

FDA Press Conference on Recall of Products Tainted with Melamine

FTS-HHS FDA

**Moderator: Veronica Castro
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Coordinator: Hello and welcome to the Briefing on the Recall of Products Tainted with Melamine Conference Call.

Following today's presentation there will be a formal question and answer session. All participants will be muted until that time.

To ask a question, simply press star-1 on your touchtone phone.

At the request of the company, this conference is being recorded should you have any objections, you may disconnect.

I will now turn the conference over to Mr. Mike Herndon.

Ma'am - sir, you may begin.

Michael Herndon: Thank you, (Glendale).

Thank you very much, ladies and gentlemen, and welcome. I'm Mike Herndon from FDA's Media Relations staff, and thanks. And welcome to this briefing on the recall of products tainted with melamine. I want to first apologize for us starting late. We wanted to make sure everyone was on the call. We have a speaker today from the Food and Drug Administration. We also have several

FDA officials here, and an official from the U.S. Department of Agriculture available to answer any questions later on in this briefing.

Our speaker this afternoon is Dr. David Acheson, Assistant Commissioner for Food Protection with the FDA. We will have a brief question and answer segment after the opening remarks. Now at this time, I will turn it over to Dr. David Acheson.

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

On today's call, I'm going to be telling you about a recall of an ingredient that is used to make livestock feed and fish feed that's adulterated with melamine. There are a few differences from the contamination that we've reported on before, and those two main differences are, firstly, that the source of the contamination is within the United States, and secondly this is not directly related to the pet food situation. Its link to the pet food situation is essentially that it is another recall of a melamine product, but it is not a product that has wound up in pet foods.

Today FDA is alerting livestock and fish and shrimp feed manufacturers about a voluntary recall of feed ingredients by two companies -- the first, Tembec of Toledo, Ohio, and the second, Uniscope, Inc., of Johnstown, Colorado. The two companies are taking this action because several products they make have been found to contain melamine and melamine-related compounds.

Tembec is a contract manufacturer for Uniscope and makes two products, Aquabond and Aqua-tec2 -- that's A-Q-U-A-B-O-N-D and A-Q-U-A - T-E-C-2 - and distributes those products for Uniscope. The intended use for those products is for fish feed.

Uniscope makes a product called Xtrabond, X-T-R-A-B-O-N-D, using ingredients supplied by Tembec. The Xtrabond ingredient is intended for livestock feed. The Aqua-tec and Aquabond products are for exported use and domestic use. The Xtrabond product is domestic only.

Our Office of International Programs is in the process of notifying any foreign regulatory authorities in the countries where we have information that the product was shipped, and at this time that notification process is under way.

All of the products being recalled are binding agents that are used to make pelleted feed for cattle, sheep, goats, or fish and shrimp. The companies have confirmed that melamine was added by Tembec as part of the formulation of the products for improving the binding properties of pelleted feed.

Melamine is not an approved additive for animal or fish or shrimp feed, and the companies have stopped adding melamine to the feed products -- excuse me -- FDA is advising feed manufacturers and others who mix their own feed not to use these products and to contact the manufacturers. FDA is also advising feed manufacturers to recall finished feed that is made from either the Aquabond or Aqua-tec² due to the estimated levels of melamine and melamine-related compounds in the finished products.

FDA believes that no recall is warranted of the finished feed made from the Ultrabond products because the levels of melamine are lower -- I'm sorry -- FDA believes that no recall is warranted from the finished feed made from Xtrabond products - that is Xtrabond. Let me recap that and I apologize for the confusion. We're advising feed manufacturers to recall finished feed that is made from Aquabond or Aqua-tec², however, no recall is warranted of the finished feed made from Xtrabond.

This is based on the levels of melamine and melamine-related compounds in the initial ingredients. FDA estimated that the probable level of melamine and related compounds in the Xtrabond feed as being less than 50 parts per million based on the recommended mix rate of 2 to 4 pounds of the binding agent per ton of livestock feed. In contrast to that, the estimated levels in fish and shrimp feed that would be used in the Aqua-tec 2 and Aquabond products are in the region of 230 to 460 parts per million respectively, of melamine and melamine-related compounds.

And I want to emphasize that these numbers are not just melamine, that they are melamine and melamine-related compounds based on the assays that have been conducted.

These estimated levels of melamine and related compounds vary in the livestock feed and the fish and shrimp feed because of differing levels of melamine in the binding agents used in each type of feed and the subsequent dilutions of those binding agents in the final product.

These estimated melamine levels in feed made with the binding agents are similar to those discussed in the interim safety risk assessment of melamine and related compounds made available by FDA earlier this month. In that assessment, federal scientists determined that, based on currently available data and information, the consumption of pork, chicken, domestic fish and eggs from animals inadvertently fed animal feed contaminated with melamine and its analogs is very unlikely to pose a human health risk.

That concludes the end of the formal comments. I'll hand it back to Michael Herndon.

Michael Herndon: Thank you, Dr. Acheson.

Let me just add that a press release on this subject will be available on our website and also be sent to the media very shortly. At this time ladies and gentlemen, we will take your questions. And as always to be equitable, please limit yourselves to one question and one follow-up, and please state your name and affiliation.

Operator, we'll take the first question.

Coordinator: Thank you.

Once again, if you have a question that is star-1 on your touchtone phone. If you're using speaker equipment, you may need to pick up the handset before pressing star-1. Our first question comes from Andrew Martin with New York Times.

Andrew Martin: Hi. I guess there's so many questions here, but how did you find out about this? Do you have any sense of how long this has gone on, is there a criminal probe?

David Acheson: Well, this is David Acheson. Let me start with the answer to a couple of those questions, and then I can pass it on to David Elder. First of all, this came to our attention because Uniscope brought it to our attention. As you remember from the previous melamine calls, one of the activities that we have been undertaking is to raise awareness amongst manufacturers about the need to be wary of suppliers, cognizant of suppliers, knowing what they are putting into their products. Uniscope used a product that they basically thought could potentially contain melamine. It was a feed product. They decided to test it

themselves through a private lab, and found it to be present. They then informed us of that situation.

So it was essentially us getting the word out that people need to look. They looked, they found it, and they reported it to us, and then this is really a follow-on from that.

In terms of some of the history behind that, I'll pass that on to David Elder.

David Elder: Thank you, Dr. Acheson.

Yes, I think the point is well-made that FDA has been very proactive communicating with the industry so that they are taking their responsibility quite seriously and taking steps to ensure that the products that they manufacture and distribute are safe. And that was the case here. We've also published our analytical methods to ensure that companies and private laboratories can effectively analyze such samples.

So as I said, Uniscope did bring this to FDA's attention on the evening of May 18, 2007. That was a Friday evening. And the next business day, that following Monday, FDA initiated inspections at both Uniscope and the contract manufacturer Tembec. Those investigations are very much active and ongoing, and we're not going to comment on any specifics related to the investigations or where they may lead. Our priorities at the moment are communicating these findings to maintain our transparency and our effectiveness to make sure that animal health and human health is protected and to ensure that these recalls are conducted effectively.

Michael Herndon: Andy, did you have a follow-up? Guess he's gone. Next question, please?

Coordinator: Thank you.

Our next question comes from Steve Hirsch with Washington Times.

Steve Hirsch: This is Steve Hirsch from the Washington Times.

I had assumed going into this that this press conference would have to do with China, and so I do have a China question, but I'll hold that until the questions on this announcement are done if you'd like. It's up to you guys.

David Acheson: Go ahead and ask it while you're on.

((Crosstalk))

Michael Herndon: Since you're on.

Steve Hirsch: Okay.

David Acheson: You're right - this is not related to China.

Steve Hirsch: Okay, had no idea. Sorry.

There have been a couple of steps taken over the last couple of days in China in response to their own food problems. They've sentenced the head of their FDA to death and they've mounted recall operation or action I guess you'd call it. I'm wondering if, Dr. Acheson, you or any of your colleagues have any thoughts as to whether these actions and any related actions that might be taken will be effective in improving the safety of Chinese food exports. Or if on the other hand, they are just for show. Sorry. Go ahead.

David Acheson: This is David Acheson.

I really can't speak to China's actions per se. I mean, clearly we are, as you know, working with Chinese authorities at ASIC to focus on food safety issues. We met with them when they were over in the United States recently. And we're working with them on food safety issues in general and obviously this situation in particular. Their recent actions are ones that they've undertaken for their own reasons, and I can't comment on why they've done it or the impact of it.

Steve Hirsch: But isn't it a fair question? I mean this is a controversy that you've participated in several press conferences with us on. This is something that's been a major topic of discussion here in Washington among government agencies, and one would think that if the Chinese take actions the authorities in this country that have been monitoring this situation would have some thoughts on it.

David Acheson: This, you know, like I said, I can't comment specifically on the actions China has taken and the actions they've taken may have absolutely nothing to do with the recent issues on food safety. So I really can't get into a discussion of the pros and cons of what they've done.

Steve Hirsch: That they have nothing to do with the recent actions?

David Acheson: It may or may not. It's certainly, my understanding of this is that he was not taken into custody recently. This is something that's been going on for awhile and I don't necessarily have believed it's anything directly related to food safety.

Steve Hirsch: And the recall too?

David Acheson: Recall of what?

Steve Hirsch: They've announced a recall of a number of products because of food safety concerns.

David Acheson: Well, as I said, certainly I think these recent events have focused a lot of people all over the world on food safety issues, and if the Chinese as well as any other country including our own, and we've just been talking about a recall for the last 20 minutes, are doing recalls because of food safety concerns, then I applaud them for doing that.

Michael Herndon: Hey, Steve, why don't we do this in the interest of time? Just call our office and we'll see if we can follow up.

Steve Hirsch: All right.

Michael Herndon: Follow up on that, okay?

Steve Hirsch: All right. Thanks.

Michael Herndon: Thanks. Next question.

Coordinator: Thank you.

Our next question comes from Deirdre Henderson with the Boston Globe.

Deirdre Henderson: Hi. Thanks for doing this call.

This is going to take a lot of people by surprise because they thought perhaps U.S. food products were safer than the exports coming in from China. Do you

have any sense of whether this is it, or does the company that had this melamine that was used as a binding agent provide that to other companies? Are there other recalls that we should expect coming down the line?

David Acheson: This is David Acheson, again.

I think that, you know, right from the beginning of these calls, and let's predate it back to peanut butter and spinach and tacos, you know, I think we've been acknowledging that food safety is not just an international issue, it's a domestic and an international issue. The information that we have so far is that we're providing that in the press release of what I've told you in terms of the extent of this particular recall. We're not aware that it's gone beyond that. Obviously the investigation is continuing.

The reason we ever even heard about this was because of raising awareness of companies. Hopefully the awareness will stay raised, they'll do more testing, they may find things. We do also have the domestic surveillance assignment going on still that we talked about before on calls where we're actively going out and testing product from companies who use various protein concentrates.

So, I certainly couldn't rule out that there won't be more of these.

Michael Herndon: Deirdre, did you have a follow-up?

Deirdre Henderson: Yes, just a housekeeping question. Do you have any sense of how much of this feed is out there? Are we talking about millions of livestock, billions?

David Acheson: Looking at my FDA colleagues here, I think the answer is, we don't know at this point.

David Elder: This is - hi, Deirdre - this is David Elder.

Deirdre Henderson: Hi.

David Elder: That is information that will be gathered during the current inspections. As you can imagine, this recall is starting today. We are working with the firms in the execution of this recall, both Tembec and Uniscope are cooperating with each other and cooperating with FDA to initiate and execute this recall. And that type of information will be gathered during the process.

Deirdre Henderson: Thank you very much.

Michael Herndon: Okay. Thank you. Next question, please.

Coordinator: Thank you.

Next we have Steve Dale with USA Weekend and Tribune Media.

Steve Dale: Thank you.

I have a follow-up for this too, so don't let the follow-up be lost.

This all began, the pet food part of this, all began in March. If everything is held up or has been held up at the border, at what point can we absolutely say that the pet foods that we buy today or tomorrow or the next day, you have to tell me when, on the shelf of pet stores and grocery stores or on-line, is absolutely safe? At what point will there be no more recalls? I mean, maybe a recall concerning another problem down the road or another issue, though I hope not, but concerning what happened in March and what has spun off of that. The last press conference was maybe 10 days ago, and right after that

press conference, I mean literally less than an hour after that press conference, maybe 15 minutes, there was an announcement of five more recalls.

And I'm asking, I think, if everything was held up then in March, how could it be that we are just still noticing? I mean at what point will our pet food be unquestionably, undeniably, undoubtedly safe concerning the issue of the wheat proteins of various sorts and the melamine and cyanuric acid and all the rest?

Because at some point you've stopped it. Do you understand what I'm asking?

David Acheson: Oh, yeah, very clearly, and I wish I could give you a short, succinct answer. You've pointed out that the things that we put in place at the borders are going to prevent protein concentrates from getting into the United States that are contaminated with melamine that are directly imported from China. That does not mean that a particular manufacturer may not have things in a warehouse on hold somewhere, some stock of an ingredient that they're using. Hopefully, the raising awareness part of this is...

Steve Dale: Excuse me. I mean, I don't know how a manufacturer of pet foods, with all due respect, could not know about this. I don't - maybe I'm just not understanding what you're saying.

David Acheson: Well, what I'm saying is, I would agree, it's hard to believe that a manufacturer of pet food would not know about this. But, you know, I've been in this job long enough to be surprised on a daily basis about who does know something and doesn't know something or prefers not to admit that they know it. I'm simply trying to answer your question in an honest way.

What we have done is to put as many controls in place as possible to prevent melamine-contaminated protein concentrates from being freshly imported into the United States. That's number one, okay?

Steve Dale: Uh-huh.

David Acheson: The second point is, if something was previously imported that had melamine in it but it was nothing to do with the pet food recalls, something completely separate from that, and is currently being used, nobody's tested it, we're not aware of it, you can't rule out the possibility that it won't surface in some point in time.

What we can say is that the material that we know about from the two big pet food issues, the wheat gluten and the rice protein concentrate, we chased that down to the point where I think pretty confidently we can say there's none of that left. But these companies when they're using these ingredients, there's a lot of dust around in many of these manufacturers. They get cross-contamination and a number of the subsequent recalls have been cross contamination within the companies -- not direct use of the raw ingredient is contaminated, but cross contamination in the equipment and the systems.

So I can't give you an absolute never, it will never happen again, we're done with all recalls related to pet food assurance. Every day that goes by with more controls, more awareness, more testing, increases the safety margin, and that's the goal here is to continue to push this back and try to prevent the problem from recurring. But obviously as you've learned, a company just in the last few weeks decided, well, you know, maybe we should test this stuff. They made the decision to do that, they found something, and they did the responsible thing.

Steve Dale: All right. My follow-up question, although I still don't - maybe we're not communicating about that because if it happened and it did originally with Menu foods in March, and then I realized some of the follow-ups didn't come until six weeks later, but now it's six or seven or eight weeks after that. At some point - and what I'm asking is, what is that point when things will be safe again for pet food where consumers can feel absolutely confident concerning the wheat products and the importation from China? Not a new unperceived possible problem down the road, but what we've had happen, at what point will it be safe? That's what I'm trying to ask.

My follow-up question, you mentioned for fish feed. How about for food that we feed to our pet fish? Is that absolutely safe?

David Acheson: I don't know whether Aqua-Tec2 or Aquabond are used in feed for pet fish. David, do you know that?

David Elder: All the evidence that we have about the distribution of these products is that it's going to commercial applications. These products are sold in 50-pound bags that are used in the manufacture of bulk feed that isn't intended for tropical fish or pet fish.

David Acheson: That was Captain David Elder.

Michael Herndon: Yeah. Okay, thank you.

Steve Dale: Thank you.

Michael Herndon: Next question, please?

Coordinator: Thank you.

Next we have Elizabeth Weiss with USA Today.

Elizabeth Weiss: Thanks so much for taking my call.

My colleague at USA Today Weekend, having written about aquaculture, a lot of these binding agents are so that the pellets don't disintegrate in open water before the fish are finished eating, so that's why they are using something to hold the pellets together. So my question - I have two questions.

The first is, the company that was making these pellets, was it using melamine as a protein binder to hold the pellets together? And I've been trying to look on their websites - were these predominantly pond-reared fish, or were they open-water fish? And did they, were they using melamine just because, "Oh it's a protein source," or were they using it as kind of a plastic glue to hold it together? What have they told you that they were doing?

And then I have a follow-up to that.

David Acheson: I think the short answer to that is that we have no indication they were using it as a protein source. You know, and that's an important differentiation between the previous issues of the pet food where our belief is that the melamine was added to the food to artificially raise the appearance of protein. And because as we've talked about before, melamine is high in nitrogen, and if you measure the total nitrogen it's a way of measuring total protein, so you can kind of fool the system into thinking there's more protein there. That is the current hypothesis of why the pet foods were contaminated.

I think in this situation it is more the alternate and that this material, the melamine, was added to improve the binding properties of the pelleted feed.

Elizabeth Weiss: And that would clearly be illegal?

David Acheson: Well, melamine is not an approved food additive or feed additive, so it's an unapproved use.

Elizabeth Weiss: Okay. And a follow-up question, you've got a recall on the pet food going - oh, I'm sorry - on the feed going out. What about a recall on the animals which were fed this feed?

David Acheson: At this point, no. As I've said, the levels in the Xtrabond that was used for the livestock feed do not reach a level of concern. The levels in the Aquabond and the Aqua-tec were higher, but even so they didn't reach a level of concern either.

Michael Herndon: Okay, thank you. Next question, please?

David Acheson: Let me just clarify that.

Man: Oh, I'm sorry.

David Acheson: I'm sorry. A level of concern for human health. That's an important differentiation. The Xtrabond, it's a complex issue but the Xtrabond because it had less in it wasn't considered to be at the final point, it was fed to the animals, a concern to the animals either, or humans. The fish feed, the Aqua-tec, and the Aquabond, there was some concern about potential harm to the fish. And that's the reason why the recall is going down to the feed level in the Aquabond and the Aqua-tec. But in view of the risk assessment and the excretion of this product from fish and the various factors in the risk

assessment that's on the Web, the view is that those fish should they be consumed would not pose a threat to humans.

Michael Herndon: Okay. Next question, please? Thanks.

Coordinator: Thank you.

Our next question comes from Rick Weiss with the Washington Post.

Rick Weiss: Hi, thank you.

First of all, I don't see the press release. Is it up? Or am I just not finding it on the website?

Michael Herndon: Rick, it will be up in a minute.

Rick Weiss: Okay.

My question has to do with where the stuff was coming from. It sounds to me like it's, that Tembec is the company that is actually, was actually adding melamine to some of these ingredients, and some of these products or ingredients were then used by Uniscope. Is that right?

David Acheson: That's correct.

Rick Weiss: So you're telling me that after all your announcements going back to March, Tembec never approached you about this, never stopped using melamine, and it wasn't until Uniscope, the buyer of these products, recently contacted you because they had discovered it, that this came out. Does that strike you as being surprising or irresponsible on the part of Tembec or head-in-the-sandish

for a company to have lived through what we've all been writing about, and of course we assume everyone in the world is reading us, for the last few months, and didn't think to stop adding melamine to their product?

David Acheson: That's part of the active investigation. All I can tell you is that this came to our attention on May 18 when Uniscope let us know what they'd found, and we followed that up. What Tembec knew, didn't know, what their activities were, is part of the investigation. And I'm sure they all read you all the time, but I can't comment on that because I don't have any information. What I can tell you is, that this came to our attention on May 18 and we've followed up, we confirmed it, tested it ourselves, figured out the levels, and hence the current information.

Rick Weiss: One follow-up question if I may.

On what you said earlier that you believe that in this case this is probably not a case of trying to alter tested levels of protein, but added for some other properties, on what evidence, on what basis are you making that opinion?

David Acheson: That's based on discussion with the firms, and also to some extent the levels of melamine we're seeing in these products are not nearly as high as the levels that we saw in some of the wheat gluten. So that's essentially the indications that it was being used to improve the binding properties.

Rick Weiss: Just a real quick follow-up to that, are these products sold with an assayed protein level? I mean, is that part of the characteristic of this product that people are buying, a certain presumed amount of protein on the label?

David Elder: This is David Elder.

I don't believe that is the case. I don't believe these particular products are expected to be high in protein the way a rice protein concentrate or a wheat gluten is expected to be high in proteins. They have a function which is to, as was described earlier, be a pellet binder for feed.

Rick Weiss: Okay, thank you.

Michael Herndon: Thanks. Next question, please?

Coordinator: Thank you.

Our next question comes from Carrie Payton Dahlberg with the Sacramento Bee.

Carrie Payton Dahlberg: Yes, thank you for taking my question.

I have a follow-up on that. Although if the particular ingredients aren't sold with a protein assay, do they go into things that would benefit from a higher protein level or be tested for nitrogen or protein and so there would be a spin-off benefit of some kind?

David Elder: This is David Elder, again.

At this point in time, we are focusing our efforts on the recall of the pellet binder ingredients. We are in the process of tracing forward those ingredients to the finished feed manufacturers and are using this communication opportunity as well as the press release that we'll be issuing soon, as well as the direct route through recall notification by the recalling firms to inform the fish feed manufacturer, then the livestock feed manufacturers, of this potential problem. That's where our focus is right now. It's hard for us to comment

further on the type of testing that animal feed may undergo and whether or not to speculate whether or not the melamine addition here would impact any test if they were done. So it's just not the focus right now. Our focus is on the recall of these binding agents and any recalls that results of the feed subsequent.

Michael Herndon: Carrie, what was your follow-up?

Carrie Payton Dahlberg: I think I'll stick with that.

Michael Herndon: Okay, thank you. Next question, please?

Coordinator: Thank you.

Our next question comes from Abigail Goldman with the Los Angeles Times.

Abigail Goldman: Thank you very much.

I have a follow-up to with my other colleague's questions about scope because it's still not clear to me. Were either of these companies using melamine for a long time, was this always part of their ingredients, or was their method of manufacturing? If not, when did they start using it?

And do we have any idea about how far and wide these may have been distributed and for how long animals and fish and shrimp may have received it. I know you mentioned goats and sheep. Are there other livestock that might have been fed food that had used this binding agent?

David Acheson: This is David Acheson.

Part of the investigation is trying to determine just how far back in time this went. Current thinking is that this was not something that, a practice that was done just very recently but is probably been going on for a little while. But in terms of how long and to what extent, don't have specific information to share with you on that because we don't have it in terms of specifics. But like I said, we suspect this is not something that happened acutely in May 2007.

Then you had a second part of that to do with the sheep?

Abigail Goldman: Yes. How far might this have gone? How far might these have been distributed, how big a player are these companies? I know you said you don't have specific information yet, but some clue. Was it only - you mentioned sheep and goats. Are those the animals that might have received this Xtra-tec or are there other animals? And is there any idea about how far and wide it may have been distributed?

David Acheson: Well, as I said, it's cattle, sheep and goats are the animals...

Abigail Goldman: Cattle, (sir).

David Acheson: ...who - they are the ones who primarily would be the targets for the Xtrabond product, which is the one that had the lower levels in it. It's the fish and shrimp would be the targets for the Aqua-tec 2 and the Aquabond. And I really don't know the extent of where this may have gone and how far it may have gone. As I pointed out, we do know that the Aqua-tec 2 and the Aquabond are exported. We're in the process of informing countries that may have received these products from the United States. And at this stage, I can't speak to tonnage or poundage of product and where it went, which I think is probably what you're asking. We just don't have that information yet.

Abigail Goldman: Or domestically some sense of how far and wide they distribute. Is this a major player who distributes to all kinds of companies and feedlots or manufacturers, or most of it is exports? I think that would also help.

David Acheson: I think most of the Aqua-tec 2 and Aquabond are thought to be exports. In terms of the Xtrabond, the livestock feed, Captain Elder, do you have any sense of that?

David Elder: I don't have a good sense at this point. As I mentioned in response to an earlier call, this recall is generally starting today, and that's the type of information that in any recall situation we would be working with the firm to compile to determine the appropriate scope of the recall, the distribution pattern, the distribution volume. All of that information is in the process of being obtained, and as Dr. Acheson said the Aqua-tec, Aquabond products are intended primarily for export. And the Xtrabond product is primarily intended for domestic use, and as was also mentioned earlier, the feed manufactured from the Xtrabond product is not something that we would expect to see a recall of. So it's the Xtrabond pellet binder that we are expecting to see recalled, not necessarily the feed manufactured from it.

Similarly, the Aqua-tec products that are primarily exported we're expecting to see a recall. We are seeing a recall of the binder, and we're expecting to see a recall of feed manufactured from the binder. However, with a large degree of that product being exported, our mechanism to oversee the recall of any feed manufactured from it is really left to our strong international relationships with foreign regulatory bodies to communicate, to inform them of the situation of our concern, and to leave it to their capable oversight to determine the right course of actions for products produced in their countries.

David Acheson: You know - this is David Acheson, again.

You're asking great questions, and as you've heard this is early, it's always the case where when you go out with information early we don't have the answer to all these good questions. As we gather this information and as we're able to share it, we will.

Michael Herndon: Thank you. Next question, please?

Coordinator: Thank you.

Our next question comes from Tom Watkins with CNN.

Tom Watkins: Have you guys checked to see who else Tembec is selling to and if so are they being cooperative?

David Acheson: This is David Acheson.

My understanding is that Tembec are only selling to Uniscope. And everybody's been cooperative.

Tom Watkins: Terrific. And how do you spell Tembec?

David Elder: T-E-M-B-E-C.

David Acheson: Thank you.

Michael Herndon: Was that your follow-up, Tom?

Tom Watkins: That will do.

Michael Herndon: Next question, please?

Coordinator: Thank you.

Our next question comes from Sandra Young with CNN.

Sandra Young: Yes, hi, thanks for taking my question. You said that melamine and melamine products are "unapproved use." I just want to be clear. There are no approved uses for melamine in this country, are there, in terms of even additives to feed and stuff?

David Acheson: Yeah. This is David Acheson.

It is approved for use in all kinds of other situations -- plastic ware, dinnerware, as a polymer, so yeah, it is approved in those situations.

Sandra Young: But not for any kind of foodstuff like feed and animal feed, human feed of course. I mean...

((Crosstalk))

David Acheson: It is not approved for use in animal feed, and it's not approved for use in human food.

Sandra Young: Okay, and so the follow-up is, this was an unapproved use. What action if any is being taken against Tembec?

David Acheson: You're right, it's an unapproved use, and I'd ask Captain Elder to respond to your second question.

David Elder: Hi, David Elder here.

Currently Tembec and Uniscope are cooperating. They're cooperating with each other and with the agency to initiate and execute this recall. Our investigations involving both remain open, and we will continue until we're satisfied that we have fully evaluated the situation, at which point in time we'll consider any appropriate follow-up that is indicated. But right now as the cases are open, I'm not going to speculate on what the ultimate results may be.

Sandra Young: Legal action is still an option for Tembec, because they are using it in an unapproved method and knowingly?

David Elder: I'll say again, we'll consider appropriate options when we have completed our investigation. We're happy that Tembec is cooperating in initiating this recall. And we'll deal with any other issues at the - I'm sorry - any subsequent issues at the appropriate point in time. I will add that Tembec has stopped adding melamine to the products. Uniscope has stopped distributing the product. Both companies are recalling products. So in terms of the current situation, there is no unapproved use currently going on at Tembec, and there's no inappropriate distribution of products currently going on. So in terms of the current situation, it's under control. The products on the market are subject to recall. Our investigations are ongoing. And we'll consider whatever appropriate actions are indicated, but it remains very much open at this point in time.

Sandra Young: Thank you.

Michael Herndon: Thank you. Next question, please?

Coordinator: Thank you.

Our next question comes from (Julia Rovner) with National Public Radio.

(Julia Rovner): Hi. Thanks for taking my question.

I think at this point it's mostly been answered. I just want to clarify once and for all. I mean, Tembec was doing this themselves. It's not a question of they were getting something from somewhere else with the melamine already added?

David Acheson: Correct.

(Julia Rovner): Okay.

And the other question is, is on the fish food. This was fish food intended for fish that was being raised for food, not pet fish?

David Acheson: I think it was, use of Aqua-tec 2 and Aquabond. I suspect is like other fish feed. It could be for commercial establishments, directly for human food, or it could be used in hatcheries where the fish would be released out into the wild. I suspect it could be used for either.

(Julia Rovner): Oh, okay.

David Acheson: I don't know that for a fact, but that's what fish feed is used for.

(Julia Rovner): But presumably these could have also been for fish that was intended for human consumption?

David Acheson: In theory.

(Julia Rovner): But as you were saying, you don't think the amounts of melamine were large enough to be of any risk to humans?

David Acheson: Based on what we have so far, correct.

(Julia Rovner): Okay, good. Thank you.

Michael Herndon: Thank you. Next question, please.

Coordinator: Thank you.

Our next question comes from Karen Robach with the Pittsburgh Tribune Review.

Karen Robach: Hi. Thank you for taking my question.

You stated that the Xtrabond had less than 50 parts per million of melamine. I was wondering in the other two products what the level of melamine was, and I wanted to make sure it was just melamine and not the related compounds. And also, wondering why it took 12 days from the time FDA knew about this and maybe longer for the company for this to be recalled.

David Acheson: First of all, the levels that I gave you, 50, were melamine and melamine-related compounds. These were very heavily melamine. We analyzed them for the four compounds -- melamine, cyanuric acid, ammeline and ammelide. The levels of melamine were by far higher than any of the others. Cyanuric acid was low, very low relative to the melamine.

The numbers that I read out, and I'll repeat them, were total melamine and melamine-related compounds. That was the sum of all of them. And the

Xtrabond was, as I said, less than 50 parts per million. The Aquabond, this is in the finished feed I want to emphasize. This is the finished feed point of this. The Aquabond and the Aqua-tec were higher because the levels in the binding agent were higher to begin with, and they aren't as diluted, and they were in the region of 230 to 460 parts per million. That 230 to 460 is dependent on how much dilution is actually done at the point at which the feed is actually finally put together.

Michael Herndon: Karen, did you have a follow-up?

Karen Robach: Yes. I had also asked about why it took 12 days to get this started, but also I was wondering where the stuff was exported to, and specifically did any go to China?

David Acheson: We're looking at, as I said we're working actively right now on notifying the countries. Until they are notified specifically, I don't want to comment on which countries were involved. You know, in the context of, why does it take so long, we were notified on the 18th which as Captain Elder pointed out we didn't hear about this until late on a Friday. We had investigators in there first thing Monday, they pulled samples, and by the 25th of May to 26th of May we were pulling data together.

It was then a question of determining the impact of these levels on the health of the fish, the health of humans, contacting the companies, getting the recall moving, and that took us another three or four days.

Many folk were working right through the holiday weekend to get this job done, so you know you always wish for a things to go faster, but this one went pretty quick.

Michael Herndon: Thank you.

Operator, we have time for three more questions.

Coordinator: Thank you.

Our next question comes from John Rockoff with Baltimore Sun.

John Rockoff: Hi. Thanks.

How do the melamine levels and the levels of melamine-related compounds you found in Aquabond, Aqua-tec and Xtrabond compare with the melamine related compound levels you found in the wheat flour from China?

David Acheson: The wheat flour from China, some of it was as much as 20 percent, which is, you know, that's 20 parts per hundred. You can do the math and calculate that into parts per million, but it's hundreds of thousands, so way higher.

John Rockoff: Okay. Great. Thanks so much.

Michael Herndon: Thank you. Next question, please?

Coordinator: Thank you.

Our next question comes from John Wilkerson with FDA Week.

John Wilkerson: Is FDA doing anything now that would have found the melamine in these products if they had not come forward to you voluntarily?

David Acheson: Yes. David Acheson, again.

As I've pointed out, we are doing the domestic protein surveillance assignment. This is an assignment that is focused on getting out to manufacturers who use protein concentrates. It's focused on feeds and human foods which contain protein concentrates of various types. It has as I've said had a focus on imported products. Clearly this was not an imported product. So we do have things in place, but this particular situation would have been on the lower list of likelihood finds through the domestic surveillance assignment.

John Wilkerson: Okay, so you're doing this protein surveillance assignment. But how, you know, how many companies are you actually testing the products for, and how many companies are out there making this? I mean what are the chances, even though you're doing this, what are the chances of you actually detecting this if they don't come forward voluntarily?

David Acheson: Well, we're not going to get to every company. I mean that's pretty much a given that we will go as far as we can. We'll continue this for as long as we think it's warranted, but don't forget part of the strategy here is to raise industry awareness. We have been through these media conferences and all the good work that you do in terms of writing this up, getting the publicity out there. We've been trying to get the word out to manufacturers to look, see what you're getting, see where it's coming from.

Uniscope exactly did that. The methods are available on the website to test. Independent labs have tested, are setting up the assays. Uniscope sent some material in. It was tested, it was positive. So we're tackling this, not by simply trying to get an inspector to sample every lot and batch of product out there, but we're trying to raise awareness as well. So it's a multi-pronged approach, and hopefully the combination will cover most of it.

John Wilkerson: Okay, that's fine and good, but the company selling to Uniscope didn't come forward it sounds like. So what is it that you can do to a company that doesn't come forward voluntarily? I mean why would they bother?

David Acheson: If we don't know about them, there's not much we can do about them. So, I mean...

John Wilkerson: But if you find out that they did something that they didn't tell you about, somehow, then what can you do? So I'm not asking you what you're doing to the company that sold to Uniscope, but what could you do?

David Acheson: That's a theoretical question. I don't know whether Captain Elder can address what we could do to them.

John Wilkerson: No, I mean, what in law is, you know, what authority do you have to punish companies? What's in the statute?

David Elder: I mean - this is David Elder - I mean, the provisions in the statute are clear. Violative adulterated misbranded products can be seized, companies who commit prohibited acts can be enjoined, companies who commit prohibited acts can be prosecuted. Those are the provisions that we have available to us in the Food, Drug and Cosmetic Act.

John Wilkerson: Thank you.

Michael Herndon: Okay, thanks, John.

Operator, we'll take the final question.

Coordinator: Thank you.

The last question comes from David Curley with ABC News.

David Curley: Hi there.

You were kind of stepped on in the spelling of Tembec, C-H-E-M...

David Acheson: No, no, T-E-M-B-E-C.

David Curley: No wonder. A series, Dr. Acheson, so this is another use for melamine I take it, if you put melamine in water it becomes kind of - when you say it's a polymer it's a binding agent it will work that way chemically? Two, it sounds as if Tembec, I mean in essence Uniscope didn't know what they were getting. They were buying an ingredient, Aquabond, and putting it into Xtrabond, correct?

David Acheson: No. Let me make sure there's no loss of clarity on this. Tembec were the original manufacturer. Tembec manufactured the Aquabond and the Aqua-tec 2. Okay? That same basic ingredient that was used in Aqua-tec 2 and Aquabond was shipped to Uniscope, and they used it to make Xtrabond. It was the same fundamental ingredient...

David Curley: What is that ingredient called?

David Acheson: It's just...

David Curley: Just a binder.

David Acheson: It's a binding agent. That reminds me of your first question is that's what it's being used for. It's not binding the water. It's used as a binding agent that basically holds the pellet together better.

David Curley: Right. And you have at this point no idea how much Tembec has produced of this binding agent, how many pounds?

David Acheson: At this stage, we do not.

David Curley: And you said it was in finished feed. What were the ingredients inside the actual binding agent? What was the percentage of parts per million?

David Acheson: Of melamine?

David Curley: Yes.

David Acheson: I gave you the numbers in the final feed.

David Curley: Yes, you did.

David Acheson: The levels in the - let me just look for those numbers a minute. They varied. They were up to 31,000 parts per million. That's in the original binding agent, not the finished feed. The comparable levels of cyanuric acid in those were 17 to 20 because if you remember in the earlier question I pointed out there was a big difference, so melamine around about 30,000 max, cyanuric acid around about 20.

David Curley: And you've not shut down Tembec, which as some of my colleagues have pointed out, have known for 2-1/2 months, unless they've had their head in the

sand, that melamine is not approved for any kind of feed, whether it be for human or animals?

David Acheson: Tembec are no longer producing product with melamine in it.

David Curley: But they're still producing product.

David Acheson: As far as I'm aware they are producing product that does not have melamine in it.

David Curley: But how could they not know I guess is what I'm getting at.

David Acheson: Well, they know now that they are producing product that does not have melamine in it. What they knew and didn't know before will be part of the investigation as it unfolds.

David Curley: Would it have been labeled as something other than melamine that they were putting in their ingredient?

David Acheson: When it goes to Uniscope it's not labeled as melamine.

David Curley: No, I'm talking about Tembec. When they're putting something in to create this binding agent, they're putting in melamine. Would it be labeled as something other than melamine? I mean, if I was the mixer at Tembec, would I not know that I'm emptying a bag of melamine into the mixture to make this binding agent?

David Acheson: Those are good questions, and I think I can't speak to what Tembec knew or didn't know or what the mixer on the floor knew or didn't know. So it's speculation in terms of motives and who knew what at this point.

Michael Herndon: Okay. We're going to have to move on. Thank you.

I think we have one more question. Can we have that last one, please, Operator?

Coordinator: Thank you.

Our last question comes from Sally Schuff with Feedstuffs.

Sally Schuff: Yes, hi. Thank you for taking my question.

My question is, what are you expecting from private companies in terms of surveillance on domestically produced feed such as this? Is your awareness campaign, are there any regulatory issues or is it simply strictly voluntary? And what are the costs involved in the testing?

David Acheson: I don't know what it costs to run one of these tests through a commercial lab. You'd have to approach a commercial lab and ask them that question. Raising awareness is a key part of this, and clearly what this has indicated is that it's vitally important not to make any assumptions if you're a manufacturer.

And this isn't just feed. I mean I think this message is important for our foods as well. The bottom line is, know your suppliers. I mean we've said that often on these calls with regard to imported products, but it's just as important for domestic. Know your suppliers, know what they are sending you, don't assume that the practices that your supplier is undertaking are necessarily ones that you would want to use in your product.

Michael Herndon: Did you have a follow-up?

Sally Schuff: I really do in terms of what the companies are expected to do in light of this new information. I mean clearly we have a company, Uniscope, that has been getting contaminated - well not contaminated but I guess it is contaminated feed for some time, or ingredients. How does a company protect itself against dealing with what is apparently a known supplier?

David Acheson: If I was the CEO of a company, I'd be asking the question, who am I getting my supplies from and do I know exactly what's in it? I'd go out and ask that question and if you didn't get a level of comfort that you were happy with, test it yourself, which is exactly what Uniscope did. I don't know whether they asked that question or just went out and made the testing themselves, but obviously it's a good thing that they did. So I think if you're a CEO of a company you need to just ask yourself that question.

How assured am I that the supplies I'm receiving are what they say they are and don't contain something that could cause my company harm? And either do that through discussions with the supplier or if necessary get some of the sample tested.

Michael Herndon: Thank you. Thank you, Dr. Acheson.

Sally Schuff: Thank you.

Michael Herndon: Ladies and gentlemen, this concludes today's media teleconference. Thanks for your participation. The replay will be available in about an hour and will be up for about three days. If you have any follow-up questions, please don't hesitate to call the respective agencies. The press release should be available now. Just check our website. Thanks, and have a great day.

Coordinator: Thank you for participating in today's conference call, you may disconnect at this time.

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