Update on the *Salmonella* Typhimurium Investigation
FDA/CDC Joint Media Teleconference
January 28, 2009

Coordinator: Welcome 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.

At that time if you would like to ask a question the command to do so will be star 1. Today's conference is being recorded. If you have any objections you may disconnect at this time.

And now I would like to introduce your host for today's call, Ms. Judy Leon. Ma'am you may begin.

Judy Leon: Thank you operator. Ladies and gentlemen thank you for joining us this afternoon. I am Judy Leon from the FDA's Office of Public Affairs.

This is an FDA teleconference for credential media to ask questions about the ongoing investigation of the Salmonella Typhimurium outbreak linked to peanut butter and peanut products.

We have speakers today from the Food and Drug Administration and the Centers for Disease Control and Prevention.

Our speakers this afternoon are Dr. Stephen Sundlof, Director, Center for Food Safety and Applied Nutrition, FDA. Michael Rogers, Director, Division of Field Investigations, FDA, Dr. Donald Zink, Acting Senior Science Advisor, Center for Food Safety and Applied Nutrition, and Dr. Robert Tauxe,

Deputy Director, Division of Foodborne Bacterial and Mycotic Diseases, CDC.

After the speakers make brief remarks, we will move to the question and answer segment. And reporters will be in a listen only mode until we open up the call for questions.

When asking a question, please state your name and affiliation. Also please limit yourself to one question and one follow up so we can get as many questions in as possible.

At this time I would like to turn the call over to Dr. Stephen Sundlof.

Stephen Sundlof: Thank you Judy and good afternoon everybody. We are calling this teleconference today to update the public on new developments on the Salmonella Typhimurium outbreak.

As we have previously announced, tests conducted by Federal and State Regulatory authorities and FDA's own investigation have determined that the current Salmonella Typhimurium outbreak links too more than 500 illnesses in 43 states.

Has been traced to a peanut processing plant in Blakely, Georgia owned by the Peanut Corporation of America or PCA.

Today the firm announced that due to internal tests indicating Salmonella contamination in its products, which had not been disclosed to State of Federal Regulatory authorities until very recently.

The company is expanding its recall of all of the peanut products manufactured in this Blakely, Georgia plant since January 1, 2007.

These additional products are being recalled because there is concern of potential Salmonella contamination, including contamination with Salmonella strains not associated with the current outbreak.

However, it is important to note that we have not yet seen evidence of illness linked to Salmonella strains in peanut products other then the serotype Typhimurium, which is the outbreak strain.

CDC and FDA will continue to monitor incidence of Salmonella illness throughout the country.

The recall now includes all peanuts, dry and oil roasted, granulated peanuts, peanut meal, peanut butter and (gena pays) made at the PCA's Blakely, Georgia facility.

That plant has stopped production of all products. Given the increased timeframe and scope of the recall, and due to the fact that the products are used in - as ingredients in many food products.

We expect that food companies packing on this new knowledge will check their supply chain records to determine whether they sold products that contained peanut ingredients from PCA dating back to the new recall date.

An consider whether a recall is warranted. The FDA today has reached out to the food industry trade associations to ensure that they can quickly identify additional products which will be recalled. And added to the FDA's searchable database.

We urge consumers to check the FDA's Web site to determine which products have been recalled and will be recalled in the coming days.

Any product that is on the recall list should be disposed of in a safe manner. We also urge consumers to wash their hands after handling potentially contaminated products.

And if consumers are unsure whether a peanut-containing product is potentially contaminated, they should avoid consuming it or feeding it to their pet until the expanded recall is complete.

We would also like to ask the news media to disseminate the FDA's Web site address in news reports to make it easier for consumers to find the searchable database of recalled products.

That database address, or that Web site address is www.fda.gov. Then we would also like consumers to call the CDC information hotline at 1-800-CDC-INFO, especially if they do not have direct access to the Internet.

And the folks in CDC on that hotline will be able to go to the Internet for them and find the product if it's on the recall list.

At this time I'd like to turn it over to Michael Rogers of FDA's Office of Regulatory Affairs to recap the findings of our inspection at the PCA's Blakely, Georgia plant, Michael.

Michael Rogers: Thank you Dr. Sundlof. Once again, my name is Michael Rogers and I'm the Director of the Division of Field Investigations in the Office of Regulatory Affairs.

As we announced yesterday, the FDA initiated inspection of PCA's plant in Blakely, Georgia on January 9, shortly after we learned that this firm was a possible link to the ongoing Salmonella outbreak.

That inspection concluded yesterday. At the inclusion of the inspection, the inspection team presented the firm with a document which we call the FDA 43, which is a list of deficiencies noted by the FDA inspection team during the inspection

This document is currently posted on FDA's Web site. The 43 that was issued to the facility identified the number of deficiencies in the firm's operations, which indicate that the plant was not in compliance with current good manufacturing practices required by the FDA.

These deficiencies are related to cleaning programs and procedures, as well as failure to implement steps by the FDA, required by the FDA to mitigate Salmonella contamination in the facility.

In addition, there were other problems. FDA's review of the firms internal records which were not previously disclosed to FDA and state inspectors during routine inspections revealed that there was situations in 2007 and 2008 where the firm's own internal testing program identified Salmonella contamination in a product.

And after getting a subsequent negative test result, sometimes using another lab sample, the firm shipped finished products.

Salmonella can exist in small pockets in a product such as peanut butter. So it is possible to draw both a negative and a positive sample from the same product lot.

I also want to clarify what might be a point of confusion. While we found Salmonella strains at this plant, other then serotype Typhimurium, which is the cause of this current outbreak.

Our investigation and that of CDC and that States, as well as an analysis and review of the product testing conducted by State and Federal authorities show PCA's Blakely, Georgia facility is the source of contamination related to the current Salmonella Typhimurium outbreak.

The additional Salmonella strains discovered at the plant underscore the point that this plant was shipped adulterated product. But as for now, we are not aware of any illnesses connected to the other Salmonella strains shown at this facility. Dr. Sundlof.

Judy Leon: Okay actually we would like to now invite Dr. Tauxe at the CDC to make is remarks.

Robert Tauxe: Thank you very much. This is Dr. Robert Tauxe at the Centers for Disease Control and Prevention.

We will be electronically publishing an article in our Journals of Morbidity Mortality Weekly Report tomorrow that will summarize the investigation to date.

And we'll provide the set of updated numbers based on reports from the states as of this evening.

Right now we are, we still have the numbers that we're updated on January 25. So we have confirmed that 501 persons from 43 states and then an additional one person living in Canada have been infected with the outbreak strain of Salmonella Typhimurium.

Of those, 108 or 22% were hospitalized. Eight deaths have been reported that may be associated, all in person's 59 years old or older.

The eight deaths have been reported in five states. That's one in Ohio, one in Idaho, three in Minnesota, one in North Carolina and two in Virginia.

Half of the cases have occurred in children and people who are less than 16 years old. And we have put a child friendly pod cast about the outbreak on the CDC Web site for children that may be interested.

Our most recently reported onset of illness was January 9. And the outbreak is still ongoing. Although the number of reported cases has decreased modestly, even as the number of recalls goes up.

At this point I want to underline the same point made by Dr. Sundlof, all the human illnesses in this outbreak are caused by the Salmonella Typhimurium outbreak strain.

Even though in the course of testing peanut butter and other food and testing at the factory, other serotypes of Salmonella had been identified.

CDC pulse net surveillance is not seeing an increase in human cases caused by these other types of Salmonella.

I'd like to underline again, for folks that do not have access to the Internet, as this recall evolves that they can get the latest information by calling 1-800-CDC-INFO. That's 1-800-232-5636, which is available 24/7. And the folks there will look the product up on the FDA Web site.

Judy Leon: Okay thank you very much Dr. Tauxe. Operator we will take our first call now please.

Coordinator: Yes ma'am. And just a reminder if you'd like to ask a question please press star 1. Our first question today comes from Craig Schneider. Please announce your affiliate.

Craig Schneider: Yes, the Atlanta Journal-Constitution. I wanted to get a sense as to what exact laws were broken here and what charges could be filed, State or Federal. It's a little unclear.

Michael Rogers: This is Michael Rogers. The inspection revealed, and we pointed out that the 43 is posted on our Web site. Identified that this particular firm, based on the inspection observations and the records that were obtained was shipping adulterated product.

That is a deviation from current good manufacturing practices. Part of your question also asked what the agency intends to do about this.

And I think that discussion is premature at this time. We need to follow our normal process. And that involves allowing the firm to respond and implement appropriate corrective actions.

Allowing the inspection team to write what we call the establishment inspection report, which ties together all the observations as well as the supporting evidence.

And the agency is the subsequently charged with making a final agency decision regarding the compliance status of this firm. And we will consider a number of regulatory tools.

Judy Leon: Craig did you have a follow up?

Craig Schneider: Yes, are you folks looking into the lab that did this secondary testing? And if so, are they in Georgia and have you found anything in regards to this?

Michael Rogers: This is Michael Rogers. We are aware of the laboratories that were utilized by the firm as part of their internal testing program.

We have no information to suggest that there's any problems with those laboratories or the results that were reported and documented by the inspection team.

The focus here is what was reported on the 43, that those records indicate that the firm in many cases had positive samples associated with some it's finished products and subsequently obtained negative test results. And we're reacting to those observations.

Judy Leon: Okay thank you very much. Operator we'll take the next call please.

Coordinator: Our next question is from (Julie Schmidt). Your line is open.

Julie Schmidt: Thank you. Do you guys have any idea, I mean are we talking about hundreds of more products now being recalled? Or are we talking about the same companies recalling bigger lots, I mean more lots of the same products?

Stephen Sundlof: Well talking, this is Steve Sundlof, to the second part of your question. There certainly is the potential that companies will have to go back further in time to recall products that were produced before I think it was July 1 of 2007, or I'm sorry, 2008.

So that is a distinct possibility. We're not, we don't have a good idea right now, you know, in terms of how much of that product is still ou there.

It may have largely been consumed. The other question is how many additional products? And again, we don't have a good sense of that at this point and time.

We are closely working with the company to identify again any additional direct customers so we can follow out the supply chain and identify what those products are.

In addition, we again are working with the Food Trade Associations to have them help us identify potential customers of PCA, whether direct or indirect. And so we can get information, in other words, information is coming from two directions.

It's coming from the retail side all the way back to the plant. And then we're looking at it from the Blakely plant moving forward. And hopefully we'll meet in the middle someplace.

Judy Leon: Julie, did you have a follow up?

Julie Schmidt: Yes, you know, your Web site already lists I think it's like, on this spreadsheet anyway it has like 461, you know particular product that have been recalled so far.

Given that number of products, would that make this like the biggest recall in quite some time, or one of the biggest or, can you help us figure that out?

Stephen Sundlof: Yes I think we would - we feel very comfortable saying it's one - it's among the largest recall that we've had. It's difficult to say at this point since we are still in the process of identifying products. But certainly it is among the largest.

Judy Leon: Thank you (Julie). Operator we'll take the next call please.

Coordinator: Yes ma'am, next in queue is Miriam Falco. Please state your affiliation.

Miriam Falco: Hi, Miriam Falco, CNN Medical News. Finding out that the company shipped product that originally testing positive for Salmonella. And then they later found somebody to say the test was negative for is pretty, is pretty disconcerting to a lot of consumers.

How, why would a company think, you just said that it's possible that something can have both negative and positive samples. But if there is a positive sample, should it have been shipped? And why did this company think they could shop around for a lab that would give - find a negative result for them?

Michael Rogers: I can't comment on the intent of the company. I can only comment on the facts. I can tell you that the practice of initially obtaining a positive sample at a place in the facility related to a product where it shouldn’t be there.

And then subsequently obtaining a negative result, absences of any study or steps to mitigate those two conflicting results is not a common industry practice and it's something we take very seriously.

And is certainly a deviation from current good manufacturing practices.

Miriam Falco: Is there a specific FDA regulation that states that for them? That says if something tests positive for Salmonella, it cannot be shipped. It should be destroyed?

Michael Rogers: It's referenced in the good manufacturing practices, which govern food-manufacturing facilities.

Judy Leon: Okay thank you Miriam. Operator we'll take the next call please.

Coordinator: Next in queue is Ricardo Alonzo-Zaldivar your line is open.

Ricardo Alonzo-Zaldivar: Yes hi. Thank you for taking my question. Can you tell us, you said that the company took some time to give you the information on the internal testing. Can you tell us when that information was given to FDA?

Michael Rogers: I didn’t say the company took time to give us that information. What I said was this inspection identified a number of internal testing records and associated procedures that were not previously disclosed or available to investigators or inspectors conducting previous inspections.

Ricardo Alonzo-Zaldivar: Okay and when did FDA obtain those particular records, the ones on the 12 instances of where they found Salmonella?

Michael Rogers: During the course of this inspection which began January 9 and concluded yesterday.

Ricardo Alonzo-Zaldivar: Okay but can you tell us, you know, when in that timeframe?

Michael Rogers: I can't at this time. And again, that information is going to be detailed in the what I characterize as the establishment inspection report.

I can't give you the exact date of when each record was obtained related to those 12 instances.

Judy Leon: Okay thank you (Ricardo). Operator we'll take the next call.

Coordinator: Next in queue is (Kate Barrett). Your line is open.

Kate Barrett: Hi, thanks for taking my question. I'm wondering how many other plants Peanut Corporation of America has? And whether the FDA has been testing those?

Michael Rogers: The, our investigation revealed that there are a number of related facilities for PCA. They have a headquarters in Virginia, another manufacturing site in Virginia, a manufacturing site in Texas and of course we're now also talking about the manufacturing site in Georgia.

Our inspection revealed that there is no association, there's no information to indicate at this time that there is an association to this particular outbreak or

any of the recalled products associated with any of those other facilities other then the one in Blakely, Georgia.

Judy Leon: Kate, did you have a follow up?

Kate Barrett: Did you guys also say peanut meal was on that list of recalled product?

Stephen Sundlof: Yes, peanut meal and granulated peanuts as well as whole peanuts.

Judy Leon: Okay operator we'll take the next call please.

Coordinator: Yes ma'am, next in queue is David Schaefer. Please state your affiliation.

David Schaffer: Dave Schaffer from the Minneapolis Star Tribune. Please give us what you have in terms of estimates or actual pounds of product that will be included in this additional recall. And do you have any idea how much of it is actually out there unused?

Stephen Sundlof: At this time I don't think we have a good estimate of the total amount. But again we are going through the records of PCA to determine how much product was shipped out. And at this time we really don't have those numbers.

Judy Leon: Did you have a follow up?

David Schaffer: Yes I did. Did any FDA officials accompany the Georgia Department of Agriculture inspectors on their routine inspections in 2008? And if they did, why didn't they see some of these problems they're reporting to us now?

Michael Rogers: No, N/A.

((Crosstalk))

Michael Rogers: The inspections that were conducted by Georgia Department of Agriculture were done under a state contract. And that is a contractual relationship between FDA and our state counterparts.

Those inspections, and it is not remarkable, we're done exclusively by Georgia Department of Agriculture and did not have FDA officials as part of those inspections.

Judy Leon: Okay thank you. Operator we'll take the next call please.

Coordinator: Yes ma'am. Next in queue is Andrea Bruce. Your line is open.

Andrea Bruce: Yes hi, Andrea Bruce from CBS News. It's actually a follow up to the previous question. For a lot of consumers and people reading this 483, could you comment on how, you know, dripping ceilings and cracks in the floor.

And I think at one point there's something called brown glick goo was found in corners. How do inspectors miss that? And what can you tell us about the Georgia inspection process outside of microbial identification of, you know, the Salmonella how these things can be missed?

Michael Rogers: I can't comment about the previous inspections done by Georgia Department of Agriculture. I can tell you that certainly the agency is reviewing those previous inspection reports.

But let's recognize that all inspections are a snapshot in time. And it only reflects what the firm is currently doing and the conditions at that particular time.

But this is something we're reviewing. Part of your question though also was trying to identify how the agency might react to this information.

And as I said earlier, we need to follow our process. We need to allow our investigators to write up the establishment inspection report.

During that time the firm is probably also going to take some corrective action and proposals to the agency.

And then the agency would subsequently be charged with making a final decision regarding the compliance status of this particular firm. And we'll utilize the appropriate regulatory tools when we reach that point and time.

Andrea Bruce: And a quick follow, I'm sorry if this has already been answered. But could you just talk to me a little bit about the strain. I know that, you know, the Typhimurium has been found in the open can in Minnesota and the unopened can in Connecticut that came from that plant.

Which, you know, created the nexus that pointed to the Blakely plant. But have you found the plain - the strain that's been sickening people anywhere in the plant itself the way that you found these other 12 examples?

Stephen Sundlof: The answer to, this is Steve Sundlof. The answer to that is no. We found other species, or I'm sorry serotypes of Salmonella in the plant. And those were outlined in the 483.

Again though I want to reiterate that finding the outbreak strain in closed containers of peanut butter and subsequently peanut butter crackers that all

we're again closed containers came directly from the Blakely plant is sufficient evidence that that is the source of the outbreak.

Andrea Bruce: Okay.

Judy Leon: Thank you.

Stephen Sundlof: Can I just, just one other thing. One of the questions that was asked was about the dripping water. And my understanding is that since the Georgia inspection that the company had replaced its roof.

And that at that time there were, without removing the air conditioning unit, and that resulted in some actual openings in the roof where rainwater and other debris could get in.

So that was not present apparently at the time that the Georgia - State of Georgia did their inspections.

And so I think as Michael Rogers indicated, these inspections are a snapshot in time. And things can change.

Judy Leon: Operator we'll take the next call please.

Coordinator: Yes ma'am. Next in queue is (Gardner Harris). Your line is open.

Gardiner Harris: The 483 though suggests that there were some basic design problems with this plant. That's for instance the source material and the finished materials were stored in the same places.

And there were other sort of basic design problems that it seems to me anybody who had some training in infections would suggest that this plant was not appropriate for being a food processing plant.

Can you explain to us how somebody could have missed such basic problems?

Donald Zink: All right, this is Don Zink. You know, I can't speculate on, you know, what a given inspector knows. These inspectors have to go into all kinds of food processing plants.

And, you know, all kinds of processing technologies. But one of the thi - you're correct. And one of the things that unique to what we call a dry processing plant.

That's a plant that doesn't really use much water if any in it's processing. Is that you really do need to install what we call zoning where you prevent employee and equipment traffic from raw areas to processed areas.

And maybe even where you use air filters and positive air pressure in the processing area relative to the raw area.

And those are fairly sophisticated concepts. I mean they may sound simple in hindsight. But, you know, to an investigator that sees lots of different kinds of facilities in a year, you know, I can see that they might not have a deep understanding of that and probe into that.

You know, other then that I really, you know, can't comment on what the particular inspectors expertise might have been.

Judy Leon: Gardiner. did you have a follow up?

Gardiner Harris: One more on the record. You all had said in yesterdays' press conference that you had to use authorities granted to you under the 2002 bio terror legislation to get access to these records.

We're they resistant to provide these records to you previously? What did you have to - under that legislation I believe you have to sort of state that there is a potential national significance to those records.

Was there some process that you had to go through before you got access to these records through the course of this two-week investigation? Can you tell us something about that?

Stephen Sundlof: I will try and maybe Mike Rogers, you...

Michael Rogers: I think both of us can get through it. You talked about, at this point you talked about the threshold that has to be met.

And that is one that where the agency through its inspections and evaluating information identifies that there is a serious and adverse health consequence associated with that particular firm and product.

There were discussions within the agency that included representatives from our chief council, our emergency operations, our office of regulatory affairs and the appropriate center.

Which is a process grounded in our guidance that is on the Web. That threshold was met. Those discussions were and have been documented.

And so it was decided that we needed, it would be appropriate to initiate the 414 process to obtain additional records or put the firm on notice if you will that we wanted access to additional records which we may not have seen.

Stephen Sundlof: And I think the other part of your question was were they reluctant to give us those records. And I don't believe they were. And when we asked, they were responsive.

Judy Leon: Okay thank you very - operator we'll take the next caller please.

Coordinator: Next we have Lyndsey Layton.

Lyndsey Layton: I'm sorry, I think that's me, Lyndsey Layton from the Washington Post. I'm,. just a follow up on Gardiner's question. Were there any internal testing reports dating from prior to 2007 that were provided by PCA?

Michael Rogers: None were listed on the FDA 43 as part of the observations. Quite frankly, we need to get all of the exhibits that were collected by the inspection team to get all the supporting evidence.

So that question is a bit premature. And I'm unable to answer it.

Lyndsey Layton: Oh I'm sorry Mr. Rogers I don't understand that answer. I'm just, I'm asking did PCA provide any of these reports that were prior to 2007. Are you saying that they did or that you have them but you haven't seen them or what?

Michael Rogers: I don't have them in my possession. The inspection team was given access to a variety of testing records. We need to assess the appropriate window that the team looked at.

I just don’t have that window for this call.

Judy Leon: Lyndsey, did you have another question?

Lyndsey Layton: Well I guess the follow up is is it possible that this company was exhibiting the same behavior prior to 2007? That they were getting positive tests for Salmonella in their products and shipping it?

Michael Rogers: The inspection did not limit their review to 2007 and forward. I can tell you that. There's no information at this time to suggest that this was a practice that could be documented prior to 2007.

Judy Leon: Okay thank you. Operator we'll take the next caller please.

Coordinator: We have (Joann Silver). Your line is open.

Joanne Silbner: Yes thank you. Two questions, one is when you're talking about somebody that's not a good manufacturing practice, I think what we're all trying to find out is when something's not a good manufacturing practice, what can the FDA do about it?

Michael Rogers: In this case you've seen that this inspection has identified a number of deviations from the regulations. And triggered a voluntary product withdrawal, certainly working closely with the firm. That is part of our regulatory process and one of our many tools.

Stephen Sundlof: This is Steve Sundlof. And just, you know, Michael just talked about the tool that we rely on is a tool of first resort and that is ask the company to voluntarily recall product.

If they do not voluntarily recall product, then we have other legal means of preventing them from doing further distribution. We can seize product. We can enjoin them from continuing product.

Those generally require us to go through the court system. And so it's a little more - it takes a little bit more time. In almost every case, if not every case though, when we do ask the companies to recall they do recall.

The states also have authorities that they can exercise immediate stop sales and other tools that they have to prevent any further distribution of the product.

Judy Leon: Okay Joanne, did you have a follow up?

Joanne Silber: Yes and I apologize. It's unrelated. But just wanted to know if you all know whether the - whether PCA knew when its plant was going to be inspected in the previous inspection?

Michael Rogers: We don't know.

Joanne Silbner: Okay.

Michael Rogers: I'm not aware of what they knew.

Judy Leon: All right operator we'll take the next caller please.

Coordinator: Robert Bazelle your line is open.

Robert Bazelle: This is Robert Bazelle with NBC. Had the, was the FDA - when was the last time, rephrase that, when was the last time FDA officials were in this plant prior to January 9?

Michael Rogers: The FDA inspected this facility back in 2001. At the time they had a different manufacturing operation then they do now. The firm was identified as a high-risk facility if you will and elevated inspection priority in 2006.

And then the agency contracted with the Georgia Department of Agriculture to conduct inspections on its behalf in 2006...

Robert Bazelle: So just to get that clear, so you - the only, it was a different plant making a different product or something in 2001?

Michael Rogers: No, in 2001 they - it did not appear that they manufactured peanut butter for that initial inspection. It was mostly roasting or blanching type operation.

Robert Bazelle: And to follow up to that, the - to follow up on that, can you give us any sense of how many roasted peanuts or - that this plant has sent out? And to repeat this question again is there any evidence at this time that peanut butter that was purchased on grocery store shelves came from this plant?

Stephen Sundlof: This is Steve Sundlof. And the - we're trying to find out right now what the production was in terms of peanuts and the other products we talked about, peanut meal, peanut granules or granulated peanuts.

So we don’t have that information at this time. And I'm sorry, I forgot the second part of your question.

Robert Bazelle: The second part of my question had to do with is there any evidence yet that this plant, and there wasn't, you said there wasn’t before, but that this plant produced peanut butter that ended up on grocery store shelves.

Stephen Sundlof: Thank you. No there's no evidence of that. And again we have been in contact with the national brand peanut butter manufacturers and they have assured us that they did not ever purchase any product from PCA.

Robert Bazelle: Thank you.

Stephen Sundlof: So we are still, our message is still people should not be concerned about national name brand peanut butters in jars from supermarkets.

Judy Leon: Operator we'll take the next caller please.

Coordinator: Delthia Ricks Newsday, your line is open.

Delthia Ricks: Well I'm a little confused with the answer you just provided for Mr. Basel because there was another outbreak in January, February of '07 that involved Peter Pan and ConAgra.

And one of the strains if you can clear this up for me was Salmonella in Tennessee. And Salmonella in Tennessee was found at this plant. Does that indicate that there was a problem with Salmonella in Tennessee in Georgia at that time in the winter of '07?

Donald Zink: This is Don Zink. That's an interesting and an intriguing finding. And that's one we're going to follow up on in our investigation and think about further.

But you do see Salmonella serotypes showing up in different places, even matching PFGE types showing up in different place in the past with other strains where there's been no connection.

So it's intriguing and something we're following up on.

Delthia Ricks: Thank you.

Judy Leon: Okay did you have a follow up?

Delthia Ricks: No I don't. Thank you.

Judy Leon: Thank you. Operator we'll take the next caller please.

Coordinator: Scott Bronstein from CNN your line is open.

Scott Bronstein: Yes thank you. Some food safety experts blame FDA and CDC for not properly regulating this plant and other plants that have had problems.

I'd like to hear both from Dr. Sundlof and Dr. Tauxe, do you take any responsibility for allowing this outbreak to happen? Do you think that the regulatory procedures have not protected the public?

Stephen Sundlof: This is Steve Sundlof. And again I want to reiterate some of the remarks I've made in the previous media calls. And that is that it is the responsibility of the industry to produce safe product.

The FDA is not in plants on a continuous basis. We do rely on inspections to find problems when they exist. There, again, there is - when it's just as if it we're, you know, an individual citizen.

We expect individual citizens to obey the law. And occasionally people don't obey the law. And when they don't obey the law then the responsibility of the regulatory authorities to take the appropriate enforcement action.

And that is what we were doing, we are doing now. I will let Dr. Tauxe speak for CDC. But I would just say that, you know, we without the CDC out there continuously monitoring, using some very sophisticated surveillance techniques and DNA fingerprinting.

And with the states helping us in that regard, it's - we are able to identify outbreaks much quicker then we could in the past. Dr. Tauxe would you like to respond?

Robert Tauxe: Yes thank you. Thank you for the question. There are a lot of players which have different roles in the food safety system in this country.

CDC's role is non-regulatory. We do monitor surveillance that we have nationwide, surveillance for a number of infections.

And we assist states in the investigation or when it's a large nationwide outbreak we will lead the investigation to find out what was the source.

And we think it's very important in the investigations that what's found and identified as the problem, the root cause, be identified and be made available so that not just that company but the entire industry can learn about what went wrong.

But as I say, CDC is non-regulatory. I would like to mention that I misspoke when I gave the number for our CDC info line. I translated CDC info into numbers incorrectly. It is 1-800-232-4636. Thank you.

Judy Leon: Okay thank you. Operator we have time for just one more question please.

Coordinator: Okay and for our last question we have Julie Steheise your line is open.

Julie Steheise: Yes hi, I just wanted to know will there be any sanctions against, you know, Peanut Corporation of America?

Michael Rogers: I think we covered this earlier. The inspection just concluded yesterday. The agency needs time to write its report, evaluate the evidence and facts. And then make a final agency conclusion regarding the compliance status of this facility. And will utilize the appropriate regulatory tools.

Having said that, what is ongoing now is the agency is dedicating all appropriate resources to this investigation. It, presently in our primary focus right now, is ensuring that those firms who are referenced as direct companies of PCA are in fact aware of this particular recall.

A lot of those direct companies are in fact distributors that need to be subsequently followed up on. We've engaged the use of our state counterparts to assist us in this effort.

And that's our primary focus right now.

Judy Leon: Okay thank you. And I would like to reiterate at the end of this call that the main point of the call, one main point was to announce an expanded recall that will affect consumers.

And we would like the news media to help us by publishing the Web site address of the FDA Web site. That is www.fda.gov.

And for those consumers who do not have access to the Internet, to call the CDC info line at 1-800-CDC-INFO.

Please do watch our searchable database for an expanded list of recalled products as the investigation continues and the recalls expand.

I'd like to thank everybody for joining us this evening. Thank you.

Coordinator: That concludes today's conference. You may disconnect at this time.

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