we have got the same problem and I would hope you would follow that up and I would appreciate a response back to the committee on that.

Dr. PETERSEN. For equivalency with meat and poultry, if we have a country that is equivalent, if an issue arises where there is some animal disease that occurs, we can suspend any exports until that issue is mitigated and we have done so in the past.

Mr. ETHERIDGE. Are you telling me we have no equivalency with China?

Dr. PETERSEN. On China for equivalency on the meat and poultry side, it is strictly related to cooked product and they are not bringing any into this country at this time. It must be cooked, because that was the determination made by the Animal and Plant Health Inspection Service, that it needed to be cooked before it came in, so they are eligible, but nothing is coming in.

Mr. ETHERIDGE. Okay. I would like to follow it up later, Mr. Chairman.

The CHAIRMAN. Thank the gentleman. Gentleman from Louisiana, Mr. Boustany.

Mr. BOUSTANY. Thank you, Mr. Chairman, and thank you, gentlemen, for your thoughtful testimony. First question, given that the investigation is still ongoing, are the Chinese cooperating?

Dr. ACHESON. Very much so, yes.

Mr. BOUSTANY. So you are satisfied with the level of cooperation?

Dr. ACHESON. Yes, AQSIQ has been very helpful. As you are probably aware, when our investigators first went over there, there was a holiday in China. They basically came in from their vacations to support us and assist us in the investigation.

Mr. BOUSTANY. Thank you. Dr. Acheson. I appreciate your strategic approach to this, because obviously, it would be very impracticable and costly to provide inspectors across the board for 100 percent inspection, so the strategic approach that you outlined was good. I am curious to know whether or not there is a very vigorous, broad interagency process involved in this strategic planning. In other words, beyond the two agencies represented here today, is the State Department, our intelligence community involved in this? Department of Defense, perhaps? Commerce, Treasury, involved in looking at formulating a very strong and vigorous strategic approach to this problem? There are many, many ramifications, obviously, but if you could give me a straightforward answer on that, I would appreciate it.

Dr. ACHESON. At this stage, no. It is early days, but clearly, this goes beyond just FDA and it involves many of the agencies that you have just outlined and there is going to be a need to interact with them, share the information with them, share the approach with them, get their support and get their help to put it in place.

Mr. BOUSTANY. I would submit that if you need a push from Congress, I would certainly be willing to work with you on that issue. I think, clearly, it is going to require a vigorous and broad interagency approach to deal with this problem, because you outlined the challenges very succinctly with globalization, terrorism, the rapidity of change in production and so forth, and to deal with those kinds of challenges, I think clearly a broad approach is going to be necessary. One final question, what has been the budgetary impact of this particular investigation? And could both of you comment on ongoing budgetary needs as we look forward to dealing with these kinds of problems and particularly, with regard to enhancing your research capabilities?

Dr. ACHESON. Well, as I have said, there is a need to ensure the infrastructure is there. There needs to be a strong science base behind the decisions. We use science on a daily basis. The risk assessment is a classic example of that, which to get to your earlier question, involved multiple agencies. We brought all of those folk in

there and in fact, every day we have a call at 9:30 that involves many of the players that you asked me about.

In terms of resources, though, specifically, we have got to determine what we need to get that job done in terms of the infrastructure. It is not just research and science, it needs information technology infrastructure, as well. A lot of what we have got to do is data handling, data analysis, vast amounts of information. If we are going to make this work, we have got to use modern IT to drive it, as opposed to old-fashioned piles of paper and pencils.

Mr. BOUSTANY. And I trust you will come back to us with a more detailed assessment of what those needs will be as time goes forward. But what has been the budgetary impact to your respective agencies with regard to this particular investigation? Could you comment on that? Could either of you comment?

Dr. PETERSEN. For FSIS, we are appropriated to do a certain number of investigations of some nature because we know various investigatory needs are going to come up during the year. Approximately to date, and we have been involved for the last several weeks now, about a thousand man hours have been employed with the associated travel costs, so that is well within our system and so at this point, we are able to deal with the situation.

Mr. BOUSTANY. Thank you. I see that my time is about up. Thank you, Mr. Chairman. I yield back.

The CHAIRMAN. Thank the gentleman. The gentleman from Iowa, Mr. Boswell.

Mr. BOSWELL. Thank you, Mr. Chairman. I would like to kind of pick up on what Mr. Holden was talking about on the dairy situation, Dr. Acheson. I appreciate what you have said, so I will try not to repeat that, but do I understand that you are trying to accelerate the dairy products from several countries by giving testing and verification to third parties? Is that correct?

Dr. ACHESON. I am not intimately familiar with the current status of those interactions with regard to dairy products. I didn't come to this hearing prepared to address that in depth.

Mr. BOSWELL. I understand, but it does kind of fit into what we are discussing here, so would you give us that information?

Dr. ACHESON. I would be happy to and I apologize that I don't have it today.

Mr. BOSWELL. No, that is okay. We would like to know. And I am not sure, if I could, how do you plan to ensure a third party in a country with corruption problems can meet all the guidelines? And I say that because, to use the example that Mr. Holden did, the Indian standards for levels of pesticide are higher than the U.S. and I would like, as you report back to us, if you would, that you give us an indication of what kind of a sampling you have done over the last six months, to give us a feel for just what is actually going on there, understanding that you didn't come prepared for that today, but would you give that information to us?

Dr. ACHESON. I would be happy to do that.

Mr. BOSWELL. Okay. Well, I think that would add on to what Mr. Holden has already requested, say I appreciate it, and I yield back.

The CHAIRMAN. Thank the gentleman. Let us see here. The gentlelady from Colorado.

Ms. MUSGRAVE. Mr. Chairman, I apologize for not being here earlier and I will pass on the questions. Thank you.

The CHAIRMAN. Okay. I thank the gentlelady. The gentleman from Georgia, Mr. Scott. You are on the list.

Mr. SCOTT. Thank you, Mr. Chairman. I think that what this hearing points out, and this issue with China points out, is that our food safety protection operation is dangerously inadequate. I think there should be a greater sense of urgency than what I am hearing from you gentlemen today. There was a motion picture that came out a while back and it was called, Outbreak. I think that was the name of it. Dustin Hoffman was in this movie. And it had to do with this monkey who came into this country and caused an outbreak.

My concern is two-fold. Here we have got China, that you seem to think has it under control now. But this isn't the first time. China is notorious for contaminated food products. We have had all kinds of history, news reports, on its honey, for example; on its catfish, for example. So it is repeat after repeat. My fundamental question to you, first of all, is can China be trusted to deal with this problem or in fact, do you and FDA need new authority to deal with it?

Dr. ACHESON. First of all, to answer your specific question, I think we have to approach this in the context of trust and verifying. We have got to set up systems where we have to push back on manufacturers, importers, wherever they be, to put sound, safe systems in place to ensure the safety, yet we have to verify and inspect to make sure that they meet that standard. With regard to your comment of urgency, I can assure you, there is a great deal of urgency about this. One of the reasons that my position was created, just a week ago, was a reflection in FDA of that urgency and the need to take a new, strategic approach to determine what needs to be done to further protect the American food supply.

Mr. SCOTT. Here is what concerned me, and why I say I don't think you are urgent enough. In your reference to a question from one of my previous colleagues who asked you has this outbreak from the pet food gotten into our food supplies, threatening our food supply. You said no, when in fact, according to reports, the contaminant has made it into our human food supply when scraps from pet food production were fed to hogs and chickens in the United States. Now, Mr. Acheson, those hogs and chickens are going to make it onto somebody's table and whether or not we know exactly where those hogs are and which those hogs are.

Dr. ACHESON. Let me clarify that statement so that you understand where I was coming from with that. My answer to that statement and perhaps it was my misunderstanding of the question, was whether the wheat gluten and rice protein concentrate had been used directly as an ingredient in a human food and to date, we have found no hard evidence to support that. You are absolutely correct, and we have said in many press releases, that it has gone, via the pet food, into the animal feed, there is no question about that.

Mr. SCOTT. Okay. Do you feel our food supply is safe?

Dr. ACHESON. I feel that our food supply is one of the safest in the world. My mission is to make it safer and more secure.

Mr. SCOTT. Right now we are getting about 14 percent of our food that we consume in this country from other countries and I think you alluded to the fact that percentage is going to increase in the future. Do you see a threat there? Do you see a need for us to do one of two things, either begin to put up other safety and soundness measures to protect us or do you see a greater need for us to become more independent and less dependent on foreign sources for our food and begin to put more things in place to produce more of our own foodstuff in this country? For example, what I am saying, about 90 percent of the tomatoes, for example, are brought in to this country. That is a huge percentage.

Dr. ACHESON. Part of the complexities of this is the consumer demand for all kinds of food 24/7, 365 days a year, which puts a lot of pressure on American agriculture to provide that and that is a big part of what is driving the importation of food. It is consumer demand for readily available, lots of types, inexpensive, year round. That is a fact and short of changing consumer behavior, that isn't going to change. So we have got to accept that as the fact. Now, clearly your point as to whether we could grow more domestically, that is a separate issue and I am certainly not opposed to that in any way, shape or form. We have to accept the fact that we have got this global food supply and what are we going to do to protect the American consumer from not just imported foods, but clearly, within the last few months, we have had concerns with domestically grown fresh produce, as well as peanut butter, amongst other things. So this approach shouldn't just focus on imports, it needs to encompass both.

Mr. SCOTT. Thank you very much for your answers. I appreciate it very much. I yield back the balance of my time.

The CHAIRMAN. Thank the gentleman. The gentleman from North Dakota, Mr. Pomeroy.

Mr. POMEROY. Thank you, Mr. Chairman. As I understand it, then, when the pets started dying, the investigation was triggered and the two agencies working together and as you indicated in your testimony, did some very good work to retrace back the problems causing the illnesses in the pets consuming this tainted pet food. But it was the illnesses and the deaths of these animals that caused the investigation to begin, is that correct?

Dr. ACHESON. That is correct.

Mr. POMEROY. Now, obviously we are talking about matters related to the Nation's food supply; that is a little late. We want something a little more proactive than when the pets start dying. So let us talk about that one. I saw some film footage on television, it was a big old factory where they were putting melamine in as a substitute for wheat gluten because it was cheaper, has no nutritional value and indeed, has very adverse health consequences to these animals. Were you surprised at the commercial scale by which this product was being put into this commercial pet food as basically a cost savings technique, yet resulting in tainted food?

Dr. ACHESON. Well, clearly FDA was not aware that this was going on, otherwise we would have been more preventive and proactive.

Mr. POMEROY. Do you have a capacity, people on the ground over there running around looking at these places where the food is manufactured?

Dr. ACHESON. Well, as I said, we currently do not have the resources and the manpower to get an FDA inspector——

Mr. POMEROY. How about the U.S. Department of Agriculture?

Dr. PETERSEN. The pet food issue is not directly under our jurisdiction, so it is when those animals come to slaughter that FSIS becomes directly involved.

Mr. POMEROY. Now, that is a good point because probably this technique of adulterating food supply fed to animals, also available to domestic livestock and such in China. Do we have food imported from China?

Dr. PETERSEN. We have food imported, but at this point, there is no meat or poultry that is imported, although China is eligible to export cooked poultry, provided the poultry comes from a country eligible to export raw poultry to the U.S.

Mr. POMEROY. How about fish?

Dr. ACHESON. FDA regulates fish and the answer is yes.

Mr. POMEROY. I understand, a couple of States, Alabama and Mississippi, have actually taken steps to stop the import of Chinese catfish in light of concerns that these fish may have been fed tainted food supply over in China.

Dr. ACHESON. That is correct. We have had concerns about catfish particularly being contaminated with antibiotics and other fish products contaminated with a fungicide, malachite green. We at FDA have been working with those states to implement a testing program.

Mr. POMEROY. Are there Chinese catfish coming into other states?

Dr. ACHESON. Yes, I am sure there are.

Mr. POMEROY. Well, who is right in that one? Are Alabama and Mississippi right or are the other states lax? Should there be a national response?

Dr. ACHESON. What we have done is put an import alert out for eel in relation to malachite green.

Mr. POMEROY. If there is an evolving state of play relative to regulations and some states have one thing, some states have done nothing; FDA is looking at it, thinking about it. Do you think it would be helpful to have a label so at least consumers would know what is U.S. catfish, what is China catfish?

Dr. ACHESON. I would ask my colleague, Steve Solomon, to answer your question.

Mr. POMEROY. Why can't you answer it?

Dr. ACHESON. That is why I brought some other experts from our Office of Regulatory Affairs along, because I think your question is what is the current regulation.

Mr. POMEROY. My question is what do you think about consumers having notice of where their food comes from? What do you think about that?

Dr. ACHESON. Personally, I think the more information the consumer has to make informed choices, the better.

Mr. POMEROY. I think so, too. What does U.S. Department of Agriculture think about that?

Dr. PETERSEN. Well, of course, we regulate the labeling of meat and poultry and eggs products and our view is that the current labeling system is sufficient to inform the consumer.

Mr. POMEROY. Now, does the current labeling system, sir, allow a person to find out what country their food comes from, where the steak comes from?

Dr. PETERSEN. Well, what it does have——

Mr. POMEROY. No, wait a minute. I have got about 30 seconds left. I would like you to answer my question. Does the current system you think so highly of, allow a consumer looking at a grocery store shelf, to find out where their food comes from?

Dr. PETERSEN. Well, for meat and poultry products, what it will show is for domestically slaughtered animals it will have the USDA mark of inspection on it, which means that we inspected it before it went into commerce and we think that is sufficient for those products.

Mr. POMEROY. Is this a little code? Is this a little code that consumers got to know? There is a little label that says USDA Inspected and that means ah, that was an Iowa steak, not a Chinese steak, or they don't come in from China so it's not a Canadian steak. Is that it?

Dr. PETERSEN. It means that their Federal tax dollars inspected that product and found it to be safe and wholesome.

Mr. POMEROY. Where does it say, sir, this is a U.S. product, not a foreign product? Where does it say that?

Dr. PETERSEN. It would say, on a little inspection label, U.S. Department of Agriculture inspected and passed for meat and poultry products.

Mr. POMEROY. And so you have got to look for that U.S. inspected sticker and then understand, as a consumer, that Canadian steaks don't have that sticker on there, is that right?

Dr. PETERSEN. Yes, and it is required——

Mr. POMEROY. Wouldn't it just be a whole lot clearer to say Canadian steak, U.S. steak, wherever steak? What is the matter with that?

Dr. PETERSEN. That is the system we have. We think it informs the public. It has been out there for a hundred years and it is available for them to view.

Mr. POMEROY. Well, I buy steaks. I don't even know what sticker you are talking about. I can't tell if they are U.S., I can't tell if they are Canadian, I can't tell where they are from. I think we can do a heck of a lot better than what we have got now. In fact, I believe Congress has passed a directive in the last Farm Bill saying we would label where the meat comes from and the U.S. Department of Agriculture has done its very best to delay implementing this country of origin specificity. It continues to be, even in light of this incident, showing clearly that we don't have a handle on the quality of food coming into this country from other places. Even now you take the position of U.S. Department of Agriculture that consumers should not have clear labeling so they know where their food comes from?

Dr. PETERSEN. The status of where we are vis-a-vis the farm bill and the country of origin labeling, I will simply have to get back to you with the response from the department.

Mr. POMEROY. I yield back, Mr. Chairman.

The CHAIRMAN. I thank the gentleman and I just would note, as far as I understand, there is boxed beef from Canada that is slaughtered in Canada that gets the USDA stamp. So there are situations where you have got product that is from another country, slaughtered in another country that has the USDA stamp.

Dr. PETERSEN. Yes, when they are fabricated in a federal establishment.

The CHAIRMAN. Yes. I just put that out there. Gentleman from Wisconsin, Mr. Kagen.

Mr. KAGEN. Thank you, Mr. Chairman, for having this hearing. I really appreciate it. I have learned a great deal. But it wasn't clear, Dr. Acheson, have you practiced medicine, as well?

Dr. ACHESON. Yes, I have.

Mr. KAGEN. So you understand what it is like to write a prescription and have a patient fill it, and on the label of that prescription it says the name of the medication and its expiration date and the manufacturer?

Dr. ACHESON. Yes, indeed.

Mr. KAGEN. Wouldn't you like to see the same thing with the food that you buy and your family purchases and people across America?

Dr. ACHESON. I think that is a complex answer. We know, from consumer surveys, that most American consumers do not read labels.

Mr. KAGEN. That may be true, but what people really want, not just in this room, but across the country, people want reassurance that the food they are eating is safe and it won't harm them. The USDA has some interesting statistics that in the year 2000, over 1200 people died from food borne illnesses: 499 died from listeria; 553 from salmonella; 99 from campylobacter. You are aware of these numbers?

Dr. ACHESON. Yes.

Mr. KAGEN. So food is good for you. But it is healthy food that keeps people healthy, so along those lines, what have you got in place now to survey the many foods that we have coming into the country for the safety of these foods for human consumption, because as I understand it, only about 0.7 percent of the imported food is now being inspected. Bearing in mind that it was February of 2006 when we became a net importer of food, what systems do you have in place now to reassure the American public that the food that they are eating is safe?

Dr. ACHESON. Well, as I said earlier, the current systems are based on where we see the risk, both in terms of the products that are of greater concern and the agents, the pathogens or the chemicals or the pesticides that are of greater concern. That is what the focus is at the border, in terms of what you put the energies into. If we see a problem with a particular food, we will concentrate on it. An example recently was cantaloupes from Mexico. We had some problems before with salmonella. We continued to test them, they were fine for several years. Then, just recently, several months ago, there was a problem again. We picked it up. So that is what I mean by it is a risk-based strategy.

Mr. KAGEN. Well, I would like to know that the medicines my patients put in their mouths are safe. I would like to know that the food that mothers put into their children's mouths is safe, as well, and along those lines, I have been very outspoken in being an advocate for country of origin labeling and maybe we can get to that at another time. Would you agree that it might be time for people in this country to begin to think about the idea of eating locally grown foods? Would you agree with that concept?

Dr. ACHESON. I am all about people eating safe and secure food, whether it is grown locally or 5,000 miles away is moot so long as we can ensure the safety of it.

Mr. KAGEN. Well, can you reassure me that any milk products or milk protein concentrates coming from India or elsewhere are free of any pesticides? Have you done any tests? Has anyone surveyed it?

Dr. ACHESON. As I said, there are assignments that are underway, looking for pesticide residues from various places, but I don't have the specific numbers in terms of how much we are doing. But in that context, I would point out that you can get illness from local problems just as you can from global, so whatever strategies you put in place, it needs to apply to the farm down to the street as well as the farm in another country.

Mr. KAGEN. Well, along those lines, perhaps instead of repeating a phrase from a former Republican president about trust but verify, perhaps a better phrase is a more ancient one and that is caveat emptor and buyer beware. So you are working closely with the FSIS, is that correct?

Dr. ACHESON. Absolutely, yes.

Mr. KAGEN. And what further plans have you got to wrap up the melamine investigation?

Dr. ACHESON. We are working very closely with the hog and poultry issue, primarily, with FSIS. Multiple calls every day, right through the weekend, as this moves forward and that is continuing and it will continue until that part of the melamine investigation is completed.

Mr. KAGEN. Have you looked system-wide at the FSIS, USDA and FDA to determine if your budgets are adequate to meet these needs?

Dr. ACHESON. I certainly have not looked at USDA's budget, but as I have said, part of the strategic approach that we need to undertake at FDA, for which I have been given leadership, is to ask that very question. Where are we strategically? Where do we want to go with prevention, intervention and response? What resources do we need to get there?

Mr. KAGEN. I look forward to working with you in the 110th Congress to reassure the public that the food they are eating is safe and especially, as I am going to be looking at the nutritional needs of children for lunch programs and breakfast programs on our subcommittees. Thank you for your testimony and I yield back my time.

The CHAIRMAN. Thank the gentleman. The gentleman from Indiana, Mr. Donnelly.

Mr. DONNELLY. Thank you, Mr. Chairman. In regards to food products coming in from China, such as fish products, what inspec-

tion has been done to determine what foods were used to feed those fish in China?

Dr. ACHESON. At this point, we don't have the resources to determine what those fish have been fed. When the melamine situation arose, we did not have an assay, a method to detect melamine in fish. In the last couple of weeks, our scientists have developed one, they validated it and it is now in place in our labs.

As we were discussing earlier, we are already obtaining samples, looking for fluoroquinolones and other residues in fish and those same fish are now going to be tested for melamine and melamine related compounds when we have those assays. Right now it is just melamine, to get the beginnings of a surveillance assignment for fish. Now, once we have done that, that is going to give us an idea of what we are dealing with and we are going to have to then react appropriately to that. But we couldn't get the resources, the individuals into every fish farm in China.

Mr. DONNELLY. For fish products coming to this country now that are coming in, we don't know what they have been fed and they are still going into the supermarkets. Would that be a fair statement?

Dr. ACHESON. That is correct.

Mr. DONNELLY. So these fish products that are coming into our supermarkets now, there could well be melamine in those fish?

Dr. ACHESON. We cannot rule it out. That is part of what the assignment will tell us.

Mr. DONNELLY. Well, let me ask you this. In so many cases, other countries are so quick to ban our food products and shut the door on our food products. Why do we continue to let these products come into our country when this possibility exists?

Dr. ACHESON. Clearly, in order to, as I understand it with our current authorities, we have to demonstrate there is a problem. Your questioning has gone down the line of we believe or speculate there could be a problem with fish. We don't have any evidence of that at this point.

Mr. DONNELLY. Did you happen to see the article in the New York Times that discussed how animal feed producers have used this ingredient with fish farms time after time after time in China?

Dr. ACHESON. Understood. And clearly, if we reacted to everything that we read in the New York Times in terms of what we did, we would be in trouble.

Mr. DONNELLY. I am not using just the Times. I am using the fact that we found hogs and poultry in this country. I mean, at what time do we put the benefit of the doubt on behalf of the consumer where this product is coming in, instead of trying to cover these things over? When do we stand up for our consumers? As Mr. Etheridge was mentioning, his 27-pound grandchild might be eating this fish tonight. How do we let this continue?

Dr. ACHESON. Without some specific evidence that there is a problem with it, we don't have the authority to ban it based on the sorts of information that you are describing to me.

Mr. DONNELLY. Well, then that brings me to my next question, which is are we finding out who in China knew? How are we tracing back the steps? Have we found the different facilities? Obviously, we have located some of them, but have we found if any gov-

ernment officials in China knew, and who have we talked to on the government level?

Dr. ACHESON. We are working very closely with the Chinese food safety authority, AQSIQ, on this whole issue around melamine. Clearly, they are aware of this problem. We have assisted them in setting up assays to measure melamine, which they didn't previously have. I think you are asking a very good question. At this stage of the investigation, we just simply don't have all the answers.

Mr. DONNELLY. So we don't have the answers, but the products keep coming in at this point.

Dr. ACHESON. They are coming in, they are being tested and if they test positive, clearly, we are not going to ignore that and we will take appropriate action, which could potentially, at the far end of the spectrum, be an import alert on fish.

Mr. DONNELLY. Okay.

Dr. ACHESON. But we are not there yet.

Mr. DONNELLY. But at this time, these products are still landing in Seattle or somewhere else and being distributed?

Dr. ACHESON. Correct. At this point, we do not have the authority to prevent that.

Mr. DONNELLY. Do you have a list of your most likely potential problems other than melamine? Do you have an active list of scenarios of what areas we are concerned about?

Dr. ACHESON. Absolutely. Both on a food safety front and a food defense front, we have created risk-based lists in terms of what pathogen or chemical or radiological agent might be intentionally or unintentionally put in a food product, what type of food might it go into, and this is particularly true of food defense, where we have applied this very assiduously.

Mr. DONNELLY. Was melamine on any of these lists?

Dr. ACHESON. It wasn't.

Mr. DONNELLY. Okay. Could you share those lists with the Chairman, who would then share them with us?

Dr. ACHESON. I would be happy to. Those lists are classified, so within those confines, sure.

Mr. DONNELLY. Thank you very much.

The CHAIRMAN. I thank the gentleman. I was wondering if there have been different discussions about how to deal with this and apparently, you have added an new position at FDA. What are your reactions to these folks that want to create a new food agency that is separate where that they set up some separate agency and I guess put all you guys in there or something. What is your reaction to that?

Dr. ACHESON. Are you asking me?

The CHAIRMAN. Both of you.

Dr. ACHESON. Well, let me start. I think whenever one is looking to make change, you need to be very careful that in the process you don't actually make matters worse. Whether that is a big reorganization or a small one, and the one that you are alluding to would be big. Simply moving boxes around seldom solves a problem. However this is approached, it needs to be approached strategically; it needs to be approached with adequate resources and it needs to be done carefully. Ultimately, with your suggestion, could it work, po-

tentially, at some point? Sure, perhaps. But it would need to be done in the way I have described. Right now, the system, with the communication that we have between the various agencies, is working remarkably well. We have constant interaction, constant communication. And I would worry that simply embarking on a strategy like that could, in fact, put us back and not bring us forward.

The CHAIRMAN. Yes, that has been my concern too, given the experience we had with Homeland Security. Hopefully we learned our lesson, but we could actually put ourselves in a situation that seems like we are, in my opinion, not doing anywhere near what we should in terms of all this imported food coming in. If we try to do something like this, we would basically be out of commission for two years. It would probably make sense to just stop importing food while we are going through this, because we couldn't guarantee anything, during all the commotion that happens. So it seems you have some of the same concerns I do. Mr. Petersen?

Dr. PETERSEN. I would agree. Certainly we need to have a notion of what the solution is going to do as far as addressing the problem you think you are trying to solve. I think the agencies, the FDA and USDA, in this situation, certainly have complementary authorities. I don't see a lot of duplicative authorities and so this current situation, I think is an example of how the agencies can leverage their individual resources and get their arms around a particular problem. Are there always better ways to do things? Certainly. And I think we will always try to find those better ways, but our work seems to be complementary with FDA at this point.

The CHAIRMAN. We have a vote. But the other thing I am wondering about is that I am sure that whatever you guys come up with is going to take extra resources. When I look at the huge increase of volume and the fact that we haven't had any new resources, I think that is going to be pretty apparent. My concern is with rules now and us trying to finally get a handle on this budget deficit. How are we going to pay for this? I know the administration has proposed user fees, which has been dead on arrival in Congress. Has there been any thought or will there be any thought to how in the world we will finance this? One question I have is, under the trade agreements, could we put this cost on the countries where we are trying to get the food supply certified? Is it possible to actually add the cost on to what is being imported into the country to pay for this or is that in violation of the WTO agreements? Do you know?

Dr. ACHESON. I don't specifically know the answer to your question, but all of those different complexities would have to be examined and you are correct, finding a way to pay for this is a key question. But you can't do that until you figure out what it is that you want to do and we need to do it quickly.

The CHAIRMAN. Anybody else? We got a couple of minutes. Ms. Musgrave or Mr. Boustany, anything else for the good of the order here?

Ms. MUSGRAVE. Thank you, Mr. Chairman. I just want to say, that as I talked to my constituents, their main concern is food that comes from other countries. Although you have pointed out very appropriately that we also have problems with food grown in the

United States, people have talked to me especially about the vulnerability of young children and how they react to E. coli and Listeria and many of those things that are so very dangerous to small children.

It is not only the food consumed in homes of course, it is in restaurants too. Sometimes it is the way the food is handled. But we do make the assumption in this country that our food is safe, for the most part. What a horrific job you have in front of you, but this issue with the pet food has certainly illustrated our vulnerability and when we do make those assumptions that this is safe and we are going to be able to feed it to our children, we may be very wrong.

I also worry about the consequences of people that would do harm to citizens in our nation. Now that this has happened, they are now very aware of how vulnerable we are. Thank you, Mr. Chairman.

The CHAIRMAN. Thank the gentlelady. Mr. Boustany?

Mr. BOUSTANY. I would just say thank you, Mr. Chairman, for holding this hearing. Gentlemen, your testimony and your answers to the questions were very informative. I certainly appreciate it and we look forward to working with you as we go forward. Thank you.

The CHAIRMAN. I thank the gentleman and we will look forward to the information that was requested by the committee members being forwarded to us. Again, thank you for being with us today and I am sure we will be discussing this more often as time goes along. Thank you very much. The Committee stands adjourned.

[Whereupon, at 12:35 p.m., the Committee was adjourned.]

Opening Statement by
Chairman Collin C. Peterson
Full Committee Hearing to review the impact of imported contaminated food and feed ingredients and of recent food safety emergencies on food safety and animal health systems
May 9, 2007

Good morning and welcome to today's hearing of the House Agriculture Committee. I'll start by acknowledging our witnesses, Dr. Kenneth Petersen with the USDA's Food Safety Inspection Service and Dr. David Acheson with the Food and Drug Administration. Thank you both for joining us today to update the Committee about the current situation surrounding melamine-tainted products from China that have been used in pet food and animal feed.

Based on what I have heard from USDA and FDA, I am relieved that the contaminated feed does not pose a risk to the health of the poultry, swine, and farmed fish that ate it, nor do the products from these animals pose a threat to the food supply or human health. However, the explanations from USDA and FDA

leave me with the uncomfortable feeling that maybe we just got lucky this time. The next time tainted food or feed products slip through the very large cracks in our import inspection system, we may be forced to confront a much more serious situation in terms of animal or human health.

As food and feed imports from countries around the world continue to rise, the rate of inspection for those products entering this country has declined. According to recent newspaper reports, in the past five years, as food imports have grown by almost 50%, FDA has lost about 20% of its food inspectors. Today, FDA is inspecting only 1% of the products entering the U.S. food supply that it is responsible for monitoring. This is a recipe for major problems down the road, and the recalls and quarantines we have seen in response to mislabeled, melamine-tainted products are minor compared to what we could see in the future if this problem is not addressed.

There are many questions we need to answer as we move forward. First, I am interested to hear if USDA and FDA feel confident about the existing inspection procedures that are in place now. Are those procedures adequate to assure the safety of imported food and feed products? If changes need to be made or if additional resources are needed to make those changes, I think the Committee should be aware of that.

Second, I am interested in the issue of who bears the ultimate responsibility for the safety and integrity of imported products? Who will ultimately be held responsible for the melamine tainted products? According to news reports, it was common knowledge among Chinese manufacturers that melamine was routinely used as an additive to spike protein levels, yet no company or government entity in the U.S. seemed to be aware of it.

For meat and poultry products, we only accept imports from countries with food safety systems that are equivalent to our own, giving consumers here a certain level of assurance about the integrity of those goods. With FDA-regulated food and feed

products, however, we have no such assurance that producers in foreign countries are held to any safety standards whatsoever, much less the kind of standards we expect from our domestic producers.

I hope that the seriousness of the recent risk assessment efforts undertaken by multiple government agencies in the wake of the melamine incidents are not lost on our trade negotiators. Advocates of free trade have done consumers a disservice by failing to address the simple fact that expanding trade with countries that fail to enforce food safety and environmental standards makes our domestic food supply less safe.

I do appreciate the efforts by USDA and FDA to keep the Members of this Committee and the public informed about the ongoing investigation related to the contaminated food and feed products. However, moving forward, I am interested to hear not only how the agencies have reacted to and investigated the current situation but also what lessons have been learned and what we can

do to better detect and protect against adulterated, mislabeled and unsafe imports.

I look forward to hearing more about the current situation and to addressing some of these serious questions about the safety of the products we are feeding our pets, our livestock and our families.

Opening Statement of Ranking Member Bob Goodlatte
House Committee on Agriculture
Hearing to review the impact of imported contaminated feed ingredients
May 10, 2007

I thank the Chairman for calling this hearing. While this Committee has been correctly focusing its efforts on the farm bill, the recent contamination of pet and livestock feed warrants our attention and continued oversight. It is important to note, however, that the Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA) are still conducting their investigations and there are still many unanswered questions. I appreciate the efforts of both Departments to keep the members of the Committee updated with the most recent information and look forward to learning the conclusions of their findings once the entire investigation is complete.

As the representative of a district that is heavily oriented towards animal agriculture, I am always interested in any issue that affects livestock feed. And, like the rest of my colleagues, I have been approached by family and friends who are quite concerned about the health and safety of their pets. We all sympathize with those who have lost their pets or who have pets that have been adversely affected.

As we continued to learn more about this matter, we discovered that in addition to pets, some hogs and poultry may have also received contaminated feed. As part of the pet food manufacturing process, there is a certain amount of excess product or ingredients that are sold into the livestock feed processing sector.

As far as we know at this point, no one involved in the animal feed business knowingly sold or bought contaminated salvage material. Based on what we know so far, the livestock feed that had been contaminated was sold and consumed before anyone in the United States was aware of the problem.

The fact and extent of this occurrence suggests that some attention to the food safety systems of our trading partners may be warranted. I appreciate the actions thus far by the Administration to resolve this issue, specifically the FDA's recent decision to take the extraordinary action of detaining *all* vegetable protein products imported from China.

During the course of sampling various vegetable proteins and products made with vegetable proteins, the FDA has linked all

of the samples testing positive for contamination to imports from China. As part of FDA's investigation, they will identify the actual manufacturer or manufacturers of the contaminated products imported from China. While the source of the contamination in China is currently unknown, I hope FDA's detention order will send a strong signal to the Chinese industry and government that we are serious about this issue and will not tolerate violations of our food import standards.

I look forward to the testimony of our witnesses and any light you can shed on this issue.

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WC: 445

Congressman Nick Lampson
Opening Statement - Public hearing on food safety.

Full Committee on Agriculture
Wednesday, May 9, 2007

Recent incidents, including scares involving spinach, peanut butter, and pet food have highlighted the need for increased and more vigilant inspections of imported food. However, at the same time the FDA is proposing to consolidate its Office of Regulatory Affairs laboratories from 13 facilities nationwide to as few as four.

When food safety emergencies arise, such as those I noted, it is vital to respond rapidly and appropriately – not only to isolate the problem to ensure the safety of our food supply, but to ensure the piece of mind of all Americans.

Hundreds of consumers in the 22nd District, which I represent, were recently affected when Peter Pan brand peanut butter announced a recall due to Salmonella bacterium contamination. Now, I commend the FDA for its quick action in identifying the source of the outbreak and getting the word out to consumers. But I am deeply concerned over the fact that this has become a regular occurrence over the past several months. If consumers do not have faith in our food supply, it will have vast negative affects on our markets, our economy, and our moral.

I am glad that we are having this hearing today, so that our constituents can see that Congress shares their concerns and is acting to protect our food supply.

Opening Statement of Congressman Joe Donnelly (IN-2)
House Agriculture Committee

Hearing on the Impact of Imported Contaminated Food and Feed Ingredients and the Recent Food Safety Emergency.

May 9, 2007

Chairman Peterson, Congressman Goodlatte, I want to thank you for calling today's hearing and express my appreciation for your leadership on this committee.

I would also like to thank our witnesses, Dr. Petersen and Dr. Acheson, for testifying today. I know you both have been very busy investigating the recent pet food and feed contamination, as well as the safety threats that have followed. These are very serious issues, and I look forward to a thoughtful discussion on the safety of the American food supply and what we must do to strengthen our food safety system to ensure that we prevent future instances of contamination—both intentional and unintentional.

In my first four months here in Washington, I have heard numerous people talk about how America's food supply is the safest in the world. I don't doubt that this is the case. However in recent weeks, we have been reminded that our food system is not without vulnerabilities. The recent discovery that wheat gluten and rice protein concentrate containing melamine quietly entered our food supply, killing pets and threatening the health and safety of our livestock, is evidence that our current system is not adequate. In my own state of Indiana, nearly 3 million chickens were quarantined after they consumed contaminated chicken feed. This incident demands a thoughtful discussion and swift action to strengthen our inspection system and restore the confidence of both the livestock industry and the American consumer.

How did this industrial substance find its way into this country? Why did we not know about its presence until we had already put our pets and livestock operations at risk? What do we need to do to ensure that future threats of contamination, intentional or unintentional, do not impact the safety of the American people? These are all questions I hope that we can address in today's hearing.

We live in a global economy where irresponsible business practices in China can result in the death of pets and the disruption of animal agriculture half a world away here in the United States. These are complex issues, which raise serious concerns about FDA and USDA's ability to ensure that our livestock producers and consumers have access to safe and healthy food supply. I look forward to hearing today's testimony. Perhaps more importantly, I look forward to working with FDA and USDA to ensure that our food supply continues to live up to its reputation as the safest in the world.

Thank you.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

STATEMENT OF

DAVID ACHESON, M. D., F.R.C.P.

ASSISTANT COMMISSIONER FOR FOOD PROTECTION

U.S. FOOD AND DRUG ADMINISTRATION

BEFORE THE

COMMITTEE ON AGRICULTURE

U.S. HOUSE OF REPRESENTATIVES

MAY 9, 2007

RELEASE ONLY UPON DELIVERY

INTRODUCTION

Good morning, Mr. Chairman and Members of the Committee. I am Dr. David Acheson, Assistant Commissioner for Food Protection at the U.S. Food and Drug Administration (FDA or the Agency). Commissioner von Eschenbach has charged me, in this newly created position, with providing advice and counsel on strategic and substantive food safety and food defense matters, and serving as a liaison from his office to the Department of Health and Human Services, of which we are a part, and to other Federal Departments and agencies.

Thank you for the opportunity to discuss FDA's response to the importation of contaminated animal feed ingredients and the impact of this incident on food safety and animal health. I am pleased to be here with my colleague, Dr. Kenneth Petersen, from the U.S. Department of Agriculture (USDA).

FDA's COMMITMENT TO FOOD SAFETY

FDA's primary mission is to protect the public health. Ensuring that FDA-regulated products are safe and secure is a vital part of that mission. The Agency regulates everything Americans eat except for meat, poultry, and processed egg products, which are regulated by our partners at USDA. FDA's responsibility extends to live food animals and animal feed.

FDA is committed to ensuring that America's food supply continues to be among the safest in the world. But we face significant challenges. One of those challenges is the rapid increase in the volume of imported products. The volume of FDA-regulated imports has doubled in the last five years, and 60 percent of these imported shipments are food. Currently, there are over 10 million entries of imported food annually and most are large volume commercial shipments. It is estimated approximately 15 percent of the U.S. food supply is imported, but for some products such as fresh fruits, imports account for 50 to 60 percent of the supply.

Another challenge is the significant increase during the past decade in the consumption of produce, particularly "ready-to-eat" products. This is a positive development from a nutrition perspective, but it represents a new dynamic that challenges our food safety efforts. Americans usually consume these products in their raw state, harvested from the vine, stem, or soil and with minimal or no additional processing to reduce or eliminate any pathogens that may be present. Consequently, the manner in which these products are grown, harvested, packed, processed, and distributed is crucial to ensuring that microbial contamination is minimized, and the risk of illness to consumers is reduced. If even a small percentage of a harvest is contaminated, severe and widespread illness can result.

In response to the recent produce-related outbreaks, FDA has sharpened its focus in this area. To reduce the risk of foodborne illness at all points in the food chain, FDA has adopted a "farm-to-fork" approach to food safety. This approach systematically applies

risk management principles at each step as food moves from growers and producers to consumers. In view of the recent recalls involving wheat gluten and rice protein concentrate in various pet foods, FDA, in conjunction with other Federal and state regulatory authorities, is testing for the presence of melamine and other potential contaminants in a variety of plant protein ingredients and finished products commonly found in the U.S. food and feed supply.

The Agency is focusing and renewing its food safety efforts in three key areas: strengthening the scientific basis for FDA's food safety program, enhancing effective partnerships, and improving risk-based targeting of inspection resources. To enhance the safety of all human and animals foods, domestic and imported, we work closely with states, produce growers, processors, and distributors to develop and implement programs at each point in the supply chain to prevent and minimize contamination from, for example, harmful micro-organisms. In March and April of 2007, FDA held two public hearings to share information about recent outbreaks of foodborne illness associated with microbial contamination of fresh produce, and to solicit comments, data, and additional scientific information on this issue. We are soliciting input from all our stakeholders on ways to improve the safety of fresh produce.

FDA is examining recent incidents of foodborne illness and product contamination to determine what additional changes may be necessary to improve the safety of food, including animal feed. In order to better address the food safety challenges we are facing, we will pursue a vision of FDA as a multi-disciplined, science-led organization

that can lead the world in food safety and disease prevention while promoting the highest standards for public health.

ANIMAL FEED CONTAMINATION

Overview

FDA's investigations into contaminated pet food and farm animal feed are an ongoing priority for the Agency which continues unabated. The information presented herein is accurate as of this date, but we note that as we obtain more investigative and scientific information, preliminary assumptions and conclusions have changed, and may continue to do so. The investigations that began in March 2007 have revealed that the sources of the contamination were imported pet food ingredients, which contained the industrial chemical melamine and melamine analogs. So far, FDA has received thousands of reports of pet illness that owners suspect are connected with the consumption of contaminated pet food. Moreover, FDA has determined that production waste (also referred to as salvage) from the pet food manufacturing process involving these contaminated ingredients was used as an ingredient in animal feed for hogs and chickens.

At this point in time, FDA has identified the Chinese supplier, the importer, and all of the parties directly involved with the distribution of commercial pet food containing wheat gluten contaminated with melamine and melamine analogs. The Agency has conducted investigations at all pet food manufacturers that have used such wheat gluten and all have initiated recalls, the scope of which have evolved as the investigations progressed and

new information was learned. In mid-April, FDA became aware of a suspicious shipment of a product identified in labeling and import entry records as rice protein concentrate that was also used in the manufacture of pet foods. Upon inspection, FDA detected the presence of melamine and melamine analogs in the imported rice protein concentrate and the finished pet food. Some of this contaminated pet food was unknowingly sent as salvaged feed to various hog producers in several states. Additionally, FDA has learned that salvage from pet food manufactured with contaminated wheat gluten was used in chicken feed on some farms in the states of Indiana, Missouri and Arkansas.

FDA, in consultation with our colleagues from the USDA's Food Safety and Inspection Service (FSIS), and the Centers for Disease Control and Prevention (CDC) believes that the likelihood of human illness from eating products containing pork or chicken fed the contaminated feed is very low, in large part due to the considerable dilution of the contaminants. Because there is no evidence of harm to humans, no recall of products processed from these animals has been issued.

FDA is conducting a thorough investigation of the pet food and farm feed contamination. During the past eight weeks we have aggressively worked to identify the source and scope of the contamination, to assure the removal of all contaminated products from the supply chain and store shelves, and to keep the public informed. As an added precaution, we have asked CDC to use its surveillance network to monitor for signs of human illness, such as increased renal failure, which could indicate contamination of the

human food supply. Testing and the joint FDA/FSIS investigation continue. If any evidence surfaces to indicate there is potential harm to humans, appropriate and aggressive action will be taken.

FDA Regulation of Pet Food & Farm Animal Feed

The Federal Food, Drug, and Cosmetic Act (FFDCA) requires that pet foods, like human foods, be safe to eat, produced under sanitary conditions, contain no harmful substances, and be truthfully labeled. In addition, canned pet foods must be processed in conformance with the low acid canned food regulations to ensure safety from harmful bacteria or their toxins. The law requires that the ingredients used in pet food are safe and have an appropriate function in the pet food. Some ingredients, such as many mineral and vitamin sources, colorings, flavorings, and preservatives, are generally recognized as safe. Other ingredients must have approval as food additives. Absent such approval, addition of such ingredients to a food product would likely result in the product being considered "adulterated" under the FFDCA.

Assisting the pet food industry with recalls of adulterated pet food is always a regulatory priority for FDA. FDA alerts the public, classifies the recall, and works with states and industry to identify the contamination source and underlying problem. FDA carefully examines the facts behind a pet food contamination, assesses whether actions taken by the firm were appropriate, monitors the effectiveness of the recall and if appropriate,

provides guidance for the industry to alert them of the problems identified and help prevent reoccurrence.

FDA works closely with state feed control officials in establishing standards for animal feed, including pet food products. FDA prioritizes and conducts risk-based inspections targeted toward products that pose the greatest risks to public health. However, inspections cannot identify every potential contaminant and they are only one aspect of our work to detect and contain potential safety problems. It is important for all participants in the production and distribution process to maintain the highest standards for safety to protect the American consumer, whether that consumer is human or animal. As with human food safety, FDA recognizes that we need to use strong science capable of identifying both the sources of risk and effective control measures. To that end, FDA is working to develop a risk-based Animal Feed Safety System that describes how animal feed production, distribution, and use can be designed to minimize risks to humans and animals. Information on the proposed Animal Feed Safety System is available through the FDA website *(http://www.fda.gov/cvm/AFSS.htm)*.

Investigation of Contaminated Pet Food Ingredients

FDA's investigation has been aggressive and comprehensive. As soon as FDA received word that cats and dogs were becoming sick and dying from certain pet foods, our first priority was to limit the risk of animal injury and death. Within 24 hours of being notified of the problem by Menu Foods, our investigators were on-site at the Menu Foods

Emporia, Kansas plant searching for the source of contamination. Our response to the pet food contamination has been a team effort in which the Agency has:

- dedicated personnel in each of its 20 district offices to take consumer calls and conduct inspections and investigations;
- mobilized more than 400 employees to collect pet food and animal feed samples, monitor the effectiveness of the recall, and prepare consumer complaint reports;
- conducted numerous inspections of manufacturing facilities and warehouses to trace all of the contaminated product;
- analyzed more than 700 pet food and ingredient samples in six FDA field laboratories and FDA's Forensic Chemistry Center;
- issued press releases, conducted media interviews, and developed a Web site to provide current information to consumers, veterinarians, and our regulatory counterparts;
- worked with its regulatory partners in all 50 state agriculture and health agencies to share information and collaborate on investigative and analytical efforts;
- activated its Emergency Operations Center, with staff available to all FDA offices on a 24-hour basis to manage incoming information from pet owners, veterinarians, and others; and
- dispatched an investigative team to China at the earliest opportunity.

FDA identified the supplier of the contaminated wheat gluten as a Chinese firm, Xuzhou Anying Biologic Technology Development Company, and we issued an import alert

providing for detention without physical examination of all wheat gluten imported from that firm to assure that contaminated product does not enter U.S. commerce. FDA's import controls have evolved as new information has been learned during the investigation. The import alert currently covers all vegetable protein products from China. All entries from China are detained by FDA upon arrival into the U.S. by FDA and not released into domestic commerce unless third party analysis demonstrates the entry is not contaminated with melamine or melamine analogs.

We have issued a high-priority domestic food defense protein surveillance assignment to our field staff to focus on imported protein extracts and finished products within the United States, and the Prior Notice Center directed assignments for ingredients and products of interest being imported to the United States (with the exception of corn, wheat and rice extracts, which are covered under a separate ongoing assignment).

Contamination of Hog Feed

On April 16, FDA began an additional investigation into product labeled and identified in import records as rice protein concentrate imported by San Francisco-based Wilbur-Ellis, an importer and distributor of agricultural products. The Agency detected the presence of melamine and melamine analogs in the imported rice protein concentrate, and found that it was used to manufacture pet food.

FDA determined that the product was supplied by Binzhou Futian BiologicalTechnology Company in China. Prior to expanding the import alert to cover all vegetable protein products from China, FDA immediately put this company on import alert to prevent any further introduction of adulterated ingredients. As it did with the wheat gluten from Xuzhou Anying, FDA also reviewed import records to ensure all importations originating from this company were identified and fully traced. FDA's investigation is ongoing in order to fully trace all contaminated products originating from Binzhou Futian.

Some of the contaminated pet food was sent unknowingly as salvage feed to various hog producers in several states, and some hogs were found to have levels of melamine in their urine. Pork producers in the states of California, Illinois, Kansas, North Carolina, New York, South Carolina, and Utah are known to have purchased the feed. Some of these animals are currently being held from commerce.

On April 26, FDA and USDA/FSIS notified state authorities that these hogs were not being approved to enter the food supply. Currently, hogs and poultry on farms suspected of receiving contaminated feed are being held under state quarantine or voluntarily by the owners. In several of these cases, feed samples have tested negative for melamine and related compounds. These tests were conducted by federal laboratories or state laboratories using approved methods. It is assumed that because only small amounts of the contaminated feed were mixed with other rations, the melamine and related compounds were no longer detectable. On May 7, the two agencies announced that a human health risk assessment had been completed with the input of scientists from FDA,

CDC and FSIS, as well as the Environmental Protection Agency and the Department of Homeland Security. FSIS has concluded that, based on the human risk assessment and the inability to detect melamine in the feed samples, animals on farms with a negative feed test no longer need to be quarantined or withheld from processing.

In other cases, animals continue to be withheld from processing, but are not yet being culled, pending the results of an animal risk assessment. These are cases where feed samples have tested positive for melamine and related compounds; feed samples were not available; or feed samples have not yet been submitted for testing.

Contamination of Chicken Feed

In late April, through further investigations, FDA and USDA learned that salvage feed from pet food manufactured with contaminated wheat gluten had been used in chicken feed on some farms in three states. At this time, the investigation indicates that approximately 30 broiler poultry farms and eight breeder poultry farms in Indiana received contaminated feed in early February and fed it to poultry within days of receiving it. All of the broilers believed to have been fed contaminated product have since been processed. The breeders that were fed the contaminated product are under voluntary hold by the flock owners. As with exposure from hogs fed contaminated pet food, and based on risk assessment, FDA and USDA believe the likelihood of illness after eating chicken fed the contaminated product is very low.

HUMAN HEALTH IMPACT

At this time, we have no evidence of harm to humans associated with the processed pork or poultry products. Testing and the joint investigation continue. If any evidence surfaces to indicate there is harm to humans, the appropriate action will be taken.

The assessment that, if there were to be risk to human health, it would be very low, is based on a number of factors, including the dilution of the contaminating melamine and melamine analogs from the original protein concentrates as they move through the feed system. With respect to hog or poultry populations, the contaminated rice protein is only one ingredient in the pet food; and it is only part of the total feed given to the hogs. Additionally, melamine and melamine analogs are not known to accumulate in the animals and the animals excrete melamine in their urine. Finally, pork is only a small part of the average American diet.

In addition to the dilutional factor and the lack of evidence of illnesses in the animals fed the salvaged pet food, we are not aware of any human illness that has occurred from exposure to melamine or its by-products. While the CDC detection systems would have limited ability to identify subtle problems due to melamine and melamine analogs, no such problems have been detected to date.

To further evaluate any potential harm to humans, FDA is developing and implementing additional tests and risk assessments based on the toxicity of the melamine and melamine

analogs and how much of the compounds consumers could be expected to actually consume. FDA has also begun testing a variety of protein ingredients and finished products commonly found in the U.S. food and feed supply for the presence of melamine and melamine analogs. Some of the protein concentrates being tested include wheat gluten, corn gluten, corn meal, soy protein, rice bran, and rice protein concentrate.

CONCLUSION

The animal feed investigation has been a massive effort drawing from many parts of FDA and it will continue until we are completely satisfied that the underlying cause has been determined, the scope identified, and corrective action is initiated and found effective. Many dedicated professionals from Federal and state agencies are working to respond to this contamination. USDA and FDA continue to conduct a full, comprehensive examination to protect the nation's food supply and will provide updates to the public as new information is confirmed.

FDA is working hard to ensure the safety of all food, including animal feed, in collaboration with our Federal, state, local, and international food safety partners, and with industry, consumers, and academia. In spite of the challenges which face us, the American food supply continues to be among the safest in the world. We have made significant progress, and we will continue striving to reduce the incidence of foodborne illness.

Thank you for the opportunity to discuss these important food safety issues with you. I will be glad to answer any questions you may have.

TESTIMONY OF DR. KENNETH E. PETERSEN
ASSISTANT ADMINISTRATOR, OFFICE OF FIELD OPERATIONS
FOOD SAFETY AND INSPECTION SERVICE
UNITED STATES DEPARTMENT OF AGRICULTURE
BEFORE THE
U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON AGRICULTURE

May 9, 2007

Good morning, Mr. Chairman, Congressman Goodlatte and other Members of the Committee. I am the Assistant Administrator for Field Operations for the Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA).

I appreciate the opportunity to appear before you today to discuss the ongoing investigation of the animal feed supplemented with pet food scraps containing melamine and melamine-related compounds. I am pleased to be here today with my colleague, Dr. David Acheson, from the Food and Drug Administration (FDA) of the United States Department of Health and Human Services (HHS).

Before I get into details, let me begin by emphasizing that FSIS takes very seriously its responsibilities to ensure the safety of meat, poultry, and processed egg products. We do not believe the current incident poses a threat to human health, and we are not aware of any human illnesses that have ever been linked to melamine or melamine related compounds.

Our inspection program personnel form the backbone of FSIS' public health infrastructure in laboratories, plants, and import houses throughout the country. In FY 2006, the Agency had approximately 7,600 full-time personnel protecting the public health in 6,000 federally-inspected establishments nationwide where FSIS inspection program personnel performed antemortem and postmortem inspection procedures to ensure public health requirements were met in the processing of over 46 billion pounds of livestock carcasses, almost 57 billion pounds of poultry carcasses, and about 4.4 billion pounds of liquid egg products. Approximately 60 cents of every food dollar in the United States is spent on foods that FSIS inspects.

In FY 2006, FSIS inspection program personnel conducted more than eight million procedures to verify that establishments met food safety and wholesomeness requirements. In addition, during FY 2006, approximately 3.9 billion pounds of meat and poultry and about 5.9 million pounds of egg products were presented for import inspection at U.S. ports and borders. FSIS also has Program Investigators nationwide who conduct food safety, food defense, and outbreak investigations and enforcements.

FSIS' Role Responding to Melamine in Animal Feed

FSIS has been working cooperatively with the FDA on the investigation into swine and poultry feed containing imported wheat flour contaminated with melamine and melamine related compounds.

from chickens that had consumed feed supplemented with pet food scraps contaminated with melamine and melamine-related compounds.

However, as was the case with the swine, because the feed in question was contaminated, and given the information that was available at that time, FSIS could not apply the mark of inspection. Therefore, the Agency determined that chickens fed the contaminated chicken feed would not be approved to enter the human food supply, pending further investigation. As with the hogs, chickens on the affected farms were held voluntarily by the producers at the request of Federal and State authorities.

This past Monday, May 7, FSIS determined that the mark of inspection could now be placed on meat and poultry products when the animals are from farms traced to contaminated feed that, when sampled, tested negative.

This determination was made after a risk assessment was conducted by scientists from FDA, FSIS, CDC, the Environmental Protection Agency (EPA), and the Department of Homeland Security. The risk assessment found that consuming meat from hogs and chickens known to have been fed animal feed supplemented with pet food scraps that contained melamine and melamine-related compounds represent a very low risk to human health. In the most extreme risk assessment scenario, the scientists assumed the unlikely event that *all* the solid food a person consumes in an entire day was contaminated with melamine. Even then, the potential exposure was about 2,500 times lower than the dose considered safe; well below any level of public health concern.

very low risk to human health from eating meat from animals that were fed the contaminated product.

Current Status

As soon as the situation arose, we ensured that swine and poultry on farms known to have received or suspected of receiving contaminated feed that had tested positive for melamine and melamine-related compounds were held under State quarantine or voluntarily by the owners. As the investigation has proceeded, we now know that, in several cases, on-farm feed samples have tested negative for melamine and related compounds. These tests were conducted by federal or State laboratories using approved methods. Most likely because only very small amounts of the contaminated feed were mixed with other rations, the melamine and related compounds were no longer detectable. USDA has concluded that, based on the human risk assessment and the inability to detect melamine in the feed samples, these animals no longer need to be quarantined or withheld from processing.

In other cases, feed samples have tested positive for melamine and related compounds; feed samples were not available; or feed samples have not yet been submitted for testing. These animals continue to be withheld from processing, but are not yet being culled, pending the results of the animal risk assessment. New scientific information is expected to be completed soon -- hopefully within one week. Upon completion of further risk

We recognize how important it is to communicate with our stakeholders, our partners and the general public in an open and transparent manner. Throughout the ongoing investigation with FDA, we have been sharing information with State departments of agriculture and State veterinarians. We continue to keep trading partners informed through the Foreign Agricultural Service. We have been updating our stakeholders from industry and consumer organizations. We have been working with the FDA to keep the general public informed. We will continue to reach out to our stakeholders, our partners and the general public to keep them informed as the investigation continues and provide the opportunity for them to provide comments for our consideration. And we will continue to keep Congress informed of our ongoing investigations.

Thank you again for providing me with the opportunity to address the Committee on this issue. I would be happy to respond to any questions you have

Congressional Research Service

Memorandum May 10, 2007

TO: House Agriculture Committee
Attention: Craig Jagger and Chandler Goule

FROM: Geoffrey S. Becker
Specialist in Agricultural Policy
Resources, Science, and Industry Division

SUBJECT: FSIS and FDA Regulated Food Imports

This is in response to your rush request for data comparing the quantities of food imported under the respective jurisdictions of the U.S. Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS) and the U.S. Food and Drug Administration (FDA) and the number of personnel within each agency monitoring those imports. You asked that data be provided that could compare current levels with those of 10 years ago.

The following tables were prepared by CRS using, unless noted, readily available data from the House Appropriations Committee's hearing records on agriculture appropriations for various fiscal years, primarily the FY1998 and FY2007 volumes. These data should be considered preliminary until confirmed by the agencies.

For questions about the FSIS data in table 1, please contact me at 7-7287. For questions concerning the FDA data in table 2, please contact Donna Porter at 7-7032.

Table 1. FSIS-Regulated Food Imports and Inspection Resources			
(FY unless noted)	1996	2005	2006
Meat & poultry imports (*WASDE CY data*) (a)	2.769 billion lbs.	4.846 billion lbs.	4.325 billion lbs.
Meat & poultry imports presented for inspection (*FSIS CY data*)	2.3 billion lbs.	4.3 billion lbs.	N/A
Percent examined (b)	20% (est.)	9.7%	N/A
FSIS international food safety budget	$11.235 million	$19.18 million	$19.355 million
Border reinspection budget *(subset of above)*	$10.2 million (b)	$10.837 million	$11.75 million
FTEs (Total international)	167	166	165
Import inspectors *(subset of above)*	75	75	N/A

Source: Unless noted, House Appropriations Committee Hearings, Agriculture Appropriations, various years. Excludes egg products. N/A: Not readily available by request deadline.
(a) WASDE: USDA, *World Agricultural Supply and Demand Estimates*, various years.
(b)Source: For 1996, figure is from Vogt, *The Safety of Imported Foods: The Federal Role and Issues Before Congress* (archived CRS Rept. 98-850 STM). Represents physical examinations of shipments. FSIS has explained that although percentage examined has declined, the agency implemented in the early 2000s a new "Automated Import Inspection System" which targets resources on imports of relatively higher risk.

XPΣ–3

Table 2. FDA-Regulated Food Imports and Inspection Resources			
(FY unless noted)	1996	2005	2006
Line entries: *(shipments, size of each varies)*	2.766 million (FY97 data) (b)	8.672 million	10.06 million (est.)
Percent examined	1.7%(b)	1.27%	1.06%
Field operations budget (c)	N/A	$283.3 million	$285.2 million
FTEs (c)	1,452(b)	2,059	1,962
FTEs *(involved with imported foods, subset of above)*	595(b)	N/A	N/A

Source: Unless noted, House Appropriations Committee Hearings, Agriculture Appropriations, various years.
(b) Source: Vogt, *The Safety of Imported Foods.*
(c) Includes domestic as well as import operations in field; import only not readily available by deadline.

SAFE FOOD COALITION

1620 I Street, NW, Suite 200, Washington, DC 20006 202-797-8551

May 8, 2007

The Honorable Collin Peterson
Chairman
House Committee on Agriculture
1301 Longworth House Office Building
Washington, DC 20515

Dear Chairman Peterson,

The undersigned members of the Safe Food Coalition respectfully request that this letter be placed in the hearing record for the Committee's hearing on imported foods and food safety scheduled for May 9, 2007. Founded in 1986, the Safe Food Coalition is composed of consumer research and advocacy organizations, groups representing victims of foodborne illness, and trade unions who share the goal of reducing the burden of foodborne illness in the United States. For 20 years the Safe Food Coalition has built a reputation for analysis and advocacy on issues related to food safety and foodborne illness. We participate actively in both USDA and FDA forums and representatives of our member groups serve on the National Advisory Committee on Microbiological Criteria for Food, the National Advisory Committee on Meat and Poultry Inspection and the FDA Food Advisory Committee.

Our members have been particularly active with regard to the recent food safety emergencies, which we understand to be the main focus of your hearing. We appreciate this opportunity to address this issue and share our views with the Committee.

Safe Food Coalition members vigorously oppose any efforts to move any public health functions from the Department of Health and Human Services (DHSS), which is the primary location for public health functions in the executive branch, to the U.S. Department of Agriculture (USDA), which is the primary location for promoting production and consumption of agricultural commodities. Although USDA's Food Safety and Inspection Service is designated as a public health agency, the USDA suffers from an inherent conflict of interest in executing public health programs. Congress created the Department for the purpose of promoting the production and sale of agricultural commodities. Congress also placed responsibility for assuring the safety of meat and poultry products within USDA. Frequently those two interests conflict, and when they have, food safety has often not been the Department's primary concern.

For many years USDA treated meat, poultry and egg inspection as a subset of animal health. Since foodborne pathogens generally do not make animals sick, the Department paid little concern to addressing foodborne illnesses. Both animal health and food safety functions of USDA have been, for most of their history, administered as part of the Department's marketing functions, with an orientation toward industry concerns rather than public health. Ten years ago Congress created a separate Under Secretary for Food Safety. However, that agency is isolated in an institution that is more concerned with agricultural production than public protection. No Secretary of Agriculture has ever been chosen because he or she had primary expertise in public health.

Even if it has the institutional will, the record shows that FSIS does not have the ability to administer an effective public health program. The agency does have experience with maintaining a food inspection program and its inspectors are dedicated to protecting the safety of our meat and poultry supply. However, the current meat and poultry inspection laws are neither science-based nor risk-based. The courts have ruled that the Agency has no capacity to close down permanently plants that regularly fail to meet microbiological performance standards. In addition, the USDA declined to challenge a court ruling that USDA could not close permanently plants that regularly failed to meet their own HACCP and sanitation plans. The National Academy of Sciences has recommended that Congress give USDA power to develop and enforce performance standards including limits on microbiological contamination.

Despite industry efforts to improve, these weaknesses in the USDA program keep the health risk from meat, poultry and egg products far higher than it should be. While produce is a very serious food safety problem, data from the Center for Science in the Public Interest shows that meat and poultry products as a class are responsible for more foodborne illness outbreaks than produce as a class[1]. Testing by Consumers Union, the publisher of Consumer Reports, found in January that 83 percent of the broiler chickens they tested in a nationwide sample harbored *Campylobacter* or *Salmonella*, two dangerous foodborne pathogens[2]. This was a considerable increase from 2003 when only 49 percent tested positive for one or both pathogens.

Finally, the Centers for Disease Control and Prevention, in this year's FoodNet report on the nationwide incidence of foodborne illness, revealed that after declines in 2003 and 2004, incidence of *E. coli* O157:H7 infections has increased markedly over the past two years[3]. The CDC noted in its report that this increase coincided with an end to the decline in frequency of positive *E. coli* O157:H7 samples in ground beef over the same time period.

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[1] Center for Science in the Public Interest, "Outbreak Alert: Closing the Gaps in our Federal Food Safety Net," December 2006 at http://www.cspinet.org/foodsafety/outbreak_alert.pdf.

[2] Consumer Reports, "Dirty Birds," January 2007, at http://www.consumerreports.org/cro/food/chicken-safety-1-07/overview/0107_chick_ov.htm.

[3] Centers for Disease Control and Prevention. *Preliminary FoodNet Data on the Incidence of Infection with Pathogens Transmitted Commonly Through Food – 10 States, United States, 2006.* April 13, 2007, MMWR, 56(14), 336-339.

Neither the USDA nor the FDA is being sufficiently funded to protect the public. While the USDA has far greater resources to expend on protecting food safety than does the FDA, these resources have not been used effectively because of weaknesses in the law and institutional support. Nothing in the record suggests that USDA would do a better job of implementing programs now administered by the FDA. Functions of the FDA were originally administered by USDA and were removed in the 1930s because the Department frequently overturned the counsel of the food safety staff in favor of industry interests.

There are steps that Congress could take to improve food safety.

1. As recommended by the 1998 National Academy of Science Report, which Congress directed to be conducted, revise and modernize our food safety laws.

2. As recommended by a multitude of government reports, create an independent food safety agency that would consolidate the food safety activities now located in 15 different agencies administering 30 different laws. This agency would have the sole charge of protecting public health.

3. Follow the recommendations of the National Academy of Sciences (2003) and provide USDA specific authority to develop and enforce microbiological criteria including microbiological performance standards.

4. Provide adequate financial and staff resources to the food safety functions of the FDA. The Department of HHS is the nation's primary public health agency. It has the proper orientation to make food safety programs work. However, the FDA and especially its food safety functions have been starved for resources. For a decade the agency has had to reduce staff positions because Congress has not increased its budget even to cover required cost of living increases for staff. The total budget for FY2008 gives FDA $2 billion but would only increase food safety by $10.6 million. No agency can protect the public if it is systematically starved for resources.

5. Pass legislation that would give both FDA and USDA clear recall authority for contaminated food products and require both agencies to disclose to consumers the retail establishments involved in food recalls.

6. Provide both agencies the ability to assess civil and criminal penalties for companies that routinely violate food safety laws.

We support efforts to bolster the staff and resources of the FDA so that it can perform the food safety functions Congress has mandated. The recent attention surrounding the FDA's ability to protect the food supply is a result of a lack of resources, not a lack of will or expertise. The FDA has an institutional focus on public health and is located in a Department dedicated to public health. Congress should either create a separate food safety agency capable of focusing all national resources for protecting the public from foodborne pathogens and others dangers or Congress should provide sufficient structure

and resources to all of the federal agencies to carry out the food safety work that Congress has charged them to do.

Sincerely,

Patricia Buck
Center for Foodborne Illness Research & Prevention

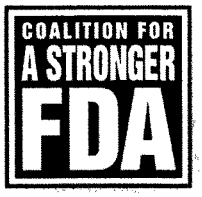
Caroline Smith DeWaal
Center for Science in the Public Interest

Chris Waldrop
Consumer Federation of America

Sally Greenberg
Consumers Union

Jacqueline Ostfeld
Government Accountability Project

Nancy Donley
Safe Tables Our Priority



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Statement for the Record

Ladd Wiley
Executive Director

House Committee on Agriculture's Hearing on Imported Contaminated Food

May 9th, 2007

The Coalition for a Stronger FDA is a broad-based and bi-partisan group calling for a renewed public resource commitment to the FDA. The Coalition unites a diverse collection of patient groups, nonprofit organizations, consumer advocates, public health organizations, trade associations and companies. While the coalition does not have a position on the consolidation of the food safety regulatory function at the USDA, the members of the coalition believe that Congressional analysis of FDA's challenges in the food safety area should consider the severe lack of resources the agency has to fulfill its mission.

As a coalition we believe lack of funding at FDA's Center for Food Safety and Applied Nutrition (CFSAN) and at the Office of Regulatory Affairs (ORA) significantly affects the ability of the agency to fulfill its vital food safety mission. The Coalition is deeply concerned that Congress has greatly increased the responsibilities of FDA without a corresponding increase in appropriations. Indeed, recently, the Institute of Medicine concluded that the FDA is chronically and woefully under funded.

The Coalition believes that FDA funding should be consistently increased over the next five years. We respectfully call upon Congress to increase funding of the food safety programs by $115 million for Fiscal Year 2008 ($45 million for CFSAN and $70 million for ORA's field food function) in order to:

- Address gaps in food safety oversight with enhancements in inspection, auditing, and compliance
- Promote health and wellness
- Speed approvals for safe new products and technologies for food

- Enhance scientific and policy programs, including risk assessment, risk management, and analysis
- Promote globalization through harmonized, science-based food standards
- Provide leadership in food defense

As the Agriculture Committee reviews the effectiveness of FDA's food regulatory function, we respectfully recommend the Committee consider the implications of the serious resource needs of the FDA.

Sincerely,

Ladd A. Wiley,
Executive Director, Coalition for a Stronger FDA

Comments From Brandy Carter
Executive Director of the Kansas Cattlemen's Association
May 9, 2007
Impact of Imported Contaminated Food and Feed Ingredients and of Recent Food Safety Emergencies on Food Safety and Animal Health Systems
U.S. House of Representatives Agriculture Committee

Mr. Chairman and Members of the House Agriculture Committee,

Thank you for the opportunity to provide some additional insight as to the impact of imported contaminated food.

Recently, we have seen the impact of contaminated wheat gluten entering the United Sates. Moreover, it has entered the swine industry and now the chicken industry. However, imported contaminated food is not rare. In 1997 over 1,000 people became ill from contaminated berries from Guatemala, and in 1995 over 200 people were sickened by alfalfa sprouts from the Netherlands. In 2006 $75.1 billion worth of food was imported into the United States only 1.3 % of all imported food was inspected. [1]

Not only a concern with fruits, vegetables and grains, but the potential for contaminated beef needs to also be addressed. More than three billion pounds of beef enter the United States every year. Cattle from one country can be slaughtered in another and often complete traceability is not in place in case of contamination or a foreign animal disease. We have controls in the United States to ensure that our beef is the safest product in the world. However, the US needs better protection and safety provisions to place better controls on imported products.

Even more, live cattle entering the Unites States slated for our food supply can be a safety concern. In 2006, 2.289 million head of cattle were imported. 1.032 million were imported from Canada. 1.257 million were imported from Mexico. [2] As with other countries, we cannot control the safety standards Canada and Mexico place on their live cattle industry. And, the standards in which cattle are produced are not of the same high safety standards as in the United States.

The ability to identify imported cattle and beef is critical due to the potential importation of animals previously and unknowingly exposed to new and emerging diseases. Some diseases have long incubation periods; bovine spongiform encephalopathy (BSE) and bovine tuberculosis are two of the most common. The need to locate contaminated animals may not be realized until many years after the date of importation. The recent cases of BSE in the United States, and the inability to locate cohorts of all contaminated imported animals have illustrated this need.

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[1] Andrew Bridges, "Imported Food Rarely Inspected", Associated Press April 16,2007.25.
[2] USDA, Economic Research Service, 2007. Background Statistics: US Beef and Cattle Industry (http://ers.usda.gov March 16, 2007).

This month Canada verified its 10th case of BSE. The 66 month old dairy cow was determined BSE positive in British Columbia. [3] Had the animal been imported into the United States under USDA's OTM proposal, which would allow Canadian cattle over the age of 30 months to be imported, this could have created a safety hazard within our own live cattle industry.

I would like to offer an opportunity to move toward food safety. Removing cattle from the J-List would add additional security efforts to the food supply and would reinforce the United States' dedication to ensuring animal and food safety. The J-list is a commodity list that is exempt from a permanent mark of origin. Currently cattle are on the J-list and do not have to be marked as to their origin. Removing cattle from the J-List would ensure that cattle entering the U.S. are permanently marked as to the country of origin. From an animal health and food safety perspective, this is extremely important.

To prevent foreign animal diseases, such as BSE, the U.S. Congress should review USDA's plan to allow over thirty months of age cattle (OTM rule) enter into the United States from Canada. Upon review, Congress will conclude that this rule will endanger our domestic cattle herds and threaten our US food supply.

Please take into consideration these two added food security features. The people of the United States have experienced imported contaminated food, and I offer the opportunity to resolve these problems.

Thank you for your time and consideration.

[3] Canadian Food Inspection Agency. BSE Case Confirmed in British Colombia. Canada: May 2, 2007.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

The Honorable Collin C. Peterson
Chairman
Committee on Agriculture
House of Representatives
Washington, D.C. 20515-6001

SEP 2 0 2007

Dear Mr. Chairman:

Thank you for providing an opportunity for the Food and Drug Administration (FDA or the Agency) to testify at the May 9, 2007, hearing before the House Committee on Agriculture, which reviewed the impact of imported contaminated food and feed ingredients and recent food safety emergencies on food safety and animal health systems. This letter provides responses for the record to questions asked at the hearing and an additional follow-up question sent to FDA by e-mail.

We have reprinted the questions in bold below, followed by the Agency's response.

The Honorable Tim Holden and The Honorable Leonard Boswell

1. What steps are being taken by FDA to monitor dairy imports from India, specifically with respect to pesticide residues?

The emphasis of FDA's pesticide residue regulatory monitoring program is on raw agricultural products, analyzed as the unwashed, whole, raw commodity. However, FDA has in the past undertaken some monitoring of processed foods, including dairy products, for pesticide residues. Within the dairy products category, pesticides are more of a potential concern for high fat dairy products, such as butter and ghee, because the pesticides involved are lipophilic (i.e., fat soluble).

In Fiscal Year 2006, 524 shipments of imported dairy products, mostly caseins, came from India. FDA has not examined any dairy products from India as part of its routine pesticide monitoring program over the past year. However, we have become aware of some surveys conducted in India indicating levels of organochlorine pesticide residues in Indian dairy products that might be of concern. Therefore, the Agency is planning to issue an assignment to specifically monitor dairy products from India to complement our normal regulatory pesticide monitoring program. The focus will be on butter and ghee (high fat dairy products) and not milk protein concentrate (MPC), although some MPC samples will probably be

collected. This assignment will determine incidences and levels of residues of organochlorine and organophosphorous pesticide chemicals in Indian dairy products.

2. What is the status of third-party verification for Grade A milk imports?

The National Conference for Interstate Milk Shipments (NCIMS) is the organization of the milk regulatory agencies in all 50 states. The NCIMS has representation from industry as well as states, and FDA has a Memorandum of Understanding with NCIMS that describes a process for the regulation of Grade "A" milk products that the states agree can be sold within their jurisdictions.

In the past there were only three options for states to receive Grade "A" milk products produced outside the United States. Those options were:

- A determination of nation-to-nation equivalence of milk regulatory systems;
- Another country could join the NCIMS as if it were a U.S. state; adopt all the necessary regulations and have FDA Check Ratings (inspections), laboratory evaluations and the other checks and balances included in the U.S. system; or
- A firm in another country could contract with an individual state and be regulated as if it were a firm within that state's jurisdiction.

To provide another option, during its 2005 meeting, the NCIMS decided to implement a pilot program to certify three firms that would provide services equivalent to those provided by a state regulatory agency. Each of these firms could list two foreign firms. During the NCIMS meeting of May 7 – 11, 2007, the pilot was extended until 2009.

At this time the third party certifiers have been selected, and they are working with the six foreign firms (and their milk suppliers) to bring them into compliance with the Grade "A" Pasteurized Milk Ordinance and other NCIMS requirements.

The Honorable Joe Donnelly

3. Do you have a list of your most likely potential problems other than melamine?

FDA looks for a number of contaminants in imported foods. There are over 550 potential contaminants for which FDA routinely monitors imported foods, including pesticides, biologic pathogens, chemical contaminants (other than pesticides) and other agents. While this list is confidential, the Agency is willing to make it available for your examination.

In addition, imported foods are collected and analyzed for agents of concern as part of FDA's food defense supplemental field and laboratory activities. These are included in both selected routine compliance programs as well as stand alone food defense related assignments. The commodities and agents chosen for screening are selected using a risk-based approach. Some examples of previously targeted imported commodities include tomatoes, green onions, fruit juice, and mineral water; and agents include arsenic, *B. anthracis*, cyanide, and *C. botulinum* toxin.

4. According to the USDA, scientists from the Food and Drug Administration and the Centers for Disease Control and Prevention of the Department of Health and Human Services, the Environmental Protection Agency, the Department of Homeland Security, and the Food Safety and Inspection Service of the U.S. Department of Agriculture all participated in the Melamine and Analogues Safety/Risk Assessment. Which agencies were involved in the initial melamine investigation and to what extent? At what stage of the process was the Department of Homeland Security brought into the investigation? Who determines which agencies should be involved? (Question submitted by e-mail from Committee staff on May 31, 2007.)

The investigation into the contamination of pet food and farm animal feed began on March 15, 2007, when FDA learned of Menu Foods' decision to recall certain types of cat and dog food manufactured by the firm. FDA's investigation led to the determination that the source of the contamination was product imported from China labeled as wheat gluten that was contaminated with high levels of melamine and melamine analogues. Subsequently, the Agency learned on April 15 that imported Chinese product labeled as rice protein concentrate was similarly contaminated.

FDA began working with Customs and Border Protection, part of the Department of Homeland Security (DHS) early in the investigation, stemming from the Agencies' long-standing joint operations at ports of entry and other facilities where FDA-regulated products are imported into the U.S. FDA continues to cooperate with DHS and the Federal Bureau of Investigation in investigating this incident under the National Response Plan and the National Infrastructure Protection Plan.

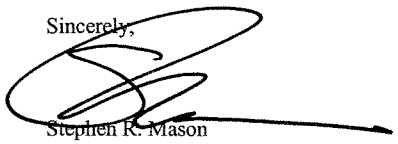
Since mid-April, FDA has worked closely with our regulatory partners at the Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture to carry out our joint responsibilities for the safety of the U.S. food supply. We also involved the Centers for Disease Control and Prevention (CDC), which used its surveillance network to monitor for signs of human illness that could indicate contamination of the human food supply.

By late April, the joint FDA/FSIS investigation confirmed that salvage feed from pet food manufactured with contaminated wheat gluten and rice protein concentrate had been inadvertently used in hog and chicken feed on farms in a number of states. Due to the potential impact on the human food supply, FDA convened an inter-agency scientific panel to assess the risk to human health posed by the animal feed contamination. The assessment was prepared by FDA in collaboration with FSIS and in consultation with scientists from CDC, the Environmental Protection Agency, and DHS. The review panel was composed of 14 scientists from these agencies, who were chosen because of their expertise in human and animal toxicology and their diversity of scientific viewpoints.

On May 25, the Interim Melamine and Melamine Analogues Safety/Risk Assessment was made available to the public. Based on available data and information, the safety/risk assessment indicated that the consumption of pork, chicken, domestic fish, and eggs from animals inadvertently fed animal feed contaminated with melamine and its analogues is very unlikely to pose a human health risk.

Thank you again for the opportunity to provide this information. Please let us know if you have any further questions or concerns.

Sincerely,



Stephen R. Mason
Acting Assistant Commissioner
for Legislation

cc: The Honorable Tim Holden
Committee on Agriculture
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Washington, D.C. 20515-6001

The Honorable Leonard Boswell
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