

FDA Press Conference on Contaminated Animal Feed

FTS-HHS FDA

Moderator: Julie Zawisza

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1:00 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 objections you may disconnect at this time.

I'd like to introduce your host for today, Mr. Rob Ali, with FDA Public Affairs.

Sir, you may begin.

Rob Ali: Thank you operator.

I'm Rob Ali from the FDA's Media Relations Shop, and welcome to this briefing on the melamine investigation. We have speakers today from the US Food and Drug Administration and the US 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 Inspection Service.

After these opening remarks, we will have a brief question and answer segment.

At this time I'd like to turn it over to Dr. Petersen.

Kenneth Petersen: Thank you, and thank you all for joining us for this update.

On May 7, FDA and FSIS announced the results of a risk assessment that studied the potential human health risk from consuming hogs and poultry that may have come in contact with small amounts of melamine. Based on the confirmation of very low risk to humans, we said that USDA would reevaluate the appropriate course of action regarding swine and poultry that consumed the contaminated feed.

Those animals have continued to remain on farms either under quarantine or being held voluntarily.

We appreciate the cooperation that we've received from each of those affected farmers.

We said that in cases where the contaminated feed could be traced to farms but the concentration of melamine in feed consumed by animals was so diluted because the pet food scraps would be used only as a supplement to other feed as to be undetected by testing, animals could be released.

As you know, last Monday some poultry were released based on that criteria.

In cases where the feed on the farms tested positive or where there was no feed available to test, we indicated that those swine and poultry would continue to be held either under state quarantine or voluntarily by the owner pending the results of a validated test or other scientific data.

Today we're announcing that we do have a validated test for the presence of melamine in swine.

Testing confirms that meat from swine fed rations supplemented with pet food scraps containing melamine and related compounds is safe for human consumption. Therefore, it's no longer necessary for these swine to be held on farms. They can be safely sent for further processing.

Testing of meat from swine exposed to the feed in question confirms that melamine does not accumulate in pork and is filtered out of the body by the action of the kidneys.

The testing also bolsters the conclusions reached by the human health risk assessment that there is a very low risk of any adverse health effect from the consumption of meat from animals exposed to the feed in question. Swine known to have eaten this feed appear to be healthy.

There are up to 56,000 swine that consumed the feed in question and were held on farms in California, North Carolina, South Carolina, New York, Kansas, Utah and Illinois. For context, approximately 100 million swine are processed each year in the US

USDA will provide compensation to producers for additional costs incurred as a result of voluntarily holding these animals.

A separate test is still being developed for poultry and birds will continue to be held until that test is validated.

With that, I'll turn it back to the moderator.

Rob Ali: Thank you, Dr. Petersen.

The next speaker is Dr. David Acheson from the FDA.

David Acheson: Thank you and this is David Acheson of FDA.

I'm going to touch on three issues this afternoon.

Firstly, an update on the melamine health risk assessment; secondly, an update on where we are with the fish components of this situation; and finally a very brief update on the - on China.

Firstly, to the melamine health risk assessment.

As Dr. Petersen said, we - a interim risk assessment was discussed previously and FDA and USDA have continued to update that assessment over the preceding days. The overall conclusion remains that there is still a very low risk of harm to humans from eating pork, fish, poultry or other foods containing these low levels of melamine or related compounds that we've been seeing.

The human health risk assessment that we're talking about used three different scenarios.

In the most extreme scenario the scientists presumed that all the solid food consumed by a person in an entire day contained melamine and melamine related compounds at levels potentially present in the affected swine.

That's an important concept that you understand. This is an extreme scenario, and just to repeat what we're talking about here is that we're assuming that all food consumed in a person - by a person in a given day contain the melamine and melamine related compound. This is not just the pork or the fish, it's all the food consumed in a day.

When you take that into account at those levels, the potential exposure is about 250 times lower than the dose considered to be harmful.

Previously the FDA and USDA had reported that the potential exposure was about 2,500 times lower than the safe level or the level that would be harmful, so one of the questions obviously is, where is this difference coming from

And what I want to try to do is explain two factors that have been taken into account in this recent analysis that explains this.

The first is the - one of the key differences is that the initial assessment was based on the presence of melamine alone. This new assessment is taking into account cyanuric acid.

So the new assessment has added cyanuric acid to the melamine, thereby adding a second level of melamine-related compounds to the overall assessment.

The second factor to weigh in here is that the original assessment assumes that tests could detect levels of melamine and its related compounds as low as 10 parts per billion in pork. That's 10 parts per billion.

The new assessment assumes that we're not able to detect down to that level and that in fact testing is only sensitive down to a level of 50 parts per billion in pork, thus is a more conservative assumption.

So when you take those two factors together, firstly the fact that we have added cyanauric acid plus melamine into the assessment, secondly that we have become more conservative in our detection levels of going back from 10 parts per billion to 50 parts per billion in terms of the risk assessment. Those two factors are what account for the reasons that the safety level has dropped from 2,500 to 250.

But again, to emphasize that this 250 times lower than the dose considered to be harmful is based on an individual in whom all food consumed in a given day contains melamine. Clearly a very unlikely situation.

What does this mean? If we take a 250 times lower level, what is actually translated into real numbers in terms of what an adult would have to consume to get to a level that would be harmful? Well, if you translate this into a 130-pound adult, they would have to eat more than 800 pounds of melamine-contaminated product in a day to reach that level. That - and if it was just the pork, it would have to be 800 pounds of pork.

In the scenario I discussed it would be all foods, so an individual would be having to consume 800 pounds of food per day if they weighed 132 pounds, clearly an impossible situation.

The reason I've gone into this into such depth is, it is complex, there are multiple numbers, they do keep changing, but essentially that all of us is just trying to be transparent and keeping you up to date on the way this investigation is moving forward.

The FDA and USDA are currently working to identify experts to convene a scientific advisory board to review this human risk assessment. This group would also be asked to contribute to future scientific analysis related to the risk of melamine and its compounds to both humans and animals.

Moving on now to my second point, the fish.

FDA is continuing its investigation into to the presence of melamine in fish feed manufactured by Skretting, which is a Canadian company located in British Columbia.

As we discussed last week, Skretting, is recalling fish feed containing melamine from all commercial fisheries and fish hatcheries that received it including those in the United States.

The FDA has confirmed that two US commercial fish farms received the feed. The fish in those two establishments are on hold and samples of the fish and feed are currently being tested to determine the levels of melamine.

We do not yet have specific information on the levels of melamine in those fish.

Based on the human health risk assessment that I have just been discussing, there's a very low risk associated with eating fish that consumed feed containing melamine.

Finally, turning to China, the FDA investigators have returned from their inspections of the sites in China that were linked to the melamine-contaminated products which were imported into the United States labeled as wheat gluten and rice protein concentrated. The inspectors who were on that visit are preparing their reports and these are going to be submitted to FDA Office of Regulatory Affairs in the near future.

FDA and USDA are continuing their investigation. As additional information is confirmed, updates will be provided and decision will be made using the best available science to protect the public's health.

Thanks for your attention.

Rob Ali: Thank you, Dr. Acheson.

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, please.

Coordinator: Okay. Thank you.

We're now ready to begin the question and answer session. If you'd like to ask a question, please press star-1. To withdraw your question, you may press star-2.

Our first question comes from Dietra Henderson.

Dietra Henderson: Thank you very much...

Coordinator: I'm sorry. Please star-1 Ms. Henderson.

One moment please.

Ms. Henderson, your line is open.

Dietra Henderson: Hi. Thank you very much for doing this. This is Dietra Henderson with the Boston Globe.

I just had a housekeeping question. I heard a figure for the number of swine and would love to hear that repeated. I'd also love to have an up to date number for the poultry in question and the fish, with the breakdown for the commercial versus the state hatcheries.

Thank you.

Kenneth Petersen: Okay, this is Dr. Petersen. I'll start with the first two.

The swine that are still and have been on hold really since we began discussing this a couple weeks ago is up to about 56,000 head in the seven states that I mentioned, and those states are the same ones we mentioned previously.

And then, that's again in the context of about 100 million head of swine that are slaughtered annually in the US.

The poultry that's still on hold are again roughly the same number that we discussed previously. That's approximately 80,000 of the breeder birds exclusive to the state of Indiana. And so, those will remain on hold until we get the additional information that we just laid out for the swine.

And then Dr. Acheson can update you on the fish.

David Acheson: This is David Acheson.

The total number of - well, let me back up a little bit because it - again, its complex numbers tied up with all this and it's an ongoing investigation.

When we contacted the company in Canada we got a list of up to 198 recipients of this fish feed in the United States. It's not clear at this point that they all received the contaminated feed and our investigators are following up on that.

Of those 198, two are commercial fisheries and the rest are hatcheries, and I think one of your questions is focused on do we know how many fish? And at this point we don't know how many fish.

And while we're still on the fish, I want to just again emphasize that the contaminated wheat gluten that was used in the fish is essentially only a portion of the total fish feed, so the dilution factors we discussed on previous calls would pertain to the fish feed as they did to the other situations.

Dietra Henderson: Thank you very much.

Rob Ali: Thank you.

Operator, next question.

Coordinator: Next question is from Miriam Falco of CNN.

Miriam Falco: Hi. I've got a couple questions.

Number one, I just want to make sure I heard this right. You're saying 56,000 pork - pigs have been housed? Before you said there were only 6000 total. So, can you clarify that before I ask my real question?

Kenneth Petersen: Okay.

I believe it was last Thursday's call where your current - previously last Thursday we've been discussing the 6000 head that had been on hold, and then last Thursday we mentioned that there were an additional 50,000 that had been on hold in the state of (Indiana) - State of Illinois, so that was the 56,000.

Miriam Falco: Okay.

And can you - and either one of you can explain this. Tell us a little bit more about this test that you did to determine that the pork can be released into the system because you're again just saying melamine, testing for melamine whereas Dr. Acheson is saying that the risk, although still very minimal, has gone up because you're also looking at melamine and cyanuric acid. So are you testing the pig for cyanuric acid too?

Kenneth Petersen: Okay, I'll start with the test and then perhaps Dr. Acheson can circle back on the risk assessment.

The test is specific for melamine, and previously as he suggested we've been looking at levels of approximately 10 parts per billion, and that was what was inherent in the initial risk assessment. And then in the course of validating the test, the scientists agreed that today they're comfortable saying the limit of detection if you will is 50 parts per billion. And so below that the test would be reported as negative. And so that's taking a more conservative assumption.

We actually believe the results are quite under 50 parts per billion but we're comfortable today just saying it's 50. And so that's how it came about, but it is specific to melamine and the test was validated in one of the FSIS laboratories, and then the test methodology was circulated among the appropriate peers in the laboratory community.

They're continuing to pursue additional design of it, but that's where they are today.

And then the - in the risk assessment information I'll ask Dr. Acheson.

David Acheson: Sure, this is David Acheson.

As Dr. Petersen just said, that the current assay for the hog, for the pork muscle is a melamine assay. It isn't yet at the point where it can measure cyanuric acid.

So the obvious question is, well how do you address that? And that's what the risk assessments did.

We know the levels of cyanuric acid in the feed, we know the dilution factors, so we know what the hogs received in terms of levels of cyanuric acid. Those levels have been built into the risk assessment in order to add that level of

assurance in terms of the risks to human health. So the risk assessment has taken both into account, but the assays to measure it in the hog tissue are not there.

As with melamine, there's no indication that we're aware of from the science of this that cyanuric acid is likely to significantly bioaccumulate in the hogs so I think it - because it is essentially a breakdown product of melamine and it's likely to behave in a very similar way.

So we kind of covered it in the risk assessment. The assays are just essentially catching up.

Rob Ali: Thank you.

Operator, next question, please?

Coordinator: Next question comes from Carrie Peyton Dahlberg of Sacramento Bee Newspaper.

One moment.

Carrie Peyton Dahlberg: Hello?

Man: Hi, Carrie, go ahead.

Carrie Peyton Dahlberg: Hi, thank you.

Can you tell us when you did these tests of the pork meat? What were the parts per billion of melamine found in the meat?

Man: As I suggested, the test, what's been agreed to among the scientists is that 50 is kind of the cutoff, and so that was really the point of discussion. Should they - where the various scientists comfortable saying this one's 15 or this one's 17, or what have you, and they weren't, given the current status of the test.

Carrie Peyton Dahlberg: I'm sorry. I don't think I put my question quite right.

I understand you had a cutoff but you could have found 50 or you could have found 500 or you could have found 75, what were the actual parts per billion test results on some of this pork meat that tested positive, i.e. over 50?

Man: Okay. None of the results were over 50.

And then one university that was initially involved with the test developments reported a number in the 10 to 12 parts per billion range so somewhere between 10 to 12. Closer to that end of the spectrum, and 50 is quite likely where we may end up at the end of the day but not today.

Carrie Peyton Dahlberg: I see.

And then can I follow-up, who actually devised the test?

Man: The FSIS has several laboratories that are internationally recognized, and our laboratory out in - on the West Coast was the one that actually was involved with developing, refining the test.

Carrie Peyton Dahlberg: Thank you.

Rob Ali: Thank you.

Operator, next question please.

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

Rick Weiss: Hi. Thank you.

A two-fold question.

The toxicity that you might expect to see if a person ate 800 pounds of this stuff in a day, what are we really talking about? Is this a - would it be a passing minor toxicity of some kind or some kind of a serious, deadly effect? What are you using as your cutoff?

And secondly, to help put that 1 out of 250 fraction into perspective, since I assume there's some error bars here and you filled in safety factors when we decide what food is okay to eat, is that well within the range of what is typically used when food toxicologists decide whether something is okay to eat? Is it 1 in 250 chance or 1/250th of a minimum toxicity considered okay, or is that considered too close to the edge when most foods are being measured for how risky they are to eat?

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

And you asked various components of questions here and if I missed anything please come back.

To get to your second point, a level of 250 is conservative. That is providing a great level of comfort. Often in these sorts of assessments we would set a level if we were saying "safe setting of tolerance," which is - that's not what

this is, but if we were setting a tolerance for something or an action level which was built around a concern of a health hazard, then you might put in a 10-fold or possibly 100-fold safety factor. It would vary somewhat, though certainly 250 is right in the ballpark of where we may be and is giving us a significant sense of comfort.

In terms of what might happen to a human if they were exposed to those kinds of levels which clearly are impractical, but if they were, there are no studies that I'm aware of that is looking at melamine toxicity in humans so having to extrapolate from animal model.

When you feed a rat a very high dose of melamine, you see stones forming in the kidney systems and the bladder. This is what we saw in the cats and other pets that were affected at high levels of exposure and I would only have to assume that's what would happen in humans.

Because melamine and melamine-related compounds appear to be excreted by the kidney -- that's how they get out of the body -- they would be more concentrated in urine than they would be elsewhere in the system, and it would appear that when they reach a certain concentration that is when the crystals begin to form. It's like old-fashioned chemistry. If you put salt into water, you'll get to a point where you can't dissolve any more salt into water and eventually the salt will begin to precipitate out and you get crystals as when it reaches a certain level. That's what we believe is going on here with the melamine in the urine.

So you've got to reach a pretty high level. And I would speculate that that's probably what we would see in humans, but I don't have any firm indication of that.

Rick Weiss: Thanks, I think that does it. I just missed one number though. You said normally when you're - if you're looking at tolerance or an action level you might be satisfied with something like a ten-fold margin of safety or something else. What was your second number?

David Acheson: Ten or a hundred.

Rick Weiss: A hundred.

David Acheson: You know...

Rick Weiss: Okay.

David Acheson: ..., it's variable depending on what data you're dealing with in terms of what degree of safety margin you build in.

And it depends on the reliability of the data. If you feel the data is really reliable you may be fine with a ten-fold safety margin. If you think the data is not so reliable, then you'd be upward of like 100.

Rick Weiss: Thank you.

Rob Ali: Thank you, Rick.

Operator, next question, please?

Coordinator: Next question is from Abigail Goldman of the Los Angeles Times.

Abigail Goldman: Good afternoon.

This is for Dr. Acheson. I wanted to go back to something you said on a previous call about what the import alert actually means or does.

And you said the companies come to you with validated test paperwork and insurances, so I'm wondering for the import alert on the vegetable protein concentrates from China, what does a company need to do to get past that? And is the company responsible for the test, and if so, what does that mean in terms of FDA oversight of whether or not those tests are done properly or in proper labs?

David Acheson: Well, there's two parts to this, and I'll start and I'll ask Michael Rogers to fill in some of the blanks.

One of the questions revolves around when a product gets held at the border, what are the requirements to allow that to proceed in terms of it being safe? And the second is, what gets the company off the testing strategy?

The first part relates to the company providing FDA with adequate information to convince the agency that the product does not contain melamine or melamine-related compounds.

Now that could be a variety of things. It could be a validated test from a certified lab that we would need to insure is indeed that, it is a certified lab. That the tests are bona fide, it's not just some piece of paper with a number written on it. It could be documented, certified, manufacturing practices that were unequivocal in terms of where the product came from. That's two examples, and there may be more, and I'd ask Mr. Rogers to speak to that.

In terms of what gets individuals off this import alert, that's explained in a fair degree of detail in the import alert documents and in the interest of time I'd

refer you to that specifically. But, Mr. Rogers, anything further on the - what would it take for the testing?

Michael Rogers: No, not much more than that, Dr. Acheson. I would add that if it would be a third party lab that FDA would review the methods and documentation. But that process is described in detail on the Web. This particular countrywide import alert detain without physical exam and requirements are illustrated in Import Alert 99 dot - dash 29 so I'll direct the audience's attention there and it could describe the process.

Abigail Goldman: Thank you.

Rob Ali: Thank you.

Operator, next question, please.

Coordinator: Next question is from Steve Hirsch of Washington Times.

Steve Hirsch: This is Steve Hirsch from the Washington Times. My question is for Dr. Acheson. Can you - the investigators reports you referred to, can you tell us when they will be made public?

David Acheson: Are you're referring to the reports from China?

Steve Hirsch: Yes.

David Acheson: At this stage I don't know the answer to that question.

Steve Hirsch: Can you tell us that they will be made public?

David Acheson: Typically, during an ongoing investigation the answer is no.

During an active, ongoing investigation these sorts of things are not made public because it is an ongoing investigation. Once the investigation is closed, just like spinach, a report was issued.

In terms of the timeline on that, I couldn't tell you. Obviously it's going to be dependent as to how long this investigation remains active.

And as you've heard on previous calls, we're doing a domestic surveillance assignment where we're not just focused on the two companies that we know we had some issues with. It's going broader than that, and it will continue until we're satisfied that everything is okay.

Steve Hirsch: So you mean you're not just concentrating on two Chinese companies?

David Acheson: No. No, indeed not.

I mean, the domestic assignment that we've talked about and the import alert, the import alert was originally focused on just the two companies. The import alert now applies to all vegetable protein concentrates coming from China irrespective of the company.

The domestic assignment that we talked about, that is having inspectors from FDA and states getting out to manufacturers and processors in the United States, raising awareness about their supplier chain and taking samples, looking for melamine and melamine related compounds.

Steve Hirsch: Okay.

But is it in China is it more than the two companies?

David Acheson: I don't know. At this point the only two positives we've got have been linked to those two companies.

Steve Hirsch: Okay.

Rob Ali: Thanks, Steve.

Operator, next question, please?

Coordinator: (Liz Osbey) of the Greenville News, you may ask your question.

(Liz Osbey): Yes, thank you. If it would take 800 pounds of contaminated food to reach a harmful level in humans, can we assume that there would be that much necessary to harm a cat or dog? And if so, how is it that so many cats and dogs died?

David Acheson: Okay, I knew these numbers would cause confusion. Let me try again.

I'm talking about 800 pounds of food, not 800 pounds of melamine.

(Liz Osbey): Yes.

David Acheson: Okay?

(Liz Osbey): Yes. Understood.

David Acheson: The amount of food that you would have to consume is dependent on the concentration of melamine in that food. But even under the current scenarios of the melamine concentration which we believe is in this food, you would

need to consume 800 pounds. If theoretically the level of melamine in the food was double what we think it is, you'd only have to consume 400 pounds.

(Liz Osbey): Uh-huh.

David Acheson: Are you following me?

(Liz Osbey): Yes.

David Acheson: So the reason the dogs and cats got sick is because the level of melamine in their food was way higher.

(Liz Osbey): Okay.

Thank you.

David Acheson: Okay.

Rob Ali: Thank you.

Operator, next question, please?

Coordinator: Next question is from Andrew Bridges of AP.

Andrew Bridges: Hi. Thanks for taking my question.

Did you look specifically in the pigs at their kidneys and was there - were you able to detect any sign of damage that would be in any way comparable to what was seen in any of the dogs and cats that ate the melamine-contaminated pet food?

The question being, are you able to figure out basically what level melamine becomes and cyanuric acid becomes lethal to mammals in general whether they be pigs, dogs or cats, much less humans?

Kenneth Petersen: This is Dr. Petersen.

Well, we looked at a couple things related to that based on the information that we had available.

The first of which, when animals go to slaughter we do track some of the diseases that we see when those animals go through. And so for swine in this case we'd be looking for things like kidney disease or, you know, renal - other urinary disease.

And we're not seeing any increase in either one of those in the database, so that's not particularly surprising given, you know, what we've said about the exposure and the dilution factors and the brief period of time that they were fed.

Then we also had some - just a few, actually available kidneys from one or two of the pigs that had gone to slaughter very early on and those were looked at by some of our pathologists at one of our other labs, and they didn't see any remarkable pathologic changes in those kidneys. So that was from a known exposure.

So again, that kind of fits in with the same things we're finding now when we actually test the levels in the feed and test the levels in the muscle and then incorporate that into human health risk assessment. These other overt signs we're just not seeing them, so that's obviously good news.

Andrew Bridges: Also, how much melamine was in the pet food that was lethal to dogs and cats? And how much was in the animal feed that apparently wasn't lethal to pigs?

David Acheson: This is David Acheson of FDA.

The dogs and cats first of all ate exclusively the same food, that's one factor.

That the wheat gluten was used as a constituent in manufacturing that dog and cat food, and the wheat gluten itself contained - well, between 2% or 0.2% and 8% of melamine, and then there were some melamine-related compounds on top of that.

Dr. Sundlof is here with us, and he may be able to give you more specifics on the concentrations in the pet food itself.

Stephen Sundlof: Yeah, I don't have the numbers in front of me right now, but I recall that some of the wheat gluten had melamine and related compounds in it as high as 10% which I believe is somewhere on the order of 10 - well it would be 100,000 parts per million which is extremely high.

And that was used in about 2% of the diet so I can't do the numbers off the top of my head right now. But it is several, several orders of magnitude greater in the pet food than it would be in the meat from animals that may have received a much lower concentration of melamine in their diet and then have that transferred through to the human food supply.

So it's just an interesting problem that I'll sit down and put pen to paper to, but just on - off the top of my head we're talking several orders of magnitude

greater in the diet of pets than it would be in the - in meat from animals that have consumed a lower concentration of melamine than what the pets received and then transferring that to the human food supply through the meat.

Rob Ali: Thanks, Dr. Sundlof.

Operator, next question, please?

Coordinator: Next question is from (Martin Katz of NPR.

(Martin Katz): Hi. I'm just wondering if you could clarify on the fish farms, the two farms that you said they are on hold? What exactly does that mean? Is that - because in a lot of these cases they are fed different locations, hatcheries, than raised elsewhere? Does that mean that they're not supposed to be harvesting fish at all right now?

Man: The - to clarify that, the two that are on hold are the commercial operations. They're the operations that are growing fish up to a size that's ready for human consumption directly into the human food supply. The hatcheries...

(Martin Katz): I understand that, but I'm saying the commercial - those that raise them to, you know, for human consumption also have their own hatcheries and have different sites and the fish get mixed up. So I'm just wondering if all of the fish they produce are on hold right now or are they selected out? Are they supposed to be harvesting at all?

Man: Any fish that may be fed this material that may be destined for the human food supply directly as far as we are aware, that's our instructions, is to have it on hold irrespective of whether they hatch their own fish and grow them up.

I mean, obviously if they fed them to the hatchlings, the fish, it's going to take months before these fish grow big enough to enter them to the human food supply.

So the key element is to make sure that any fish that are large enough that's received this feed that are about to go in the human food supply would be stopped, getting in there to a voluntary hold.

Our investigators are right now getting out to these various places to gather more information so that we can - as we learn more we'll update you, but that's the state with the two commercial establishments.

(Martin Katz): Thank you.

Rob Ali: Operator, next question, please.

Coordinator: Next question is Jennifer Smith of FDA Week.

Jennifer Smith: Hi. Thank you very much for taking my phone call.

Two - a couple of questions to try to wrap them all together about - last week at the telephone - teleseminar, I'm sorry -- (that in)the phone call, there was some talk Acheson had made about formalizing future cooperation with China on food safety and food defense issues. So, are there specific treaties in the works right now to establish food defense or food inspection standards with China or with other countries?

That would be the first, the main question I had.

But when you're talking about this risk assessment, will this change or it's going to be used or will - I guess reformulate the current animal feed safety system that you have right now with which the public hearing is going to be in I think next week?

I mean, in other words, will it change like the entire risk model for the animal feed safety system, what you're just using, from melamine?

David Acheson: First of all, in terms of strategies moving forward...

Jennifer Smith: Uh-huh.

David Acheson: ...part of my role in my new position here at FDA is to look at what strategies are going to work for the safety of the food supply, and that applies to both domestic and international.

Clearly we were looking for ways that are going to work with countries and importers and manufacturers overseas as well as domestic and that would include China.

There's nothing specific right now that is in the works with China. In the context of this particular situation, the Chinese authorities have worked very closely with us, particularly their AQSIQ...

Jennifer Smith: Uh-huh.

David Acheson: ...to get a handle on what's going on here and there's been good dialogue.

Jennifer Smith: Could there be the possibilities for new treaties or for new type of standards to be set because of what's happened?

David Acheson: I think as we move forward we're going to need to look at how to further safeguard the importation of food into the United States. Exactly what form that will take we're not quite there yet, but certainly we need to make some shifts.

In terms of the answer to your second question, the risk assessment was done solely for the purpose of understanding the risks to human health around melamine for no other purpose.

Jennifer Smith: Okay, so therefore this will not be considered when you talk about evaluating the animal feed safety system?

David Acheson: I would (just throw) that to Dr. Sundlof specifically.

Stephen Sundlof: Yeah, the meeting that's scheduled to take place on the 22nd of May is separate and apart from this particular issue but obviously this is going to be used. The melamine pet food issue is going to be used as an example of why we need a - an animal feed safety system - a robust animal feed safety system and one of the parts of that is making sure that the - all ingredients that go into pet food or any other animal feed are found to be safe and certified and verified to be safe before they are ever used in these feeds.

But other than that, the negotiations that may take place with our trading partners are not part of the subject of the meeting next week.

Jennifer Smith: I'm sorry; I didn't hear the last part. What's going on with the training (part)?

Stephen Sundlof: I mean - that any kind of agreements that might be taken up with our trading partners...

Jennifer Smith: Uh-huh.

Stephen Sundlof: ...is not - as it occur - as it applies to melamine or other product is not specifically the subject of that meeting next week.

Jennifer Smith: Okay. And is - (well I guess) this will be tangential to that question. Is, when it comes to just that meeting with - (are those tons of) issue with animal feed, have you heard any input from Capitol Hill or other stakeholders yet on what maybe they are looking for?

Stephen Sundlof: On the animal feed safety system, no, I have not.

Jennifer Smith: Okay.

Rob Ali: Thank you, Dr. Sundlof.

Operator, next question, please.

Coordinator: Next question is from (Karen Robach) of Pittsburgh Tribune Review.

(Karen Robach): Hi, thank you.

When can I have a copy of the Health Risk Assessment when the conclusions were announced eight days ago, the press release said the study would be available as soon as the - hello?

Man: Yeah. I can hear you.

(Karen Robach): As soon as the executive summary was done.

And now we hear you're still doing the study and looking at other things. And also, why wasn't the cyanuric acid included in the initial assessment when it was well known by then that it was the combination of the two chemicals causing the problems in the pets?

Man: Well, as you heard me say before, it was our intention to get this out into a public forum as quickly as possible, and it still is.

This particular risk assessment has been moving and since we last discussed it these two new additional factors have come in. And in fact, the first one was the cyanuric acid which was added in essentially late on Friday and then subsequently the 50 parts per million conservative approach for the testing in the muscle was added in over the weekend.

I don't want to say I feel confident that that's it, that we won't be changing this anymore, but obviously we don't want to be getting out multiple different versions. And we're trying to ensure that we've got some degree of I won't call it finality but an interim risk assessment that isn't about to change.

I can assure you that with these changes it's getting rapidly reviewed internally, cleared with the intention of trying to get it out there just as quickly as possible because I understand there's a real desire to see this.

And the sooner we can get it out, the better. And I apologize that it's taking so long but every time we think we're there there's another shift.

As to why the cyanuric acid was not included in the risk assessment initially, it was because the initial assessments were focused on melamine alone. And in terms of the absolute quantization of cyanuric acid as a separate compound,

we're still not entirely clear if the initial risk assessment included just melamine. But it soon became clear that we needed to add cyanuric acid in there.

The other part to this was as we've discussed before, there are other breakdown products. There's ammeline and ammelide to mention just two. And one of the questions was, well should they be included?

And further analysis of the feeds indicated that typically both ammeline and ammelide are both very low and therefore not really relevant whereas, the cyanuric acid and the melamine are the two that require most consideration.

Part of the problem here for all of us is that you're witnessing an unfolding investigation. We're not coming to you with the finished document all wrapped up. You're witness to ongoing investigations, changing science, changing assays, changing situations, and that's just part of the frustration for you all. I understand that.

(Karen Robach): Can I just follow up on that?

Rob Ali: Sure, (Karen), go ahead.

(Karen Robach): Well, I understand about the ongoing investigation and things change and that's perfectly reasonable and understandable, but since you are making decisions on the study that was completed eight days ago and releasing animals into the market because of that, isn't it also reasonable that we also have the information along the way?

Man: It's not an unreasonable request. And believe me, we're trying to get this thing moved out as quickly as we can.

(Karen Robach): Okay. Thank you.

Rob Ali: Thanks, (Karen).

Operator, next question, please?

Coordinator: Next question is from Elizabeth Weise of USA Today.

Elizabeth Weise: Hi. Thanks for taking my call.

And this may have been addressed earlier. It's just a technical point. On the West Coast at least we got emails about this meeting 23 minutes after it started. (Unintelligible) there.

The question I had was regarding FDA staffing of this. How many people do you guys have on the ground doing this, and where are they coming from? You don't have a huge staff to begin with, so I'm wondering what do you - having to pull people away from to do all these tests?

David Acheson: This is David Acheson, let me take a first cut at your question which - you were breaking up a little but I think you were asking how many people have we had working on this investigation?

Elizabeth Weise: Correct.

David Acheson: In my understanding, and I'd ask Mr. Rogers to expand on that, is that we had about 400 or so investigators working on this out in the field, plus the people at headquarters.

And you asked, well what's not getting done? And the answer is that we are simply just shifting from the lower priority areas into higher priority areas. So some of the lower priority assignments are just being put on hold or slowing down while we address this problem.

But I'd ask Mr. Rogers or Captain Elder if they've got a particular comment on whether the 400 is accurate.

Michael Rogers: I would add that we're dedicating all appropriate resources to this investigation. It is considered a top priority for the agency. We're also collaborating and leveraging resources with our state counterparts who are assisting in determining the effectiveness of the recall as well as getting unsafe products off the shelves.

But to date, that we've been successful with the resources that we've had to follow up on trace forward and trace back, and identify consignees that would have received this product as well as done inspections at those consignees to get a better scope of the problem.

Rob Ali: Thanks, Mr. Rogers.

Operator, next question, please?

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

Dawn House: Yes.

For the two commercial growers - fish growers in question, can you name the region or states in which they are located and do you have any ballpark estimates of the number of fish on hold?

David Acheson: This is David Acheson. I'll ask Mr. Rogers to answer that.

Michael Rogers: The two commercial farms - and maybe we'll take this time to clarify what that represents. That that represents farms that have market weight fish versus hatcheries. Those farms - one is located in Hawaii and one is located in Washington.

At this time we don't have any idea of the volume of fish there or quite frankly the degree of exposure to any contaminated product.

Dawn House: Thank you.

Rob Ali: Thank you.

Operator, we have time for one more question, please.

Coordinator: Okay.

Next question is from (David Hirsh) of NHK.

(David Hirsh): Yes. Understanding that 800 pounds consumption in one day by a human is somewhat exclusionary, I wonder does it make any sense to look at what the cumulative effect of eating a much lower amount over a much longer time might be, and if not, which I assume it doesn't, why not?

David Acheson: You're asking certainly an important toxicological question.

Right now the answers to what's the long-term exposure to lower levels, what's the impact of that on animals including humans, I think the answer to that is unknown. The studies in rats were high levels of exposure.

Based on the chemistry that we know of here with these compounds, it would appear that at lower levels you essentially just excrete these compounds out in the urine and nothing significant seems to happen. They're water-soluble, they go out in the urine. It's only when they reach a certain level that they seem to cause a problem. When they reach a certain concentration in the urine, they form these crystals. That blocks up the kidney and you end up with kidney failure.

So, we could speculate that longer-term exposure to lower levels would not lead to significant problems. As we've discussed before, one of the areas that we're investigating right now, setting up some studies, is planning some broader based toxicological studies, and I think some of those longer-term exposure questions will need to be looked at in that context.

But based on sort of first scientific principles, this is not something which would appear to bioaccumulate in a mammalian system.

Rob Ali: (David), did you have a follow-up?

(David Hirsh): No, thank you. Clearly answered.

Rob Ali: Okay, (David).

Dr. Acheson had a clarification on a previous point.

David Acheson: Yeah, one of the things that I want to just return to is the situation with China. I want to just point out that obviously in this particular instance with the melamine and the melamine related compounds, this has a very clear China focus, and there has been some discussion earlier of developing a -an MOU, memorandum of understanding, with China, that I know our commissioner has mentioned publicly.

The reason I didn't mention it is because essentially it's very much in the works. It's an area that's currently active, it's being looked at, but in the context of the specific target working with China that is a start.

But I want to emphasize that the need or our desire to look at imports more broadly than China still remains that while this was a China issue, clearly we need to ensure the safety and security of the food supply from all countries that we import from not just China. So I just wanted to clarify that.

Thanks, Rob.

Rob Ali: Thanks, Dr. Acheson.

And thank you, ladies and gentlemen. This does conclude today's media teleconference.

Thank you.

Kenneth Petersen: Rob, this is Dr. Petersen, and I've got one...

Rob Ali: Yes, sir. Go ahead.

Kenneth Petersen: I've just been told there is going to be a news release on this - what I mentioned at the top of the hour, and that will be posted very shortly on the Web sites of both agencies, FDA and USDA. Sorry to interrupt.

Rob Ali: That's okay. Thanks, Dr. Petersen.

This does conclude the media teleconference. A replay will be available in about an hour, and will be up for about three days.

And like Dr. Petersen said, there are - there is a press release posted on both agency Web site. FDA is fda.gov and USDA is usda.gov.

If you have follow-up questions, please don't hesitate to call the respective agencies.

Thanks, and have a great rest of the day

END