FTS-HHS FDA

Moderator: Rita Chappelle
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Coordinator: Good afternoon and thank you for standing by. All lines will be in listen-only until the question and answer portion of the call.

At that time to ask a question depress star then 1. Today's call is being recorded. If you have any objections you may disconnect at this time. Ms. Chappelle you may begin.

Rita Chappelle: Thank you. Good afternoon everyone. My name is Rita Chappelle and I'm a press officer in FDA's Office of Public Affairs. I want to thank you all for joining us today for this important call.

There are a number of callers on this line and I just wanted to remind everyone that this call is for credentialed media only. All others will be in listen mode.

At the end of our opening remarks we will take a question and answer session. I ask that all media limit themselves to one question and one follow-up question. And please identify yourself by name and organization before you begin your question.

At this time I would like to introduce FDA's Commissioner Dr. Margaret Hamburg. Dr. Hamburg?

Dr. Margaret Hamburg: Yes. Thank you. This is Dr. Hamburg, the FDA Commissioner. And thank you for joining this call on an important food safety issue.

I'm running between meetings so I apologize I won't be with you the whole time. But I did want to have the opportunity to open this session.

Several weeks ago FDA received a report through our new Reportable Food Registry of Salmonella contamination in a common ingredient in processed foods.

The ingredient is called hydrolyzed vegetable protein sometimes called HVP. And it's used primarily to enhance flavors in many different products.

When FDA investigated the report that we'd received we found evidence of Salmonella contamination in the facility that was making this ingredient.

We also analyzed the Salmonella strain in the laboratory. At this time there are no known illnesses associated with this contamination. And obviously we'd like to keep it that way.

FDA staff are working with the Centers for Disease Control and Prevention, the US Department of Agriculture, and the Nevada State Health Department to instruct industry and protect consumers.

As we learn more through additional testing and assessment we will update our actions to protect public health.

You'll be hearing a little bit more about the actions that we are taking. But I wanted to underscore that this outbreak is important in a couple of additional aspects.

FDA identified this contamination through the Reportable Food Registry before any major outbreak. And I think that is very good news.

We are working hard to respond to this particular outbreak. We also are working hard to put in place the kinds of preventive control measures to prevent this kind of contamination from happening in the first place.

And I do want to take this opportunity to underscore how important it is to support passage of strong food safety legislation which would give us the tools to focus on prevention.

So thank you for allowing me to introduce this call and to underscore some of the important issues here.

I'm pleased to turn this over to Dr. Jeff Farrar, FDA's Associate Commissioner for Food Protection who will provide additional and important details about the actions that are under way.

And we also as you heard have other partners joining us to provide information to fill in the picture of this contamination incident. Thank you very much.

Dr. Jeff Farrar: Thank you Commissioner Hamburg. This is Dr. Jeff Farrar, with the US Food and Drug Administration. I am the Associate Commissioner for Food Protection here at the FDA.

Thank you for taking time to join us today. We want to share some information on a current investigation involving a Salmonella contamination of a food ingredient HVP that Commissioner Hamburg mentioned.

This hydrolyzed vegetable protein ingredient is a widely used flavor enhancer in the food industry used in items such as soups, cheese, sauces, hot dogs, frozen dinners, snack foods, dips, and dressings and so forth.

Commissioner Hamburg mentioned we're working closely with our colleagues at CDC and USDA. I wanted to take just a second to introduce those folks.

We have Dr. Ian Williams from the Centers for Disease Control on the line. I'll turn to Dr. Williams in just a moment.

In addition we have Carol Blake and Judy Riggins and Phil Derfler from the US Department of Agriculture Food Safety Inspection Service.

The affected product, this hydrolyzed vegetable protein was manufactured by a firm called Basic Food Flavors in Las Vegas, Nevada.

FDA was - learned of the contamination event through a customer of Basic Food Flavors through our recently implemented Reportable Food Registry.

Upon learning of this report the US Food and Drug Administration with the Nevada Department of Health implemented an investigation at the facility.

Our investigation is still in progress but did reveal a positive finding of Salmonella Tennessee within the food processing facility.

At this time we believe the risk to consumers from this low level ingredient widely dispersed in the food industry is very low.

I'll turn to Dr. Williams now to get - provide any input on any cases, human illnesses that may be associated with this product.

Dr. Ian Williams: Thanks Jeff. Good afternoon everyone. This is Dr. Ian Williams from the Centers for Disease Control in Atlanta.

I am the Chief of the Outbreak Response and Prevention branch here at CDC. So CDC is actively involved with our federal partners, the US Food and Drug Administration and the US Department of Agriculture in this collaborative effort.

At this point we are not aware of any human illnesses associated with hydrolyzed vegetable protein products.

Our national surveillance system is continuing to monitor this situation should it change. At this time CDC is asking that healthcare providers and public health departments continue the routine reporting of Salmonella to the Salmonella surveillance systems here at CDC so that we can detect cases should they occur.

But I want to stress at this point we are not aware of any human illnesses associated with this product. Thank you.

Dr. Jeff Farrar: Thank you Dr. Williams. This is Dr. Farrar again at the US Food and Drug Administration. Sorry I failed at the introduction to introduce my other colleagues here on the line at FDA.

We have Dr. Joshua Sharfstein, Principal Deputy Commissioner for the US Food and Drug Administration and Dr. Jenny Scott with the Center for Food Safety and Applied Nutrition.

To follow-up, FDA is taking active steps in this investigation. Our investigation is continuing.

Even though no illnesses have been reported we are proceeding with special studies to ensure that the foods containing this ingredient are safe.

You heard Dr. Williams mention the increased surveillance that will be implemented at state and local health departments.

We are also working with food -manufacturers and distributors to provide specific guidance regarding products that may need to be recalled.

In addition we're creating a Web page on our fda.gov Web site and foodsafety.gov as well where consumers can access a searchable database to find any recalled products that may be in their pantry.

I want to emphasize however that this recall process is ongoing. There are multiple consignees who sold this product to multiple sub-consignee's. So the recall process may continue for some time.

We believe that the risk presented by this recall is very low to consumers. Many of the foods that incorporated this product at a very low level have kill steps in place that would eliminate Salmonella.

For those that don't we are providing specific guidance around the need to recall those products.

We want to take this opportunity as well to remind consumers that another thing that they can do is to be sure and read and follow the label instructions on food preparation and cooking.

We want to advise that our current position in working with industry is based on our current information.

Obviously as that information changes the FDA will take the appropriate steps to update our actions and notify the public.

With that I'll turn it back to Rita Chappelle.

Rita Chappelle: Thank you Dr. Farrar. At this time operator we would begin the Q&A session with credentialed media only.

Again we ask that they limit themselves to one question and one follow-up. And please identify themselves by name and organization. Thank you.

Once again to ask a question depress star then 1. One moment.

(Derek Savoe) you may ask your question.

(Derek Savoe) Hi. Thank you all for taking my question. My first question is is this the first time that there's been I guess major recalls related to I guess, a flavor enhancer?

Dr. Jenny Scott: This is Jenny Scott from FDA. So far as we know this is the first time we have had a recall with respect to something - an ingredient such as this.

We have had recalls in the past related to other ingredients that may be widely incorporated into food products.

(Derek Savoe): Okay. But this is the first with this ingredient is what you're saying?

Dr. Jenny Scott: Yes.

(Derek Savoe): Okay. And then my follow-up question is how are your announcements yesterday regarding the warnings to the food companies and then Hamburg's comments today this morning on enhancing food safety connected to your efforts to get a food safety bill passed?

Dr. Joshua Sharfstein: Hi. This is Dr. Sharfstein. I'll try to take that but could you just could you repeat the question so I can understand better?

(Derek Savoe): Sure, sure, excuse me. How are your announcements today and yesterday on food safety connected to your efforts to get a food safety bill passed?

It seems like there's just a lot going on at once and I'm just wondering if - how is that tied to efforts to get food safety the Food Safety Bill passed?

Dr. Joshua Sharfstein: Well I think our announcement on this situation is just prompted by the facts of this situation. And we think it's important to let people know about the situation and that we're working closely with industry in providing recommendations to consumers in order to keep it as Dr. Hamburg said, about people getting sick.

I think it does illustrate the broader point though that we would like not to have episodes like this in the future.

And the shift in the food safety system that we can accomplish with the food safety legislation is one towards prevention.

And we would like to be able to set strong preventive standards that keep contamination from occurring in the first place.

And, you know, we would like not to be in a position to have to be discussing situations where there is contamination ingredients that has gone into many food products?

(Derek Savoe): Thank you.

Rita Chappelle: Thank you (Derek). Next question please?

Coordinator: (Elizabeth Weiss) you may ask your question.

(Elizabeth Weiss): Oops, thanks so much for taking my call. I had two questions. First off do you have - is Salmonella a zero tolerance bacterium for FDA or does it depend on whether or not the products involved have a kill step?

And is that going to be decided on a case by case basis in terms of what will be recalled?

And secondly do you have any sense of how large this recall might get?

Dr. Jeff Farrar: (Elizabeth) this is Jeff Farrar here at FDA. Regarding your second question how large will this recall get, we don't know precisely.

The manufacturer had many first level consignee's who obviously had individuals and firms that they sold to who sold to other firms.

We expect this to get larger over the next several days to actually maybe several weeks. Regarding your other question I'll turn to Jenny Scott here.

Dr. Jenny Scott: FDA considers that Salmonella in a ready-to-eat product should not be there. So we in effect have a zero tolerance for it in ready-to-eat products.

In raw products that may come in with contamination we do not have a zero tolerance in effect.

For a situation like this this is a bit unusual and we are taking a risk based approach to this and making sure that the products that are out there on the marketplace for consumers are safe.

Rita Chappelle: All right. Thank you (Elizabeth). We'll take the next question please.

Coordinator: (Mary McKenna) you may ask your question.

(Mary McKenna): Thanks so much for doing this. This is a follow-up to the question that was just asked on the possible magnitude of this recall

I'm looking at the list on the Web site of the producer of the HVP. And it's five single spaced pages plus some additional lines on a sixth page. That looks like a lot of products.

So is there anything else you can say about the potential dimensions of this given that just the number of lots and batches that they have listed?

Dr. Jeff Farrar: Yes. It - we unfortunately - this is Jeff here again with FDA. We don't know the precise number that you're looking for. That's going to have to follow.

The potential amount of product that could have been covered under this recall is quite large.

However we suspect that a very large proportion of that amount did receive a kill step. So we don't know the exact amount or percentage that will wind up being recalled.

(Mary McKenna): Can I ask a follow-up question?

Dr. Jeff Farrar: Just to clarify that, we are - our approach to this as Dr. Sharfstein and Dr. Scott mentioned, is a risk based approach.

So we are not asking firms to recall product that may have been produced with this HVP product if it received a validated kill step. I hope that clarifies a little.

(Mary McKenna): So my follow-up questions. Could we have a little bit more detail about the manner in which this contamination was discovered?

How - what the manufacturers or the business that received this ingredient, did they receive it from Basic Food Flavors from an intermediary?

Did they do a test as it came in-house? What sort of product it was destined to go into -- anything like that?

Dr. Jeff Farrar: Yes this is Dr. Farrar again with FDA. Yes a customer of Basic Food Flavors did testing of the incoming ingredient that was used to make a flavoring base if you will, and found the positive Salmonella and reported that through our mandatory Reporting Food Registry, our RFR. That's how we learned of the event.

Rita Chappelle: All right thank you very much. We'll take the next question please.

Coordinator: (Mary Claire Delonnick) you may ask your question.

(Mary Claire Delonnick): Hi. Yes I'll try it again with the scope. I mean would you say this is going to be hundreds or products or thousands of products? I mean it sounds like it could get into the thousands?

Dr. Jeff Farrar: We this is Dr. Farrar again. We honestly don't know. So we're a little reluctant to put a range on it even at this point.

The - what we do suspect is that the recall, the amount of products is going to increase over the next several days or weeks but we can't give you an estimate unfortunately.

(Mary Claire Delonnick): Okay. And just on a follow-up question. I mean since this is a flavor enhancer you have to assume there's not a lot of this product in the products that it's in. Does that make it a lower risk recall?

Dr. Jenny Scott: Well certainly it would reduce the number of Salmonella present if using contaminated ingredient at a low level.

But we still consider that Salmonella at any level in a ready-to-eat product presents a risk to the consumer and we would want those products off the marketplace.

(Mary Claire Delonnick): Okay thank you.

Coordinator: (PJ Hoffstedder) you may ask your question.

Rita Chappelle: Thank you.

(PJ Hoffstedder): Hi guys. Thanks so much. Just to kind of roll back onto - not to keep bringing all these questions back full circle, but with regards to the timeline could you at least walk us through a little bit like on this day, you know, this is when we actually got the report, this is when we realized what was going?

Like how far back had this product been to your guys' experience had this product been in the food chain before, you know, you guys got this report? I mean had it been in the food chain for days, for weeks?

Dr. Joshua Sharfstein: Sure. This is Dr. Sharfstein. I'll try to answer that. See the recall that was - I'll do the last part first.

The recall is of products coming out of Basic Foods since September 17, 2009.

And so we anticipate that there has been - have been products that have been out there for a little while.

And that's why it's reassuring that we have not seen any matches like Dr. Williams said for illnesses.

We became aware of this in February. The report I believe was in the first, end of the first week of February. And then FDA went in and inspected.

And the inspection identified that there was contamination in the facility. So it wasn't just one report from a company. We went in and we found contamination in the facility. And we also understood that the company then identified contamination in that lot.

At that point the firm stopped production and put it pieced and powder HVP on hold.

And we began to - there was further analysis done of the sample. At that point we understood that there were no illnesses.

And that led us to determine what a reasonable risk based approach would be which is where we are now where we are supporting the recall of some products with the HVP in it but not products where there has been a kill step or where there will be a kill step for Salmonella, kill steps that are validated.

And we will be putting on the Web site if it's not already there, you know, very a clear information for industry.

And we had a industry call earlier today that goes through the different scenarios. And in summary it's basically that bulk product we expect to be recalled or reconditioned according to a process that FDA approves.

If it's ready-to-eat we would expect it to be recalled unless there was a kill step that was validated as part as the production process.

And if it's ready-to-cook we would expect that it would - we are - it would if it's ready-to-cook and there's a validated cooking steps then we believe at this point it does not pose a significant risk to merit a recall.

Having said all those things, we are actively looking for more information about the products. We're going to be doing some additional testing and surveillance and if that changes our assessment it may change our recommendations to industry.

(PJ Hoffstedder): Okay. Can I ask just a very quick follow-up question on something you said?

Dr. Joshua Sharfstein: Sure.

(PJ Hoffstedder): The with regards to obviously the investigation that you guys went to the facility where it was being manufactured was there - is there any indication so far as how it was introduced into the manufacturing process, like what actually caused it?

Dr. Jeff Farrar: This is Dr. Farrar with FDA. Those types of investigations are - we absolutely do those in trying to get to what we call the root cause of the contamination is very important to us for the purpose of making sure that we can implement adequate preventative controls to keep that incident from recurring.

These root cause investigations are extremely difficult. They often occur months or, you know, weeks or months after the event.

So it's very difficult in these investigations to determine the root cause. But having said that, we are still attempting to find that source of contamination.

Rita Chappelle: Thank you very much. Can we take the next caller please?

Coordinator: (Lindsey Leighton) you may ask your question.

(Lindsey Leighton): Hi. Thanks for much. Dr. Farrar I'm wondering if you can tell us a little bit about the inspection history of this facility.

Had it had any documented sanitation problems in the past that, you know, were either checked by FDA or by the state of Nevada?

Can you just tell us when you were last there, when the FDA was last there and just give us a sense of the history?

Dr. Jeff Farrar: Hi (Lindsey). This is Dr. Farrar. Unfortunately I don't have those inspection dates handy (Lindsey). We'll have to circle back with you and get those to you.

Rita Chappelle: (Lindsey) you can email me your questions and we'll handle it.

(Lindsey Leighton): Okay. Thanks Rita. Can I ask...

Rita Chappelle: Do you have another follow-up?

(Lindsey Leighton): Yes I do. And I'm going to just try this again. I know this is getting frustrating for you all.

But in terms of the universe of products that could be affected by this, I've heard some numbers as much as maybe 10,000 products. Would that be in the - in a realistic ballpark?

Dr. Jeff Farrar: (Lindsey) this is Dr. Farrar again. And Dr. Scott can chime in here. Again it's - at this point we just don't have a firm estimate of the number of products that included this recall product.

We suspect that number is very large. However again, we suspect that the vast majority of those products would have received a kill step or a lethality step that would mean that those products would not be subject to recall.

Rita Chappelle: All right. Thank you. Next caller please?

Coordinator: (Gardner Harris) you may ask your question.

(Gardner Harris): Hi. A couple of questions, I mean first I mean just if you guys could help us and we - obviously you keep getting the same question so it would be nice just even an order of magnitude like tens, hundreds, thousands, tens of thousands, in terms of the - let's just say that includes this product not that's subject to a recall, not whatever, but just that they sell to if you could sort of give that?

And secondly you describe a process here, your RFR for instance. When we looked back at the peanut stuff that, you know, it was controversial because Nestle had gone in there and investigating the plant, found Salmonella contamination but hadn't reported it the FDA.

Is there something about this process that is different than the process in the past that you guys got this report from a customer?

Are such reports routine? Have they been routine for a long time? Are they routine now? And how might this process be different under the food safety legislation that you all are saying, you know, is so important? So I guess that's...

Rita Chappelle: Many follow-ups.

Dr. Joshua Sharfstein: You packed a few questions in there.

(Gardner Harris): I did...

Dr. Joshua Sharfstein: Hi (Gardner). This is Josh Sharfstein.

(Gardner Harris): Yes.

Dr. Joshua Sharfstein: ...the - let me do the last one and then we'll save the first one for someone else here.

But the - this was different. It was actually quite different because it came as a report to the Reportable Food Registry.

The Reportable Food Registry was just established by FDA I think in September 2009.

And what it requires is that when companies receive among other things, when companies receive an ingredient that they identify contamination in that they believe could be elsewhere in the food supply they have to notify FDA.

And so there was a company that got this, tested it, found Salmonella, and let FDA know. And within a couple days FDA was in the facility trying to figure what was going on.

And our team found a environmental contamination and other evidence of product contamination. And we were also able to get the fingerprint of the Salmonella and learn from CDC that there weren't associated illnesses.

So contrast that to the peanut butter outbreak where it was hundreds of illnesses before we figured out what the product was, here we identified contamination because of the system that's been set up since that peanut butter outbreak.

So it's very different now. The Food Safety Bill gets to the issue of prevention. Because under the Food Safety Bill the FDA would be able to set up preventive standards for companies like Basic Foods and support Basic Foods and inspect against a preventive standard.

And so that when, you know, as Dr. Farrar said, we don't know at this point what the root cause was but we would certainly expect that when those standards are in place we are preventing the root causes of contamination and that under the Food Safety Bill we would hopefully not have this at all.

So the summary statement would be what's new is we learned about this so quickly. But what we want is not to have problems like this at all.

And let me maybe just ask Dr. Scott, I think what - there’s interest in just the question of where this HVP just as an ingredient, not as a threat to consumers and not as subject to recall, just as an ingredient is there an order of magnitude on how many food products it would be in?

Dr. Jenny Scott: I would say it's likely to be in thousands of food products.

Dr. Joshua Sharfstein: Great. And but we're not - we don't know and we don't want to give an estimate of how many are going to be recalled because many of these will have a validated kill step as part of it and really pose negligible risk to consumers.

Rita Chappelle: All right. Thank you (Gardner) for your many questions. We'll take the next caller please.

Coordinator: (Joann Fillburner), you may ask your question.

(Joanne Fillburner): Yes hi. Actually (Gardner) asked most of mine except just one little one on the kill step.

What's involved in a kill step and is it something people can do at home?

Dr. Jenny Scott: Yes. The kill step usually involves cooking a product. This can be done by a manufacturer. It could be done at food service or it could be done by the consumer.

We would expect that the cooking instructions on packages that consumers would be using would be adequate to kill Salmonella in products that contain this ingredient.

(Joanne Fillburner): Thanks.

Rita Chappelle: Do you have a follow-up?

(Joanne Fillburner): No. (Gardner) asked them all.

Rita Chappelle: Can I just for point of clarification Dr. Scott, could you explain to our callers what ready-to-eat means and what that would encompass?

Dr. Jenny Scott: What we are talking about here with respect to a ready-to-eat product is one that the consumer would take and consume without any further preparation steps that would kill Salmonella.

So they don't have to cook it. It might be a snack food that has a seasoning on it that they would just open the package and pop it into their mouth as opposed to something like a ready-to-eat meal that still has to be cooked in the microwave or in the oven.

Rita Chappelle: All right thank you. We'll take the next caller and that will be our last.

Coordinator: (Brian Hartman) you may ask your question.

(Brian Hartman): Hi. Can you tell us which customer tipped off the FDA? And also when you went to this facility was it sort of a model facility would you say or a sanitation nightmare? Can you characterize in any way what was going on in this place?

Dr. Jeff Farrar: Hi. This is Dr. Farrar. And no we really prefer not to identify the customer that reported this.

As far as what was observed in the facility I actually have not seen the investigation report. So I can't really comment on what they found in the facilities.

As Dr. Sharfstein through the firm's own testing and through our testing within the facility we did find environmental contamination in the facility.

I think it's important to note that even in very sparkling facilities occasionally one might be able to find a pathogen. So a visual assessment of these facilities is not always a good indication of what's there.

(Brian Hartman): What does environmental contamination mean though?

Dr. Jeff Farrar: Environmental contamination means we found the Salmonella Tennessee organism in the production facility in the equipment used to produce the HVP in that processing environment in the immediate facility.

Rita Chappelle: All right. And operator I'm sorry we're going to take just one more question and that will end the call after that.

Coordinator: (Daniel Denoon) you may ask your question.

(Daniel Denoon): Thanks for taking my question. I've - is there any sense of how long this contamination was going on at the plant?

And any sense of how many pounds, or tons, or whatever this HVP is produced in? And any sense of how - just how much mass of this possibly contaminated product is out there?

Dr. Jeff Farrar: Yes. This is Dr. Farrar again. The scope of the recall as we mentioned goes back to mid-September.

That obviously will encompass a large amount of product. We don't know exactly how much product. I'm not sure if that answers your specific question.

(Daniel Denoon): I'm still struggling at just at some sense does this product go out in lots of pounds or tons? Is there any sense of the quantity that went out of from the plant and any sense of how much or how little of an amount is used in an average product?

Dr. Jenny Scott: This is a bulk product. So it was going out in boxes that maybe 50 pound boxes or something on that order.

Please keep in mind that not all of this product is contaminated. There is just the possibility that it may be contaminated and that is the reason for most of this product being recalled.

Rita Chappelle: Did you have a follow-up?

(Daniel Denoon): I guess that gives me a sense. Do you - is there any sense of how many of these 50 pound boxes went out?

Dr. Jenny Scott: I do not have that information at hand. I'm sorry I can't answer that. I do recall you did ask how much of this goes into food products? This will depend upon the specific product. It in many products it may be less than 1%.

(Daniel Denoon): Thank you very much.

Rita Chappelle: Thank you very much. And I want to thank everyone that joined us today on - for the call. There will be a replay available one hour after this call ends.

If you have follow-up questions please be sure to email me and we will work on getting you timely responses. Thank you again.

Coordinator: This concludes your conference call. You may now disconnect.

Man: So we're not posting anything on this right now?

Woman: Mm-mm.

Man: Okay. We'll let FDA take all that...

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