## Transcript of FDA Press Conference on Contaminated Animal Feed

## FTS-HHS FDA

Moderator: Julie Zawisza May 3, 2007 3:00 pm CT

Coordinator: Good afternoon and thank you all parties for standing by.

I would like to inform you that your lines will be on a listen-only until the question and answer session of today's conference.

The call is being recorded. If you do have any objections, you may disconnect at this time.

I would now like to turn the conference over to Ms. Julie Zawisza.

Thank you, ma'am.

You may begin.

Julie Zawisza: (Carol), thank you very much.

Ladies and gentlemen, welcome to our media briefing this afternoon. I'm Julie Zawisza, Assistant Commissioner for Public Affairs.

We're very pleased you could join us this afternoon.

Today, we'll be giving you an update on the contaminated animal feed. And we have one speaker, and then we have a number of FDA officials and a USDA official who would join us for questions and answers.

Our speaker today is Dr. David Acheson whom many of you know. He's the Assistant Commissioner for Food Protection here with the Food and Drug Administration.

And after he speaks, we'll go to the Q&A section and we'll have the following people available to answer your questions.

We have Kenneth - Dr. Kenneth Peterson who's Assistant Administrator for Field Operations with the Food Safety and Inspection Service at the US Department of Agriculture.

And we have, from the Food and Drug Administration, Dr. Steven Sundlof, Director of our Center for Veterinary Medicine, Capt. David Elder, Director of the Office of Enforcement, Michael Rogers, Director, Division of Field Investigation, and Walter Batts, Deputy Director, Office of International Programs.

At this time, I would like to turn this call over to Dr. Acheson.

David Acheson: Thank you, Julie.

This is David Acheson, Assistant Commissioner for Food Protection of FDA.

What I would propose to do on this call is to go over some old ground to make sure that we're all on the same page. And I'm going to cover five principal targets to (pop) and topic.

The first is - and just to reiterate the whole story around wheat gluten and how some of it can wind up in pet food and some of human food.

The second is to briefly mention an expanded recall for Menu Foods.

The third is to discuss the human health impact of the findings in the investigations to date.

The next is to discuss our current proactive strategy looking at both imports and domestics.

And the third point is just to mention where we are on the investigation in China.

So that's the five points that I propose to cover.

For the first point, just to put us all on the same page with regard to wheat gluten and I want to just remind everybody that when wheat gluten comes into the United States, it essentially can follow two predominant paths. It can either wind up in the pet food system or it can wind up in the human food system.

In the current investigation, all of the contaminated products ended up in the pet food system.

As you are well aware, this whole situation came to our attention because of sick and dying pets. That led to investigations to determine what was causing the problem. The problem was identified as wheat gluten initially.

The wheat gluten was then investigated and found to contain melamine and melamine-related compound, and the belief is that the melamine and melamine-related compounds is what is toxic to the pet.

Once we knew that the contaminated wheat gluten had ended up in the pet food supply, the obvious question was, had any of those contaminated lots gone down the human side of the arm? Had they gone into the human chain?

We have done extensive investigations and follow up tracing forward and tracing back into that system and have found no evidence that any of those contaminated lots have ended up in the human food chain as an ingredient in human food. And I emphasize as an ingredient.

So what I'm talking about there is that wheat gluten is used in a range of human food, including a variety of different breads and pastas et cetera. And none of the contaminated wheat gluten ended up in the human food chain as a direct ingredient.

Now, as you all know, the - a portion of the contaminated pet food from the pet food arm of this scenario I'm painting to you, what incorporated at some level into feed for hogs and poultry. Some of those hogs and poultry have entered the human food supply.

I'm going to say more about the specifics of that in just a minute. But I specifically wanted to just outline these two tracks of pet food track and the human food track and explain that all of the contaminated wheat gluten has only gone down the pet food track and likewise the rice protein concentrate.

It's all down the pet food track, and there is no evidence of crossover other than in the poultry and the hogs, which we'll get to.

Sticking with the pet foods, Menu Foods have announced an expanded recall. I'm not going to go into the specifics of that. The information is on their Web site.

Their belief is that this was due to a cross-contamination situation in which some of the previously contaminated products that cross-contaminated some new products, which came to their attention, so they have expanded the recall.

If there are specific questions about that we have experts in the room who could answer those (but) as I say the information on that is posted already.

Turning to my third point, the human health impact.

We - again, being over some of this ground on previous calls, but I want to go back over this again with you.

Bearing in mind my first comment, so this has all gone down the pet food side and the only connection to human food is when some of this pet food has been used as human food.

Let me just reemphasize that our current belief is that the threat to humans from contaminated poultry or pork is extremely low. It's very unlikely that there is a human health effect here. And the reason for that is several faults, and essentially is based on what we know of the levels of melamine that are toxic and what we know of the dilution effects of the pet food.

And what I mean by the dilution effects are when the contaminated wheat gluten comes into the country, only a relatively small proportion of the wheat

gluten is containing melamine and melamine-related compounds, so it's very between 5% and 8% of the gluten is melamine.

Of that, wheat gluten is not an exclusive ingredient to the pet food. It's mixed with other things so it's further diluted as it is turned into the pet food.

When it comes to feeding that pet food to hogs and poultry, only a small portion of pet food is used as the feed for the animals. That's preferred - of this.

Once it's got into the poultry and the hogs, the - a small portion of the meat that's out on the market, it's certainly not all the pork, it's not all the poultry, it's a very small proportion of it, will potentially contain very low levels of melamine.

But again, the melamine that's present in that meat and poultry does not form an exclusive part -- the poultry and pork do not form an exclusive part of the human diet. People who eat poultry and pork do not eat exclusively poultry and pork.

So what we're doing to recap, and this is a little complicated, is that there is a series of dilution steps that take the original contaminated wheat gluten in terms of the way it's used to make the pet food in the first place, in terms of the way that pet food is used to make the animal feed, and then the amount of the animals that the humans ultimately consume.

And what that result is a dramatic dilution of the contamination taking it down to the point where we really believe the likelihood of the human illness is - it is very remote.

I want to just clarify going back to my first point to make sure that you all understand what I meant about pet food being used as human food.

Well, I'm not trying to suggest that people are consuming pet food as part of a three-square meal. This is simply pet food that has gone through this pathway that I just alluded to in which it ended up in poultry and hogs, and therefore, wound up in the human food chain.

So - and again, I know this is complex, and that's certainly part of our challenge, and obviously, if there are questions around that, please ask us for clarification.

The next point that I want to mention is our proactive strategy.

So we covered the basic areas of the pet food to human food split, the expanded recall where we are on the human health impact. And so the fourth point is our proactive strategy, and there are two key elements to that.

Firstly is what we're doing in the context of imports and the other is where are on the domestic side.

As we discussed before, FDA, working with Customs and Border Protection, has an import alert in place that is focused on protein concentrate of vegetable origin from China.

What that means is that protein concentrate of vegetable origin from China are held at the border and are only allowed to enter US commerce when we are satisfied that they are safe to proceed. There are some specifics around what that safe to proceed means, which I'm not going to go into on this opening comment, but we have experts in the room who could address that if needed.

So what that is doing is preventing any further import of contaminated protein concentrates of vegetable origin coming into the country from China.

On the domestic front, we have now initiated our assignment. It's now operational in which working with states and locals are investigated the going out to manufacturers in the United States who use protein concentrates as an ingredient in food.

And they're doing two main things. They're raising the awareness of those manufacturers about the importance of their supply chain, making sure that they know all the risks, know about where they got their ingredients from.

And secondly, if they have received the ingredients from China and they're still onsite and have not been used, that they are tested for melamine and melamine-related compounds.

As I said, that assignment has just begun. It began this week.

To date, we do not have any results from that, but it will continue until we have (disputed) the domestic side with some considerable way to ensure that anything that is currently in the United States is safe to consume.

I want to just point out with regard to this proactive strategy and the testing that we have done just to give you a few numbers around that, we have currently tested approximately 700 samples that are either finished pet food or the ingredient.

Of those 700, approximately 400 samples are tested positive. Some of those have been multiple samples from the same lot resulting in a total of 92 positive lots.

So out of those 700 samples tested, approximately 400 have been positive melamine and about 300 have been negative.

All of the positive samples have come from the two importers and companies that we already know about, and a number of the negatives have come from other companies.

So what I'm saying here is that so far all of the positive have tracked back to companies that we're already aware of, we're on top of, and that's what all the recalls have been about. And we're already beginning to get negative data on some other importers, other companies, obviously, not currently under recall because they don't have melamine in them and they're not a problem.

Those numbers I have confidence will expand over the coming weeks as we do more testing through the domestic assignment.

The final point I want to make is where we are in China. I don't have a great deal to say about that other than the HHS, Human Health Sciences -- Human Health Services FDA team are on the ground in China, and they're working with the Chinese government on the investigation.

At this stage, I don't want to go into any further specifics on what the operations in China sufficing to say that we are there and the investigation has begun.

With that, I'll hand it back to Julie, and take it from there.

Julie Zawisza:

Thank you, Dr. Acheson.

(Carol), at this time, we're ready to take questions from our listening audience, so we'll give people a moment to get in the queue.

And ladies and gentlemen, we ask that you limit yourselves to one question and one follow-up, and state your name and affiliation please.

Coordinator:

Thank you.

We'll now begin the question and answer session, and if you would like to ask a question, please press star-1.

To withdraw your question, press star-2.

Our first question comes from Abigail Goldman.

Please state your affiliation.

Abigail Goldman: Good afternoon.

Abigail Goldman with the Los Angeles Times.

I have a couple of questions. Can you confirm an arrest made in China related to this from the producer?

And secondly, if you were testing or holding imports from China, but those imports are mislabeled as non-food or fraudulently labeled as non-food, what assurances do you have that you are preventing those ingredients from getting into either the pet food chain or human food chain.

Thank you.

Julie Zawisza: Abigail, this is Julie Zawisza.

Your first question should be directed to the Chinese law enforcement authorities. This is really a matter for them to speak to.

Your second question, I think Michael Rogers is going to take.

Michael Rogers: Okay.

Julie Zawisza: Is that right?

Michael Rogers: Sure.

Julie Zawisza: Okay.

David Acheson: Yes. Thanks, Michael.

I think basically the answer to that question is if it's fraudulently labeled and arrives in the country under some other labels and is not therefore identified saying it's coming in say as car parts, we're not necessarily going to know about that.

But clearly, if we find that in itself, it's something that we would follow up on. But we're not opening every container to make that it says what it says on the outside. Abigail Goldman: Let me clarify.

Is that the situation here or do you believe that that was part of the situation here and part of the problem here?

David Acheson: No, no. No, we believe this was - this came into the country labeled as wheat

gluten and wasn't labeled as something else.

We have no evidence that would suggest that that is going on.

Julie Zawisza: And that was Dr. Acheson, not Michael Rogers.

Next question please?

Coordinator: The next question comes from Diedtra Henderson.

Please state your affiliation.

Diedtra Henderson: Hi. Thanks for doing this call.

This - I'm with the Boston Globe.

There's been a number of stories about Chinese agricultural practices. And I'm wondering if your investigators are on the ground or seeing domestic use of melamine and melamine products in the animal feed.

And would that have any implications for food that's coming into the US from China? Not just ingredients, but seafood, poultry.

David Acheson: That's a very good question.

And clearly, our investigators will be looking into many aspects including those kinds of things.

At this point, we're not in a position to make any comments in terms of what they're finding until their back in the US and the investigation is complete.

Diedtra Henderson: Thank you.

Julie Zawisza: Thank you.

Next question?

Coordinator: Joe Johns, please state your affiliation.

Joe Johns: Hi. This is Joe Johns with CNN.

Pretty straightforward question. Could you give us some sense of sort of the data and the amount of data you've been able to recover on your testing in order to be able to say with any degree of confidence that the melamine did not actually reached into the human food chain except for those animals?

David Acheson: This is David Acheson.

I feel confident to say that the investigation of the contaminated pet food has been exhausted. We have followed that multiple different direction.

The investigation continues so I'm not going to say never, but we - that has been exhausted in terms of tracing -- originally tracing back from the sick

animals to what the problem was, then tracing forward from the contaminated wheat gluten and to all kinds of different areas, and hence, the host of recalls that you've seen.

So based on that, I'm very confident that none of that contaminated -- those of contaminated batches have ended up in the human food supply.

Part of the reason for the domestic assignment that we're doing is to answer the second part of your question, that is getting out ahead of the curve looking in areas that we've not currently looked at, looking in areas where we don't have any evidence that there's a problem, but it's prudent for FDA to get out there and look in those areas even though there's no evidence that there's a problem.

Hopefully, when a domestic assignment is complete, we'll be able to say with confidence what that showed, but that part of it is very early and very active.

Joe Johns: A simple follow-up if I can just have one.

And that is, it was said on one of these calls earlier on that the wheat gluten went into baby food. To what extent have you been able to look into baby food to find out if there's a problem?

David Acheson: Well, I think there was a lot of speculation early on because wheat gluten and rice protein concentrates go in many different directions.

But as I said, we have chased the contaminated lots in many different directions and there's no evidence that it's ended up in baby food or for that matter in any other human food as an ingredient.

The only connection with the human food is through the animals.

Julie Zawisza: Thank you.

Next question?

Coordinator: Randy Schmitt, please state your affiliation.

Randy Schmitt: Associated Press.

Dr. Acheson, when you were talking earlier about sending these investigators out to look at the supplies of wheat gluten that are still in the hands of manufacturers, is that primarily pet food or is that - does that extend to human

food too?

David Acheson: This is David Acheson.

And thank you for asking that question. I should have clarified that point, it's

both.

Randy Schmitt: Okay.

David Acheson: We are going to manufacturers so on the pet feed side -- pet food side as well

as the human food side.

Randy Schmitt: Even though there's no evidence of human food contamination?

David Acheson: Correct.

Randy Schmitt: Thank you.

Julie Zawisza: Next question?

Coordinator: (David Curley), please state your affiliation.

(David Curley): ABC News.

I got a bunch, Julie, but...

Julie Zawisza: One and one follow-up, (David).

(David Curley): All right.

Do you say these contaminated lots did not get into the human food chain? That sounds like standard practice for the Chinese. How long has this been going on? How do we know that a year and a half ago that wheat gluten that went to the human food chain didn't get to us?

And then, do we have new poultry numbers yet? And why is it okay for melamine in human food, but it's not okay for - to be in pet food?

David Acheson: Well, you got a whole host of questions there and your one question.

Let me see if I can remember what you asked me.

The - first of all, could this have been going on in prior years? Sure it could. We don't know that. We don't have samples from last year, the year before, the year before that test. We cannot rule that out.

All we can say is that if it's something was different this time where the contamination led to sick pets and so it came to the attention of obviously pet owners as well as federal authorities.

We can speculate for hours as to why that was, what was different with this. We can speculate how long this may have been going on. The bottom line is we don't know.

In terms of the - I think getting at one of your other questions of how do we know this hasn't gone into human food. I think that was one of your questions.

(David Curley): No. The question is - you've said on several of these calls. This can't be in pet food.

But you've just said that, you know, it's 3 million chickens have already gone into the human food supply and they may have had melamine in them. And apparently, that's okay.

David Acheson: The - one of the - that's a whole issue around the dilution factor.

When pets eat pet food, for the most part, they would be consuming a single type of food as their exclusive diets that they only eat for their breakfast, lunch and dinner. And if that food is contaminated, they're going to get a pretty hefty dose of problems.

And if they are eating, the most contaminated part of this whole thing, they are eating the pet food which has got the greatest concentration of melamine and melamine-related compounds in it.

On the animal side, only a portion of that pet food to the hogs. And what I mean is that when farmers mix up the feeds for the hogs for the day, they might take - I'm just (putting) these numbers on here, they may take one scoop of pet food, nine scoops of something else. So there's the dilution factor, and that's what is in their hog meal.

Once it's in those hogs, we have no evidence that it bio-accumulates. The hogs and the chicken have been physically fine. There's been no evidence they have suffered any illness.

The - further, even if there is any in the hogs or the poultry, the amount of poultry meat or pork meat that is consumed by humans is only a small proportion of their total daily diet. Unlike the pets which typically have a specific type of pet food as their exclusive diet. So there's two pieces to that.

So when you compute all that out, the level that the - of melamine and melamine-related compounds that the pets are going to get is going to be significantly higher than anything that would be left in the pork or the poultry.

(David Curley): Updated poultry numbers?

David Acheson: Okay. The poultry numbers I would ask Ken Peterson of USDA to do - did you have any information on that?

Ken Peterson: Okay. Thank you.

Dr. Peterson with USDA.

Now, the poultry numbers that we outlined on the call on Tuesday are still the numbers that we're working with the 30 broiler farms in the one state of

Indiana with the approximately 270 million head that we believe went to slaughter back in March.

And then, the...

Man: 2.7, yeah.

Ken Peterson: ...2.7 made by (these both).

2.7 million head that we believe went to slaughter in the one - in out of the one state in Indiana.

And then, the approximately 100,000 head of breeder birds that are still resident on the farm. So that's - the poultry number from Tuesday's call and those - the numbers we're still working with today.

Julie Zawisza: Dr. Acheson had another comment.

David Acheson: Yeah. Just to get back to this question of what do we know about happened in the past.

I mean, I stick with what I said before as we don't know for certain, but the one thing that I forgot to mention is that we have looked at the incoming shipments for the two importers where we had the problem -- the wheat gluten and rice protein concentrate.

We've looked back to 2007 and to 2006 to see where that material went to, and it all went into the pet food side of the arm here.

None of the wheat gluten or the rice protein concentrate that was imported by either of two importers that we've recently had concerns about had anything that went as an ingredient into the human side of this food chain.

Julie Zawisza: I'm going to go ahead and move us along then because we have a number of

other callers.

Next question please?

Coordinator: Julie Schmitt, please state your affiliation.

Julie Schmitt: (Unintelligible) my question, USA Today.

Can you tell us anything about this SmartPak recall? Are you aware of that?

Man: Yeah.

Julie Zawisza: Julie, did you SmartPak recall?

Julie Schmitt: Yeah.

David Acheson: Sorry. Can you repeat that question?

Julie Schmitt: Well, this pet food company name SmartPak has recalled one product that it

says - in which it says it found melamine, but the product doesn't include any

of the vegetable protein raw ingredients from China.

Do you have further information (with that)?

David Elder: Julie, this is David Elder.

And the SmartPak product was under recall. It was manufactured for SmartPak by a company called Chenango Valley that has issued a press release. And that product did contain the rice protein concentrate as an ingredient, so it's contaminated with melamine.

Julie Schmitt: No. This is another product. This is something they just did last night.

David Elder: Yes. (They thought) but it's essentially the same reason. It's the contractor

manufacturer, and that may not have been an ingredient, but there could have been a cross-contamination issue. But it was - we understand that it was tested

and found to contain the same compounds, and we believe it to be a cross-

contamination issue at that same manufacturer.

Julie Zawisza: Anything else, Julie?

Julie Schmitt: Dr. Acheson mentioned 92 positive contaminated lots out of - how many?

David Acheson: What that was is - if that was in relation to the 390 - 400 or so positive test

results that we've had, that was 90 - that represented 92 lots.

I don't know whether we have - we don't have total lot number because if it's negative, we're not going to go chasing it down. (Although) I can give you is

a positive information.

Julie Schmitt: Thank you.

Julie Zawisza: Next question?

Coordinator: Nancy Cordez, your line is open.

Please state your affiliation.

Nancy Cordez:

I'm with CBS News.

And I'm wondering if you have any comment on these new reports that it was apparently common practice for Chinese manufacturers to label food products as non-food products in order to be able to elude Chinese inspectors. And if that is the case, what new concerns now you have about other food products?

David Acheson:

Well, this is David Acheson.

I think part of the answer to your question is we need to see what the investigators come up within China.

Clearly, there are a number of reports and things that are like that, which are an interest. But I think we need to wait and see what the facts are and then, make some determinations on how to respond to them.

But clearly, this whole episode has raised questions in areas that previously we were not thinking about so specifically.

Julie Zawisza:

Thank you.

Next question?

Coordinator:

(Brooke Turnbull), your line is open.

Please state your affiliation.

(Dan Reitnik): Actually, (Dan Reitnik) from CNN.

My question is regarding the cross-contamination. What exactly does cross-contamination means? Because I've gotten reports from some vets that pets were still dying eating the food that was contaminated by cross-contamination.

But it seems like - I mean, if they're just implying a little food left over in a machine, that doesn't seem like that would be enough to kill these animals.

David Acheson: This is David Acheson.

I - cross-contamination can mean all kinds of things. And to take a completely different example, cross-contamination in the kitchen with E.coli 0157 is a frequent cause of human illness.

So, you can get bacteria crossing between raw meat and salad. This is a situation in which the manufacturer believes it was cross-contamination in the facility.

I don't have the specifics of the levels that they found of melamine, but they saw melamine and melamine-related compounds. And based on that they said, we need to do a recall.

How the cross-contamination happened and to what extent, I don't know.

(Dan Reitnik): But it seems like it's - if the cross-contamination they're talking about is enough to cause the death in animals, and obviously that, you know, they're implying that it's a very small amount.

Wouldn't that then crossover that we should be worried about, you know, small amounts in human food?

David Acheson:

Well, cross-contamination is a statement of what happened. It doesn't speak to its quantitative nature. You can get massive cross-contamination going on.

And nor do I know specifically whether they were doing this because of this implicated lot that was cross-contaminated was causing illness or whether they were just doing this out of caution because they became aware of the cross-contamination, and they said, we don't want to take any chances here.

(Dan Reitnik):

Are you aware of any human foods that are processed in the same factories that is the pet food?

David Acheson: No.

Man:

No.

David Acheson: No, there are not.

Julie Zawisza:

Next question?

Coordinator:

Lauren Etter, please state your affiliation.

Lauren Etter:

Hi. I'm with the Wall Street Journal.

Thank you.

Is there any contaminated pork and poultry on the market right now, currently

today?

David Acheson: I will ask Ken Peterson to - that please?

Ken Peterson: Okay. Thank you.

Dr. Peterson with USDA.

No. When we described the other day, the swine farms in the six states that were of interest, and then, of course, the poultry farms that I just mentioned.

For the poultry, those two 2.7 million heads were chickens that it gone to slaughter. They had eaten contaminated feed on one or more days going back as far as February.

But having looked at those animals and speaking to the dilution factors that Dr. Acheson mentioned, we have no reason to believe that those animals are of any risk to the public. And the same principles apply to any swine that have gone to the market.

The 6000 heads of swine that we mentioned last week, I believe it was are still about the same 6000 on farms that we were identified. And of those 6000, it appears that perhaps 300 or so had gone to slaughter, and so the same notion of the dilution factors and given what they have been fed would apply to those animals.

So, again, we don't believe that those are of any risk to the public either.

Lauren Etter: I understand that you don't believe that they're a risk to the public. I'm just

wondering if you believe that there's any meat that might have been

contaminated by the feed on the market today.

Ken Peterson: No, we have no reason to believer there's any contaminated meat related to

the melamine on the market today.

Lauren Etter: Okay. So you've rolled out a recall of any meat?

Ken Peterson: Yes.

Julie Zawisza: Next question please?

Coordinator: Steve Hedges, please state your affiliation.

Steve Hedges: Chicago Tribune.

Dr. Acheson, you mentioned that the 394 positive test for melamine, can you explain what exactly that means? What levels of melamine were in those tests?

And also, could you address whether you're confident that it's melamine that was causing animals to fall sick and die or if there's some other possible ingredient that are causing (unintelligible) in the death?

David Acheson: Let me just try to deal with your first question very quickly.

It was variable and it vary between 2% and 8% of the ingredients contain melamine and melamine-related compounds.

And can you just reiterate your second question there quickly for me?

Steve Hedges:

So, (in this) speculation including stuff from the Chinese government that melamine did not caused the pets to fall sick and die because it hasn't affected other animals, I'm just wondering if you're confident that it was melamine that has caused the animals to fall sick and die.

David Acheson:

Yeah. The toxicity studies that we're aware of would indicate the melamine alone is not particularly toxic unless you feed it in extremely high doses. And that was conundrum from the very beginning as to the explanation, most - many of the veterinarians of how could melamine be doing this?

The discovery of the melamine-related compounds, which include a number of things, but one of them that there has been - some mentioned of it something called cyanuric acid.

The combination of melamine plus these other compound appears to be more toxic than either one alone. So melamine alone or cynanuric acid alone is not particularly toxic. You mix the two together, it becomes more toxic.

And the thinking is that when you put the two together, there is a greater tendency for them to form crystals in the kidneys and lead to kidney failure.

So, we believe the current hypothesis is it's a combination of the melamine with the other compound that is the problem, not just pure melamine itself.

And I just want to correct something I said the first time around, that just been corrected here. It wasn't 2% to 8%. It was 0.2% to 8%, just to correct those numbers. So our positive samples are approximately 400 positive melamine samples had ranges between 0.2% and 8%.

I apologize for that.

Julie Zawisza: Thank you.

Next question?

Coordinator: Susan Heavey, please state your affiliation.

Susan Heavey: Hi. I'm with Reuters.

You mentioned the investigation in China was ongoing. Can you tell us about how many investigators you have over there now, and if you will be sending more and if so, how many?

David Acheson: This is David Acheson.

No, I really can't say anything more about that.

Susan Heavey: Okay. And this maybe a question for Dr. Sundlof.

Last week, the FDA said they had gotten reports of - with about nearly 2000 dead cats and about, I guess, 2000 dogs. I know they're not confirmed yet, can you give us an update on the numbers?

And I think also 17,000 complaints.

Steven Sundlof: Yeah. I think we don't have any new numbers from that, so I would have to go

back and tell you the numbers again.

Susan Heavey: Okay.

Steven Sundlof:

We are continuing to add the - we have more phone calls and we've actually been able to log into our system. And so right now, what we're doing is we're trying to catch-up with the backlog and get all of those logged in, and I imagine when we get our next press conference, we can update the numbers.

But right now, those are still the same numbers that we reported on last time.

Susan Heavey:

Okay.

Michael Rogers: This is Michael Rogers.

I can update or provide some context to that number (simply that) as we provided this group last week. We've stated that the agency has received more than 17,000 calls from consumers that alleged animal illness and their associated pet food products.

Our preliminary review of those, and we've certainly entered a subset of those into our official data system, but the preliminary review suggested as many as 50% alleged and animal deaths associated with those pet food products. But we're, as part of a long-term process, (unintelligible) group will be evaluating those calls and determine their direct association to the implicated products.

David Acheson: And this is David Acheson.

I want to emphasize what Michael Rogers said "alleged" does not mean that the definitive proof, as I understand that.

Julie Zawisza:

Thank you.

Next question?

Coordinator: Bil

Bill Thompson, please state your affiliation.

Bill Thompson:

Bill Thompson with Dow Jones.

I just want to get back to the pork and the poultry meat that's on the market or apparently not on the market. Is it because it's not on the market that it is because it's already been eaten?

And what about frozen products, I mean, how do we know that there's none of that left on the market?

Ken Peterson:

This is Dr. Peterson.

As Dr. Acheson indicated, the investigation is quite active, and so the farms that we mentioned are the ones that were well aware of that appeared to have received the contaminated feed, and so those farms are the ones that either some type of control is being exerted at the state level. So those are the ones that we're aware of.

As - it was also mentioned, this relates to the pet food trace back and that pet food trace back is - I understand, it's winding down. They've pretty all gone to all these pet food manufacturers, and then through that process as I would became aware of some of this pet food making its way as a small component of animal food.

So those - what that investigation is still going on, so the farms who were aware of and the animals that - from those farms, those poultry or those swine that have gone to slaughter are the ones that I mentioned.

There are still other animals resident on those farms, and the local actions are preventing them from moving to slaughter.

We're continuing to look for additional information, and what additional information can inform us about the status of those animals particularly on the farm. But we have no reason to believe there's any risk to the public from those animals that are already - those birds or those few 100 head of swine that were already slaughtered that made this way into the marketplace.

Bill Thompson:

But I just want to be clear, there's 3 million head of chicken that were slaughtered in February.

It is - I just want to make sure I'm clear on this. Is your belief that those well, you said that they are processed and they land the commerce, that they've already been consumed by the public. And it is unclear whether or not the meat itself is tainted, but if it is, it's already been consumed by the public.

David Acheson:

There's just no evidence of any harm to humans from that chicken or from that pork.

Julie Zawisza:

Thank you.

Next question?

Coordinator:

Andrew Martin, please state your affiliation.

Andrew Martin: Hi. I'm with the New York Times.

I had a question about this current proactive program you're talking about, Dr. Acheson, and that is given the fact that you mentioned that these vegetable

protein concentrates (just) veer off in all sorts of directions, how have you determined which manufacturing facilities to visit?

David Acheson: This is David Acheson.

Based on our import record and based on company registrations and other information that we have about who does what and what ingredients, that's been the basis of the data set we've used to initiate this investigation.

That's been combined with local knowledge of our state's locals and our local investigators in terms of who they know and to visit. But essentially, it's based on the data that we have of what ingredients go to which manufacturer.

Bill Thompson: And do you have any sense of extent of that, how many manufacturers you're talking about, how long it might take?

David Acheson: I'm thinking 100, but that's pretty much of a guess. It's in that range.

And yeah, this is going to go on until we feel satisfied we've got it covered. We're not setting the bar at 50 or 100 or 1000. We'll keep doing this until we're confident that we've got our arms around it.

Julie Zawisza: Next question please?

Coordinator: Jon Rockoff, please state your affiliation.

Jon Rockoff: Hi, from the Baltimore Sun.

I was just wondering whether you've found any melamine or related compounds and any other vegetable protein products besides the three you've

identified so far, and whether you've identified any other importers who received tainted imports.

David Acheson: Just to clarify.

So far in the United States, we've only found it in wheat gluten and rice protein concentrate.

You maybe thinking the third one is corn gluten. That's not been found - their problem in the United States, that was found in South Africa several years ago, so we've only - we're only aware of two in the United States.

Can we rule it out being in any others? No, that's why we're doing what we're doing at the borders and with the domestic assignments.

Jon Rockoff: But you haven't found it in any of the others?

David Acheson: That is correct.

We have not found it in any of the others.

Jon Rockoff: And what about any other importers besides, you know, Wilbur-Ellis and

ChemNutra?

David Acheson: No. We have - obviously, the importer (lurk) is not been going more than

several days. So - but to date, all the positives that we have found have been

linked to those two companies that we were already aware of.

Julie Zawisza: Next question?

Coordinator: (Heather Harland), please state your affiliation.

(Heather Harland): NHK Japan.

I have some questions regarding the import alert, and I just want to make sure I understand it properly.

Then reported in different ways in different media, and looking at the documents, my understanding is there were three separate import alerts issued one for each of the two Chinese companies involved, and then that would detain those products, and then the separate one, which detains all vegetable proteins coming from China.

But my understanding that when I called the FDA, they said that in the case of the two Chinese companies, there was an outright ban of products from that - those companies.

Then it was also reported, I think, in the New York Times that - or wheat gluten from China is indeed banned.

So - and then, but my understanding is the import alert for all of China is different in that way that it's not a total ban. It's merely a detention of those products subject to further testing.

So I just wanted to clarify that because the language in all those documents is identical, but it seems as though the situation was all been this different.

Michael Rogers: Yeah. This is Michael Rogers.

Let me put into context.

You listed a lot of facts, but many of which were things - activities the agency

took over a period of time.

(Heather Harland):

Okay.

Michael Rogers: It is true when we encountered this problem, we were initially focused on two

suspect sources in China.

As we announced last time though, the agency has taken a more proactive

approach and initiated a country-wide import alert, which is the detention

without physical examination for various Chinese vegetable protein products

that includes from all manufacturers, including the two suspect firms that are

associated with all of our positive samples.

What this means, for clarification, is that these products are targeted active

order for 100% priority review and hold, which shift the burden on the import

of record to demonstrate that their product is not contaminated or adulterated.

The import -- present import alert -- the country-wide import alert for various

vegetable protein products is posted on the FDA Web site and provide

additional guidance as to what firms need to do to go through this process.

(Heather Harland):

Okay.

Julie Zawisza:

(Heather), does that make sense?

(Heather Harland):

Yeah.

Julie Zawisza:

That helped?

(Heather Harland): Sure. (Just) have one follow-up question.

You said earlier that there - that the wheat gluten was labeled as wheat gluten went and came to United States because there have been reports that said it was labeled - or as textiles or came through a third party textile manufacturer. It was not labeled as a food product when it came from China. Is that still true or did you determined that wasn't the case?

David Acheson: No. The fact we're aware, it came and labeled as wheat gluten.

Possibly some of that confusion may have been linked to the fact that the exporter from China or exports a variety of different product. They don't just export wheat gluten. They export a variety of things, and textile is maybe one of them.

And it maybe that the part of the mix message is the exporter exports a variety of different things, one of which were textiles. But we're not aware that it came into the United States labeled as textile.

But you're still not aware of how it went out of China, then it's still possible it went out of China labeled as textile. Is that possible or not?

David Acheson: I'll let Michael Rogers to address that.

Michael Rogers: This is Michael Rogers.

What we're referencing is how the shipment were declared in our import record as they were off of - were imported to the country. We don't have records and we don't capture how products are declared, I believe, in China.

(Heather Harland): Okay.

Julie Zawisza: Next question please?

Coordinator: Steve Dale, please state your affiliation.

Steve Dale: WGN Radio, USA Weekend, Tribune maybe of services.

And one of you - and I don't know which one mentioned that going back to 2006 conceivably, you know, let me not say - let me say that correctly.

Going back to 2006, it is a fact that melamine was found not in the human food route, but in the pet food route. If that's the case, you know, pets have been suffering from kidney failure for a very long time. I wonder if it's possible that this has played a role in animal health -- our companion animal health for a very long time or at least much longer than just the pet food recall.

Speaking of which, and some of my colleagues have mentioned - now, let me just put it in very - I don't know about international trade at all. I'm very ignorant about this, but it seems as though if there's any question whatsoever, any doubt whatsoever rather than checking just possibly everything, why isn't there, at least for the time being, a ban on these products that are being imported into the United States on the protein concentrates?

Why don't we just say, let's stop it until we're certain?

Julie Zawisza: I think there's some confusion here, and I want to make sure that - because

this is a very important topic, I want to make absolutely sure that it's clear

what we're saying and what the situation is.

Let me ask Dr. Acheson and others to go back and explain this again.

David Acheson: Yeah. Let me try to clear up the 2006 issue that they started out with.

Our investigations of imported product involved two specific aspects that I want to clarify with you. One is some testing and the other is some tracing in terms of where that product was used.

In terms of the testing, the - certainly, some of the products used in 2007 was positive and some of the products in the latter part of 2006 was positive for melamine and melamine-related compounds.

Based on the records of - that we have traced back, we've asked the question, if you go back prior to the point at which we've got positive, and we don't know that they're positive because it's all gone, but the record is there.

We asked the question, where did that product go, and it all went into pet food rather than human food.

So, if some of those samples early in 2006 had been positive, and we don't know they were because they're gone. What we can say with certainty based on the records that we reviewed is that if they were positive, they went into pet food, not human food.

Now, you're asking why that didn't make the pets sick.

Well, we can't exclude that it didn't make pets sick. All we can say is that it didn't make them as sick as in 2007 because it didn't come to anybody's attention, but we cannot rule out that it didn't make pets sick.

Steve Dale: So, it's possible the pets have been infected by this in an undescribed way for

a lot?

David Acheson: It's certainly possible. But as I've said, we - it did not come to anybody's

attention, but it's certainly possible.

And then you're asking why there isn't an outright ban on this.

Well, essentially the import alert is - it's not a ban because there are many people importing products into the United States probably with no melamine

and whatsoever.

The purpose of this is to catch those that are coming in with melamine in them, stop it and then following specific set of criteria that are laid out in the import alert. If it's negative and it can be proven to be negative for melamine,

then by all means, allow it into United States for use and US commerce.

So the goal there is not an (out in our) ban, but use a filter if you like to make

sure everything is held up, examined, looked at, assessed, and then only let

through the filter. Let me know it's okay.

Steve Dale: Are you confident that filter is 100% foolproof?

David Acheson: Nothing is 100% foolproof.

Julie Zawisza: We're going to go onto the next question please.

Thank you.

David Acheson: Thank you.

Coordinator:

Karen Roebuck, please state your affiliation.

Karen Roebuck: Hi. I'm with the Pittsburg Tribune Review.

Thank you for taking my call.

I was wondering if any of the contaminated feed made it's way to cattle or any animal other than chickens or swine, and how many farms are being

quarantined in the US or put on hold pending an investigation even if you

don't know, you know, that you have stopped even if you don't know that they

are positive.

And also, I'm hearing from readers who are concerned that once the pet food

is recalled, they started making chicken for their pets, and now since the pets

are more susceptible to melamine and the related compounds, they're worried

that they may just be giving them another contaminated product. And do they

need to worry about that?

David Acheson: This is David Acheson.

You've asked a lot of questions there. Let me see if I can remember where

you started out.

Cattle -- cattle.

Thank you.

Julie Zawisza:

Any animal (feed).

David Acheson: We're not aware that any of these went anywhere other than hogs and poultry as we described. No evidence whatsoever that it went into cattle.

In terms of the numbers of farms, I'll ask Dr. Peterson to address that one.

Ken Peterson:

Okay. The total number of farms has been static the last couple of days and it remains that 30 poultry -related farms -- broiler-related farms in the one state of Indiana and the eight swine-related farms in the six states -- California, North Carolina, South Carolina, New York, Utah and Kansas.

So the 38 farms total are the ones that more of interest today.

Julie Zawisza:

Dr. Sundlof, could you address the - (return) their question.

Steven Sundlof:

The question about concerns from pet owners because now they are preparing their own pet food at home, and they contain chicken and whether or not these animals are more susceptible to melamine.

Well, there's no - first of all, there's no indication that animals are - pets are more susceptible to melamine.

At this point, we still don't really understand how this whole syndrome is affecting animals.

But one thing that we can - that we've try and make a point of - repeatedly is that, we don't recommend that pet owners prepare their own pet foods, at least not over a long term because pet foods are nutritionally balanced to meet all of the nutritional needs of the pet. And just feeding chicken or single other ingredient is now in the best interest of the pet.

And so, the veterinary community in general is opposed to homemade diet unless you really know what you're doing and understand how to nutritionally balance a pet food. And most people, myself, included, would not be able to do that.

Julie Zawisza:

Thank you.

Let's take the next question.

And if folks - I know you are bearing (unintelligible) all of these, so if you could limit yourself to one question and one follow-up, we'd appreciate it so we can try to get to everyone this evening.

Thank you.

Coordinator:

David Brown, please state your affiliation.

David Brown:

Yeah, with the Washington Post.

If this has occurred in humans -- human food supply, presumably there would be a case-controlled study done early on to see what the - how strong the relationship was between various foods with the illness.

Has anyone done that? Is there some, you know, analog to the Epidemic Intelligence Service in the, you know, veterinary world so that we can get some sense of how, you know, how much of a dose it takes to get this and sort of how different this is from the general epidemiology of renal failure in cats and dogs?

Steven Sundlof: This is Dr. Sundlof.

There is no equivalent to the EIS in the veterinary world. We are in close contact with a number of the veterinary professional organizations, including the American Veterinary Medical Association and the Association of -- the American Association of Veterinary Laboratory Diagnosticians. These are the folks that operate in the animal disease diagnostic laboratory and see a lot of these cases.

And while there is no similar organization for veterinary medicine, in this case, the correlation was so strong that it really doesn't require a case-controlled study. We pretty much know which products were causing death and illness in the animals. They had that very dramatic in fact.

And so now, we are trying to understand - you asked about the dosage and how much it would take. We still don't know the answer to that.

We know that - certain that the wheat gluten contains variable amounts of melamine, but some of those concentrates were very high, as high as 9%, I think is the highest number I've heard.

And there are a lot of people right now trying to work on that issue as I mentioned the number of the veterinary organization, certain colleges of veterinary medicine are also trying to conduct studies to understand better the relationship between the melamine cyanuric acid -- cyanuric acid, I'm sorry, and some of the other components that we've found in the wheat gluten and rice protein concentrate.

So as things go on further, we should have a better understanding of this, but right now, we're still gathering information.

David Brown: Okay. Thanks.

Julie Zawisza: Thanks.

Next question?

Coordinator: (Liv Osley), please state your affiliation.

(Liv Osley): Yes, thank you. The (Green Bay) News.

I'm having a - kind of a hard time understanding how such a small amount can do so much damage.

You said that a fewer than half of the samples tested positive. And then only between 0.2% and 8% contained melamine or melamine compound, what portion of the pet food is wheat gluten or rice protein?

And considering the low levels, is FDA investigating any other possible contaminants?

David Acheson: I think I might have confused you a little bit. I apologize for that.

Let me - because we talked about a lot of numbers today, and it's - I think your question just illustrates the complexity of this whole investigation.

When I mentioned 0.2% to 8%, what I was referring to is in the wheat gluten samples that we have tested that were positive, the question was what level, what was the percentage of the wheat gluten -- the melamine content of the wheat gluten?

And there - what that means is that in the sample of -- specific sample of wheat gluten, in some, it was up to 8% melamine, and others, it was at level of 0.2% melamine. That's where those numbers came from.

The contaminated wheat gluten was then used in varying proportions to make the pet food, and then it was those pet foods that were fed to the pets.

(Liv Osley): In what proportions?

David Acheson: I think it was probably fairly variable. I don't know whether Dr. Sundlof got -

I'm hearing about 5% to 10% of the pet food ingredient is wheat gluten.

Man: And that might be high.

David Acheson: It's (made) that maybe on the high end.

If you want a specific number on that, I'm sure we can get that to you, but that's what the estimate is right now. I don't have a specific number.

(Liv Osley): Okay. Well, that still sounds so like just a small amount. So are you looking at

other possible contaminants?

David Acheson: What do you mean by other possible contaminants?

(Liv Osley): I mean, is there something else that might have caused this?

David Acheson: Well, we found no evidence of anything else causing this.

The one thing that it changed in the formulation was the wheat gluten, which

is why we focused on the wheat gluten.

We looked to that for a variety of potential agents that could cause harm. And

the melamine and melamine-related compounds is the only thing that's come

up.

I think the - as I've tried to explained earlier, we don't believe that the

melamine alone is the cause of this. It is somehow the combination of the

melamine and the melamine-related compound. It seems in the certain

conditions in certain pets to form crystals in the kidneys, and that's the

problem.

And as Dr. Sundlof, eluded to earlier, there's a lot of questions that we don't

have answer to in terms of exactly how that happens and how frequently, and

the precise concentration that is needed. But that's the current hypothesis as to

how this happened.

Julie Zawisza:

Thank you.

We started late, so why don't we take two more questions, and that will get us

right around (on that hour).

David Acheson: Okay.

Julie Zawisza:

Okay?

Next question please?

Coordinator:

(Allen Birga), please state your affiliation.

(Allen Birga): Bloomberg News.

So, to understand this, since you put in the import restrictions, you've done

about 700 tests and about 394 of them have been positive, correct?

David Acheson: Too many numbers -- too many numbers in one press conference.

The 700 samples that I said have been tested are not from the import alone.

(Allen Birga): Okay.

David Acheson: Those are total number of tests that we've done. The vast majority are related

to the recalled products...

(Allen Birga): Uh-huh.

David Acheson: ...and then there are some others.

So, this is - that not just not import alert, that's everything.

(Allen Birga): Okay. But all of the positives have been related to the two plants that you've

had problems with.

David Acheson: That is correct.

(Allen Birga): Okay. So do you think that shows that this is a limited problem?

David Acheson: To date, yeah.

But we would be complacent to not be proactive and get out there and look in other areas, which is exactly what we're doing through the import alert and the domestic assignments.

(Allen Birga): Thank you.

Julie Zawisza: And our final question this evening, please?

Coordinator: Elizabeth Weise, please state your affiliation.

Elizabeth Weise: Yes. Elizabeth Weise with USA Today.

Thanks for taking the call.

Can FDA rule out other cross-contamination likely in other foods or plant?

David Acheson: I don't quite understand your question now.

Elizabeth Weise: It is - what we've talked about cross-contamination would be a problem even in products which extensively don't contain wheat gluten or rice protein concentrate but they were cross-contaminated in the factories where they were

made.

David Acheson: Well...

Elizabeth Weise: (Would) this point rule out that possibility in other foods or other plants

making different foods than these pet foods?

David Acheson: Well, let me try to answer that in a slightly different way, and hopefully, it

will address your question.

I want to reiterate that all of the contaminated wheat gluten and rice protein

concentrate have only gone into pet food industries. They have not gone into

the human ingredient food. The only connection with the human food is

through the poultry and the hogs as we've discussed.

So, even if there were a cross-contamination going on in a human food

facility, it would be (mood) in the context of this argument because there's no

contaminated wheat gluten or rice protein concentrate gone in there in the first

place from the two sets that we know are problematic.

To get to your specific point, no, of course, we cannot rule out the cross-

contamination isn't happening in a food plant. Cross-contamination is

something that our investigators are always on the lookout for because it's

always a bit concern, for example, in the area of allergens, so it's an important

thing that we look at.

But hopefully, if you understand where I'm going with that is because none of

these has gone into the human food supply that we're aware of with all the

extensive trace forward and trace backs, the question is kind of (mood) in the

context of the human food.

Elizabeth Weise: And they're - don't exist anymore plants that make both human and pet food.

David Acheson: I...

Elizabeth Weise: I am presuming, but I just want to check.

David Acheson: No. Not that we're aware of.

And certainly, the ones that were part of this outbreak, the answer is no.

Elizabeth Weise: Okay.

David Acheson: I wouldn't like to say 100%. There is some small person somewhere in the

back - the backroom making (human) for - I don't know. But...

Elizabeth Weise: It's unlikely.

((Crosstalk))

David Acheson: ...definitive, never on that. But I want to emphasize that everything that we

have investigated as part of this situation, the answer is no.

Elizabeth Weise: Okay. Thanks very much.

Julie Zawisza: You're welcome.

With that, ladies and gentlemen, I'd like to conclude this briefing and thank our speakers and our FDA officials and an official from USDA, Dr. Peterson, for joining us today.

If you have follow-up questions, I invite you to call FDA and USDA. FDA's number is 301-827-6242. USDA's number is 202-720-5509.

I suspect you already have those numbers, but I've always like to give them out.

We will plan another briefing on Tuesday afternoon at 4:00 pm. We invite you to join us then.

And until then, if you again have follow-up questions, just call us or send us an email.

Thank you very much. Have a nice evening.

**END**