



U.S. Food and Drug Administration

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Transcript of FDA Press Conference on Contaminated Animal Feed

FTS-HHS FDA

Moderator: Julie Zawisza

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12:00 pm CT

Coordinator: Good afternoon and thank you for standing by.

At this time all participants are in a listen-only mode. After the presentation we will conduct a question and answer session. To ask a question at that time, please press star-1.

Today's conference is being recorded. If you have any objection, you may disconnect at this time.

I'd like to introduce your host for today, Mr. Robert Ali with FDA Press Shop.

Sir, you may begin.

Robert Ali: Thank you very much. Ladies and gentlemen, welcome.

I am Rob Ali from the FDA's Media Relations Shop and thanks and welcome to this briefing this afternoon on the melamine investigation.

We have speakers today from the Food and Drug Administration and the U.S. Department of Agriculture. We also have several FDA officials here and officials from USDA and Customs and Border Protection available to answer any questions later on in this briefing.

Our two speakers this afternoon are Dr. David Acheson, Assistant Commissioner for Food Protection with the FDA; and Dr. Kenneth Petersen who is the Assistant Administrator for Field Operations with the USDA Food Safety and Inspection Service.

We will have a brief question and answer segment where we'll ask Dr. Stephen Sundlof, the Director of our Center for Vet Medicine of the FDA; and Mr. Michael Rogers, Director of the Division of Field Investigations and Mr. Walter Batts, Deputy Director of our Office of International Programs, both of the FDA.

At this time I'd like to turn over to Dr. David Acheson.

David Acheson: Thank you. Good morning or good afternoon to everybody. This is David Acheson of FDA.

Today I'd like to update you on three specific areas. First, what we know about the contaminated fish feed; secondly, what we're currently doing on sampling and testing; and the third area I'll cover is an update on the current investigation in China.

First of all I'd like to talk to you about the nature of the situation that we're currently in.

Since this all began in March, we've been conducting an investigation that started with the discovery of melamine-contaminated pet food. It's been a complex investigation that has led us places that we may not have predicted.

Like any good investigation, we've gone where the leads have taken us and continue to do so. We discussed publicly every aspect of the investigation as soon as our information was valid.

Often as with the announcement Tuesday of the fish feed development, we announced things before we have complete information. We believe that it is in the public's best interest to know the facts as soon as they are validated. That will often leave us with unanswered questions and even as I speak we are finding out answers to these questions and clearly posing new ones.

We'll continue to update the media and through them the American public for as long as we have to.

As announced during Tuesday's press briefing, FDA has confirmed the presence of melamine in fish feed manufactured in Canada.

Skretting, a Canadian company based in British Columbia, is recalling fish feed due to contamination with melamine. To date, FDA analysis has shown one positive sample of contaminated fish feed from a hatchery in the United States, and that's Marion Forks Hatchery in Oregon.

The hatchery manager had discontinued use of the feed which according to the Oregon Department of Fish and Wildlife was used as a starter diet for juvenile salmon and trout. The fish feed was manufactured in Vancouver, Canada, by the Skretting Company and distributed under the Bio-Oregon label out of Longview, Washington.

Oregon Department of Fish and Wildlife also reported that same lot from Skretting was sent to the Willamette Gnat Creek, Big Creek, Cold River, Butte Falls and Leesburg Hatcheries throughout the state. Skretting is

undertaking its own investigation and notifying all commercial fisheries and fish hatcheries that received the product including U.S. customers and advising them not to use the feed. The company is offering replacement feed to affected customers.

FDA investigators are working to determine the scope of fish feed distribution and whether any of the fish that were fed the melamine-containing products have been released into the environment or eaten by humans.

The human health risk assessment that was announced this past Monday on May 7 also included an assessment for eating fish. Based on that assessment, federal scientists from multiple agencies concluded that humans who may have eaten fish fed the melamine-containing feed face a very low health risk.

The investigation, including additional sample collections analysis is continuing and we will continue to update all of you as we obtain validated information during that investigation.

FDA is in constant communication with the Canadian Food Inspection Service, the U.S. Fish and Wildlife Service, and other state agencies and continues to work collaboratively with all agencies in the investigation.

I want to turn now to do - to discuss the second area, which is what's currently ongoing with regard to sampling. But first of all, I want to focus on imports.

You've heard much of this before, but I want to try to just summarize where we currently are related to import and domestic.

Firstly, with regard to imports, all vegetable protein products imported or transshipped from China cannot come into the United States unless they've

been tested for melamine, cyanuric acid, or other melamine-derived compounds. So those products are not allowed into U.S. commerce until they have been shown to be safe.

Also, at the port we have a sampling assignment underway for pet food imported from China, and that is pet food that specifically could contain melamine or melamine-related compounds. And we also have a sampling assignment that is due to begin very soon focused on animal feed, and that will include directed and targeted samplings of fish feed, again, all imported from China.

So that's a summary of what we're doing at the border.

With regard to domestic inspection, we have our domestic assignments currently underway which I've already discussed before with you, which includes visiting manufacturers and processors in the United States who use protein concentrates of various types, obtaining samples from those firms to check for melamine and melamine-related compounds, raising awareness with those manufacturers about the importance of understanding all there is to know about their suppliers and the safety of the material they receive, and finally doing some targeted sampling of finished food products.

This assignment that I've just described, this domestic assignment, is targeted at both pet food, animal food, as well as human food, and that's an important point covering both human and animal.

Finally, I'd like to turn to just give you a brief summary of where we are on the China front.

As you know, the HHS/FDA team has been on the ground in China since the week of April 30. The team has received good cooperation and support from the general administration for quality supervision inspection and quarantine. That is the group that I have been referring to as AQSIQ. And to repeat, that is the general Administration of Quality Supervision, Inspection and Quarantine known as AQSIQ.

AQSIQ has been briefed on the results of our investigations, and there has been continued an extensive cooperation between our investigators and the Chinese authorities. Our team has visited both of the firms that exported the contaminated products to the United States as well as an independent test lab that is analyzing samples collected by AQSIQ at the two firms.

Visits to the two firms indicate that they are no longer in business.

AQSIQ has confirmed the reports that you as well as others have heard that officials of the firms have been detained.

Our investigation in China continues. There are preliminary discussions about formalizing future cooperation with China on food safety and food defense issues, and those discussions will continue in the forthcoming weeks.

That concludes the statement.

Thank you, Rob, and I hand back to you.

Robert Ali: Thank you, Dr. Acheson.

At this time, Dr. Kenneth Petersen, Assistant Administrator for Field Operations with the USDA Food Safety and Inspection Service.

Dr. Petersen.

Kenneth Petersen: Thank you and thanks again everybody for joining us on the call today.

As I indicated on the call Tuesday in describing our joint May 7 press release, the same group of scientists who participated in the human health risk assessment are working to complete an animal exposure assessment which will focus on the concentration of melamine and its compounds in feed and in animal tissue and assess how any levels will dissipate from the animal's body over time. That animal exposure assessment is not yet complete, nor is the validation process for the test for melamine in swine muscle meat.

Therefore, pending the results of the animal exposure assessment or any other scientific and investigative data, the situation remains the same for USDA.

Swine and poultry remain under control on the farms that we've previously noted on these calls.

And with that I'll turn it back to the moderator.

Robert Ali: Thank you, Dr. Petersen.

At this time, ladies and gentlemen, we will take your questions, and as always to be equitable please limit yourselves to one question and one follow-up, and please state your name and affiliation.

Operator, we'll take the first question.

Coordinator: Thank you.

Once again, to ask a question, please press star-1. And our first question comes from Sandra Young of CNN.

Sandra Young: Yes. Hi. Thank you for taking my call.

I have a question about the protein surveillance assignment memo on your Web site dated May 1.

In the Table Number 1, the chemical sample testing per assigned product, there are five agents. One - the last one is redacted. And I'm wondering if you can tell us what that mystery agent is, what that fifth contaminant is that was being tested?

David Acheson: This is David Acheson from FDA.

It's redacted for a reason. I will have to check into that further, but at this point on this call I'm not able to specifically answer that question.

Michael Rogers: And this is Michael, just to add to that.

You know, we've routinely answered questions about the duration of this assignment, and that's information that we don't want to disclose.

The assignment is currently in place and will be indefinite. But also about the variety of tests that we intend to engage in, it's a scale of test that we routinely do, but that's not something that we want to disclose.

Robert Ali: (And) do you have a follow-up?

Next question, please, operator.

Coordinator: Next question comes from Dawn House of Salt Lake Tribune.

Dawn House: Yes. Dawn House, Salt Lake Tribune.

In Utah, we have 3,000 hogs on hold. They are way past their prime.

There are tens of thousands of dollars of contaminated feed in the landfill and these small family farms are anxiously awaiting results on whether those hogs will be sent to slaughter. What is the timetable for these families to know what's going to happen to those hogs?

Kenneth Petersen: Okay. This is Dr. Petersen with the USDA.

Well, we've been working on those two. There are several factors that I suggested in my comments, the factors on the animal exposure assessment in any - the validated test for the swine meat.

That validated test is important because it helps in forming the decisions that would be in the exposure assessment and then of course investigative information that's happening not just in Utah but elsewhere.

And so we hope it's ready soon. As we said in the release and I think in some other public discussions, we believe that will still be completed sometime within the week. That means this week. But we want those scientific assessments to be based on - for those scientists that have the time to make the appropriate judgments and decision-making.

And so, until that line of inquiry by them and that line of, you know, due diligence by them is completed, I can't give you a firm timeline.

I do think it will be soon, but their status is, they are actively working on it. We certainly understand the economic impacts and the difficulty this is creating for those farmers. We're quite sensitive to that.

We have, as you may recall, from a couple weeks ago, the other bodies in USDA, particularly Agriculture Marketing Service, have contacted them regarding Section 32 funds for restoring of purchasing power related to any economic losses.

Understandably, they may be waiting for the final outcome before they make that decision, but no matter which way it goes for them that still is going to be at least a safe harbor for their market share.

So soon is the best I have. They are actively working on it, we want to make sure they're doing the right things in the right way, and we'll communicate that as soon as we have it.

Dawn House: Can you describe the nature of the test regarding whether the meat is tainted or not?

Kenneth Petersen: Well, I don't know if I can give too much detail. Of course it's a rather sophisticated analytic method that looks for melamine and/or some other compounds.

There's some testing done at various laboratories. There's some interagency laboratories called FERN, and they are collaborating on making sure the validation is consistent with recognized scientific methods.

So they're doing the testing. They want to then reach agreement among the scientists that this is the right test and it's recognized by everybody.

I don't want to suggest that that's going to draw things out, but that's kind of the normal process.

Robert Ali: Thank you, ma'am.

Next question, please.

Coordinator: Next question comes from Steve Dale of the Tribune Media Services.

Steve Dale: Hi. Thank you very much.

Let me see if I could ask this so everyone can follow.

If the wheat flour, wheat gluten, melamine and related substances represented protein, truth is this wasn't real protein. And it may have been going on for a very long time. So, where our pets, cats in particular since they do require so much protein, not getting enough protein, or at the very least we were paying for something that we weren't really getting and maybe over time this lack of protein if you will impacted our cats or dogs health. If you follow, I hope you follow what I'm asking?

Stephen Sundlof: This is Steve Sundlof from the Center for Veterinary Medicine in FDA.

Yeah, that's a reasonable point to raise. All of the pet foods that are commercially available are nutritionally balanced to meet the requirements of

dogs and cats, and so obviously if there were ingredients that were underrepresented like protein, that could result in health problems for our pets.

In terms of the duration of this, we know that in terms of the rice protein concentrate that entered in the United States in August of 2006 the wheat gluten that was contaminated with melamine first entered the United States in November of 2006, so it has not been a long time, at least for these two companies. And again, those are the only two companies that we are aware of that sold this contaminated protein concentrate.

And so we don't believe it was a widespread event. Obviously in the case of the rice protein concentrate and the wheat gluten, the more immediate impact was the impact of the melamine on the health of the animals themselves.

So at this point we are not aware of any nutritional deficiencies that have resulted as the - due to this substitution of a less-than-potent protein supplement into the pet foods.

Steve Dale: Okay, thanks.

((Crosstalk))

Robert Ali: Next question, please?

Coordinator: Next question comes from Lynn Terry of the Oregonian.

Lynn Terry: Yeah. Hi. Thanks for taking my question.

And unfortunately I've got a number of them.

I have some things I want to ask clarification about. For instance, for the (unintelligible) on it. Let me just take a few things perhaps.

In terms of the domestic animal feed initiative that you're going to be testing I'd like to - could you give us some details about that? How extensive is that going to be? And in relation to that, you're going to be testing all these imports from China, but imports travel all over the world, as we saw with the Canadians, they get made into other products, and then they come back to the United States.

I don't see how the two agencies can possibly (police) all this.

David Acheson: This is David Acheson from FDA. Let me start to answer some of that and then I'll hand over to my colleague Michael Rogers to give you more specifics.

With regard to the domestic surveillance assignment, that as I said is targeted on raising awareness and also on feed for animals and for humans. It's focused on protein concentrate.

Clearly we're not going to get to everybody in the first few days, but the intent here is to keep this assignment rolling long enough to make sure that we have covered everybody as quickly as we can with the resources that we have.

Don't forget, this is a proactive approach. We're getting out there looking for melamine and melamine-related compounds in places that we don't currently know that there is a problem.

So clearly the resources need to be devoted on tracking down areas where we do know there's a problem.

Initially that was focused on pet food, it then swung more recently to poultry and hog situation, and now it's swinging yet again to the fish issue. So the priority for us is to track and trace and get on top of anything that we know is a problem and at the same time to do the proactive preventative piece to the best of our ability, but to cover all of it in the forthcoming weeks.

So that's the issue on the assignment.

In terms of the - of what you're suggesting about products coming into the United States we do look for what we call transship products which are essentially products that are exported from China that go to another country then they come in to the United States.

We do - we take the work associated with that. We are looking at that and doing the same thing with transship product. If it comes from China and it's a vegetable protein concentrate it's getting the same treatment whether it's direct or via some other country.

With regard to Chinese ingredients that may have been turned into food, which is kind of the third arm of this, and then imported back into the United States as some finished product, that is part of, as we move forward on this, looking at finished food products. We will be getting more into that. But right now the focus has been on the areas of maximum concern based on the risk that we know is there, and broadening it into the feeds and the ingredients component.

Mr. Rogers, do you have anything to add to that?

Michael Rogers: Sure. I think you've covered most of it.

In my mind I separate the two issues. The caller asked about what sampling we're going to be doing of bulk products from China.

Let's clarify. The countrywide import alert which is 99-29 is a countrywide import alert for bulk vegetable protein products from China for which all of those shipments are screened for and targeted 100% sampling. That puts the burden on the importer or ultimate firm to demonstrate that the product does not contain melamine or related compounds to the agency. And of course there would be some verification by the agency on that supporting data.

That is different than from our assignment that has both an import and a domestic component.

From the import perspective, we'll be looking at ports of entry for bulk vegetable protein shipments from other sources to determine whether or not it is possible that those products would be transshipped ultimately coming from Chinese origin.

Some of those shipments will also be samples, but we're also going to be looking at the consignees and the domestic arena who receive those products and targeting those for sample and inspection as well.

Lynn Terry: Okay. Can I ask another question which has been lingering with me for a couple weeks, and that is that, you've repeatedly said that there's no harm to humans even though hog meat or pork did get to dinner tables and no results were ever released as far as I know. Maybe I missed that about the concentration of melamine or cyanuric acid in those.

Now, scientists believe that it's the interaction of the two compounds that cause the crystals in the pets. There's very little scientific data. So, I'm just a little bit confused about how you can say it's safe when we really don't seem to know and how do you know what the effects of cyanuric acid and melamine would have on humans.

Thank you.

David Acheson: This is David Acheson of FDA. Let me address some of that.

The risk assessment that was done trying to determine the risk to humans was obviously using animal exposure data for a large part.

You're correct, there's been no feeding studies that I'm aware of that has ever been done on melamine to humans as a part of a clinical study to see the impact of melamine on humans. So one has to extrapolate and that's standard toxicological way of doing business. You do the animal studies and you extrapolate to humans.

That extrapolation typically includes some sort of level of uncertainty because you are translating rat data to human biology. So the risk assessments typically include a safety factor, and that may be a ten-fold safety factor or a hundred-fold safety factor, simply because of the species differences.

So they do take that into account.

Secondly, we know at what level melamine causes a problem in a rat. And the literature is out there for anybody to look at, and it's orders of magnitude higher than anything that we have ever seen in any of these products.

Despite that, the risk assessment team went through the process of looking at the levels in the pet food, how much got into the poultry feed and the hog feed at the point at which those animals ingested it, what we knew about the metabolism of bioaccumulation of melamine or cyanuric acid in the - in mammals, rats or whatever it would be, and again, put that all into account in terms of the risk assessment.

When you do all of that and it's a long, complex process, you still end up with over two thousand-fold safety margin between the level that's likely to be in the muscle tissue and the very lowest level at which you may see a problem in a human.

Now you mentioned these compounds working together.

All the indications are - is - what happens here is if you have pure melamine, you don't run into a problem until you have extremely high levels. If you take the melamine and you add cyanuric acid into the equation, which the risk assessors did -- they took account of this -- when you put the two together, there is a tendency for crystals to form. The melamine and the cyanuric acid get together in the kidneys and form crystals and lead to kidney failure.

That's what we believe is the most likely scenario in the pets. Bearing in mind the pets received a much higher level of exposure than humans ever would through consuming muscle meat from hogs and poultry, so that's again an important difference.

But this is a scientific process, and all the indications are -- and we have a lot of confidence around them -- this was not just the FDA's determination, it was a joint effort with risk assessors from multiple federal agencies to make the determination. And we feel a great deal of confidence that consumers can be

reassured that eating muscle meat from these animals is not going to pose a threat.

Robert Ali: Thank you, Dr. Acheson.

Next question, please?

Coordinator: Next question comes from Andrew Bridges of Associated Press.

Andrew Bridges: Hi.

Actually I'd like to follow up on that. Can you point to a single study that has looked at the interaction of these two compounds and at what level they become dangerous or toxic or pose any kind of risk to any species of animal?

David Acheson: I'm not aware of any published studies on that. This is David Acheson, again.

I have seen some preliminary data that would indicate that they are additive. When you put the two together, they are additive rather than synergistic, an

I'm getting into some technical terms there. What I mean is, that if you take compound one and compound two, you end up with 1 and 1 equaling 2 as opposed to 1 and 1 equaling 5 in terms of their effect.

Synergism means that when you put the two things together you get more than just the sum of the two in terms of their effect on the body.

But all of the indications are -- and I agree with you -- it is limited, that this is an additive phenomena. The risk assessors took account of that. The risk assessors also estimated that even if synergism were to occur, they would be

unlikely to result in more than a ten-fold increase in overall toxicity, and that still gives you a very large margin of safety.

Andrew Bridges: Can I ask you a quick follow-up?

Have you looked at how - seeing the stuff is wheat flour and not gluten or rice protein concentrate, have you looked at how soluble or less soluble wheat flour might be and how it might have clumped up in producing pet foods and then counted for greater concentrations of melamine perhaps in some batches more than others?

I mean, how does wheat flour perform in mixing and manufacturing as compared to a pure wheat gluten or rice protein concentrate?

David Acheson: Well, I don't know specifically whether the company looked at that, but as I've said on previous calls, companies go through an extensive product quality ingredient and quality process, and if they're using an ingredient and it doesn't perform properly and they can't make their finished product, they are going to know about it and it's not going to work, they're not going to get the product they want.

So I can only assume, and it is an assumption, that the melamine was not there in high enough quantities to interfere with the performance of the product, the wheat flour.

And bear in mind that wheat flour does contain some wheat gluten because you get wheat gluten by extracting it from wheat flour. So this material is actually a combination of ground up wheat flour with its natural level of wheat gluten plus melamine.

Robert Ali: Thank you.

Next question, please?

Coordinator: Next question comes from Rick Weiss of the Washington Post.

Rick Weiss: Hi, thank you. Two questions.

One, with regard to your domestic assignment, you said you've started testing some - a variety of human food and animal feed products. Can you give us a sense of how many you've tested so far and whether -- I know it's not complete yet -- but whether you've had any positive tests yet?

And secondly, we heard yesterday about a second distributor in the United States, one in Illinois, that apparently has also accepted some - what is reported here as rice protein concentrate, that may have been contaminated with melamine from China. Can you tell us a little bit more about that and whether it really is rice protein concentrate or whether it too has been mislabeled?

David Acheson: Let me try to take your first question.

We do have total numbers of samples in the lab, and Michael Rogers can give you that specific number, and I can say that we found absolutely none that are positive other than the ones that we were already aware of -- the pet food related material that came in labeled as wheat gluten and rice protein concentrate that was mislabeled.

Let me ask Mr. Rogers to follow up on the numbers for you, and then I'll ask you to repeat the second question, please.

Rick Weiss: Thanks. Okay.

Michael Rogers: To date the labs have analyzed a total of 880 samples of a variety of products that represent finished products, bulk vegetable protein products, and consumer (unintelligible). Of these, about more than 500 have tested positive, but ultimately it relates to 92 lots of vegetable protein products.

You asked for some specific numbers associated with our proactive efforts as part of the domestic sampling investigation inspection assignment. Again, that's a proactive effort by the agency. We have no knowledge at this time to suggest any of the contaminated bulk products were shipped directly to firms that manufacture products intended for humans.

Having said that, from a proactive standpoint trying to get a better understanding of what these firms do with this product, we initiated our domestic assignment that had both a domestic focus for firms receiving these products and targeting firms importing products at the border. But what I can't give you at this time is a split on the number of samples that relate to the sampling assignment versus those that are analyzing in follow-up to this melamine investigation.

Rick Weiss: Thanks. The second question was about the second import - imported stream of what's been called rice protein concentrate.

Representative DeLauro mentioned this in a release yesterday, a company in Illinois that has initiated a recall apparently. Can you tell us anything about this? This is I think the second one after ChemNutra -- the only other one I'm aware of -- and whether this is really rice protein concentrate and how much of it went where.

David Acheson: Well, I can tell you that some of our testing has indicated that some of the melamine-positive material labeled as rice protein concentrate was not rice protein concentrate. It was indeed the ground up wheat flour with melamine.

So certainly, some of the rice protein concentrate that we tested was not - was mislabeled. In terms of the specifics of Illinois, I don't think we have any further specific information to give you on that.

Rick Weiss: Can you confirm the representative's statement that there is a company in Illinois that has been found to have been distributing this as ChemNutra was?

David Acheson: I'll ask Michael Rogers to answer that.

Michael Rogers: Yeah, that's correct. But I think the headline continues to be that all of the positive bulk wheat gluten and rice protein concentrate have been associated with two suspect sources in China, the firm that you're referencing in Illinois is consistent with that statement.

David Acheson: Yeah, that's an important point. This is David Acheson again.

That - as this unfolds, as I said in my opening statement, this is an ongoing investigation, and we can anticipate that other things will come to light as we're following and tracking this down. But everything that's testing so far positive to melamine is still ultimately linking back to that same two sets of problems with the two companies in China. Nothing so far has gone outside of that scope and that's an important point.

And again to emphasize, we're looking. Domestic assignment is looking outside of that scope and so far nothing else has come up.

Robert Ali: Thank you, Rick.

Next question, please.

Coordinator: Next question comes from Elizabeth Weiss of USA Today.

Elizabeth Weiss: Hi. Thanks for taking my call.

And having now become a connoisseur of these I really like the new music they are playing for the hold music. Thank you.

To follow up on that, if this has been an ongoing issue in China for a long time do you have theories on why so far it appears that only two companies have exported these faked vegetable proteins to us? Why haven't we gotten more of this stuff, and why haven't we seen problems before?

And just a quick follow-up question, do we have any sense of what percentage of the U.S. vegetable protein products we use in the United States come from China?

David Acheson: To answer your first question, it's a very reasonable question to pose in terms of how long has this been going on, and you're not the first to ask that.

Obviously without the ability to turn time back we're not going to know.

What I can say is that it never came to light before. Possible explanation to that is, as I've said, melamine alone in relatively low doses is not toxic, it's not problematic. But when you start mixing it with cyanuric acid and other related compounds, it does appear to more readily form crystals.

And it may be that these two batches were high in cyanuric acid and melamine as opposed to just melamine. I'm speculating. I don't know.

So it's certainly possible that this has been going on longer. I mean - and obviously that's why we're taking this prudent approach to look to the extent of this. And that's why we're testing many areas proactively and not assuming that it is limited to just these two points.

And then you asked a second question which has just escaped me.

What was that?

Man: (The percentage of usage).

David Acheson: Oh, yeah, the amount of - the percentage of rice protein concentrate that we use in the United States. I don't know that number. I don't think we have that at hand.

Robert Ali: Elizabeth, we'll try and get back to you with that.

Next question, please?

Coordinator: Next question is from Chuck Abbott of Reuters.

Chuck Abbott: Great, thank you.

I'm hoping you can give us a little more detail on the fishmeal investigation. You listed five or six hatcheries in Oregon that may have received the stuff.

How many other states are you looking at? I mean, what sort of tonnage of fishmeal is involved? Is it only one manufacturer that received the bad stuff?

David Acheson: I'm going to ask Michael Rogers to answer that question and tell you where we are in the current investigation.

Michael Rogers: The short answer is no.

The long answer as Dr. Acheson mentioned in the opening remarks is that a firm, Skretting, in Canada went public and began the process of notifying their customers. Our trace back and trace forward investigation again related to a rice protein concentrate that is ultimately associated with one of the two suspect sources in China.

A bulk product was shipped to a manufacturer in Canada that made a premix that ultimately sold it to Skretting. Discussions with the firm suggest the firm may have as many as 198 domestic consignees. Most of those facilities are in fact hatcheries. We believe only two are commercial manufacturers.

Skretting has initiated the process of notifying all of the consignees that they definitely know received the suspect product as well as firms of a subset of that 198 that they may have received some of the suspect product.

Firms were instructed to return this product, certainly to discontinue its use. And as for the two commercial facilities, FDA will be visiting those and determining how that product was used and what product may be on hand.

Chuck Abbott: But there's no - at this point there's only two facilities you need to worry about? How big are they, and where are they located?

Michael Rogers: I don't have the size - the volume of production of those two facilities if that's the nature of your question.

As far as location, I'd like to get the firms corrective action first. We first need to determine - we believe they received it, but there's no confirmation at this point.

This is information that came to light yesterday. We don't know that they actually used it, and in what products it may have been used and what fish it may have been fed to.

So at this point I don't know that we want to disclose that, certainly not the states and more importantly not the firm names.

David Acheson: This is David Acheson. I'll make just to follow up on that.

As I said in my opening comments we are sharing with you everything that we're able to that we believe is validated.

And to Mr. Rogers' point, we just got information, we're following it up, and we don't have it validated and so it would be inappropriate of us to share that at this point.

Robert Ali: Thank you.

Next question, please.

Coordinator: Next question is from Gary Chittim of King-TV 5.

Gary Chittim: Thank you very much for taking my call.

Back to the fishmeal issue for just a moment, there are several hatcheries in Washington State that use that product.

Two questions. Number one, what are you instructing them to do as far as the fish they have in their system that were fed the suspect product? And secondly, what are your concerns about fish, some of which have already been released into the wild that may have consumed it?

David Acheson: First of all, let me just make sure everybody understands, it's a minor correction here of fishmeal versus fish feed. They are different.

Its fish feed that we're talking about. This is material feed fish.

Fishmeal is a compound that's made from fish as a type of a rendering product from fish. There's a difference. This is fish feed. Technical point.

In the context of what the other - what the various hatcheries are doing, that's part of the investigation. We've got to validate is it there, what's going on, what are the fish, what's the state of the fish, have they been released into the wild or elsewhere -- that's what the investigation is going to tell us.

And the third point in terms of some of these may have been released into the wild and what's the impact on that.

I think that as we learn more about the toxicology of these compounds one of the questions that will be addressed is, what's the long-term bioaccumulation in fish. If you feed them this feed for two weeks, then you take it off the fish, and in an experimental model and at a later time point determine levels of

melamine in the fish flesh, what do you find. Those experiments aren't done because this is a brand new issue.

But I just would like to reiterate that we did put - we did include fish in the risk assessment. And as I said before, that the risk assessment indicates that any risk to humans consuming fish that may have been exposed to these kinds of levels is considered to be very low.

Gary Chittim: I think the question got lost though.

The first part of my question was, what are you instructing the operators of those hatcheries to do if they have those fish in the system? To hold the fish?

David Acheson: At this point, we're trying to determine whether they've even for sure or received the feed. If they've received the feed, we're telling them to - if they have -- we haven't confirmed that - if they have we're telling them to stop using it and we're trying to find out by getting to those places what the status of the fish is and then we can give them appropriate advice.

Robert Ali: Thank you, Dr. Acheson.

Next question, please.

Coordinator: Next question is from David Barbosa of the New York Times.

David Barbosa: Hi. Could you tell us a little more about the China investigation? Are there any details of what the officials are finding in China? Have they interviewed any of the producers there? Have they learned anything more than what you've said?

David Acheson: I'm going to ask Walter Batts from our Office of International Programs to answer that question for you.

Walter Batts: Thank you, David. This is Walter Batts.

As Dr. Acheson reported earlier, we are getting very good cooperation from officials at AQSIQ. We visited the two facilities but there's essentially nothing to be found and that they are currently closed down, not operating.

The officials are being detained. Our investigators have not interviewed them directly, and that's all I can report on that at this time.

((Crosstalk))

David Barbosa: Can I just ask whether they found anything at these two firms? There have been some reports that buildings were destroyed or that things have been cleaned up.

Are - if they are getting cooperation, why aren't they getting access to the detained officials or being able to survey those facilities on their own?

Walter Batts: Well, as I mentioned, the facilities - there's essentially nothing, as they have determined, that is available to be seen at the facilities. They've been closed down, machinery dismantled, nothing to really get access to.

The AQSIQ officials did collect samples when they did their investigation, which was before our team arrived in China. Those samples are being analyzed by an independent laboratory, and we presume that we will have access to those results.

Robert Ali: Thank you, Mr. Batts.

Next question, please?

Coordinator: Next question is from Abigail Goldman of LA Times.

Abigail Goldman: Good afternoon.

I'm wondering if we can - we went through a lot of companies involved in this issue. I wonder if we can slowly and perhaps with spellings or if you can issue them later, go over the names of the companies first that you mentioned involved with the contaminated fish feed.

And secondly, in general is it true that fish bioaccumulates chemicals and other contaminants at greater rate, or that they have more toxicity or can contain more toxicity than other animals? Thank you.

David Acheson: This is David Acheson of FDA.

With regard to the names, I'd refer you to the press release from Oregon. I think it was the Oregon Department of Fish and Wildlife who put that press release out. That way you'll get the spelling accurate and you can get it directly from them.

With regard to the second question about bioaccumulation in fish, I'd ask Dr. Sundlof (to answer) that.

Stephen Sundlof: Thank you. This is Stephen Sundlof.

Certainly when we talk about bioaccumulation in aquatic systems, we're talking about fat-soluble compounds that accumulate up the food chain, with fish being - certain fish and a lot of the ones that we eat being the top predators in those food chains. The food chains are fairly long, and therefore as it accumulates on the way up you get this cumulative effect where it gets concentrated in the top carnivores, in this case being the fish.

Melamine is very water soluble, and as result of that it is eliminated very quickly. Probably one of the reasons that it causes the kidney damage that it does is because it is excreted in such high concentrations in the kidney so rapidly that it doesn't have the potential to accumulate in body tissues like fats and muscle.

So we wouldn't - we would not project melamine to be a compound which would bioaccumulate in aquatic systems.

Robert Ali: Thank you, Dr. Sundlof.

Was there any follow-up?

Next question, please, operator?

Coordinator: Next question is from Jennifer Mann of the Kansas City Star.

Jennifer Mann: Hi. Thanks for taking my question.

It's my understanding that visually wheat gluten and wheat flour look different. I mean, you can look at the two products side by side and tell the difference. Can you explain to me how this came to light weeks after you started looking at this-- that it wasn't in fact wheat gluten, but wheat flour?

David Acheson: This is David Acheson. I would have to get back to you on the specifics of that.

All I can say is that as a follow-up to this, and I can only assume that it was not an obvious difference, but we will get back to you on the specifics.

But the - it was when our forensic chemistry center specifically looked into that that they were able to measure the starch level of this product and determine that it wasn't in fact wheat gluten but the wheat flour.

I think the point to remember here is that this may not have been pure wheat flour contaminated with melamine. In truth we don't exactly know what they did.

It may have been a partial extraction, so it's got some wheat flour, it's got some wheat gluten and it's got melamine in it which would - may have changed it. Because just on first principles, and again this is speculation on my part, if this product looked different than wheat gluten then the manufacturers would look at it and say, this doesn't look right. That's part of their quality control.

So I can only assume that it did not look that different, and I think there's some further subtleties here. The main message is that it was definitely mislabeled and the proportions of wheat gluten versus wheat flour versus melamine I think is more complex than just wheat flour plus melamine as that's the simple way of looking at it.

Jennifer Mann: All right. Thank you.

Robert Ali: Thank you.

Next question, please.

Coordinator: Next question is from Emily Brown of Bloomberg News.

Emily Brown: Hello?

Robert Ali: Hi, Emily, go ahead.

Emily Brown: Actually you answered my question, so I'm going to pass.

Thank you.

Robert Ali: Thanks, Emily.

Next question, please, operator?

Coordinator: Next question is from Nima Nather of CBS News.

Nima Nather: Yes, a CBS affiliate in Austin, Texas.

I just want to confirm on the number of facilities that you're looking at with the fish. So there's the one in Oregon and then there's two other commercial facilities, correct? So it's three suspicious facilities?

Michael Rogers: No. This is Michael Rogers.

What we said was that in discussions with the firm we learned that they have a total of 198 domestic consignees. What led us to this point was a finished feed

product that ultimately tested positive in Oregon, and in tracing forward and working with the firm and looking at what products may have contained the lot associated with that positive sample, we identified a universe of 198 facilities in the domestic arena that may or may not have received feed that contained the suspect lot.

The firm announced yesterday that they were going to engage in the process of notifying all of those consignees. The number two came up in our previous discussion because that relates to two commercial manufacturers that may or may not have received feed contaminated with the lot referenced in the Oregon positive sample. We will certainly be visiting those two facilities as well as many of the firms in the other subset which as we stated previously are hatcheries and of course have an associated minimal risk.

Nima Nather: Okay. And then - actually just one more thing. With the number of pet deaths, is there an updated number on that?

Michael Rogers: We've covered that in previous calls. The short answer to your question is, no, there's not an updated number on that. We've not, in previous calls, quantified that number quite frankly.

What we've said was that the agency has received as many as 18,000 calls. We've entered a number of those into our database data capturing system as official complaints, and we continue to enter those. But a quick review of these calls that allege animal death or illness associated with a recall product suggests that as many as 50 percent allege in animal deaths.

Certainly as part of a longer-term process, the agency is going to be evaluating this data, and we'll certainly come out with a final characterization of - in total the number of confirmed deaths associated with these recalled products.

Robert Ali: Thank you, Mr. Rogers.

Next question, please?

Coordinator: Next question is from Steve Hedges of Chicago Tribune.

Steve Hedges: Yes. I wanted to ask Dr. Acheson or Mr. Rogers whether they can confirm that there's an Illinois company that did receive contaminated rice protein and then distributed it, definitively?

Michael Rogers: Yes.

David Acheson: Mr. Rogers just responded yes.

Steve Hedges: Can you name the company, (please)?

Michael Rogers: I think we've explained in the past what our process is.

Again, these press conferences are designed to alert the public, individuals like yourself, so we get a message out there. But our investigatory process involves, determining what firms may have received the scope of the issue, and whether or not products were in fact actually distributed. I can tell you that we are in discussions with these firms, and to the degree when it's necessary that a public notification or a recall will be necessary, the firm will notify as well as FDA. We'll publicize that on the Web site.

Robert Ali: Thank you, Mr. Rogers.

Next question, please?

Coordinator: Next question is from Heather Harland of NHK.

Heather Harland: Hi. Just to follow up on what you said before, you said you had received was it 8000 or 18,000 calls alleging people who were affected by the pet food, and 50 percent alleged an animal death, so that would be 9,000?

Michael Rogers: I never said 9...

Heather Harland: Hello?

Michael Rogers: I said the agency has received as many as 18,000 calls into the agency.

Heather Harland: Uh-huh.

Michael Rogers: That alleges an animal illness or death associated with potentially a recalled product.

Heather Harland: Right.

Michael Rogers: A quick review of those calls...

Heather Harland: Yes.

Michael Rogers: ...suggests that as many as 50 percent may, may allege or be associated with an animal may involve an animal death.

The final numbers as far as the confirmed deaths based on whatever criteria we come up as part of a longer-term process, we're not comfortable giving here.

Heather Harland: Okay.

Another question is, when are the FDA inspectors coming back from China?

Walter Batts: Yes, this is Walter Batts.

They are in the final stages of their work in China, and we expect that they will be returning within the next week.

Robert Ali: Thank you, ma'am.

Next question, please?

Coordinator: Next question is from Brian Hartman of ABC News.

Brian Hartman: Hi. You say you're getting very good cooperation in China, but you get to the factories and there's nothing there, you can't interview the people who have been detained, and you couldn't get visas into the country. I just wonder if - whether you could get - be more clear on what they are cooperating on.

And the follow-up, if you can tell me if anyone is testing melamine on live animals right now to better understand how it moves through the systems of animals? Thank you.

Man: Could you repeat the first part of your question having to do with...

Brian Hartman: Well, sure. You just - you said a couple times here that you're very happy with the cooperation in China, and I guess this is for Mr. Batts, and, but it sounded to me like what you're sharing with us about what's happening in

China is getting to a factory that's been dismantled and there's nothing to look at, you can't do any tests on anything, you can't talk to the people who have been detained, and you had trouble even getting visas into the country. So I'm just wondering, you know, what is it that you're not telling us about how cooperative China is being?

Walter Batts: Well, first of all concerning the visas, I'm not sure where the information came about China not being cooperative concerning the visas.

We found them very cooperative and in fact when the passports of our travel representatives went to the embassy for visas, they were taken care of within the same day, one of them within an hour of receipt, which is an unprecedented turnaround for the Chinese embassy of fixing visas.

So let me, you know, dispel that point about no cooperation on the visas.

Concerning what's going on in China, the agency that we are working with that Dr. Acheson mentioned earlier, AQSIQ, has been cooperative. They do have limited authority over the firms in this instance, and so that has hampered some of this. It has hampered what they were able to do before we even arrived on site. And they carried out an extensive investigation before our team arrived in China.

But, we are satisfied in that they have shared with us -- documents that they have obtained and anything that they found during their investigation.

The fact that facilities may have been closed or shut down by the companies and there wasn't much to see is just a fact and not necessarily to be blamed on lack of cooperation by the Chinese authorities.

Robert Ali: Brian, your second question I think USDA may be in the best position to address that. You may want to repeat it?

Brian Hartman: Sure, and thank you, Mr. Batts, that was very helpful.

Just - I'm wondering if anybody right now is trying to understand better how melamine and cyanuric acid and whatever else is passing through the animal systems. Are there tests being performed now on animals in labs somewhere in the country where somebody is trying to get to the bottom of understanding this, or is most of that work being done on the remains of the animals that ate the bad pet food?

Kenneth Petersen: Dr. Petersen with USDA.

I'm not aware of any current studies that are being done. Of course oftentimes the normal process when something like this happens then researchers at various universities may develop grant proposals and then no doubt the USDA or other agencies would be looking at whether to support funding for those kind of proposals to do a study for these kind of agencies.

Our focus is what I suggested earlier that, here's the situation today, what kind of information do we need to make some final decisions regarding hogs that are on farms or poultry that may still be on farms? And so we've completed part of that which is the human risk assessment on any worst-case exposure. And then the second part is what I mentioned earlier on the animal exposure assessments and other aid or investigation that we're doing.

So we're focusing on here's what's happened and what other questions do we have and pursuing the answers to those questions.

But formal studies would be a little more long and drawn out process that I think would be on a different track.

David Acheson: This is David Acheson of FDA. Thanks Dr. Petersen. I would add just one extra little thing to that.

Is that we have here initiated some discussions with our researchers in both the Center for Veterinary Medicine Center and our Food Safety and Applied Nutrition and our toxicologists at NCTR to begin to map out what sort of studies would need to be done to get to some of these basic toxicological questions that you raised in your question.

They are valid, they are important. Right now the key focus has been on understanding the risks -- excuse me -- developing the assays so that we can determine the degree of safety of the food supply in planning these experiments. And you are right, they are important, and they are definitely in the planning stages.

Robert Ali: Brian if you're still on line or if you can hear, Walter Batts correct spelling is B-A-T-S. Last name is Batts, B-A-T-T-S.

Brian Hartman: (Not like the fish).

Thank you.

Robert Ali: Operator, next question, please?

Coordinator: Next question is from Richard Knox of NPR.

Richard Knox: Hi. Thanks very much.

With regard to the import alert on vegetable protein imports from China, can you tell me the volume of shipments involved and what proportion are being released or held for testing?

And second, is FDA testing these vegetable protein imports, and if not who is? And what have the test results shown so far?

David Acheson: Let - this is David Acheson, let me answer some of that and again I'll ask Michael Rogers to fill in the holes when I leave them.

The - I want to emphasize the import alert is 100%. It is stopping every vegetable protein concentrate from China, period. That's what it's going to do.

To get that stuff released, the company has to come to us, the FDA, with validated tests, paperwork, insurances, and they can be of various types, but we review it on a case by case to say, "Yeah, you know, this material that's held is okay, free of melamine and melamine-related compounds, and it may proceed." That is the import alert.

The sampling assignment is a little different. That is a situation in which we typically target foods of concern, and right now we've got 100% sampling assignment on animal feed - I mean -- I'm sorry -- on pet food. The assignment on the animal feed is pending.

We have 100% percent sampling on the pet food that might contain melamine. That means that we take the samples and process them through our labs, so there's little difference between the two.

Richard Knox: I was interested in knowing what the volume of shipments coming in of vegetable proteins is and if we have any information at all on what the tests results from the companies are.

David Acheson: At this stage we don't have any specific information on the results of the testing, at least I don't. I'll pass this to Mr. Rogers so he can provide you what information he has.

Michael Rogers: Yes. We don't have at this time the volume of shipments, but we do have an idea of the quantity on an annual basis. It could be as much as 300 kilograms of bulk wheat gluten and rice protein concentrate. You asked about who would be doing the analysis, and FDA would be analyzing the samples that we would be collecting.

Robert Ali: Thank you, Mr. Rogers.

Operator, we have time for one more question but before we do we want to go to Dr. Sundlof who can probably clarify some of the discussion about number of pet deaths.

Stephen Sundlof: Thank you, Rob.

Yes, this is Steve Sundlof and everything that Mr. Rogers said is correct but I don't want to leave the miss-impression that FDA thinks that there are 9,000 deaths in pets associated with this outbreak.

We have received over 18,000 calls. Of those approximately 8,000, or half of those, have been actually entered in. That is, operator took the calls and then those have to be entered into our system. And of those 8,000 approximately half of those are people that have reported deaths but a lot of these have not

been - and in fact very few if any have actually been substantiated as to the cause.

A lot of these were from varies concerned and distraught pet owners and may or may not have been associated with the pet food, and we just don't know at this point.

We are working with our professional colleagues in the American Veterinary Medical Association, the American Association of Laboratory Animals Diagnosticians and also the people that are doing actually the autopsy work on many of these pets, and with some of the larger hospital networks like Banfields Pet Hospital to collate all of the reports that have come in, develop criteria for assessing whether or not the pet food was actually the cause of the death, and then coming up with a final determination of what we believe to be the true prevalence of death and injury associated with the pet food.

That will not be available for some time, probably not until the (fall) until we can actually really evaluate all the data that has come in not just to FDA but to other organizations as well and numbers are substantial.

And again this is just going to take a matter of time until we can feel that we are comfortable in making some kind of assessment.

Robert Ali: Thank you, Dr. Sundlof.

Operator, please take the last question.

Coordinator: Next question is from Dorothy Griffith of Sacramento Bee.

Dorothy Griffith: Thanks for taking my call. Dorothy Griffith, Sacramento Bee.

Just a little bit, I just need a clarification. On Tuesday you were talking about fishmeal being of concern. Today we're talking about fish feed. Can you just explain the difference and the discrepancy in the information? Thank you.

David Acheson: This is David Acheson of FDA.

The product of concern is fish feed. I apologize if I got my nomenclature mumbled up on last time I spoke with you between fish feed and fishmeal. And this is an opportunity to correct that.

It is all fish feed. This is the food that is fed to fish. Fishmeal is the - is a byproduct, an end product from rendering certain components of fish. It has served a completely different purpose.

So if I said fishmeal and confused you, I apologize. It is fish feed.

Dorothy Griffith: Thank you.

Robert Ali: Thank you.

Ladies and gentlemen, at this time that concludes this media teleconference and briefing. Thank you for your participation.

The replay will be available in about an hour and will be up for about three days.

If you have follow-up questions, please don't hesitate to call the respective agencies. We plan on doing another briefing tentatively scheduled for next

Tuesday at 2:00 pm and we'll keep you updated as more information becomes available.

Thanks, and have a great evening.

END