

Transcript of FDA Press Conference on the Pet Food Recall

FTS HHS

**Moderator: Julie Zawisza
April 24, 2007
3:00 pm CT**

Julie Zawisza: Welcome and thank you for standing by.

At this time, all participants are in a listen-only mode. During the question and answer session, please press star one on your touch tone phone.

This conference is being recorded.

If you have any objections, you may disconnect at this time. Now I will turn the meeting over to Mr. (Rob Aleigh).

Sir, you may begin.

(Rob Aleigh): Thank you.

Ladies and gentlemen, welcome and thank you for joining us. Today, we would like to bring you up-to-date on FDA's investigation of the contaminated pet food. We have four speakers here who I will introduce in a moment.

Please put your phones on mute and when you call for questions and answers, please give your name and media outlet. Thank you.

The format for this afternoon is you will hear remarks from several speakers and updates, and then we will take questions. Our four speakers for today are follows: Dr. Stephen Sundlof, the Director of our Center for Veterinary Medicine, Dr. David Acheson from the Center for Food Safety and Applied Nutrition, Michael C. Rogers, Director of Division of Field Investigations and FDA's Office of Regulatory Affairs, and Captain David K. Elder, Director of the Office of Enforcement in FDA's Office of Regulatory Affairs.

At this time, I would like to it turn over to Dr. Stephen Sundlof.

Stephen Sundlof: Good afternoon. On behalf of the FDA's Commissioner, Dr. Andrew von Eschenbach, I would like to thank you for joining the call. Today's call is a regularly scheduled update to bring in new information in the pet food recall investigation.

FDA's investigation continues nonstop. As I have mentioned last week, these includes 100% sampling of wheat gluten, rice protein concentrate, and corn gluten coming in to the United States from China for melamine and related compounds.

Any and all products from the two firms in China that where the source of melamine contamination are stopped as they come into the country and are examined and sampled.

In addition to the increased surveillance of products imported for China, FDA is announcing today that it will begin testing a variety of protein ingredients and finished products commonly found in the US food and feeds supply for the presence of melamine.

The assignment will focus on both newly-imported ingredients from all sources, as well as products currently in the US, and will supplement the melamine testing already being conducted.

Some of the protein concentrates being tested include wheat gluten, corn gluten, cornmeal, soy protein, rice bran, and rice protein concentrate.

Dr. David Acheson, Chief Medical Officer and Director of the Food Safety and Security Staff at FDA's Center for Food Safety and Applied Nutrition will be here to answer questions about this new sampling assignment.

FDA reported last week the detection of melamine and some melamine-related compounds in imported rice protein concentrate used to manufacture pet food. Three pet food distributors have issued recall, Natural Balance, Blue Buffalo, and Royal Canine.

As part of our work tracing the contaminated products from the importers through the pet food manufacturers, FDA learned that some of the contaminated pet food was sent as salvage feed to various hog producers and several states including North Carolina, California, South Carolina, New York, Utah, and possibly Ohio.

Hogs that had been sent salvaged pet food in North Carolina, South Carolina, and California were tested, and levels of melamine were detected in their urine.

As a precautionary measure, the hogs and all of the farms identified have been quarantined. FDA is working with the states, the US Department of Agriculture, both the Food Safety and Inspection Service and the Animal and

Plant Health Inspection Service to make to sure that there is no further distribution of the meat from these farms.

FDA, our state and local counterparts in the pet and human food industries are working very closely together to identify and halt any further contaminations. We will continue to provide updates as soon as any information is available.

Thank you and I will return the phone to (Rob Aleigh).

(Rob Aleigh): Thank you, Dr. Sundlof.

At this time Dr. David Acheson, the Chief Medical Officer for the Center for Food Safety and Applied Nutrition of the FDA will give a short opening statement. Dr. Acheson.

David Acheson: Thank you Rob. Good afternoon everybody. This is David Acheson, Chief Medical Officer in FDA Center for Food Safety and Applied Nutrition. I am going to speak briefly about food surveillance assignment that Dr. Sundlof referred to, and essentially, what we are doing is developing a food surveillance assignment around this melamine contamination problem.

Beginning sometime this week, FDA in conjunction with the states are proposing to test a variety of protein ingredients in finished products commonly found in the US food and feeds supply for the presence of melamine.

As part of this approach, FDA and the state authorities are going to raise awareness with manufactures and processors about the importance of knowing all there is to know about their suppliers.

At this time, I want to emphasize that there is no indication that melamine has been added to ingredients other than those used in the pet foods. However, we believe that it is very important to further raise awareness about food protection and food defense, and that is one of the reasons why we are undertaking this assignment.

The assignment is going to focus on both newly-imported ingredients as well as products currently in the United States, and we will supplement the melamine testing that is already being conducted.

Some of the protein concentrates that we are going to test initially are wheat gluten, corn gluten, cornmeal, soy protein, rice bran, and rice protein concentrate. Over the next few weeks, this assignment may expand in size and scope to include other products, other type of proteins as learn more about this.

I wanted to just emphasize that these proactive steps. As you are all well aware, we already know that melamine has been found in wheat gluten and rice protein concentrate and there has been concerned of corn gluten in the other parts of the world being contaminated with melamine.

This assignment is to get out ahead of the curve, and to start to, not only raise awareness amongst manufacturers about the importance of knowing a lot about their suppliers and where they get their suppliers from, but also to undertake testing of commonly used protein concentrate that could potentially be contaminated with melamine, and I want to emphasize, (could) in this stage that there is no evidence or whatsoever that anything other than what we have already talked about is contaminated.

This is a proactive assignment that is focused on a preventative strategy, looking more broadly. So, in essence, as I've said, this will begin in the latter part of this week. It will focus on a number of protein concentrates and it will have two components of raising awareness and sampling and testing.

Thanks Rob.

(Rob Aleigh): Thank you Dr. Acheson. At this time, we will turn over to questions and answers in the next 45 minutes or so, ending at approximately 5 p.m. If you would state your name and your outlet and limit yourself to one question and a quick follow-up, will be we could get through more of your colleagues on the call.

So with that, we will take the first question.

Julie Zawisza: We will begin the question. In the session, if would like to ask a question, press star one, to withdraw your question press star two. One moment please.

The first question comes from (Daniel Reitnik) with CNN.

(Daniel Reitnik): Yes. Hi, my name is (Dan Reitnik). I'm with CNN. I have heard that there has been an additional contaminate found besides melamine, cyanuric acid. Are you aware of that? Is that something that we should be aware of? Because I understand it is used as a pool cleaner.

Stephen Sundlof: That is true. We have found cyanuric acid. It is somewhat related to melamine. Another compound that is very high in nitrogen and we are testing for that compound as well.

(Daniel Reitnik): Follow-up question. Has the FDA authorized a criminal investigation or was that a misquote in the Washington Post?

Stephen Sundlof: I am going to ask our folks from the Office of Regulatory Affairs to respond to that.

David Elder: Sure. This is David Elder, Director in (the Office of Enforcement) and the Office of Regulatory Affairs. There is no per se authorization of a criminal investigation.

Our Office of Criminal Investigation, which is the component of the Office of Regulatory Affairs, has been monitoring this situation in the way they monitor other situations across the country.

There has been no authorization of the criminal investigation. That is actually not the right word even if there were such a thing. But OCI has been monitoring the situation and we will stay abreast with any development.

It is important to know that the Food, Drug, and Cosmetic Act is a statute where the shipment of an adulterated product does constitute a prohibited act which is punishable by the penalties in the Act, which includes criminal prosecution.

Though monitoring of the situation for potential criminal conduct does not necessarily raise the stakes, so to speak, of questions about intentional or deliberate or other contamination of the food supply, what it does is monitors the situation to exercise authority that the Congress has given FDA and our statute. So it remains being monitored and we will continue to be monitored by our Office of Criminal Investigation.

(Rob Aleigh): Thank you sir. Next question.

Julie Zawisza: Our next question comes from Elizabeth Weise with USA Today. Your line is open.

Elizabeth Weise: I would like to follow up on the cyanuric acid that was found in what product?

David Elder: I believe it was the rice protein concentrate.

Elizabeth Reese: And that was, it was not simply a by-product that the melamine but it, I mean, I just thought, the chemical structure and it is separate. Correct?

David Elder: It is. I think, as we have found that this is not probably a highly purified source of material that went in to these products and it could be that what we are finding is a mixture of waste products from chemical manufacturers.

We do not really know at this time, but certainly, even in the beginning, when we were testing for melamine, we are finding compounds other than melamin, and this appear to be probably by-products of the production.

Elizabeth Weise: So they are just pouring anything that has got high nitrogen content in it?

David Elder: That we do not know at this point.

(Rob Aleigh): Thank you and next question.

Julie Zawisza: Next question come from Andrew Bridges with Associated Press. Your line is open.

Andrew Bridges: Hi. Thanks. My question, any of this hogs in these various states under the food (supply), were any of them slaughtered and distributed? I have a followup.

(David Elder): At this point, we are working with the USDA Food Safety and Inspection Service to identify whether or not that it may have occurred and whether further actions are warranted.

So, at this point, I do not have a definitive answer, only to say that the issue was being addressed by the Food Safety and Inspection Service and with the assistance of FDA.

Andrew Bridges: Okay, and a quick followup. Did your inspectors get visas or the letter they needed in order to visit the factories in China where these ingredients were made?

(David Elder): I am going to ask Michael Rogers to answer that.

Michael Rogers: Thank you. Your comment about our attempts to work with the Chinese Government and initiate activity that would help us further understand about the sources of these products from China. The answer is: That process is ongoing and current.

We have, in fact received, the letter of invitation. We continue to have dialogue with the Chinese Government, and we are still pursuing and trying to identify the actual manufactures or additional information about the firm that will be targeted as part of our inspection trip to China, but, again, that process is ongoing and current.

(Rob Aleigh): Thank you and next question.

Julie Zawisza: Our next question comes from Nancy Conners with CBS news. Your line is open.

Nancy Conners: Of these six new ingredients that you are going to be testing, are you going to be testing 100% of product or is that possible? What percentage of these products are you going to be testing?

(David Elder): David Acheson is probably should answer that question.

David Acheson: Sure. This is David Acheson. What we are going to do is to get in to manufacturers that are using imported products. Using the information that we have through the Prior Notice Center which is system that logs imports combined with our own data set. We are going to target firms that we know are receiving imported products.

Depending on what they have on hand, we will sample, and I anticipate that as this goes on over the next couple of weeks, it will broaden, and the goal obviously is to sample as much as we can to ensure that this problem is not occurring in places that we do not already know about.

(Rob Aleigh): Thank you and next question.

Julie Zawisza: Our next question comes from Ricardo Alonzo-Zaldivar with Los Angeles Times. Your line is open.

Ricardo Zaldivar: Okay, thank you. This is a follow-up question for Dr. Acheson along the lines of previous questions about the additional testing. Could you tell us what a product the additional ingredients that you mentioned, the wheat gluten, corn gluten, rice bran, rice protein, and I forget what else, but could you tell us

what kinds of products they are found in and you are saying these include products the human consumption, as well, I take it.

David Acheson: Correct. This is David Acheson. Yes, this is focused on ingredients that are used in both human and feed production. I want to emphasize, again, that at this stage, we have no evidence that these contaminate ingredients have been used.

This is a proactive activity. Just to go over the list one more time, we are initially focusing on wheat gluten, corn gluten, cornmeal, soy protein, rice bran, and rice protein concentrate.

Ricardo Zaldivar: But what kinds of products would you find them in?

David Acheson: We are coming to that.

Ricardo Zaldivar: Oh great.

David Acheson: I want to make sure that you had all the information. These different types of ingredients are used in a whole range of human foods, typically things like bread, pastas, cereal, pizza dough, and certain kinds of foods which are manufactured for individuals who are gluten allergic, individuals who have a condition as celiac disease.

Frequently, rice protein concentrate will be used in place of wheat. So it can be used, in that context, that in certain kinds of baby formulas, often in meal replacement beverages, protein shakes, energy bars, and when you get into some of the more specialized foods that are often eaten by vegetarians, these can be made almost purely of wheat gluten.

Obviously, the total amount of those that are consumed are less, but the percentage that it's wheat gluten is high because they are, essentially, made to look and taste like a meat product, but in fact are made from a protein concentrate.

Ricardo Zaldivar: Ha! Okay. And now this Prior Notice requirements that you mentioned, can you tell us a little bit about that? This is some kind on post 9/11 measure and do these Prior Notice requirements also tell you anything about the foreign manufacture? For example, you know, what would they tell you about that manufacturer? Does it tell you anything about the practices that they follow or anything like that?

David Acheson: This, again, is David Acheson. The Prior Notice System was put in place post 9/11 and with part of the Bioterrorism Act. It was enacted to protect the United States. That particular piece of it relates to imported products and it is a requirement linked with registration.

Every company that wants to import into the United States has to register. And then when they want to import an item into the United States, they have to submit Prior Notice before it is allowed to come in to the country.

That Prior Notice will essentially link with the registration information, which gives us some information about the manufacturer. It gives information in terms of where it is headed and essentially where it comes from. It does not get in to issues regarding how the product was manufactured per se. Michael Rogers from RRA may want to expand on that if needed.

Michael Rogers: Yes. Thank you Dr. Acheson. You know it is important to mention, certainly from a proactive standpoint, and in response to both the Menu Foods investigation in the rice protein concentrate and the associated positive results

for melamine and melamine-related compounds that using the Prior Notice Center intelligence, the agency has initiated an import alert to specifically target the source in China that is associated with positive samples for the wheat gluten, as well as the source in China that is associated with positive samples for melamine and melamine-related compounds, with respect to rice protein and protein concentrate.

Those two companies are also being screened for any products that they bring in. The agency is also reviewing all shipments, regardless of source in China, for rice protein products, wheat gluten, and corn gluten, as well as other products that may be of interest from a proactive standpoint.

(Rob Aleigh): Thank you. Next question.

Julie Zawisza: Next question comes from Susan (Unintelligible). Your line is open.

(Susan): Hi. Thanks for taking my call. Could you just clarify a little for me the scope of this new expansion? You are going to be looking at more ingredients. Are you going to be looking at them from any country or companies in any country are looking to import them? For export, I may add, I should say.

Michael Rogers: I think that is Dr. Acheson's question.

David Acheson: I apologize. It was very quiet. Can you repeat that? I did not hear all of it.

(Susan): I am trying to find out- you are saying that you are going to expand your testing of products, including the six ingredients. What I am just hoping you can do is clarify the scope of that new testing.

Are you going to test 100% of all of those ingredients from any company from any country? I mean, we've just have been looking at China. So how far is this expansion going to go?

David Acheson: Okay. I understand. The initial focus is on imports, not domestically produced. And as I've said, that the intent is that by linking our information that get from Prior Notice Center with our current record, we will be able to target those firms that we know that are receiving imported product. In terms of countries of origin, we really interested in protein concentrates that where manufactured in China. So there are two levels of focus there.

It is not practical for us to get out and test every protein concentrate, in every manufacturer, every lot, in any short timeframe. So we are going to be, essentially, selecting where we go initially based on those criteria and get to as many of them as we can, as quickly as we can.

(Susan): Okay. And as a followup, since Senators yesterday said that they were hearing some industry sources that there is a second distributor that has received the rice protein concentrate that was subject of the recalls last week. Can anyone there confirm whether that is the case?

Michael Rogers: This is Michael Rogers. What we will say is all of the positive samples for rice protein concentrate for melamine have been associated with one source in China and all of the positive samples for wheat gluten that has tested positive for melamine is associated with another single source in China.

(Susan): Sorry if my question was not clear. I meant the import on the US side. From last Thursday, there is one distributor that had given it to five companies, and yesterday, two Senators said that there is another importer or distributor, if you will, who had received rice protein from this company in China.

Michael Rogers: Our importer records focus on the actual identified source in China, irregardless of the (company) or the importer of record. What we have done is reviewed all of those shipments going back and we have worked with firms to make them aware of the problems associated with these foreign sources, as well as any positive results that might have been associated with (that).

David Elder: This is David Elder. I would like to add to that. I may be able to clarify some of the information. One of those five US manufacturers did receive rice protein concentrate from a second source, and has since recalled all of the products that they produced from either of the sources.

So let me clarify a little bit further. The origin of the product was still that single source in China. However, they did receive distribution from two US companies manufactured products with both, and recalled all products manufactured with either.

(Rob Aleigh): Thank you Captain Elder. Next question please.

Julie Zawisza: Next question comes from Gina Damron with Detroit Free Press. Your line is open.

Gina Damron: Hi. Thanks. Dr. Acheson, you had just mentioned that you guys are going to be focusing on imports only. How many manufacturers in the US are you giving testing to actually get into to look at? Do you guys assess with that number might be at this point?

David Acheson: This is David Acheson. At this point, no. We are essentially working through our record and adding to them in terms of the initial focus. With the resources that we have put on this project, what we are doing is essentially, as I've said

before; it is starting out with the intention of expanding it. I do not know what the total number is going to be at the end of the day.

We will have a better idea as we go through all the data. But in the interest of getting out there quickly, making a move as soon as we can, we are getting out with the information that we have, we hope we can do that before the end of the week and I think over the next week or two, we will have a much better handle on the extent of what this assignment will ultimately look like. So we will evolve over the next couple of weeks as we learn more.

Gina Damron: Quick followup. Will you guys be testing for these six different ingredients? Will you be testing those as they're imported as well? Or only at manufacturers that already have them right now?

David Acheson: Both.

Gina Damron: Okay.

David Acheson: Michael Rogers can add to that a little bit?

Michael Rogers: Yes. Just to answer with Dr. Acheson said, you know, this is a proactive effort that the agency is undertaking. We're developing based on our import data, a number of which criteria that is going to be used to target some domestic farms/companies.

But it is all part of a bigger effort to sensitize the industry, to make them aware of the need to pay attention to, and have knowledge about their sources.

(Rob Aleigh): Thank you, Michael. Next question please.

Julie Zawisza: Our next question comes from the Lynne Terry, The Oregonian. Your line is open.

Lynne Terry: Yeah, thank you for taking my call. Lynne Terry from The Oregonian. I would like to get back to the hog farms. You said salvage contaminate pet food gone to farms in North Carolina, California, South Carolina, New York, Utah, and possibly Ohio. How many farms are we talking about? How many hogs we are talking about and over what period of time?

Michael Rogers: I don't have the numbers on that right now. But it is, you know, this potentially affects thousands of hogs as my understanding. I can't tell you exactly how many farms and how many animals are included in that, but we know that some of the hog operations were fairly sizeable.

(Rob Aleigh): Thank you.

Lynne Terry: Wait, wait, wait. Sorry, sorry. I was just typing there. Is there any sense that melamine and these other compounds, it's been traced back to November. Is there any sense that it what was going on previously in terms of having contaminated vegetables, proteins coming in into this country? I hope that my question is clear.

Michael Rogers: Well, I think, in both of the cases with where the pet food was involved with the rice protein concentrate and with the wheat gluten, we know when those suppliers, the brokers in the United States, changed to these new companies.

I believe one was in July of 2006 that was rice protein concentrate, and the other one was in November of 2006, and prior to that, neither of those imported brokers had dealt with those companies prior to that. So, at least as it

pertains to these pet food issues, it appears to be limited back to the earliest, again, July of 2006.

(Rob Aleigh): Thank you, Lynne. Next question please.

Julie Zawisza: Our next question comes from Jon Rockoff, that's Baltimore Sun. Your line is open.

Jon Rockoff: Thanks. I was just wondering, is there any particular reason, for instance, that prompted you to be proactive as you said, and test all protein products now from melamine?

David Acheson This is David Acheson. Let me try to answer your question on that. When this began, the focus was solely on wheat gluten. As you know, about two weeks ago, the issue of the rice protein concentrate surfaced, and what they did within the agency is clearly make us ask the question, I think quite rightly, where else may this be? Is this is happening in other protein concentrate products that were not even aware about?

Both of those instances wheat gluten and the rice protein concentrate came to a public attention because of sick pets and what this assignment is all about is trying to get out ahead of the curb based on the information we have.

We know that there were two and we are simply asking the question, could it have gone to other places that we don't yet know about. No evidence that it has. No evidence that we got sick animals or sick humans that are related to contaminated protein concentrate other than the two that we know about.

So, it is essentially when the second one came along, obviously it is prudent to ask the question where else may this be.

That is the strategy that we're going out on here and just trying to get out ahead of thing and look in areas where we have not already looked. Without any specific indication that there is a problem, it is just a smart public help move.

Jon Rockoff: Just one follow up on-

(Rob Aleigh): Jon, are you there?

Julie Zawisza: (Just a last minute Q). Do you want to go to the next question or you would like to track him back down?

(Rob Aleigh): Track him back down, please.

Jon Rockoff: Hello?

Julie Zawisza: Mr. Rockoff, the line is open.

John Rockoff: Thanks. I just had a question about the hogs. Which states again did the (testings) find a presence of melamine in their urine?

Michael Rogers Okay. Hogs that have been said salvaged pet food in North Carolina, South Carolina, and California have tested positive for melamine.

Jon Rockoff: Great. Thanks.

(Rob Aleigh): Thanks Jon. Next question, please.

Julie Zawisza One moment, please.

Next question comes from Karen Roebuck, Pittsburgh-Tribune Review. Your line is open.

(Rob Aleigh): Karen, are you there?

Julie Zawisza Ma'am, your line is open.

Karen Roebuck Hi. Can you hear me?

(Rob Aleigh): Yes.

Karen Roebuck: Okay. These salvaged pet food and the potentially contaminated ingredient just went to a hog feed not other animal feeds and why would that be?

Stephen Sundlof: I think there maybe one poultry farm, but we're still checking into that, but all the rest of it appears to be in hogs.

Karen Roebuck: And, who's speaking and where-

Stephen Sundlof: I'm sorry. This is Steve Sundlof with the Center for Veterinary Medicine.

Karen Roebuck: Okay. Where is that poultry farm?

Stephen Sundlof: I don't have that information in front of me right now.

Karen Roebuck: Okay. And the chemicals that you're checking are cyanuric acid, amiloride and amilorine. Are there any other someone referred to a chemical mix?

Stephen Sundlof: I'm not familiar with the compounds other than cyanuric acid and melamine.

David Elder: This is David Elder. I think it is safe to say that the analytical work being done is to test for melamine and melamine-related compounds which may include those other ones that you just mentioned.

Karen Roebuck: You know what the health effects are of cyanuric acid?

(Stephen Sundlof): Were looking in to that. I'm trying to find out through literature what the potential health effects might be.

(Rob Aleigh): Thanks, Karen. Next question, please.

Julie Zawisza: Once again, to ask a question, press star one. Our next question comes from Diedtra Henderson with Boston Globe.

Diedtra Henderson: Hi. You know, I have to apologize I did not get a hit when I press star one, so if you see me in the queue more than once, feel free to take me out.

I'm a little curious about this poultry farm and the hog producing farms. Is this just the process like what we were seeing out on California when there is dog food that spills out from the manufacturing process that is used elsewhere? Or is there another way that they're getting these tainted foods?

(Stephen Sundlof): No, it's the same process when pet food manufacturers produce product that is somewhat damaged such that it can't be sold for pet food. It does not meet their quality standards or what have you. They often times sell that product to the livestock manufacturers and then they reformulate those into livestock feeds.

Diedtra Henderson: Are you targeting the testing of these six ingredients by the company testing? Are you looking in places where companies have already gotten hits?

(Stephen Sundlof): I'll ask Dr. Acheson to respond.

David Acheson: If I understand your question correctly, where we are trying to put this very broadly. If your question is on where we are targeting-

Diedtra Henderson: Well, the industry itself would already be tested for melamine and wheat gluten. Are you following some of the industry tests for corn gluten, cornmeal, soy proteins to figure out which facilities to test?

David Acheson: We're focusing our testing not on what industry is doing, but where imported protein concentrates that are of this initial interest are going to, though we're going to manufacturers that are importing those various protein concentrates from China and talking to them.

Diedtra Henderson: Thank you very much.

(Rob Aleigh): Thanks Diedtra. Next question, please.

Julie Zawisza Our next question comes from (Nakheel Fromanesen) with Scientific American, your line is open.

(Nakheel Fromanesen): Hello. Can you hear me?

(Rob Aleigh): Yes.

(Nakheel Fromanesen): Thank you so much for having this conference and I just wanted to ask a question about the rice protein concentrate which I've heard was found

in relatively, well obviously, the melamine inside is not supposed to be there at all.

But in terms of cyanuric acid I also heard that it was found in the rice protein concentrate and I'm just curious in the first place what rice protein concentrate would be used for and I believe it was a dry food.

I understand that wheat gluten is used to thicken the gravy in wet food, but I'm sure why you would need one of these sources in dry food other than to kind of artificially or just add protein to something that does not really have any

Stephen Sundlof: This is Steve Sundlof.

I don't have a definitive answer for you. Obviously, rice protein concentrate is a substance that is used in food and animal feed. The exact reason that it was used in dried food, I do not know. It certainly could be to increase the protein concentrate.

But certainly it is an acceptable feed substance that can be used and there is no problem with it being used that it obviously cannot be contaminated and now it is the problem here.

So, it is - that is a question that I just do not have the answer to and it is probably something that the pet food manufacturers could better answer.

(Nakheel Fromanesen): Okay and just a quick follow up. I have spoken to a person that worked at Wilbur-Ellis yesterday and he had mentioned that there was a spot check of the rice protein concentrate that came in from the Chinese supplier in question and that it was checked for a number of things including protein

based on the theories that has sort of been swarming around, it sounds as though, and based on what this man implied, it sounded like it was a nitrogen analysis and not per se a comprehensive test for protein content and other sort of material inside the ingredient.

I am curious as part of this new proactive effort, the know your supplier effort, are you going to recommend or even require that these companies, when they switch to new suppliers, especially in places, those that come from maybe China, that they are do for comprehensive analyses of what they are getting rather than the sort of hand waving test like maybe the nitrogen one was?

Stephen Sundlof: Well, that is certainly something that I think as this investigation continues and as we try and determine, you know, the cause of why these nitrogen-rich compounds were added or found their way into these food products, that certainly may be something that gets discussed.

But that is traditionally the way that food firms have analyzed for protein, is by looking at total nitrogen and maybe that is something that needs to be changed in light of this outbreak, but that is something we still would take under advice as we move through this investigation.

(Rob Aleigh): Thank you sir. Next question please.

Julie Zawisza: Our next question comes form (Sally Shaw) of (Feed Stop). Your line is open.

(Sally Shaw): Oh yes. Thank you and thank you for taking my question. On the feeds that went to the hog farms in Carolina and some parts, did that salvaged pet food come from the wheat gluten recall or from the rice?

And is there any regulation for having contaminated pet foods being sent to feed animals? It does not quite follow that that make sense?

Stephen Sundlof: So, Sally, the answer is that these hog farms that we are talking about today got their products from the companies that were using the rice protein concentrate not the wheat gluten.

(Sally Shaw): Okay.

Stephen Sundlof: And yes, food is - pet food is food, animal feed is considered food and any food that is adulterated cannot be fed to humans or animals. So contaminated rice gluten or rather, I am sorry, rice protein concentrate, if it has no (meat) in it, it should not be fed to food animals or any other animal because it is adulterated.

David Elder: To add on to that, this is David Elder. These firms that the shipped the salvage products to the hog farms did not do so after learning that their products were contaminated, it is part of the routine business that salvaged and scrapped products that result from production is sent to farms like hog farms.

So these weren't recalled products that were turned into animal feeds. It was not after the companies learned of the contamination. It was just part of the routine process and none of that continued now that the contamination is known.

(Sally Shaw): Thank you.

(Rob Aleigh): Thank you Sally. Next question please.

Julie Zawisza: Our next question comes from Mark Kaufman with Washington Post. Your line is open.

Mark Kaufman: Thank you. Does the FDA require any kind of inspection of a foreign facility that would be providing some of these ingredients and is there any requirement on the part of the American importer to actually have a hands-on inspection of the plant where the product is coming from?

Michael Rogers: The agency does, as part of a pre-approval context, require inspections of foreign food farms prior to importing products into the U.S. as it was treated. This is Michael Rogers.

As previously mentioned, there is a registration requirement, but to gain access to the US market does not require an inspection by FDA. Our resources are though targeted in the foreign arena on some food facility using a risk-based approach.

(Rob Aleigh): Thank you Mr. Rogers. Next question please.

Julie Zawisza: Our next question comes from Deb Kollars of Sacramento Bee. Your line is open.

Deb Kollars: Hi. I would like it very much if you could name the states again that received the farm - where you are looking at farms. My questions are, how many firms ship melamine tainted salvaged pet food to farms? Is it one, is it two, is it dozens? I am really unclear on that. And second, while we are talking, can somebody there get us the state where the poultry farm is?.

Stephen Sundlof: To answer your first question, I understand that the number of firms that ship to livestock producers, I understand it less than ten. I do not have an exact number.

Deb Kollars: Is this Dr. Acheson?

Stephen Sundlof: No I am sorry, this is Stephen; this is Stephen.

Deb Collins: Sundlof? Thank you.

Stephen Sundlof: The states that have affected hog farms are California, North Carolina, South Carolina, New York, Utah, and possibly Ohio.

Deb Kollars: Thank you.

(Rob Aleigh): Now I think we have the entity of followup.

Deb Kollars: (Okay).

(Rob Aleigh): It was (unintelligible) where we are working with a particular poultry farm.

Deb Kollars: Thank you.

(Rob Aleigh): Next question please.

Julie Zawisza: Our next question comes from Diane Lade with South Florida Sun-Sentinel. Your line is open.

Diane Lade: Hello, good afternoon. Sorry about that.

It seems like we have talked a lot about this contaminated material, perhaps endangering the human food supply by way of going to the hogs and possibly the chicken.

Is there any possibility that some of these tainted material went directly into the human food production?

Michael Rogers: At this time, you know, as we've mentioned that this is an ongoing investigation that certainly the purpose of these exercises is to disclose what we know to be fact at the time.

And so we can certainly say, with talking to us now that there is no evidence that suggests that there were any direct shipments of contaminated rice protein concentrate or even wheat gluten to farms that make food for human or food that make food for food producing animals. Direct shipments, that is.

Diane Lade: Alright, so then we are not going to be looking then at any human food manufacturers at this point. You are going to concentrate on the other providers that we have been discussing.

Michael Rogers: This is Michael again. I will answer it this way and certainly Dr. Acheson what would want a comment and add what the agency is doing from a proactive standpoint.

The ongoing investigation related to the positive sample we have seen associated with the single source in China for the rice protein concentrate is strictly within related to animal food manufacturers.

But there are things that the agency is doing from a proactive standpoint that is under the umbrella of human food. We have no direct link or evidence that

that contaminated product was shipped to a food producing facility or used in human food, but Dr. Acheson may want to add to that.

David Acheson: This is David Acheson. I do not have much to add, just to reiterate right Michael Rogers' point. No evidence that these ingredients have been used directly in the human food supply number one, number two, the proactive assignment is focused on both human and animal foods.

Diane Lade: Thank you.

(Rob Aleigh): Thank you. Next question please.

Julie Zawisza: Our next question comes from Gina Spadafori with Universal Press. Your line is open.

Gina Spadafori: Yes. Is there a protocol for the disposal of these contaminated ingredients or products? Where is the stuff going after it has been pulled out of the food stream?

David Elder: This is David Elder. The disposition of the recalled material is going to be an obligation of the recalling firm pulling it back and ensuring that it does not re-enter any type of food supply, human or animal.

And they will need to dispose of it in accordance with State and Federal Environmental Laws. A possible way of doing so could be at a landfill or could be by incineration, but the recalling firm will ensure that the disposition is done appropriately and FDA will witness the disposition to make sure that nothing gets back out there into the food supply.

Gina Spadafori: Thank you.

(Rob Aleigh): Next question please.

Julie Zawisza: Our next question comes from Joe Johns of CNN. Your line is open.

Joe Johns: Hi. Thanks for taking my question. Looking at all of this and how long it's gone, sort of begs of question, at what point do you get to start considering a stand down or what you might call a ban even, temporarily perhaps on imports of grain products from China until you know what you've got. You may know there's an activist group here in D.C. that has called for that.

David Elder: This is David Elder again. You know, we- it's not easy to condemn the exports from an entire country. At this point in time, we have two known firms that have exported contaminated wheat gluten and contaminated rice protein concentrate into the United States.

No shipments from those two firms are being allowed entry into the country and similar products from China, as David Acheson mentioned and Michael Rogers and Dr. Sundlof mentioned are under 100% screening.

So, we believe that the safety net is in place to make sure that no additional products in this general category are going to get into the commerce of the United States.

Joe Johns: Could you just give me - just to followup, I'm sorry. What- Is there some standard or is there something that would trigger, is there a point that you would get to where you actually have to consider that? What would have to happen?

David Elder: You know, it's hard to say how many it would take to require all shipments from a particular country to be kept out in that type of means. I think, what we're doing right now is about as good as we can do, and I think it's very effective to keep this product out where we have suspicion of contamination.

Joe Johns: Thank you.

(Rob Aleigh): Thank you Joe. Next question.

Julie Zawisza: Our next question comes from Julie Schmit with USA Today. Your line is open.

Julie Schmit: Oh, thank you very much. The hog farms in New York and Utah, you said the testing had some melamine in the urine in the three hog farms or the farms in North Carolina, California, and South Carolina. If testing being done in New York, Utah, and Ohio, and we just don't have results yet? Or have those been negative?

David Elder: Well, this is David Elder again. We're not aware that any testing has been done yet. We're not aware of negative results. We are in communication with the USDA and state regulatory bodies, and the jurisdiction over the animals themselves, at that point in time, is a shared responsibility, but in terms of testing of the urine or the meat, we do defer to the state and USDA authorities.

Julie Schmit: Your understanding is that it- it will be done or is being done, but we just don't have results?

David Elder: I gave you my full understanding. I know that we don't have results yet and the USDA and the state have the lead to determine the appropriateness of the testing.

Julie Schmit: But they've all been quarantined?

David Elder: I understand the farm in New York has, and I don't have information on the other.

(Rob Aleigh): Thank you. Thanks Julia. Next question.

Julie Zawisza: Our next question comes from Elizabeth Weise with USA today. Your line is open.

Elizabeth Weise: Yeah. Actually, my question has been answered. Thanks so much.

(Rob Aleigh): Thank you. Julie Zawisza, we have time for one more question.

Julie Zawisza: Okay. Our final question comes from Richard Read with the Oregonian. Your line is open.

Richard Read: Thank you. I'm wondering what exactly were your investigators be doing in China? And what are the Chinese authorities doing if anything now? Are they investigating at this point?

(David Elder): Yes.

Julia Ho: This is Julia Ho. The Chinese government, ever since they received information from FDA, they have been very actively doing their own investigation in their organization structure. They have local government, as well as their central government, inspecting and doing investigation very actively right now.

And they also want to start the testing - they're also embargo ordered wheat gluten, as well as the rice protein concentrate from those two companies export.

The Chinese government also plan to conduct their own melamine testing for these two products that the destination is for export purposes. They are active - they're very active because they only heard about the rice protein concentrate last Friday from FDA, and they're doing investigations over the weekend.

And they are already in conference with the FDA, and as well as US Embassy rather in Beijing, and they will be helping us, and we're going to be sharing information in the future.

David Elder: That's Julia Ho from the FDA's Office of International Programs. Michael Rogers has something to add to that.

Michael Rogers: In the first part of the question was what will FDA be doing in China given all of these, the criteria is met for us to get there. FDA's activities and inspection efforts in China will be designed to look at the manufacturing process for rice protein concentrate and wheat gluten at the actual manufacturers that make those products.

Our efforts in China will also be designed to try to identify how this contamination could have occurred, whether or not there are opportunities for cross contamination and what affiliation these manufacturing facilities might have to firms that may be associated with melamine or melamine-related compounds or products.

But, those activities will be to assess manufacturing practices, food GMPs if you will, but to identify whether or not from a manufacturing prospective, has any opportunity for cross contamination or other opportunities to introduce melamine into products that shouldn't have it.

(Rob Aleigh): Thank you, Michael.

Richard Read: Thank you. Has there been any enforcement action?

(Michael Rogers): Where?

Richard Read: In China? Have you had any arrests or any penalties?

Julia Ho: I don't believe so. This is Julia Ho again. The message that they gave us is their investigation is ongoing, but they have detained or rather prevent all the wheat gluten and rice protein concentrate on those two foreign firm exports out of China. But it is active and still ongoing. We have not heard about arresting. I don't believe they got to that point.

(Rob Aleigh): Captain Elder has something briefly to add.

David Elder: Yes. Just in followup to those questions previous, we do have information that, at the hog farms in North Carolina and Ohio that the state has also a place to hold on those particular hog, as well as the previously announced California hold.

And I'll just - maybe add one other thing that's not related to the hogs, but - there has been another recall announced of pet food products manufactured from the rice protein concentrate received from Wilbur-Ellis and that was announced by a company called SmartPak.

They made one lot of dog food from contaminated rice protein concentrate and has recalled it. You can get some more information about that particular recall at the SmartPak website and FDA will be updating our website shortly. The SmartPak website where you can find this information is Smartpakcanine.com.

We are still working with one additional firm. As we mentioned on the call last week, there were other firms that have - where we were tracking the rice protein concentrate to determine if any pet food products has been made.

One additional firm has received products and is undertaking their own private laboratory testing to detect the presence of melamine or melamine-related compounds on their pet foods.

A recall has not yet initiated by that last firm. We expect to get FDA test results of their finished products within a day, but the firm has, at this point in time, exercise their rights to have the product tested themselves by a private laboratory and has not yet initiated a recall.

(Rob Aleigh): Thank you Captain Elder. Julie Zawisza, at this time, we're going to conclude the briefing.

Ladies and gentlemen, thank you for joining us today. Thanks to our speakers Dr. Sundlof, Dr. Acheson, Captain Elder, and Mr. Rogers. We hope that you found us helpful, and we really do appreciate the work that you're doing, in getting this type of information to the public.

We're still on the heat of this investigation and want the answers just as much as everyone else does and just as much as all the other pet owners do.

So, our intention here is to have regular briefings twice a week at about this time, probably on Tuesdays and Thursdays, although we may have briefings sooner if we have briefing information that you need to have or what that we need to get to you.

So, I would in interim, and check our website regularly for updates and for a list of any other products that maybe recalled.

And if there are specific media questions, you may call our press office at 301-827-6242 or log on to fda.gov/contactpress.

Thank you very much. Have a pleasant evening.

Julie Zawisza: Thank you for your participation. You may disconnect at this time.

END